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End-Stage Renal Disease Treatment Choices (ETC) Model

First Annual Evaluation Report

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Glossary of Terms

Acronym	Definition
AAKH	Advancing American Kidney Health
ACO	Accountable Care Organization
APM	Alternative Payment Model
ADI	Area Deprivation Index
AFS	Annual Facility Survey
AHRF	Area Health Resource File
AKI	acute kidney injury
BMI	body mass index
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
CKCC	Comprehensive Kidney Care Contracting
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
DiD	difference-in-differences
ECE	extraordinary circumstance exception
ED	emergency department
E/M	Evaluation and Management
EQRS	End-Stage Renal Disease Quality Reporting System
ESRD	end-stage renal disease
ETC	ESRD Treatment Choices
ETCLC	ESRD Treatment Choices Learning Collaborative
FFS	fee-for-service
HD	Hemodialysis
HDPA	Home Dialysis Payment Adjustment
HRR	Hospital Referral Region
ICH CAHPS	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems
IRF	inpatient rehabilitation facility
KCC	Kidney Care Choices Model
LIS	Low-Income Subsidy
LTCH	long-term care hospital
MA	Medicare Advantage
MCP	Monthly Capitation Payment
MPS	Modality Performance Score
MY	Measurement Year
NF	nursing facility
NGACO	Next Generation ACO
PAG	patient advisory group

Acronym	Definition
PCP	primary care physician
PHE	public health emergency
PPA	Performance Payment Adjustment
PPPM	per patient per month
QoC	quality of care
QoL	quality of life
RQ	research question
RUCC	Rural-Urban Continuum Code
SD	standard deviation
SMD	standardized mean difference
SNF	skilled nursing facility
SRTR	Scientific Registry of Transplant Recipients
U.S.	United States

Executive Summary

ES.1. Introduction

Effective January 1, 2021, the Centers for Medicare & Medicaid Services (CMS) launched the End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model under the authority of the Centers for Medicare & Medicaid Innovation (CMMI). The ETC Model establishes incentives to encourage greater use of home dialysis and kidney transplantation, while reducing Medicare expenditures and preserving or enhancing quality of care (QoC) provided to beneficiaries with ESRD. By supporting patient selection of home dialysis and transplant through enhanced patient education, and other strategies, the model is intended to result in lower Medicare payments while preserving or enhancing QoC for beneficiaries.

CMS selected approximately 30 percent of Hospital Referral Regions (HRRs) for inclusion in the ETC Model. These HRRs were selected at random using a United States (U.S.) Census Region stratified design, except for the Maryland HRRs which were included in conjunction with the ongoing Maryland Total Cost of Care Model.[1] Participation in the ETC Model is mandatory for dialysis facilities, known as ESRD facilities, and clinicians, known as Managing Clinicians, in the selected HRRs. During the model performance period, which started in January 2021 and ends in June 2027, participating ESRD facilities and Managing Clinicians receive performance-based adjustments to certain Medicare fee-for-service (FFS) payments. The performance of participants is based on levels of home dialysis use, waitlisting for a deceased donor transplant, and living donor transplantation among FFS beneficiaries in their care.

Effective January 1, 2022, CMS also adopted two changes to the Performance Payment Adjustment (PPA) that together are intended to reduce disparities in home dialysis and transplantation for underserved beneficiaries. First, CMS introduced a Health Equity Incentive that enables ETC participants to earn additional improvement points when demonstrating significant improvement in rates of home dialysis or transplantation among beneficiaries who are dually eligible for Medicare and Medicaid or eligible for the Part D Low-Income Subsidy (LIS), which provides assistance with prescription drug costs for those enrolled in a Part D plan. In addition, CMS also stratified achievement benchmarks based on the proportion of attributed beneficiaries who are dually eligible or receive the Part D LIS during the Measurement Year (MY).

The primary goals of this evaluation are to understand how the ETC Model impacts aspects of ESRD care and outcomes for beneficiaries with ESRD. We will also assess whether the refinements to the model introduced in the second year of the model to promote health equity have implications for the care of beneficiaries who are underserved. To achieve these goals, we will employ a mixed methods research design that will incorporate analyses of home dialysis use, transplantation, and other outcomes of interest as well as results from interviews and surveys involving model participants and beneficiaries.

In this first annual evaluation report, we examine impacts of the ETC Model during the first year of the model (CY 2021). The model introduced two distinct types of financial incentives in calendar year (CY) 2021. First, ESRD facilities and Managing Clinicians were eligible to receive a Home

[1] In addition to the HRRs that were randomly selected, the ETC Model also includes HRRs for which at least 20 percent of the component zip codes are in Maryland.

Dialysis Payment Adjustment (HDPA) of three percent for FFS beneficiaries receiving home dialysis. This adjustment was applied to the payments ESRD facilities and Managing Clinicians would otherwise receive for the care of FFS beneficiaries. Second, levels of home dialysis use, transplant waitlisting, and living donor transplantation among beneficiaries during were used to determine the PPA for each participating ESRD facility and Managing Clinician. The PPA for CY 2021 was then applied to Medicare payments to ESRD facilities and Managing Clinicians starting on July 1, 2022. Levels of performance on home dialysis and transplant measures during CY 2021 determined initial PPAs for ETC participants that could range from up to a five percent reduction to up to a four percent increase in certain Medicare payments subject to adjustment.

This annual report includes the results of quantitative analyses of a range of outcomes through December 31, 2021. Outcomes include home dialysis use, transplant waitlisting, transplantation, acute care hospitalizations, outpatient emergency department (ED) visits, hospital readmissions, Medicare payments, and patient experience of care. Future annual reports will examine additional topics that are highly relevant to the design of the model such as the strategies employed by ESRD facilities and Managing Clinicians in responding to the model, the quality of life (QoL) of beneficiaries, and health equity.

ES.2. Overview of Findings

We found mixed evidence regarding early impacts of the ETC Model on home dialysis and transplantation, which are the direct targets of the ETC payment adjustments (see **Exhibit ES-1** for a summary of the evaluation findings). While there has been recent growth in home dialysis use nationally, during its first year the ETC Model did not lead to faster growth in home dialysis use in the areas selected for the ETC Model (i.e., Selected Geographic Areas or ETC areas) relative to a comparison group of HRRs not selected for the ETC Model (i.e., Comparison Geographic Areas or comparison areas). The ETC Model resulted in an estimated 546 additional patient months with home dialysis training in ETC areas, which corresponds to a nine percent increase over pre-ETC home dialysis training rates. Assuming one or two months with home dialysis training claims per patient, an additional 273 to 546 patients underwent home dialysis training in ETC areas in CY 2021.[2]

For transplant-related measures, there is evidence that the ETC Model resulted in a relatively smaller decline in waitlisting rates in ETC areas relative to comparison areas in CY 2021. As a result, there were an estimated 663 additional patients waitlisted for a transplant in ETC areas than would have otherwise occurred, which corresponds to a four percent increase over pre-ETC waitlist rates. There is also evidence of an estimated 225 additional kidney transplants in ETC areas in CY 2021, which corresponds to a 10 percent increase over pre-ETC transplant rates. This observed growth in overall transplants is attributed to growth in deceased donor transplants. We did not find an impact on living donor transplant rates which are used in determining future PPAs for model participants.

[2] Medicare will routinely cover up to 15 training sessions for PD and up to 25 training sessions for home HD. This estimate is based on an assumption that most training sessions would take place within a one- to two-month period.

Exhibit ES-1. Summary of Evaluation Findings

Domain	Outcome	ETC Model Impact (% Relative Change)
Dialysis Modality Measures	Home Dialysis	-0.9%
	Peritoneal Dialysis	-1%
	Home Hemodialysis	0.6%
	In-Center Hemodialysis	0.1%
	In-Center Self-Dialysis	65%
	Nocturnal Hemodialysis	-4%
	Home Dialysis Training	↑ 9%
Transplantation	Overall Waitlisting	↑ 4%
	Active Status	3%
	Inactive Status	4%
	Overall Transplants	↑ 10%
	Deceased Donor	↑ 12%
	Living Donor	0.6%
	Living Donor (Dialysis and Pre-emptive)	0.8%
Utilization	Acute Care Hospitalization	0.8%
	Readmission	-2%
	Outpatient ED Use	-1%
Medicare Payments	Total Parts A & B	-0.2%
	Total Part A	-0.4%
	Part A Acute Care Hospitalization	0.3%
	Part A LTCH and IRF	↓ 8%
	Other Part A	-1.4%
	Total Part B	-0.1%
	Part B Dialysis	0.1%
	Other Part B	-0.6%
In-Center HD Patient Experience of Care	Rating of Kidney Doctors	-0.02%
	Rating of Dialysis Center Staff	-1%
	Rating of Dialysis Center	-0.4%
	Nephrologists' Communication and Caring	0.2%
	Quality of Dialysis Center Care and Operations	-0.4%
	Providing Information to Patients	-0.1%

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

Arrow indicates the direction of the statistically significant impact estimate. DiD impact estimates are reported in terms of the relative percent change of the outcome measure, compared to the pre-ETC period. Detailed impact estimates of the absolute change in the value of the outcome measure among ETC beneficiaries, relative to the comparison group, are included in the body of the report.

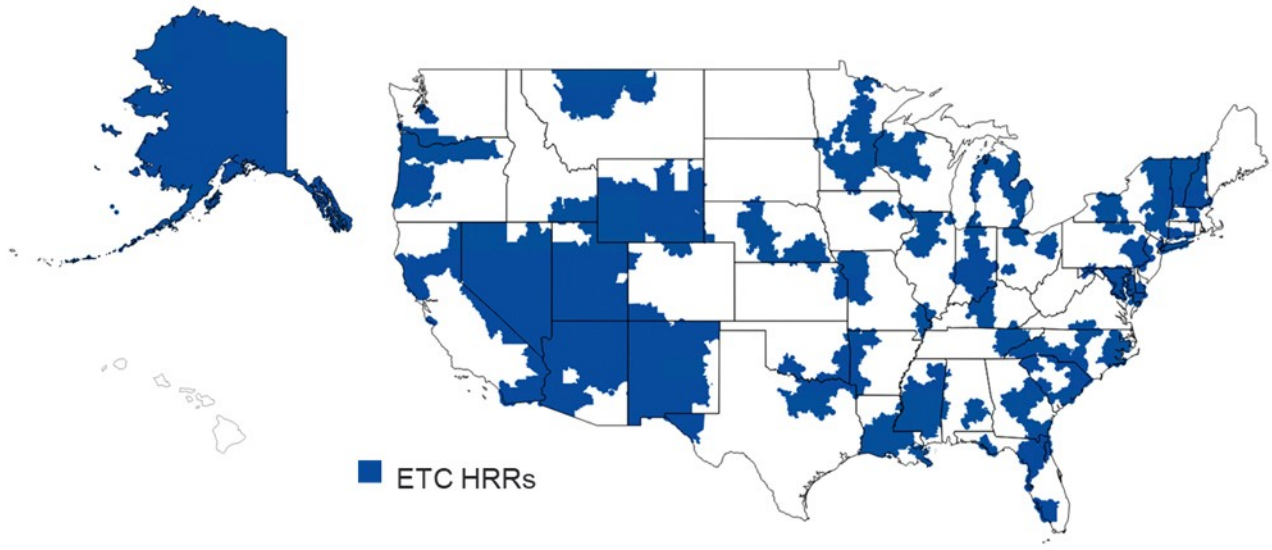
There were no major shifts in overall Medicare payments and utilization in the first year of the model. We found no evidence that the ETC Model led to a change in total Medicare payments per patient per month (PPPM) for Medicare Parts A & B services or in overall Part A or Part B payments PPPM. There was also no impact of the model on overall acute care hospitalizations, outpatient ED use, or hospital readmissions. There was a statistically significant reduction in payments for services provided by long-term care hospitals (LTCHs) and inpatient rehabilitation facilities (IRFs) of eight percent relative to pre-ETC levels which represents a very small change in magnitude relative to average overall Part A and Part B payments.

With respect to other patient outcomes, there was no early impact of the model on measures of in-center hemodialysis (HD) patient experience of care.

ES.2.1. Who Participates in the ETC Model?

The selection process for the ETC Model resulted in the inclusion of 95 HRRs, with 91 HRRs that were selected at random from the four U.S. Census Regions, and four HRRs in Maryland.[3] Together the selected HRRs account for 31 percent of HRRs in the 50 states and District of Columbia. Reflecting the random selection of HRRs within the U.S. Census Region strata, the selected ETC HRRs are distributed geographically throughout the U.S. (see **Exhibit ES-2**).

Exhibit ES-2. Location of ETC Participants



ETC Model participants include ESRD facilities and Managing Clinicians located in one of the 95 HRRs selected for the ETC Model, for whom participation is mandatory. Managing Clinicians may include nephrologists as well as other practitioners, such as internal medicine physicians and nurse practitioners, who oversee care for beneficiaries with ESRD and who furnish and bill Medicare for the Monthly Capitation Payment (MCP) for the management of ESRD. In 2021, ETC Model participants included 2,519 ESRD facilities and 4,749 Managing Clinicians, corresponding to 32 percent of ESRD facilities and 36 percent of Managing Clinicians in the 50 states and the

[3] 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.

District of Columbia.[4] The ETC Model included 99,699 eligible ESRD patients with Medicare FFS coverage who were attributed to ETC Model participants during CY 2021, corresponding to 34 percent of Medicare FFS beneficiaries with ESRD nationally.

To describe ETC participants and inform our comparison group approach, we examined several market, provider, and patient characteristics for the Selected Geographic Areas) and HRRs in the 50 states and District of Columbia that were not selected for the ETC Model (i.e., Comparison Geographic Areas). These characteristics reflect a wide range of factors, such as local health system resources and socioeconomic indicators (i.e., based on county-level data), ESRD facility ownership and services offered, and patient demographic, clinical, and socioeconomic characteristics.[5] Overall, we found that most factors were balanced between the two groups prior to the start of the model, which may reflect the randomized process for selecting participants and mandatory participation. The results of this analysis informed our decision to employ all non-selected HRRs (i.e., the Comparison Geographic Areas) as the comparison group for the evaluation and as a reasonable counterfactual for what would have been observed in the absence of the ETC Model.

ES.2.2. What Were the Impacts of the ETC Model?

We examined potential impacts of the ETC Model on outcomes across several domains: home dialysis, transplant waitlisting, transplantation, utilization of services, Medicare payments, and patient experience of care. Model impacts were estimated using difference-in-differences (DiD) analyses, and reflect changes observed in the ETC areas in the post-ETC period relative to a comparison group consisting of HRRs not selected for the model (i.e., the Comparison Geographic Areas or comparison areas). Below we discuss the results of these analyses.

Dialysis modality measures. Results for the first year of the ETC Model do not provide early evidence that it led to growth in the use of home dialysis among beneficiaries with ESRD. DiD analyses do not indicate an impact of the model on overall home dialysis use during CY 2021, with similar growth in home dialysis use occurring in both the ETC and comparison areas between the pre-ETC period and CY 2021. Similarly, we did not find evidence of an early impact of the model on the use of either of the two major types of home dialysis, peritoneal dialysis and home HD.

There is evidence of a modest, positive impact of the model on patient training for home dialysis. During the pre-ETC period, approximately 0.8 percent of beneficiaries with ESRD were reported to be training for home dialysis, in both the ETC and comparison areas. The results of DiD analyses indicate the model resulted in a statistically significant increase in home dialysis training of 0.07 percentage points ($p \leq 0.05$) which corresponds to a nine percent increase relative to the pre-ETC period.[6] Assuming one or two months with home dialysis training claims per

[4] The model participants reflect the count of unique facilities and National Provider Identifiers in the evaluation analytic sample.

[5] Medicare FFS beneficiaries can be attributed to ETC participants if they enrolled in Medicare Part B (whether alone or in conjunction with Part A), are at least 18 years of age, reside in the U.S. (excluding U.S. territories), and were either receiving dialysis or other services for ESRD during the month or received a pre-emptive living donor transplant. Exclusions are made for beneficiaries treated for acute kidney injury (AKI), receiving dialysis, or residing in a nursing facility (NF), diagnosed with dementia, receiving hospice services, or have a functioning transplant.

[6] For a summary of the results of DiD analyses of home dialysis measures, waitlisting, transplantation, Medicare spending, utilization, and in-center HD patient experience of care, see **Exhibit 10** in Section 3.

patient, this DiD estimate implies an additional 273 to 546 patients in ETC areas underwent home dialysis training in CY 2021 due to the ETC Model. This impact, while small in absolute terms, could be an early signal of future growth in the use of home dialysis. Whether this impact remains similar in subsequent years of the model and whether it has implications for future levels of home dialysis use will be a topic for future annual reports.

Kidney waitlisting and transplants. Findings from analyses of transplant-related events are mixed regarding an early impact of the ETC Model. DiD analyses indicate that the model resulted in higher transplant waitlisting rates than would have otherwise been observed in the absence of the model, in the form of somewhat smaller declines over time in waitlisting rates in the ETC areas relative to the comparison areas. The DiD estimate indicates a statistically significant increase of 0.83 percentage points ($p \leq 0.10$) in waitlisting among beneficiaries with ESRD which corresponds to a four percent increase relative to pre-ETC levels.[7] This DiD estimate corresponds to approximately 663 additional patients on the waitlist in ETC areas during CY 2021 compared to what would have been observed in the absence of the model. When separately examining waitlisting rates among transplant candidates who have active status or inactive status, the impact estimates for these two components are both positive but not statistically significant.

Consistent with the increase in overall waitlisting rates, we found that the model resulted in a statistically significant increase in overall rates of transplantation among patients in ETC areas. The DiD estimate indicates a statistically significant increase in overall transplants of 0.37 ($p \leq 0.10$) transplants per 1,000 patient months, which corresponds to a 10 percent increase relative to pre-ETC levels. This impact estimate corresponds to approximately 225 additional transplants in ETC areas during CY 2021. Since the vast majority of kidney transplants continue to involve deceased donor organs, this measured impact of the model was driven by an increase in deceased donor kidney transplants, which is consistent with the increase in waitlisting incentivized by the model. Despite the direct incentives under the model involving living donor transplants, we do not find evidence of increased rates of living donor kidney transplants due to the ETC Model.

Utilization. There is no early evidence of major shifts in utilization among dialysis patients, which could have important implications for both the quality and cost of care. Based on the results of DiD analyses, we do not find the model to have an impact on the percent of patients with at least one acute care hospitalization in a given month, which is a relatively common event for this population. We also do not observe impacts on the percentage of patients with at least one outpatient ED visit or hospital readmission in a given month.

Medicare payments. We observe similar growth in overall standardized Medicare Parts A & B payments in ETC and comparison groups in the first year of the model.[7] DiD analyses of Medicare payments PPPM provide no early evidence of either overall cost savings to Medicare or of an unintended increase in overall payments due to the model. Similarly, when separately examining major components of payments, we do not find evidence of a change in overall average payments PPPM for Part A services (such as acute care hospitalizations) or Part B services (such as dialysis). When examining more specific types of services, DiD analyses indicate a statistically significant

[7] Analyses are based on standardized Medicare payments so that differences in payments reflect differences in utilization and not ancillary parameters (i.e., wage index, Disproportionate Share Hospital, Indirect Medical Education payments, quality incentive payments, and others that determine payments under Medicare Prospective Payment Systems).

reduction of $8 PPPM ($p \leq 0.05$) in payments for services provided by LTCHs and IRFs as a result of the model.[7] However, this estimated reduction in LTCH and IRF payments represents a very small change in magnitude relative to average overall payments for dialysis patients of approximately $5,700 PPPM prior to the start of the model (<0.2 percent). The absence of an early impact on Medicare payments for acute care hospitalizations is aligned with our finding of no early impact on the number of hospitalizations.

Patient experience of care. The perspective of patients was an important consideration in the design of the ETC Model, given the potential benefits of home dialysis and transplantation for patient independence and QoL and their experience of care for kidney disease. We convened a Patient Advisory Group (PAG) in October 2022 to help address the evaluation research questions (RQs) and inform specific areas of primary and secondary data collection and analysis. The goal of the PAG meetings was to capture patient perspectives on the ETC and Kidney Care Choices (KCC) Models from patients with a range of experience with dialysis modalities, receiving a transplant (including pre-emptive transplants), or living with late-stage chronic kidney disease (CKD). The discussions and feedback from the PAG better positions us to understand what is meaningful to patients from their perspective and experiences, and, for example, what they think is important to ask participants about approaches to care delivery, and ways dialysis and transplant care and patient experiences can be improved for people with kidney disease.

To explore any early effects of the model on measures of patient-reported experience, we used available data from the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) survey. This ongoing survey captures data on patient experience of care in both the ETC and comparison areas for those undergoing in-center HD, who continue to represent most patients undergoing dialysis for ESRD. Data on patient experience for those who are dialyzing at home are not currently available and will be collected through a future survey. For in-center HD patients, the model could potentially affect patient experience of care either positive or negatively. For example, if the model encourages more effective communication with patients about treatment options including home dialysis and transplantation and shared decision making, there could be benefits for patients, even for those who choose in-center HD. However, there is also a risk that the model's focus on home dialysis and transplantation could divert attention and resources such as staff time away from the care of in-center HD patients. Based on DiD analyses of six measures which include both global ratings and composite measures of patient experience derived from the ICH CAHPS survey, we find no early impact of the model on the experience of in-center HD patients.

ES.3. Discussion

Through the first year of the ETC Model, we found evidence of modest early gains in some aspects of care incentivized under the model such as transplantation, and no early evidence of unintended impacts. These findings for CY 2021 include no early evidence of an increase in the overall use of home dialysis. However, we found the model resulted in a modest increase in home dialysis training, which may have been encouraged by the model incentives for home dialysis. With respect to transplantation, we found evidence of a smaller decline over time in waitlisting rates in the ETC areas (i.e., the Selected Geographic Areas) than in the comparison areas (i.e., the Comparison Geographic Areas) which resulted in higher waitlisting rates than would have been observed in the absence of the ETC Model. We find no early evidence of a change in rates of living donor transplants, which account for a small fraction of transplants but are a specific focus of the ETC

Model incentive structure. However, we found the model resulted in increased rates of deceased donor transplants. Consistent with this finding, given that the majority of kidney transplants continue to involve deceased donor organs, we found the model also resulted in an increase in overall transplant rates.

Finally, we observed no changes in key utilization and payment outcomes. We found no model impacts on utilization of acute care services that are relatively common among beneficiaries with ESRD, including acute care hospitalizations, outpatient ED visits, and hospital readmissions, and no changes in measures of in-center HD patient experience of care due to the ETC Model. With no statistically significant impact of the model on total payments PBPM for Medicare Parts A & B services, there is no indication that the model generated overall savings for the Medicare program in its first year. When accounting for the increased payments to ETC participants through the HDPA, which are not reflected in our estimated payments, it is likely there was a net increase in overall Medicare Parts A & B payments for dialysis patients in 2021.

As we consider these initial evaluation findings, we note that early impacts of the ETC Model may not necessarily be representative of later impacts. First, certain features of the model changed after the start of the model in 2021. The adjustments to Medicare payments to ESRD facilities and Managing Clinicians applied through the PPA did not begin until July 2022, at which point the financial impact of the model on participants may become more visible and concrete. In addition, as the magnitude of the payment adjustments under the HDPA gradually become smaller over the first three CYs of the model and are phased out entirely in the fourth year, the potential magnitude of the payment adjustments under the PPA also become steadily larger over time. Since the ETC Model was accompanied by a waiver of certain requirements for clinicians to furnish and bill Kidney Disease Patient Education Services, any increases in the use of this benefit among patients with Medicare FFS coverage has potential to facilitate future growth in home dialysis modalities under the model. Further, the introduction of the Health Equity Incentive in the second CY of the model strengthens incentives to encourage home dialysis and transplantation among beneficiaries who are underserved.

Going forward, the potential role of other factors will also need to be considered. It will be important to account for possible effects of the related KCC Model which began January 1, 2022. Given the overlap in certain ETC and KCC Model goals (e.g., involving transplantation) and in participation (i.e., for providers participating in both models), as well as the Comprehensive Kidney Care Contracting (CKCC) shared savings incentives, effects of the two models could be mutually reinforcing and also represent potential confounders that will need to be considered in CY 2022 forward. In addition, we will continue to consider the potential impact of the COVID-19 Public Health Emergency (PHE). The model was launched within a year of the onset of the COVID-19 PHE in the U.S. We note the growth in home dialysis use among patients in both ETC and comparison areas since CY 2019, which may have been influenced in part by the COVID-19 PHE. While we observed similar overall COVID-19 infection rates in ETC and comparison areas in CY 2021 and included COVID-19-related covariate adjustments in our impact analyses, any potential longer-term effects of the pandemic will need to be considered in future years of the model.

As the ETC Model continues, we will also expand the focus of the evaluation. As part of our mixed methods approach, one of our future priorities will be to understand the perspectives of

participants regarding the model's incentives, the strategies they are employing in response to the model, and factors that they perceive as barriers and facilitators to improving their performance under the model. This information can provide context for the quantitative findings and inform both future analyses and our conclusions about model impacts. Other potential impacts of the model that will also be considered include outcomes related to patient QoL, experience of care for home dialysis patients, and other indicators of QoC. With both evidence of past inequities in ESRD care and the new ETC incentives promoting greater equity in home dialysis and transplantation that were adopted in January 2022, it will also be important to understand impacts on underserved patient populations relative to other patients in future years of the evaluation.

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 July, 2022, the model design was amended to also promote greater equity in home dialysis and transplantation.

CMS contracted with The Lewin Group, Inc. (Lewin) and its partners Arbor Research Collaborative for Health and the University of Michigan Kidney Epidemiology and Cost Center to conduct the evaluation of the ETC Model. Lewin has designed an evaluation of the effects of the ETC Model during the life of the model from January 2021 through June 2027. Outcomes of interest for the ETC Model evaluation include (1) use of home dialysis, kidney transplant waitlisting, and kidney transplantation, which are the direct targets of the model incentives; (2) Medicare payments, utilization of services, QoC, and patient experience and quality of life (QoL), which can be affected by changes in modality selection; and (3) disparities in modality selection given the ETC Model incentives to increase use of home dialysis and transplantation among patients who are underserved. In evaluating effects of the ETC Model, we are employing a mixed methods research design that incorporates both quantitative and qualitative data. We will use CMS administrative data as well as data from patient surveys to conduct quantitative impact analyses. In addition, starting in the second year of the evaluation, we will collect and analyze qualitative data through interviews with ETC participants and patients to provide context for the quantitative findings and inform future quantitative analyses.

In this first Annual Report, we describe early effects of the ETC Model during the initial year of the model (CY 2021). We describe the comparison group used to evaluate the ETC Model and examine changes in key outcomes of interest during calendar year (CY) 2021 including use of home dialysis, waitlisting for a kidney transplant, living donor and deceased donor transplantation, utilization of services, Medicare payments, and patient experience of care. Subsequent annual reports will address additional research questions (RQs), examine additional outcomes of interest such as mortality and QoL, and will draw from qualitative data that will be collected from patients, ESRD facilities, and Managing Clinicians for this evaluation.

1.1. Overview of ETC Model

The ETC Model is a mandatory model that is currently underway in approximately one-third of hospital referral regions (HRRs) throughout the United States (U.S.).[8] The model is designed to encourage greater use of home dialysis and kidney transplantation among Medicare beneficiaries with ESRD as well as pre-emptive kidney transplantation among Medicare beneficiaries 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 who were 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

[8] 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.

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 was accompanied by a waiver of certain requirements for clinicians to furnish and bill Kidney Disease Patient Education Services. The goal of this waiver was to support beneficiaries in more advanced stages of disease in making informed decisions about their ESRD treatment. Further, CMS initiated a voluntary collaborative, the ETC Learning Collaborative (ETCLC), 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) health equity policies. We discuss each of these features below.

Randomized selection and mandatory participation. To identify ETC Model participants a random sample of 31 percent of HRRs in the U.S. was selected 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, four HRRs for which at least 20 percent of the component zip codes are located in Maryland were also included in the ETC Model, in conjunction with the ongoing Maryland Total Cost of Care Model. ETC Model 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 were designed to achieve the goals of the model: the Home Dialysis Payment Adjustment (HDPA) and the Performance Payment Adjustment (PPA). The first type of payment adjustment, the HDPA, 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 will be in effect for the first three years of the ETC Model, with the largest payment adjustments occurring during the first year and declining thereafter. Specifically, the HDPA includes a three percent payment adjustment during 2021, a two percent payment adjustment during 2022, and a one percent payment adjustment during 2023. These positive payment adjustments are applied to the Medicare payment amounts that would otherwise be made to ETC Model participants for services provided to beneficiaries with FFS coverage.

The second type of payment adjustment under the ETC Model, 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 and MCP claims based on the performance of participants on a combination of measures of home dialysis use, transplant waitlisting, and living donor transplants.

For the PPA, participant performance is measured based on a combination of levels of achievement and improvement, for both the home dialysis rate and the transplant rate among attributed patients (where the transplant rate is the sum of the waitlisting rate and the living donor transplant rate). Achievement scores are calculated for each participant based on their performance during the measurement year (MY) relative to historical benchmarks based on rates in Comparison Geographic Areas. Improvement scores are calculated for each participant based on how their performance during the MY compares to their 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.

The initial PPA performance period, referred to as a MY, spans the period from January 1, 2021, to December 31, 2021. The performance of ESRD facilities and Managing Clinicians during 2021 will be used to determine initial PPAs ranging from -5.0 percent to +4.0 percent starting on July 1, 2022 (see **Exhibit 1**). As such, the incentives that accompany the initial PPAs could have implications for both home dialysis and transplantation among beneficiaries starting in 2021. The range of potential PPAs increases over time for both facilities and Managing Clinicians. Starting with PPA Period 7, there is a larger potential negative payment adjustment for facilities than for Managing Clinicians.

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%
8	7/1/2024 – 6/30/2025	1/1/2026 – 6/30/2026				
9	1/1/2025 – 12/31/2025	7/1/2026 – 12/31/2026	-10.0%	+8.0%	-9.0%	+8.0%
10	7/1/2025 – 6/30/2026	1/1/2027 – 6/30/2027				

Source: CMS (February 2023). End-Stage Renal Disease Treatment Choices (ETC) Model Performance Payment Adjustment Report User Guide (MYs 1-2) End-Stage Renal Disease Treatment Choices (ETC) Model Performance Payment Adjustment Report User Guide (Measurement Years 1-2) (cms.gov)

Health Equity Incentives. The model was amended in the second year to include provisions that are intended to promote greater equity in home dialysis and transplantation among beneficiaries

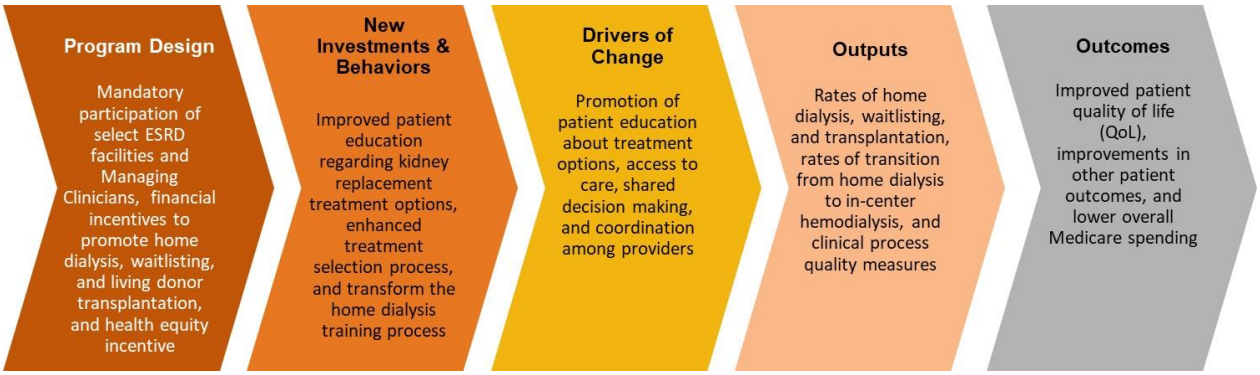
with ESRD.[9] First, starting with MY3, which began on January 1, 2022, the PPA achievement benchmarks are stratified by the proportion of beneficiaries with FFS coverage who are dually eligible for Medicare and Medicaid or who are eligible for the Part D Low-Income Subsidy (LIS). This change was made in recognition of the historically lower home dialysis and transplant rates among patients with lower socioeconomic status.[10,11,12]

In addition, CMS incorporated a Health Equity Incentive into the PPA scoring methodology. The Health Equity Incentive allows ETC Participants to receive a higher improvement score if they achieve sufficient improvement in home dialysis and transplant rates among attributed beneficiaries who are dually eligible for Medicare and Medicaid or Part D LIS recipients. These refinements to the original ETC Model design represent novel features of a health care payment model that are designed to promote health equity.

1.2. 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 main RQs for the evaluation. A high-level overview of the structure of the logic model is shown in **Exhibit 2**. The RQs addressed in this first Annual Report are discussed below.

Exhibit 2. ETC Logic Model (Abbreviated)



[9] 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.

[10] 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.

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

[12] 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.

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 and inform development of the comparison group, we describe both types of model participants and include comparisons with providers in other geographic areas (i.e., in HRRs not selected for the model). We also describe characteristics of ETC markets and of beneficiaries who are attributed to model participants that may be related to beneficiary outcomes or may affect model impacts. These market and beneficiary characteristics are compared with those for ESRD facilities and Managing Clinicians in other geographic areas not selected for the model. These comparisons are used in assessing levels of balance on beneficiary, provider, and market characteristics between the ETC and comparison areas and in determining whether the geographic areas not selected for the model represent a valid comparison group for the evaluation.

1.2.2. What were the Impacts of the ETC Model?

In this annual report, we examined potential impacts of the model on several outcomes that include home dialysis use, transplantation, service utilization, Medicare payments, QoC, and patient experience of care. We began by assessing 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 impacted by the model. Increased use of home dialysis and/or transplantation are also the primary mechanisms through which we would expect to see any impacts on other outcomes of interest such as QoC, QoL, patient experience of care, and cost of care.

Dialysis modality. Home dialysis is a major focus of the model design as well as the evaluation, as levels of home dialysis use among attributed beneficiaries determine the HDPA and also generally constitute two-thirds of the MPS which is used to determine the PPA. In addition to examining overall changes in the use of home dialysis, we also separately explored impacts on peritoneal dialysis, the most common form of home dialysis, and home hemodialysis (HD). While home dialysis training does not directly affect the payment adjustments of participants under the model, it can 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 beneficiaries with ESRD undergo training for home dialysis.

Waitlisting and transplantation. The other area of performance measurement under the ETC Model, kidney transplantation, includes two major dimensions that we examined during the first year of model: waitlisting for a deceased donor transplant, and living donor transplantation.[13] Since the performance of participating ESRD facilities and Managing Clinicians along both of these dimensions during CY 2021 was used to determine the initial PPAs starting in July 2022,

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

we examined whether there is evidence of changes in these outcomes during the initial year of the model.

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 transplant by focusing on candidates who are considered ready for transplant, which is not the case for candidates placed in an inactive status. Therefore, in addition to examining whether the ETC Model is associated with changes in overall waitlisting rates, we also separately examined rates of active and inactive waitlisting for a transplant.

For living donor transplantation, we examined potential impacts of the model on both living donor transplants occurring among dialysis patients and pre-emptive living donor transplants among beneficiaries not yet on dialysis for ESRD.

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 beneficiaries with FFS coverage. This could occur to the extent that patterns in utilization and payments differ with the use of home dialysis and transplantation compared to in-center HD. In addition, the model's incentives could lead to changes in QoC that have implications for utilization and payments. For example, efforts to reduce treatment complications among home dialysis patients with a goal of encouraging home dialysis modalities as longer-term therapies or encouraging their use in an expanded patient population could in turn affect utilization and payments. We therefore examined changes in major types of utilization among beneficiaries with ESRD that may also be important indicators of both quality and efficiency, including acute care hospitalizations, outpatient emergency department (ED) visits, and hospital readmissions. In addition to examining potential impacts of the model on overall Medicare Parts A & B payments during CY 2021, we also examined changes in major claim types to identify drivers of overall changes.

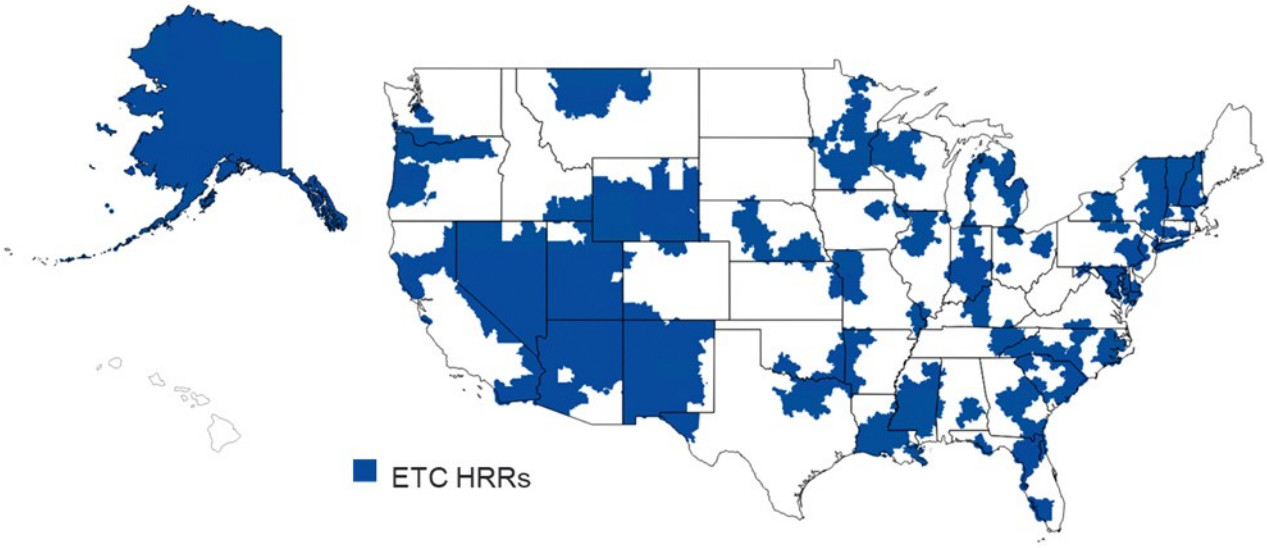
Patient experience of care. There is also potential for the model to have important implications for patient experience of care. Given the model's focus, the experience of patients using a home dialysis modality is of particular interest. Since data on home dialysis patient experience of care are not currently available, however, it is necessary for us to field a patient experience of care survey for patients using a home dialysis modality so that we can conduct analyses of these data in a future report. The experience of patients undergoing in-center HD, which continues to be the predominant treatment modality for ESRD, is also important to assess. There is potential for the model to have positive or negative impacts on in-center HD patient experience of care. If the model encourages more effective education and communication about home dialysis and transplantation as treatment options, there could be positive impacts of the model on the experience of patients, even among those electing or continuing in-center HD. However, there is also a risk that a shifting focus towards 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 patient experience of care. To explore these possibilities, we were able to examine available data on experience of care for patients undergoing in-center HD since data these are routinely collected using the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) survey. We examined both global ratings and composite measures of patient experience using facility-level ICH CAHPS data.

2. Who Participates in the ETC Model?

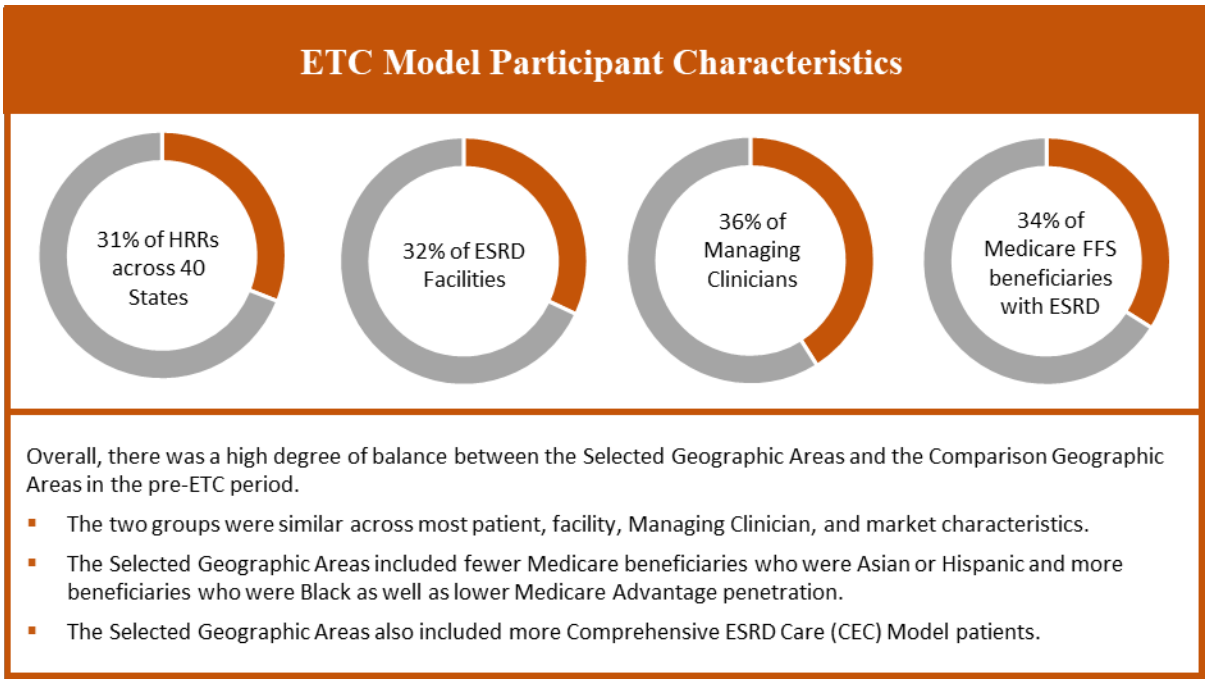
The selection process for the ETC Model resulted in the inclusion of 95 HRRs in the Selected Geographic Areas, which included 91 HRRs that were selected at random (out of 306 HRRs in U.S) from the four U.S. Census Regions and four HRRs for which at least 20 percent of the component zip codes are located in Maryland. Together the selected 95 HRRs account for 31 percent of the HRRs in the U.S. Reflecting the random selection of HRRs within regional strata, the Selected Geographic Areas are geographically distributed throughout the U.S. (see **Exhibit 3**). The Selected Geographic Areas include 40 states and the Comparison Geographic Areas include 43 states. Seven states fall entirely in the ETC areas, 10 states fall entirely in the comparison areas, and 33 states are split. All Medicare certified ESRD facilities and Managing Clinicians in the Selected Geographic Areas are model participants.

In this section, we describe the characteristics of patients, ESRD facilities, Managing Clinicians, and HRRs in the ETC Model. We also compare and assess the level of balance across multiple characteristics in the Selected and Comparison Geographic Areas to provide context for the evaluation and to inform the development of the comparison group.

Exhibit 3. Map of ETC HRRs



2.1. Key Findings



2.2. Methods

Participation in the ETC Model is mandatory for the ESRD facilities and Managing Clinicians in the randomly selected HRRs. We constructed a patient-month level dataset for analysis that included one observation per patient per month (PPPM) for 2017-2021. All months where the patient either had a non-acute kidney injury (AKI) dialysis claim at an outpatient ESRD facility, MCP claim or a living donor kidney transplant claim were included in the dataset. The dataset also included patient characteristics and primary utilization, payment, and quality outcomes from 2017-2021 Medicare claims, transplant and waitlisting outcomes from 2017-2021 Scientific Registry of Transplant Recipients (SRTR) files[14], facility-level characteristics from the 2017-2019 ESRD Quality Reporting System (EQRS), and market-level characteristics from 2019 Area Health Resource Files (AHRF). County-level AHRF characteristics were aggregated to the HRR level using zip code-county crosswalks and then averaged across ETC (95 HRRs) and comparison (211 HRRs) regions. We considered 2017-2019 as the pre-ETC period and excluded 2020 from the study (see **Section 4** and **Appendix B.3**).

We examined patient-, ESRD facility-, Managing Clinician-, and market-level characteristics of the 95 ETC HRRs and compared that with the 211 comparison HRRs. We assessed balance at three levels: HRR-, facility-, and patient-month level. As a measure of assessing balance, we

[14] 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 US, 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.

computed standardized mean differences (SMD) and compared against a threshold of 0.2 to identify any imbalance between the two groups. We also compared the ETC areas excluding Maryland and the comparison areas to examine if the non-random inclusion of Maryland HRRs in the model had any impact on the balance between the two groups.

2.3. Results

2.3.1. Characteristics of ETC Participants

ESRD facilities. Outpatient ESRD facilities located in the Selected Geographic Areas (hereafter referred to as ETC areas) are designated as ETC participants under the mandatory model. Facilities located in the Comparison Geographic Areas comprise the comparison group (hereafter referred to as comparison areas). In **Exhibit 4** we summarize the select characteristics of the ETC and comparison facilities as measured in the pre-ETC period. Approximately 32 percent of ESRD facilities are ETC participants, similar to the fraction of selected HRRs. Comparisons of ETC and comparison facilities over a broad range of characteristics revealed a high degree of balance as confirmed by consistently small SMD scores. In other words, randomization at the HRR level yielded intervention and comparison groups with similar average ESRD facility characteristics.

The random selection of HRRs was stratified by the four Census-defined geographic regions of Northeast, South, Midwest, and West. We observed balance (SMD < 0.2) in the percentage of facilities distributed across these four regions between the two groups (results not shown, see appendix for details). Of note for the ETC Model, ESRD facilities in both groups that provided peritoneal dialysis and home HD ranged between 51 to 54 percent and 29 to 30 percent, respectively. Relative to the comparison group, the ETC group had a slightly higher share of Fresenius facilities, and a lower share of DaVita and independent for-profit facilities. During the pre-ETC period, an average of 66 percent of dialysis patients treated at outpatient ESRD facilities were covered by the traditional Medicare program, which is the target population for the ETC Model. A detailed balance table is included in **Appendix B, Exhibit B-11**.

Exhibit 4. ESRD Facility Characteristics by ETC Participant Status, 2017-2019

Variable	ETC Mean N=2,514	Comparison Mean N=5,228
Number of HD Stations	17.4	17.5
Facility Ownership	-	
DaVita	36.9%	39.2%
Fresenius	38.8%	34.6%
Independent/Non-Chain For-Profit	3.6%	5.4%
Other For-Profit	10.7%	8.7%
Non-Profit	10.0%	12.1%
Facility Patient Volume (Patients)	-	
<=50	36.8%	39.3%
>50 and <=75	21.2%	21.8%
>75 and <=100	18.1%	17.1%
>100	24.0%	21.8%
In-Center HD Service Provided	94.8%	92.7%
Peritoneal Dialysis Service Provided	50.6%	54.2%
Home HD Training Service Provided	28.8%	30.4%
Facility Has Shift after 5:00 p.m.	16.6%	16.7%
Total In-Center Dialysis Patients	57.4	59.0
Total Home Dialysis Patients	7.6	8.1
Total Patients Receiving Care	65.0	67.1
Facility Region	-	
Northeast	14.7%	13.3%
Midwest	20.2%	21.3%
South	47.3%	45.2%
West	17.9%	20.3%
Facility RUCC	-	
Metro	83.1%	83.4%
Urban	16.3%	15.9%
Rural	0.64%	0.69%

Notes: RUCC= Rural-Urban Continuum Code. Facility attributes averaged, equal weight to all facilities in each group.

Managing Clinicians. Along with ESRD facilities, Managing Clinicians also participate in the ETC Model. The design features of the model require mandatory participation of the Managing Clinicians. The ETC areas include 36 percent of Medicare Managing Clinicians. **Exhibit 5** displays select average characteristics of Managing Clinicians during the pre-ETC period. In terms of clinical specialty, there was overall balance between ETC and comparison clinicians. The predominant clinician specialty was nephrology. Nephrology practices may include Nurse Practitioners and Physician Assistants, who accounted for approximately 15 percent of claims for the MCP. On average, ETC clinicians treated fewer Hispanic patients than comparison clinicians,

although the SMD fell just within the balance criteria (absolute value <= 0.2). Similar differences for Hispanic patients were seen at the HRR and patient levels (see **Exhibit 6 and Exhibit 7**).

Exhibit 5. Managing Clinician Characteristics by ETC Participant Status, 2017-2019

Characteristic	ETC Mean N=4,708	Comparison Mean N=8,195
Demographics	-	
Mean Age	48.8	49.8
Male	63.3%	64.6%
Specialty	-	
Nephrology	74.0%	73.1%
Nurse Practitioner	13.1%	11.9%
Internal Medicine	7.9%	9.0%
Physician Assistant	2.1%	2.2%
Pediatric Medicine	1.0%	1.0%
Other	1.9%	2.7%
Average Patient Volume and Characteristics	-	
Number of Dialysis Patients	74.7	79.3
Average Age	60.8	60.9
Female	42.7%	42.6%
White	57.2%	59.3%
Black/African American	34.9%	32.5%
Asian	3.5%	4.5%
American Indian/Alaska Native	2.1%	1.0%
Hispanic	11.0%	15.0%
Dually Eligible for Medicare and Medicaid	46.7%	48.1%
Average Number of Patients Treated per Month by Dialysis Modality	-	
In-Center HD	17.9	19.2
Home HD	0.37	0.37
Peritoneal Dialysis	1.8	2.1
Nocturnal	0.06	0.08
In-Center Self-HD	0.01	0.02

Notes: Demographic, specialty results from 2019 (N: ETC=3,370, comparison=6,626). Remaining measures cover years 2017-2019 (N: ETC=4,708, comparison=8,195)

2.3.2. What are the Characteristics of the Markets in which Facilities and Managing Clinicians Participate in the ETC Model?

Randomization for the ETC Model was done at the HRR level, stratified by the four Census regions (Northeast, Midwest, South, West). Accordingly, we compared select market characteristics for the ETC and comparison areas (see **Exhibit 6**). Comparing SMD against the 0.2 threshold value, the ETC areas have lower proportions of individuals with Medicare coverage who are Asian and Hispanic, a higher proportion of individuals with Medicare coverage who are Black, and lower Medicare Advantage (MA) penetration. Other market attributes were balanced

including poverty levels and density of health care resources. A detailed balance table is included in **Appendix B, Exhibit B-12**.

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

Characteristic	ETC Mean N=95	Comparison Mean N=211
Demographic Characteristics	-	
Median Age, 2010	38.9	38.4
Asian	2.6%	3.6%
Non-Hispanic Black	12.2%	9.1%
Hispanic	9.9%	14.1%
Native Hawaiian/Pacific Islander	0.17%	0.21%
Non-Hispanic White	70.4%	68.8%
American Indian/Alaskan Native	2.2%	1.6%
Persons above Age 25 without a High School Diploma	8.9%	9.4%
MA Penetration	31.1%	33.7%
Poverty	13.4%	13.0%
Market Level Capacity (Number per 100,000 Population)	-	
Short-Term General Hospitals	2.4	2.5
LTCH	0.11	0.12
Short-Term General Hospitals with HD	0.38	0.42
Non-Federal Transplant (i.e., Transplant Surgeons)	0.03	0.04
Non-Federal PCP, Patient Care	67.1	66.6
Non-Federal PCP, Hospital Resident	6.0	6.3
Market Characteristics	-	
ADI[1]	59.0	58.7
ACO Beneficiaries (%)	0.30	0.29
Comprehensive ESRD Care (CEC) Beneficiaries (%)	0.001	0.001

Notes: LTCH = Long-Term Care Hospitals. PCP = Primary Care Physician. ADI = Area Deprivation Index. ACO = Accountable Care Organization. County-level data based on publicly available AHRF. HRR market attributes averaged (equal weight to all HRRs) in each group. ADI national percentile rankings based on the University of Wisconsin's publicly available values (https://www.neighborhoodatlas.medicine.wisc.edu/). Higher ADI scores indicate area deprivation and lower socioeconomic status.

2.3.3. 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. ETC attribution status is determined monthly for each patient and may change during a year based on multiple factors including dialysis start date, facility or clinician changes, discontinuation of dialysis (e.g., due to events such as transplantation and death), and emergence of ineligibility criteria (e.g., nursing home placement, dementia diagnosis, hospice placement). Thus, patient-month is the unit of analysis for the ETC Model evaluation (see **Appendix B, Section B.2**). **Exhibit 7** displays select characteristics for 171,240 ETC patients and 336,396 comparison

patients averaged over the months in which they met the model eligibility and attribution criteria in the three-year pre-ETC period. The average patient contributed 18 observation months over the three-year pre-ETC period. In general, there was a high degree of balance between ETC and comparison patients across a wide range of characteristics. In both groups, the average patient age was approximately 62 years and patients had an average of 5.2 years since onset of ESRD, and the two groups were balanced on primary cause of ESRD and nephrology care prior to ESRD. Of note, both groups had a similar share of beneficiaries who were dually eligible for Medicare and Medicaid and who were eligible for the Part D LIS. The ETC group included fewer patients who are Hispanic and more patients who are Black or American Indian/Alaska Native patients (see **Exhibit 7**). We observed a mild imbalance for alignment with the CEC Model (20 percent of ETC vs. 12 percent of comparison patient-months). We also assessed balance on claims-based comorbidities and other comorbidities identified at start of ESRD care and noted the balance between the two groups on these factors (see **Appendix B, Exhibit B-10**).

Exhibit 7. Patient Characteristics by ETC Status, 2017-2019

Characteristic	ETC Mean N = 3,116,915	Comparison Mean N = 6,167,668
Mean Age	61.7	62.0
Median Age	63.0	63.0
Female	43.2%	42.9%
Ethnicity[1] (Hispanic)	11.1%	17.5%
Race[1]	-	
Black or African American	39.4%	34.2%
Non-Hispanic White	53.0%	57.9%
Asian	3.3%	4.8%
Native Hawaiian/Pacific Islander	1.1%	1.3%
American Indian/Alaska Native	2.7%	1.0%
Other	0.57%	0.75%
Time from Start of ESRD (Years)	5.2	5.2
Dually Eligible for Medicare and Medicaid (Full or Partial Benefits)	47.2%	48.6%
Part D Benefit Enrollment	81.6%	81.9%
Part D LIS (among Part D Enrollees)	67.8%	69.2%
Medicare Shared Savings Program	22.3%	22.3%
Alternative Payment Models (APMs)	-	
CEC	20.3%	12.4%
NGACO	2.9%	3.5%
Primary Cause of ESRD	-	
Diabetes	42.9%	44.5%
Glomerulonephritis	11.4%	11.0%
Hypertension	31.4%	30.0%
Other	14.3%	14.5%

Characteristic	ETC Mean N = 3,116,915	Comparison Mean N = 6,167,668
Health Status at Start of ESRD	-	
Diabetes	51.4%	52.5%
Congestive Heart Failure	21.6%	21.7%
Atherosclerotic Heart Disease	10.2%	10.0%
Nephrologist Care Prior to ESRD Therapy	-	
Less than 6 Months	12.4%	12.5%
6 - <12 Months	19.1%	18.3%
12 Months or Longer	29.4%	28.6%
Not under Care of Nephrologist Prior to ESRD	20.8%	21.3%
Unknown	18.2%	19.3%

Notes: NGACO = Next Generation ACO. A patient may contribute up to 12 observations per year to this patient-month summary. [1]Race/ethnicity information obtained from EQRS, supplemented by Medicare claims.

2.4. Discussion

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 healthcare 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 4**).

The market characteristics of the ETC areas were generally comparable to the comparison areas. There was mild imbalance among patients who are Asian, Black, and Hispanic as judged by the standardized mean group difference (see **Exhibit 6**). However, these factors were better balanced at the Managing Clinician and patient month-levels, probably due to larger sampling units (see **Exhibit 5** and **Exhibit 7**). The ETC areas had a lower level of MA penetration among the general Medicare population (see **Exhibit 6**). The ETC Model excludes patients enrolled in MA plans and focuses on enrollees in the traditional Medicare FFS program. Historically, beneficiaries with ESRD who are eligible for Medicare were only permitted to select MA if they were enrolled in these plans before developing ESRD. However, beneficiaries with ESRD were allowed to select MA plans without restriction in CY 2021 (the first year of ETC). The ETC sample and balance could be affected if patients who select MA during the ETC intervention period are different from those who remain in traditional Medicare. Accordingly, it will be important to assess patient balance and MA trends for each year of the ETC Model.

ESRD facilities and Managing Clinicians showed balance between the ETC and comparison groups across all measured characteristics (see **Exhibit 4** and Exhibit 5). Similarly, nearly all patient characteristics summarized at the patient-month level were balanced (see **Exhibit 7**). The only patient characteristic to exceed the SMD balance criteria was the level of participation in the CEC Model. The voluntary CEC Model concluded before the start of the ETC Model and we do not anticipate a strong residual carry-over effect that would alter the ETC Model evaluation findings. We also assessed balance of the ETC group excluding the four Maryland HRRs with the comparison areas and observed similar overall balance (see **Appendix B, Exhibits B-10-12**). We conclude that the slight imbalance between the ETC and comparison areas was not driven by the

non-random inclusion of the Maryland HRRs in the ETC Model. Although the overall level of balance between the ETC and comparison groups was high, the model evaluation will adjust for multiple market, facility, clinician and patient characteristics including, but not restricted to, those that are not completely balanced.

3. What Were the Impacts of the ETC Model?

This section summarizes quantitative findings of the impact of the ETC Model on dialysis care, transplant waitlisting, kidney transplantation, utilization, Medicare payments, and in-center HD patient experience of care for CY 2021.

3.1. Key Findings

Exhibit 8. CY 2021 ETC Model Impact[1]

Domain	Outcome	ETC Model Impact (% Relative Change)
Dialysis Modality Measures 	Home Dialysis	-0.9%
	Peritoneal Dialysis	-1%
	Home Hemodialysis	0.6%
	In-Center Hemodialysis	0.1%
	In-Center Self-Dialysis	65%
	Nocturnal Hemodialysis	-4%
	Home Dialysis Training	↑ 9%
Transplantation 	Overall Waitlisting	↑ 4%
	Active Status	3%
	Inactive Status	4%
	Overall Transplants	↑ 10%
	Deceased Donor	↑ 12%
	Living Donor	0.6%
	Living Donor (Dialysis and Pre-emptive)	0.8%
Utilization 	Acute Care Hospitalization	0.8%
	Readmission	-2%
	Outpatient ED Use	-1%
Medicare Payments 	Total Parts A & B	-0.2%
	Total Part A	-0.4%
	Part A Acute Care Hospitalization	0.3%
	Part A LTCH and IRF	↓ 8%
	Other Part A	-1.4%
	Total Part B	-0.1%
	Part B Dialysis	0.1%
	Other Part B	-0.6%
In-Center HD Patient Experience of Care 	Rating of Kidney Doctors	-0.02%
	Rating of Dialysis Center Staff	-1%
	Rating of Dialysis Center	-0.4%
	Nephrologists' Communication and Caring	0.2%
	Quality of Dialysis Center Care and Operations	-0.4%
	Providing Information to Patients	-0.1%

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

Arrow indicates the direction of the statistically significant impact estimate. DiD impact estimates are reported in terms of the relative percent change of the outcome measure, compared to the pre-ETC period. Detailed impact estimates of the absolute change in the value of the outcome measure among ETC beneficiaries, relative to the comparison group, are included in the body of the report.

3.2. Methods

To evaluate the impact of the ETC Model, we used a difference-in-differences (DiD) framework to compare changes in outcomes for patients observed 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. The analytic sample consists of all attributed and eligible beneficiaries receiving care from ESRD facilities and Managing Clinicians in a given month, in the two groups.[15] 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. For this evaluation, we leveraged the randomized selection into the model and mandatory nature of participation and designated the Comparison Geographic Areas as the comparison group (i.e., consisting of HRRs not selected for the model). Descriptive analyses of balance showed similarity in the majority of patient-, facility-, and market-level characteristics between the 95 ETC HRRs and all 211 comparison HRRs (see **Appendix B, Exhibits B-10-12).**

We produced DiD impact estimates for the first CY 2021, 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. With the ETC Model starting in January 2021, ideally the years immediately prior to 2021 would be included in defining the pre-ETC period. However, in 2020 there was both the onset of the coronavirus disease of 2019 (COVID-19) Public Health Emergency (PHE) as well as the publication of the ETC Model final rule in September 2020 which included the announcement of HRRs selected for inclusion in the model. Considering potential differential impacts of COVID-19 PHE in the ETC and comparison regions as well as the possibility of pre-emptive responses among ETC participants once the model was finalized and selected ETC areas were announced, we excluded 2020 from the study period and defined the pre-ETC period based as January 2017-December 2019. The first ETC Model year ran from January 2021 through December 2021.The DiD methodology, including data sources, outcomes definitions, methods for identifying attributed and eligible patients, construction of the comparison group, covariate adjustment in DiD statistical models, and approaches used to test the parallel trends assumption are described in detail in **Appendix B**.

For 2021, we examined trends in patient COVID-19 diagnoses reported in claims data and county level data between the ETC areas and the comparison areas. We observed relatively similar trends in the percentage of patient months with an initial COVID-19 diagnosis in the two groups throughout 2021 but still adjusted for patient and county level COVID-19 indicators to account for potential confounding. Since there may be limitations to availability of COVID-19 data we also conducted additional analyses to examine the sensitivity of impact estimates to COVID-19 covariate adjustments (**Appendix B, Exhibit B-20**) and noted that impact estimates were similar with and without COVID-19 adjustments.

We also utilized data from the ICH-CAHPS surveys that are routinely administered to in-center HD patients. Although the ICH-CAHPS survey does not include home dialysis patients, the survey provides information on experience of care among patients treated with in-center HD before and after the start of the ETC Model. We used a DiD framework to evaluate the impact of the ETC Model on a selected subset of six measures derived from ICH CAHPS data, including three global

[15] We applied inclusion/exclusion criteria, per the ETC Model Final Rule to restrict the sample to include only eligible patients in a given month with either an attributed ESRD facility or Managing Clinician.

ratings and three composite measures, to compare changes in in-center HD patient experience of care observed over time among patients who responded to the ICH CAHPS survey and dialyzed at ESRD facilities located in the ETC areas against those in the comparison group. Our facility survey wave-level analyses included ESRD facilities with ICH CAHPS survey data during the pre-ETC (spring 2017-fall 2019 survey waves) or CY 2021 (spring 2021 and fall 2021 survey waves) periods. Facilities included in the ICH CAPHS analysis correspond to approximately 60 percent of facilities included in the overall analytic sample in the pre-ETC period and 28 to 47 percent in CY 2021 (see **Appendix C.3**). Of the 3,522 ESRD facilities with ICH CAHPS data in 2021, 85% (3,006 facilities distributed as 952 from ETC areas and 2,054 from comparison areas) also had at least one ICH CAHPS observation during the pre-ETC period (2017-2019). All patients at a facility who respond to the ICH CAHPS survey are included in the analyses, regardless of whether the patients are attributed to the ETC Model.

Similar to the findings for the analytic sample described above, descriptive analyses showed similarity in the majority of characteristics between ESRD facilities with ICH CAHPS data in both the ETC and comparison areas (see **Appendix C, Exhibits C-4** and **C-5**). The six ICH CAHPS-based measures are adjusted for several patient-mix factors and survey mode and for a subset of the patient, facility, and market characteristics (see **Appendix C.4**). We estimated a DiD model that produced impact estimates for CY 2021, based on spring and fall 2021 ICH CAHPS data. Each facility-survey wave observation was weighted by the number of patients who completed the ICH CAHPS survey at the facility, and we clustered the analyses at the HRR-level. The DiD methodology, including details about the ICH CAHPS data source, measure definitions, and results from the dynamic trends test to assess parallel trends are described in **Appendix C.**

This first annual report relies solely on secondary, quantitative data. In future reports, we plan to supplement quantitative findings with qualitative findings to identify mechanisms and implementation strategies of participants that may have influenced model impacts.

3.3. Results

The analytic sample included 210,268 patients in the ETC areas and 411,535 patients in the comparison group. In Section 2.3.3. above, we showed that the demographic, clinical, and socioeconomic characteristics of patients were similar in the two groups. To understand the impacts of the ETC Model during its first year, we examined a range of impact measures across several domains (see **Exhibit 9**).

Exhibit 9. ETC Model Evaluation Outcome Measures

Domain	Evaluation Measure
Dialysis Modality Measures	▪ Percent of patients receiving home dialysis (peritoneal dialysis or home HD) in a given month ▪ Percent of patients receiving peritoneal dialysis in a given month ▪ Percent of patients receiving home HD 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

Domain	Evaluation Measure
Transplant Waitlisting	▪ Percent of eligible patients on the transplant waitlist in a given month - Overall ▪ Percent of eligible patients on the transplant waitlist in a given month - Active status ▪ Percent of eligible patients on the transplant waitlist in a given month - Inactive status
Transplant (per 1,000 Patient Months)	▪ Percent of patients receiving a living or deceased donor[1] kidney transplant in a given month ▪ Percent of patients receiving a deceased donor[1] kidney transplant in a given month ▪ Percent of patients receiving a living donor[1] kidney transplant in a given month ▪ Percent of patients with a pre-emptive living donor transplant in a given month (dialysis and pre-emptive) [2]
Utilization	▪ Percent of patients with at least one acute care hospitalization in a given month ▪ Percent of patients with a hospital readmission in a given month ▪ Percent of patients with at least one outpatient ED visit 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 (IRF) payments PPPM ▪ Other Part A payments PPPM ▪ Total Part B payments PPPM ▪ Part B dialysis payments PPPM ▪ Other Part B payments PPPM
In-Center Dialysis Patient Experience of Care	▪ Rating of Kidney Doctors: Percent of patients who gave their kidney doctors a rating of 9 or 10 (0 to 10 scale) ▪ Rating of Dialysis Center Staff: Percent of patients who gave the dialysis center staff a rating of 9 or 10 (0 to 10 scale) ▪ Rating of Dialysis Center: Percent of patients who gave the dialysis center a rating of 9 or 10 (0 to 10 scale) ▪ Nephrologists' Communication and Caring[3] ▪ Quality of Dialysis Center and Operations[3] ▪ Providing Information to Patients[3]

Note: All measures are analyzed at the patient month-level except for the hospital readmission measure which is analyzed at the index discharge level and the ICH CAHPS measures which are analyzed at the facility survey-wave level. Transplant and waitlisting measures were restricted to patients less than 75 years old. Indicators of dialysis modality are not mutually exclusive (i.e., a patient may have more than one modality in a month).[1] Among dialysis patients.[2] Among dialysis patients and pre-dialysis pre-emptive transplant patients.[3] See **Appendix C, Exhibit C-2** for a complete description of the ICH CAHPS items included in these composite measures. Nephrologists' Communication and Caring measure is the percent of patients who reported that kidney doctors "always" communicated well and cared for them as a person. Quality of Dialysis Center Care and Operations is the percent of patients who reported that dialysis center staff "always" communicated well, kept patients as comfortable and pain-free as possible, behaved in a professional manner, and kept the center clean. Providing Information to Patients is the percent of patients who reported that Yes, their kidney doctors and dialysis center staff gave them the information they needed to take care of their health.

We synthesized the evidence presented in this report to identify meaningful patterns in results across analyses of the above impact measures. We carefully weighed the strength of the evidence in terms of magnitude of point estimates taking into account any existing trends in the pre-ETC period between the two groups, consistency with prior hypotheses about impacts, and statistical significance at the $p < 0.10$ level to draw conclusions about impacts of the ETC Model. DiD impact estimates are reported as the absolute change in the value of the outcome measure among ETC patients, relative to the comparison group, and also in terms of the relative percent change

of the outcome measures, compared to the pre-ETC period. We report the statistical significance of all results.

A summary of the results of DiD analyses is provided in **Exhibit 10**. For each impact measure, we report mean adjusted values in both the pre-ETC period (CYs 2017-2019) and in the first year of the model (CY 2021), the DiD estimate with a 90 percent confidence interval (CI), and the estimated impact expressed relative to the pre-ETC level (i.e., the relative change). In the sections that follow, we discuss the results of these impact analyses separately for each of the six domains of outcomes shown in **Exhibit 10**: dialysis modality measures, waitlisting, transplantation, utilization, Medicare spending, and in-center HD patient experience of care.

Exhibit 10. Estimated Impacts of the ETC Model for CY 2021

Outcomes		ETC		Comparison		Model Estimates			% Relative Change
		Pre-ETC Mean	CY 2021 Mean	Pre-ETC Mean	CY 2021 Mean	DiD	Lower 90% CI	Upper 90% CI	
Dialysis Modality Measures (%)	**Home Dialysis**	11.8%	14.7%	12.8%	15.8%	-0.11	-0.48	0.26	-0.93%
	Peritoneal Dialysis	9.9%	12.0%	10.9%	13.1%	-0.13	-0.46	0.21	-1.3%
	Home HD	2.2%	3.0%	2.2%	3.0%	0.01	-0.18	0.21	0.61%
	In-center HD	88.3%	85.5%	87.2%	84.3%	0.10	-0.28	0.48	0.11%
	In-center Self-Dialysis	0.04%	0.02%	0.09%	0.05%	0.02	-0.04	0.08	65.0%
	Nocturnal HD	0.38%	0.25%	0.42%	0.31%	-0.01	-0.10	0.07	-3.9%
	Home Dialysis Training	0.72%	0.86%	0.76%	0.83%	**0.07****	0.02	0.11	**9.0%**
Waitlisting (%)	**Overall** [2]	19.5%	19.0%	21.1%	19.8%	**0.83***	0.01	1.7	**4.3%**
	Active Status [2]	12.2%	11.4%	13.5%	12.3%	0.41	-0.28	1.1	3.4%
	Inactive Status [2]	7.2%	7.6%	7.6%	7.6%	0.42	-0.12	0.96	5.8%
Transplant (per 1,000 Patient Months)	**Total (among Dialysis Patients)** [2 3]	3.8	5.0	3.9	4.8	**0.37***	0.03	0.72	**9.8%**
	Deceased Donor [2 3]	3.2	4.5	3.3	4.1	**0.37***	0.03	0.70	**11.5%**
	Living Donor [2 3]	0.59	0.56	0.65	0.62	0.004	-0.06	0.07	0.63%
	Living Donor (among Both Dialysis Patients and Pre-emptive Transplant Recipients) [2 4]	0.59	0.56	0.65	0.62	0.005	-0.06	0.07	0.79%
Utilization (%)	**Acute Care Hospitalization**	9.9%	9.2%	9.9%	9.1%	0.07	-0.08	0.23	0.75%
	Readmission	30.0%	29.2%	29.9%	29.6%	-0.50	-1.0	0.00	-1.7%
	Outpatient ED Use	11.3%	9.5%	11.2%	9.5%	-0.13	-0.31	0.05	-1.2%
Medicare Payments (PPPM)	**Total Parts A & B**	$5,671	$6,008	$5,754	$6,101	-$10	-$50	$30	-0.18%
	Total Part A [5]	$1,601	$1,691	$1,658	$1,755	-$7	-$49	$35	-0.44%
	Part A Acute Care Hospitalization [5]	$1,377	$1,450	$1,403	$1,472	$5	-$14	$23	0.34%
	Part A LTCH, IRF [5]	$100	$108	$120	$137	**-$8****	-$13	-$3	**-7.7%**
	Other Part A [5]	$123	$147	$131	$156	-$2	-$5	$2	-1.4%
	Total Part B	$4,113	$4,336	$4,156	$4,383	-$5	-$29	$19	-0.12%
	Part B Dialysis	$2,880	$2,972	$2,890	$2,981	$2	-$11	$15	0.06%
	Other Part B	$1,233	$1,364	$1,266	$1,403	-$7	-$28	$14	-0.56%

Outcomes		ETC		Comparison		Model Estimates			% Relative Change
		Pre-ETC Mean	CY 2021 Mean	Pre-ETC Mean	CY 2021 Mean	DiD	Lower 90% CI	Upper 90% CI	
In-Center HD Patient Experience of Care Measures	**Rating of Kidney Doctors: Percent of Patients Who Gave their Kidney Doctors a Rating of 9 or 10 (0 to 10 scale)**	59.5%	60.1%	60.7%	61.3%	-0.01	-0.86	0.83	-0.02%
	Rating of Dialysis Center Staff: Percent of Patients Who Gave the Dialysis Center Staff a Rating of 9 or 10 (0 to 10 scale)	62.5%	63.8%	63.1%	65.0%	-0.66	-1.5	0.16	-1.1%
	Rating of Dialysis Center: Percent of Patients Who Gave the Dialysis Center a Rating of 9 or 10 (0 to 10 scale)	67.5%	68.3%	68.2%	69.2%	-0.28	-1.1	0.54	-0.41%
	Nephrologists' Communication and Caring [6]	67.3%	67.0%	67.9%	67.5%	0.11	-0.51	0.72	0.16%
	Quality of Dialysis Center Care and Operations [6]	62.5%	63.0%	63.1%	63.7%	-0.23	-0.78	0.36	-0.36%
	Providing Information to Patients [5]	80.2%	79.9%	80.5%	80.2%	-0.04	-0.39	0.31	-0.05%

Notes: A summary of the results of the Pre-ETC period includes CY 2017 – CY 2019. Pre-ETC and CY 2021 means were adjusted for patient, facility, and market characteristics. Analyses of ICH CAHPS measures were performed using facility-level data; all other analyses were performed at the patient month level. DiD estimates are reported along with lower- and upper-90 percent CIs. Significance of the DiD impact estimates is indicated for each outcome where * implies significance at the 10 percent level, ** at the five percent level, and *** at the one percent level assuming a two-tailed test. [1]Not mutually exclusive (i.e., a patient may have more than one modality in a month). [2]Transplant measures restricted to patients less than 75 years old. [3]Among dialysis patients. [4]Among dialysis patients and pre-emptive transplant recipients.[5]Estimates obtained from a two-part model. [6]See **Appendix C**, **Exhibit C-2** for a complete description of the ICH CAHPS items included in these composite measures. Nephrologists' Communication and Caring measure is the percent of patients who reported that kidney doctors "always" communicated well and cared for them as a person. Quality of Dialysis Center Care and Operations is the percent of patients who reported that dialysis center staff "always" communicated well, kept patients as comfortable and pain-free as possible, behaved in a professional manner, and kept the center clean. Providing Information to Patients is the percent of patients who reported that yes, their kidney doctors and dialysis center staff gave them the information they needed to take care of their health.

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

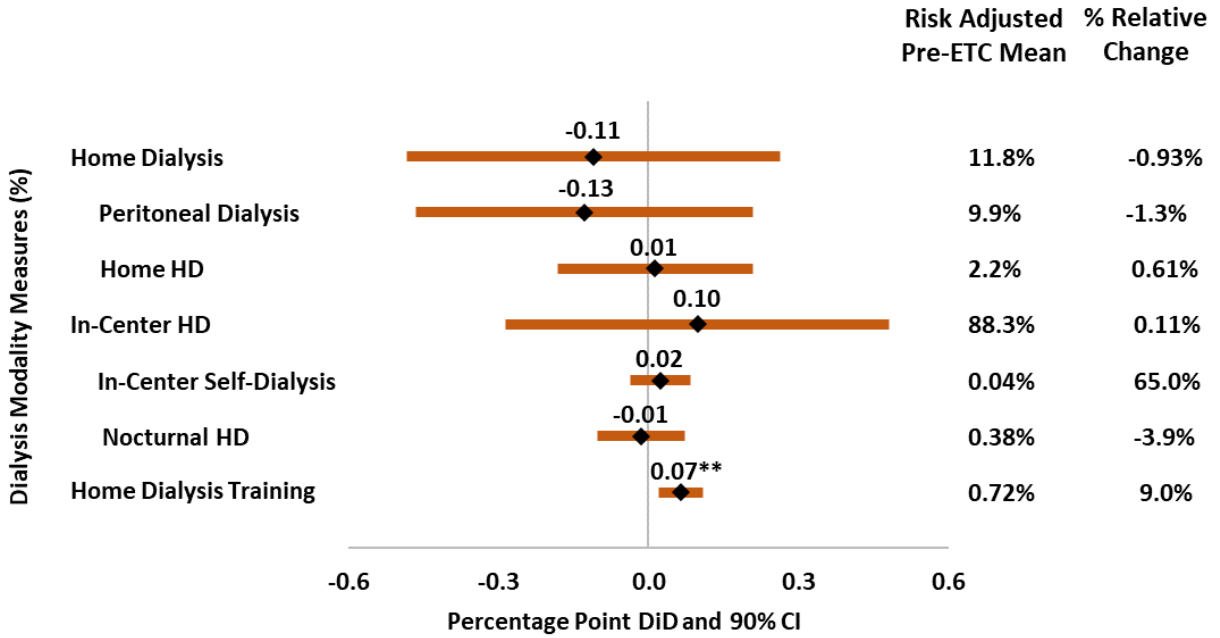
A key goal of the ETC Model is to enhance patient education and choice in the dialysis modality selection process. Expected outcomes include growth of home dialysis modalities and decreased reliance on in-center HD. The major home dialysis modalities include peritoneal dialysis and home HD. The ETC Model also awards partial credit to model participants for dialysis patients treated with in-center self- administered HD and in-center nocturnal dialysis (starting in 2022) on the grounds that these modalities promote self-care. The ETC Model started on January 1, 2021. For the first three years of the ETC Model, participants are eligible to receive the HDPA, a positive payment adjustment meant to address start-up costs associated with home dialysis expansion. For the full period of the model, participants are also eligible for the PPA, a positive or negative payment based on home dialysis and transplant performance. The first PPA payment which was determined by performance in the first model year occurred in July 2022.

The estimated impact of the ETC Model on home dialysis as of the first model year is shown in **Exhibit 11**, which displays the DiD estimates along with the mean pre-ETC values, level of statistical significance, and relative change from pre-ETC to model year 1. There were no statistically significant group DiD in home dialysis overall or in the specific home modalities of peritoneal dialysis or home HD. Home dialysis and the specific home modalities of peritoneal dialysis and home HD increased by approximately 24 percent, 21 percent, and 36 percent, respectively, from the pre-ETC period through CY 2021 (calculated based on results shown in **Exhibit 10**). However, growth was comparable in the ETC and comparison groups. As a result, the DiD impacts were small and not statistically significant (see **Exhibits 11** and **B-20)**.

Notably, the ETC Model had a modest, statistically significant impact on home dialysis training of 0.07 percentage points, ($p \leq 0.05$), representing a nine percent increase relative to the pre-ETC period. Overall, the rate of home dialysis training increased over time but to a greater extent for the ETC group, generating the positive impact. However, the rate of home dialysis training is relatively low among the entire analytic sample. We estimate that the DiD translates to an additional 546 patient months with home dialysis training in ETC areas. Assuming one or two months with home dialysis training claims per patient, the impact estimate suggests that an additional 273 to 546 patients underwent home dialysis training in ETC areas in CY 2021. Future evaluation reports will examine the rate of home dialysis gains and losses as well as the potential contributions of incident vs. established dialysis patients to these rates.

Although participants could receive partial credit (towards the PPA) for expanding the use of in-center self-administered dialysis and nocturnal center HD, the use of these options was rare and declined from the pre-ETC period through CY 2021 (see **Exhibit 11**). There were no statistically significant impacts as a result of the ETC Model on these outcomes.

Exhibit 11. DiD Impact Estimates for Dialysis Modality Measures



Notes: Pre-ETC period is CY 2017-CY 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 with the pre-ETC period relative to the same difference over time for patients in the comparison group. DiD estimates are reported along with lower- and upper-90 percent CIs. Significance of the DiD impact estimates is indicated for each outcome where * implies significance at the 10 percent level, ** at the five percent level, and *** at the one percent level assuming a two-tailed test. These indicators of modality are not mutually exclusive (i.e., a patient may have more than one modality in a month). Home dialysis modality reflects primary modality (either home HD or peritoneal dialysis) for a patient in a given month.

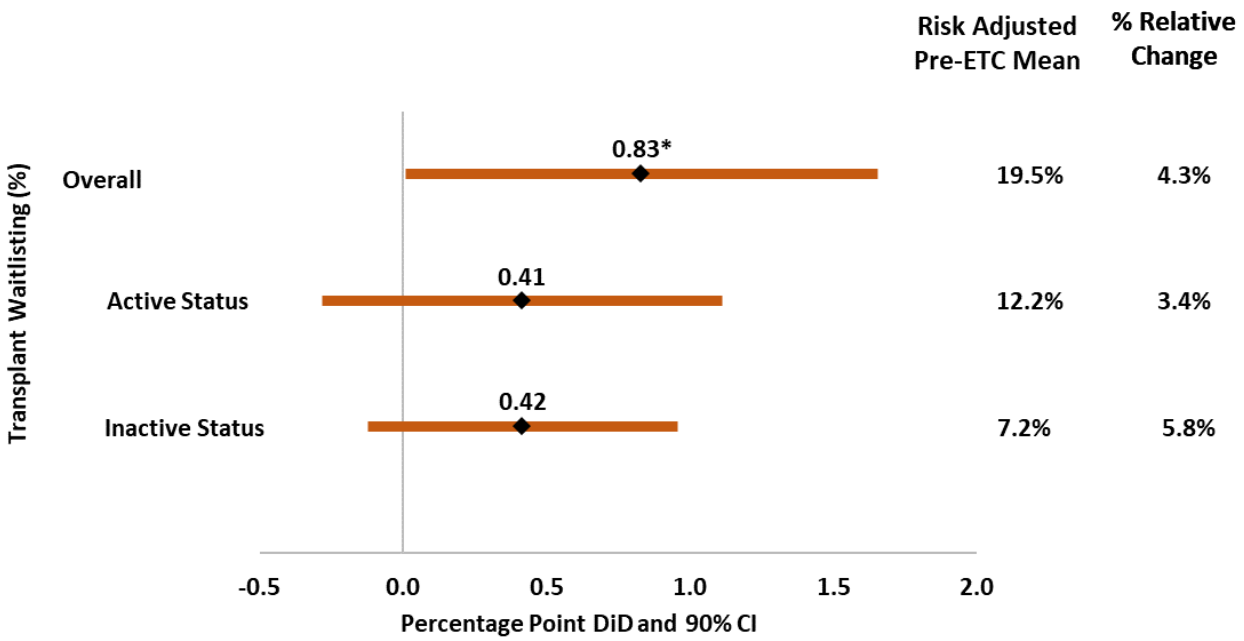
3.3.2. What Was the Impact of the ETC Model on the Kidney Transplant Waitlist?

The ETC Model was also designed to incentivize participants 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 placed in inactive status until the situation Is resolved. Dialysis providers usually make the initial referral to a transplant center and play an important role in arranging pre-transplant testing and evaluations that must be done before waitlisting. Accordingly, the transplant waitlist is an important performance measure for the ETC Model and as such we examined for the impact on overall, active and inactive waitlist status. The ETC Model transplant rate, which is calculated as the sum of the transplant waitlist rate and the living donor transplant rate, is restricted to patients less than age 75 years.

ETC Model impacts on transplant waitlisting for CY 2021 are shown in **Exhibit 12.** We observed slight declines in the trends of overall and active waitlisting rates from the pre-ETC period through CY 2021 (see **Exhibits 12** and **B-20**). However, for overall waitlisting, the magnitude of the decline was smaller for ETC participants than for the comparison group, generating a positive DiD

estimate of 0.83 percentage points ($p<0.1$), a four percent increase relative to the pre-ETC period. Similarly, the magnitude of the decline in active waitlisting was smaller for ETC participants than the comparison group, resulting in a positive, but not statistically significant, DiD estimate. Inactive waitlisting increased for ETC participants and was stable for the comparison group, resulting in a positive DiD estimate that was also not statistically significant. Within the context of declining overall and active waitlisting rates, the results show a positive impact of the ETC Model on transplant waitlisting. We estimate that the DiD represents approximately 663 additional patients on the waitlist in ETC areas relative to the expected number in the absence of the ETC Model in CY 2021.

Exhibit 12. DiD Impact Estimates for Transplant Waitlist Measures



Notes: Pre-ETC period is CY 2017-CY 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 with the pre-ETC period relative to the same difference over time for patients in the comparison group. DiD estimates are reported along with lower- and upper-90 percent CIs. Significance of the DiD impact estimates is indicated for each outcome where * implies significance at the 10 percent level, ** at the five percent level, and *** at the one percent level assuming a two-tailed test. Waitlisting and transplant measures are restricted to patients with age < 75 years.

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

The ETC Model incentivizes ESRD facilities and Managing Clinicians to increase the rate of living donor transplantation among patients undergoing dialysis for ESRD. 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 not an explicit incentive to increase deceased donor organ transplantation, however the waitlist incentive is a potential driver of deceased donor transplants. The ETC Model also credits Managing Clinicians for pre-emptive living donor transplantation in the pre-dialysis (pre-ESRD) period. Pre-emptive transplants are credited to Managing Clinicians involved with pre-ESRD care at the time of the transplant. Managing

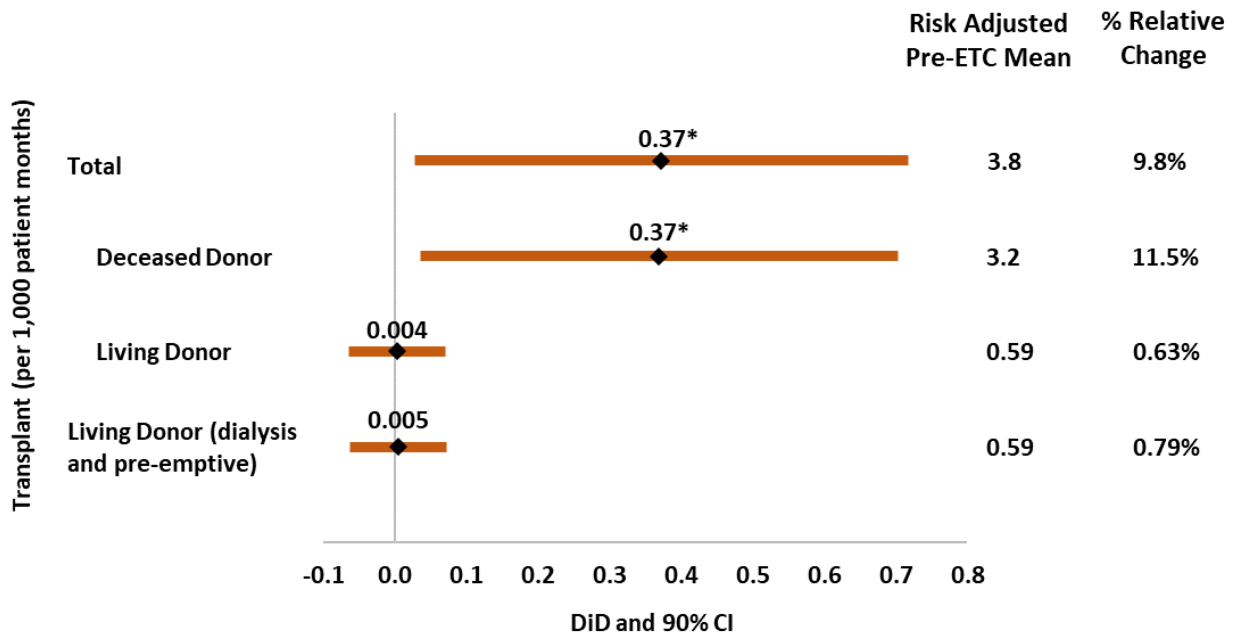
Clinicians receive credit for living donor transplants among both their dialysis and pre-dialysis patients.[16]

ETC Model impacts on kidney transplants for patients under the age of 75 for CY 2021 are shown in **Exhibit 13.** For both ETC participants and the comparison group, transplant rates (total, deceased, and living) increased from the pre-ETC period through CY 2021.[17] The rate for total transplants increased more for ETC participants, indicating the ETC Model led to an additional 0.37 transplants per 1,000 patient-months ($p<0.1$), a 10 percent increase relative to the pre-ETC period. We estimate that the increased rate of transplantation represents approximately 225 additional transplants in ETC areas in CY 2021. The overall impact on total transplants was driven by a higher rate of deceased donor transplants. The deceased donor transplantation rate increased more for ETC participants than the comparison group, resulting in a 12 percent ($p<0.1$) increase relative to the pre-ETC period. The ETC Model did not have a statistically significant impact on the living donor transplant rate (with or without pre-emptive transplants). The finding is surprising given that ETC Model incentives directly apply to living donor transplants. The increase in deceased donor transplants in the ETC group does not affect the incentive payments to participating ESRD facilities and Managing Clinicians. Further insight into the observed expansion of deceased donor transplantation should come from planned provider interviews and findings from future model years. In future analyses we will also explore the potential impact of changes in the availability of donors organs and of other providers such as Organ Procurement Organizations and transplant centers, although an important limitation of such analyses is that the areas served by these providers may cross HRRs as well as ETC and comparison areas.

[16] In calculating transplant rates, the denominator for dialysis patients consists of eligible months on dialysis. The denominator contribution for pre-emptive transplants consists of the months in the year of the transplant up to the transplant month. The pool of pre-dialysis patients is not incorporated into the pre-emptive transplant denominator.

[17] The transplant rates for ETC are higher than those reported by United States Renal Data System (2022) for dialysis patients due to the ETC eligibility rules that explicitly exclude several categories of patients who otherwise make large contributions to the denominator and small contributions to the numerator of the transplant rate calculation (e.g., patients ≥ 75 years, nursing home residents, dementia diagnosis).

Exhibit 13. DiD Impact Estimates for Transplant Measures



Notes: Pre-ETC period is CY 2017-CY 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 with the pre-ETC period relative to the same difference over time for patients in the comparison group. DiD estimates are reported along with lower- and upper-90 percent CIs. Significance of the DiD impact estimates is indicated for each outcome where * implies significance at the 10 percent level, ** at the five percent level, and *** at the one percent level assuming a two-tailed test. Waitlisting and transplant measures are restricted to patients with age < 75 years.

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

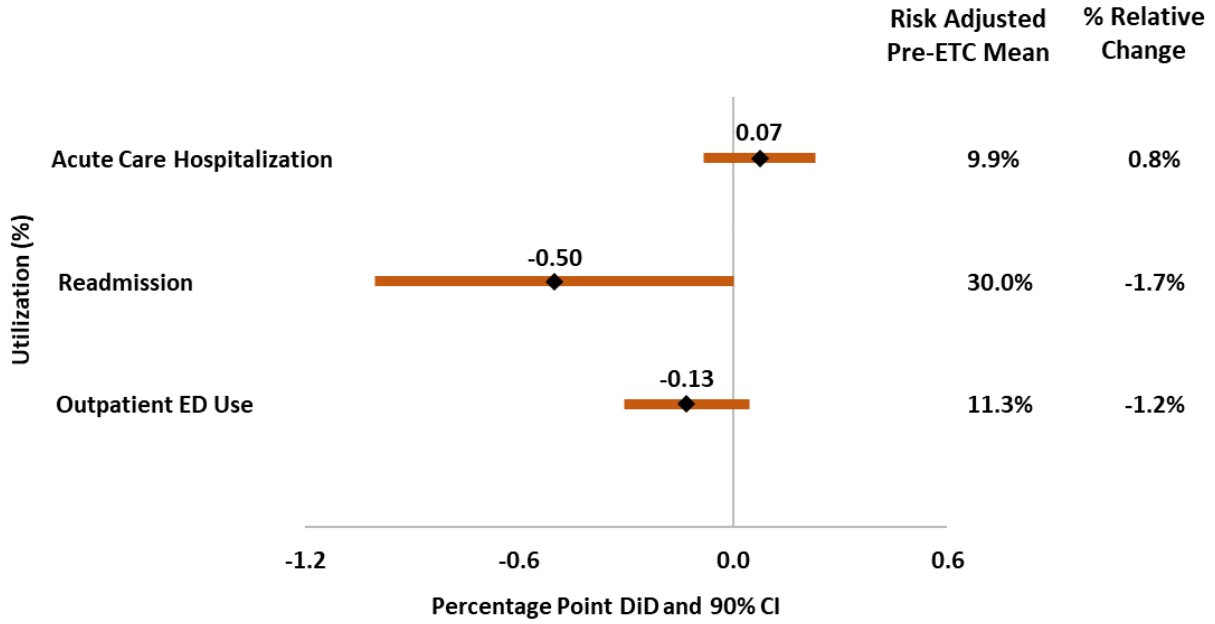
Although the model incentives focus on encouraging greater use of both home dialysis and transplantation, the model may have broader implications on utilization patterns. This could occur through changes in the frequency with which the different renal replacement therapies are used or through changes in practice. For example, efforts to sustain use of home dialysis modalities over a longer term and minimize complications, such as enhanced medication management, successful creation and maintenance of arteriovenous (AV) fistulas and AV grafts, or coordinating care with home health providers, could reflect quality-enhancing changes that have implications for utilization and provide important insights into the mechanisms which may affect Medicare payments. The ETC Model does not explicitly include measures of utilization or spending in the incentive payment adjustments.

In this report, we examined three key measures of utilization among dialysis patients: acute care hospitalizations, outpatient ED visits, and hospital readmissions. Each of these types of utilization is relatively common among dialysis patients and reflect a need for care for acute conditions that may be avoidable in some cases. For all three measures, we used Medicare claims to define indicators of whether there was at least one event during the month for the beneficiary.

Overall, there was a declining trend in all three utilization measures between the pre-ETC period and CY 2021 for both ETC participants and the comparison group. The rate of decline was similar for both groups such that impact estimates were not statistically significant, indicating no change in

utilizations patterns occurred during the first year of the ETC Model (see **Exhibit 14.)**. We will continue to evaluate all these measures in CY 2022. In particular, the differential declines in outpatient ED use and hospital readmissions, nearly but not statistically significant in CY 2021, may continue for ETC participants as the model evolves (see **Appendix B, Exhibit B-20**).

Exhibit 14. DiD Impact Estimates for Utilization Measures



Notes: Pre-ETC period is CY 2017-CY 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 with the pre-ETC period relative to the same difference over time for patients in the comparison group. DiD estimates are reported along with lower and upper 90 percent CIs. Significance of the DiD impact estimates is indicated for each outcome where * implies significance at the 10 percent level, ** at the five percent level, and *** at the one percent level assuming a two-tailed test.

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

The motivation for exploring impacts of the ETC Model on Medicare payments for FFS beneficiaries is similar to the motivation described above for utilization. Changing patterns of modality use and any related changes in QoC could have implications for utilization, which in turn could affect Medicare payments. In addition to changes in the types and volume of services being provided, however, there may also be changes in the intensity of care that drive changes in Medicare payments. Further, it is an explicit goal of the model to reduce Medicare payments.

To understand whether the model had an impact on Medicare payments, we examined standardized Medicare Parts A & B payments PPPM.[18] This measure reflects average Medicare

[18] Analyses are based on standardized Medicare payments so that differences in payments reflect differences in utilization and not ancillary parameters (i.e., wage index, Disproportionate Share Hospital, Indirect Medical Education payments, quality incentive payments, and others that determine payments under Medicare Prospective Payment Systems).

payments across patients with FFS coverage in a given month for all Parts A & B services.[19] We also separately examined major payment components to identify the source(s) of any observed overall changes in payments. We defined separate payment categories for Parts A & B services, and also defined categories for several distinct payment components of Part A and Part B, including for acute care hospitalizations as well as LTCH and IRF stays under Part A and for outpatient dialysis-related services under Part B. In particular, Medicare payments for acute care hospitalizations represented approximately 85 percent of total Part A payments for patients during the pre-ETC period, while Medicare payments for outpatient dialysis-related services represented approximately 70 percent of total Part B payments. The payments do not include the HDPA applied during CY 2021.

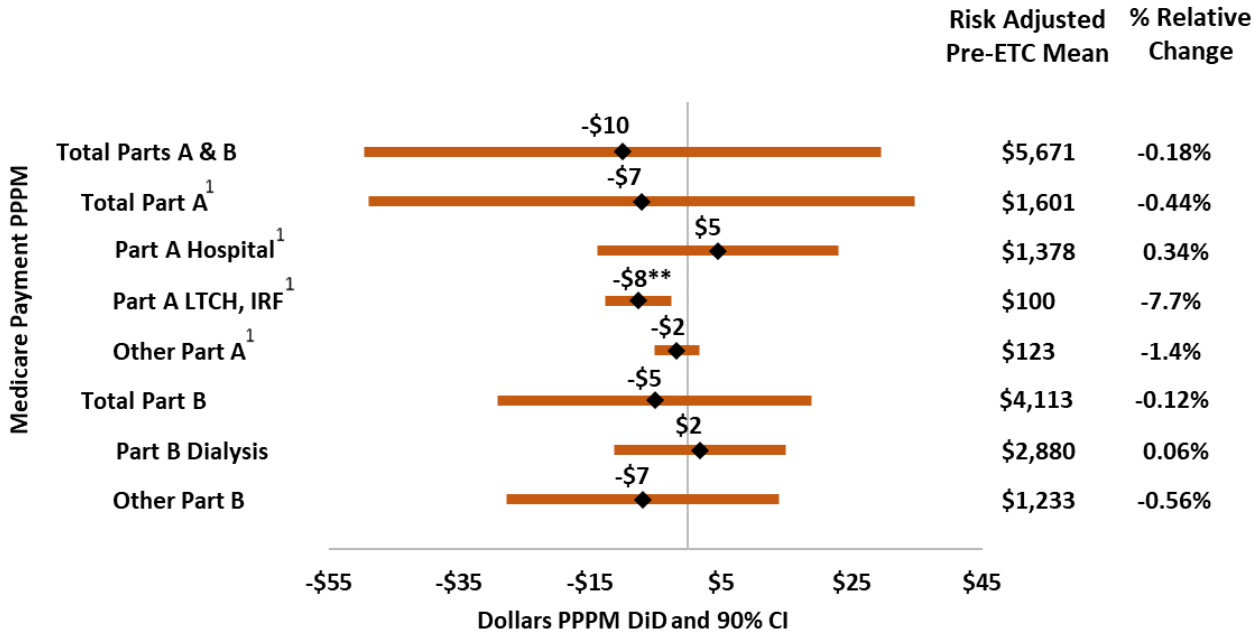
Medicare payments PPPM increased over time in both the ETC and comparison groups overall and for Parts A & B services (see **Exhibit 15**). The growth in overall payments is relatively similar in the two groups, reflecting a six percent increase in total Medicare payments PPPM between the pre-ETC period and CY 2021.

ETC Model impacts on Medicare payments in CY 2021 are shown in **Exhibit 15**. The impact estimates for total, total Part A and total Part B payments PPPM are relatively small and not statistically significant, suggesting the ETC Model did not reduce Medicare payments in ETC areas relative to the comparison group in CY 2021.

The only payment category with a statistically significant impact estimate involves Medicare payments to LTCHs and IRFs. The DiD estimate indicates $8 PPPM lower payments to LTCHs and IRFs, which corresponds to an eight percent reduction relative to pre-ETC levels. However, this estimated reduction is small relative (<0.2 percent) to total payments PPPM of approximately $5,700 during the pre-ETC period, which likely helps to explain why it is not a driver of any overall reductions in payments (see **Exhibits 15** and **B-20).**

[19] 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.

Exhibit 15. DiD Impact Estimates for Medicare Payments PPPM



Notes: Pre-ETC period is CY 2017-CY 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 with the pre-ETC period relative to the same difference over time for patients in the comparison group. DiD estimates are reported along with lower- and upper-90 percent CIs. Significance of the DiD impact estimates is indicated for each outcome where * implies significance at the 10 percent level, ** at the five percent level, and *** at the one percent level assuming a two-tailed test. [1] Estimates obtained using a two-part model (see **Appendix B** for details).

3.3.6. What Was the Impact of the ETC Model on In-Center Hemodialysis Patient Experience of Care?

Changing patterns in modality use – a key focus of the ETC Model – could potentially have important implications for patient experience with care. While the experience of home dialysis patients is of particular interest based on the design of the model, data on home dialysis patient experience are not currently available and will require a new survey data collection. 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. In this first annual report, we use existing ICH CAHPS survey data to assess any potential impacts of the model on in-center HD patient experience, whether they may be positive or negative. For instance, 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, in-center HD patients' experience of care could be affected, thereby having an unintended adverse impact.

To examine the effect of the ETC Model on experience of care among patients dialyzing in center, we used "top-box" scores, reflecting the highest level of satisfaction (e.g., 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).[20] These measures were adjusted for patient-mix factors and the DiD analyses included additional adjustments for facility-, patient-, and market-level characteristics.

We defined our population as patients who responded to the ICH CAHPS survey and dialyzed at ESRD facilities located in the ETC areas and the comparison areas. Notably, taking into consideration exemptions and suppressions that occurred during the study period, approximately 60 percent of ESRD facilities included in the overall impact analysis were included in the ICH CAHPS analysis in the pre-ETC period with similar declining shares between the ETC and comparison groups (see **Appendix C.3**). In the first year of the ETC Model, the share of ESRD facilities with ICH CAHPS data decreased further, with just 46 to 47 percent of facilities having ICH CAHPS data in the spring 2021 wave and only 28 to 31 percent in the fall 2021 wave. Survey response rates also declined which reflected differences between the earliest and latest waves in terms of the number of facilities (4,309 vs. 2,172) and of completed surveys (98,134 vs. 34,735). Participating facilities must have at least 30 completed ICH CAHPS surveys from the two most recent survey waves to have their ICH CAHPS data reported. The declining survey response rates were driving the decline in the number of ESRD facilities with ICH CAHPS data (see **Appendix C** for detailed discussion on data source, measures, study population, and analytic methods).

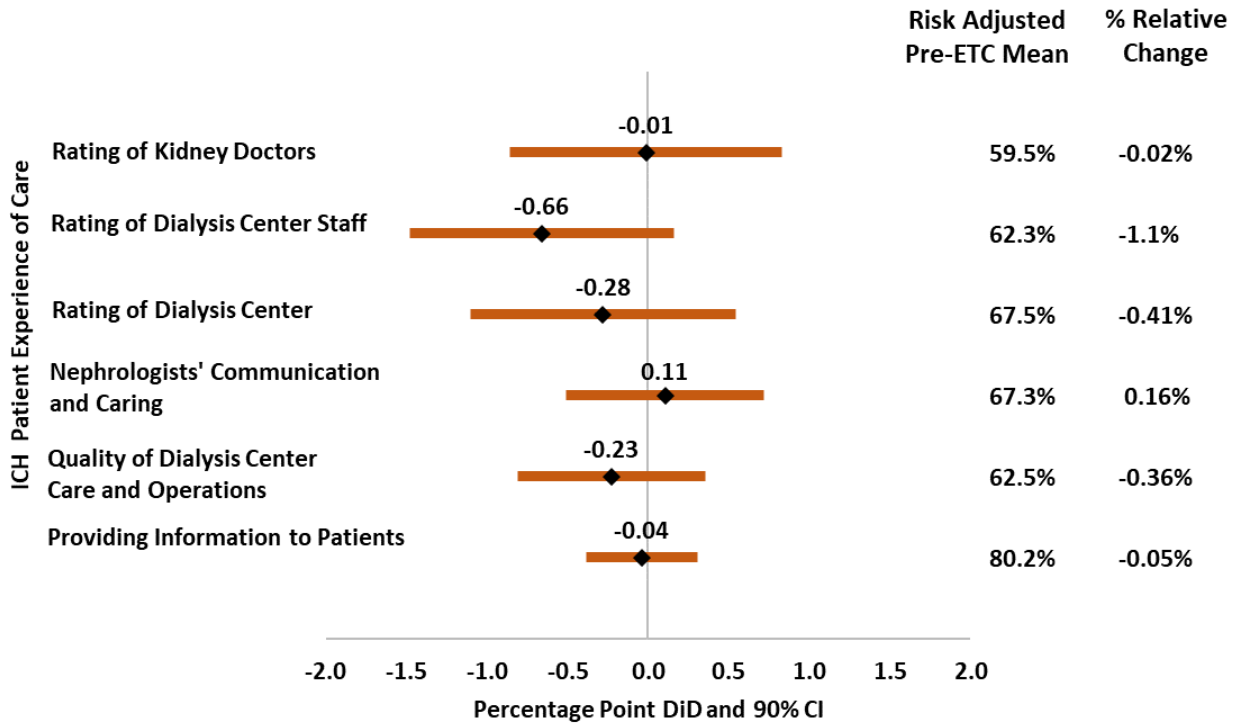
We found no statistically significant impact of the ETC Model on any of the six in-center HD patient experience measures in CY 2021, relative to the comparison group (see **Exhibit16**).[21] A limitation of the analysis was that the sample was based all ESRD patients receiving in-center HD at the facility (including patients not covered by the Medicare FFS program) rather than patients attributed to the ETC Model.

We will continue to examine patient experience of care throughout the evaluation as the ETC Model matures, not only for patients dialyzing in center but also among patients who are more directly impacted by the ETC Model incentives, i.e., those receiving dialysis at home.

[20] See **Appendix C.2** for additional information on the ICH CAHPS-based measures.

[21] 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 period and CY 2021 (see **Appendix C, Exhibit C-8**).

Exhibit 16. DiD Impact Estimates for Measures of ICH Patient Experience of Care



Notes: Pre-ETC period is CY 2017-CY 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 with the pre-ETC period relative to the same difference over time for patients in the comparison group. DiD estimates are reported along with lower- and upper- 90 percent CIs. Significance of the DiD impact estimates is indicated for each outcome where * implies significance at the 10 percent level, ** at the five percent level, and *** at the one percent level assuming a two-tailed test.

3.4. Discussion

From the time that Medicare coverage for ESRD started in 1972, 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 were utilized by a relatively limited subset of patients. Specifically, both home dialysis and kidney transplantation offer potential advantages over in-center HD. The home dialysis modalities, peritoneal dialysis and home HD, allow patients to control their own treatment at home. 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 healthcare payments. Transplantation provides a clear survival advantage to patients who meet the medical eligibility criteria. Despite these advantages, there is a growing consensus that these modalities are underused relative to their potential.

The reasons for underuse are multiple and complicated. However, participants in our Patient Advisory Group (PAG) feel that dialysis providers could do more to educate patients and discuss the possibility of all kidney replacement treatment options (see **Section 4**). Patients considering home dialysis want assurance that they can take on the added responsibility and that a medical support system is in place. However, this is not the only factor driving underuse. One other such factor is the lack of sufficient education and discussion of a home modality with patients, due in

part to providers not knowing enough about peritoneal dialysis and home HD, or assumptions on the part of providers that their patients may not be good candidates for a home modality. These discussions need to occur at multiple timepoints and using multiple methods. A key to the growth of transplantation involves a greater emphasis on living donor transplants. Patients also feel that better follow-through is needed to support patients through the whole referral process so that they can get on the waitlist. Providers play an important role in facilitating patient awareness and encouragement to seek donors. In short, dialysis providers are positioned to address the behavioral and organizational barriers to alternative treatment options.

At this early one-year mark, we found that the model had a relatively small impact overall, but there are potential signals of change in the expected direction. Home dialysis use in CY 2021 continued a 10-year growth trend. However, DiD analysis did not detect statistically significant differences in the rate of growth in ETC areas relative to the comparison group. Home dialysis training increased and more so for ETC patients relative to the comparison group, a potential early signal of accelerated growth. However, the rates are very low and the importance of the observed difference is currently uncertain. It is possible that participating ESRD facilities and Managing Clinicians spent the first model year expanding staffing and infrastructure needed to support additional growth in home dialysis. Also, the PPA, which features both positive and negative payment adjustments, did not start to take effect until July 2022.

The start of the ETC Model coincided with the period of highest impact from the COVID-19 PHE. Based on evidence of similar COVID-19 infection rates in ETC and comparison areas during CY 2021 and our inclusion of both patient- and county-level COVID-19 adjustments in impact analyses, we expect minimal risk of confounding in impact estimates. However, since the ETC Model was launched soon after the start of the COVID-19 PHE, we should also not rule out the possibility that the recent growth in home dialysis occurring in both ETC and comparison areas as well as the observed impacts of the model might have otherwise been different in the absence of the pandemic. While the potential impact of the COVID-19 PHE should dissipate in future model years, we will continue to examine this. Additionally, the current analysis is focused on home dialysis prevalence. It will also be important to look at home dialysis use among incident versus established dialysis patients.

There may have also been an impact of the announcement of the Advancing American Kidney Health (AAKH) initiative in 2019, which led to the launch of both the ETC and KCC Models. Recent acceleration in the growth in home dialysis nationally could in part reflect an increased emphasis on home dialysis in response to this announcement and the stated goals of the AAKH. If so, there would need to be additional growth occurring in ETC areas beyond any broader changes occurring nationally to be able to attribute improvements to the ETC Model.

Efforts to expand access to transplantation include placing more patients on the transplant waitlist. Waitlist expansion will not increase kidney transplants alone but does help assure full and equitable access to this highly effective treatment option. Dialysis providers play a key role in facilitating patient education, referral to transplant centers, and patient evaluation requirements. We found a downward trend in overall waitlisting rates (active decreased while inactive increased) in both the ETC and comparison group. These trends are somewhat discouraging but reflect national trends and potential recalibration of waitlisting to better capture true transplant potential

and risk. In light of the trends, the risk-adjusted DiD analysis found a significant favorable effect for the ETC group for overall waitlisting.

Actual expansion of transplantation requires steps beyond waitlisting. Key steps for growth in living donor transplantation depend on patient activation and donor support. The strategy for expanding deceased donor transplantation centers on enhancing organ procurement and minimizing organ discards. The first year of the ETC Model saw growth in the total kidney transplantation rate. Moreover, the relative growth rate was higher for ETC areas (32 percent) than comparison areas (22 percent). The largest growth was seen in deceased donor transplants. The DiD analysis found significantly faster growth in total and deceased donor transplants among ETC patients relative to the comparison group. Although the ETC Model incentives are directed toward living donor transplants, we are seeing a clear impact on deceased donor transplants. Future evaluation activities will probe the consistency and mechanisms underlying this finding.

In addition to exploring early impacts of the model on aspects of care directly related to the model's performance-based financial incentives, we also examined other key outcomes that may be affected by changes in care under the model for patients with ESRD, including measures of utilization, Medicare payments, and patient experience of care.

There is no evidence of an early impact of the model on categories of utilization that are relatively common among patients with ESRD. This includes acute care hospitalizations, which represent a large share of total Medicare payments for this population, outpatient ED visits and hospital readmissions. Utilization was examined because the ETC Model aims to expand home dialysis, which has been associated with lower rates of hospitalization than in-center HD. We will continue to track these and other utilization measures in future reports.

In line with our utilization findings, there is also no early evidence of an impact of the model on overall Medicare payments. This finding may in part reflect the lack of direct incentives under the model to reduce overall Medicare payments. We note that the Medicare payment amounts used in our analyses do not include the application of the HDPA, which represented a three percent payment adjustment to ETC participants who were billing Medicare for home dialysis services during CY 2021. Findings presented in the first annual report reflect gross savings and do not account for additional payments made in the first year of the model as part of the HDPA. Similarly, the prospect for net savings in the second year of the model will depend on whether there are savings to offset any additional payments that are made through a combination of the HDPA and the initial PPA, which was first used to apply both upward and downward payment adjustments in the last two quarters of 2022.

Changes in transplant rates like those observed in the first year could also have implications for Medicare payments over a longer-term following transplantation than we are currently able to capture. Currently, our follow-up for analysis of Medicare payments ends with the month of transplant, an approach which is intended to limit deviations from the approach used to measure the performance of participants under the ETC Model. However, 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. We also note that since the analyses presented in this report focus on Medicare payments for services billed under Parts A & B, it is not yet known whether the model may have an impact on Part D payments.

Experience of care for in-center HD patients, based on ICH CAHPS survey data, appears to be relatively comparable in both ETC and comparison groups. We found no impact of the model on these patient outcomes of perceived QoC. Our analyses leveraged secondary data to focus on in-center dialysis patients, and we will continue to examine these outcomes for potential unintended consequences for this group of patients with a greater focus on home dialysis and transplantation. However, to fully address the ETC Model's impact on patient experience it will be important to examine measures collected from patients who are more directly impacted by the ETC Model incentives, i.e., those receiving dialysis at home. These analyses will be based on a cross-sectional survey among ESRD patients dialyzing at home in both the ETC and comparison groups fielded in future years of the evaluation.

Another important limitation at this early stage of the evaluation is how participants perceive the model's incentives and any challenges that they may be experiencing in responding to those incentives. Gaining a better understanding of the perspectives of participants may provide valuable context for understanding some of the early impacts of the model discussed in this first report. As described further in **Section 4**, the analysis of qualitative data from participants will be one of the upcoming priorities for this evaluation.

4. Discussion

The ETC Model design reflects 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. We found high overall level of balance between ETC areas and non-ETC areas with regard to a wide range of factors. Specific areas of imbalance included market-level population characteristics for race and ethnicity as well as MA penetration. These findings informed the development of a comparison group that consists of all non-ETC areas, which leverages the random selection and mandatory design components of the ETC Model, and our analytic approach which includes adjustments for patient-, provider-, and market-level characteristics. To evaluate impacts of the model, we employed a DiD framework to examine relative changes during the first year of the model in the ETC areas relative to the comparison group, which was further identified as robust based on comparisons of pre-ETC trends in outcomes between the two groups.

The first year of the ETC Model shows evidence of modest early gains in some aspects of care that are incentivized under the model. Based on data for CY 2021, there is no evidence that a combination of the application of the HDPA as well as the introduction of the PPA performance incentives that would determine future payment adjustments under the PPA led to increased use of home dialysis during the model's first year. It may be that more time is needed for participating ESRD facilities and Managing Clinicians to expand staffing and infrastructure needed to support additional growth in home dialysis beyond the similar recent growth occurring in both the intervention and comparison groups. It will also be important to consider whether the magnitude of the payment adjustments under the model will be sufficient to encourage additional growth in the ETC areas. There is evidence of growth in the frequency of home dialysis training, however, which if successful for patients undergoing training could have implications for future levels of home dialysis use. In future reports, it will also be important to look separately at any changes in home dialysis occurring among new versus established dialysis patients.

It is possible that the COVID-19 PHE may have had an important influence on home dialysis use during CY 2021. The model began in a context where patients may have perceived additional advantages of selecting a home dialysis modality to minimize the risk of contracting COVID-19. In this report, we observed growth in home dialysis modalities between CY 2017-2019 and CY 2021 that was similar in the ETC and comparison groups. Based on the similar overall rates of COVID-19 infections observed in the two groups during CY 2021 and our inclusion of patient- and county-level adjustments for COVID-19 infections in the DiD analyses, we do not expect COVID-19 to be a source of bias for the impact estimates reported for CY 2021. At the same time, it is important to recognize that we are evaluating model impacts that occur during the COVID-19 PHE and may be different from what might otherwise have occurred in the absence of the COVID-19 PHE. We will continue to examine the relative trends in COVID-19 infections in the two groups and will consider whether there may be longer-term effects of the pandemic on home dialysis use in subsequent years of the model.

Early findings regarding changes in transplantation, which is the other major target of the incentives reflected in the PPA, are mixed. There is evidence of a positive impact of the model on overall waitlisting rates which reflects a slower decline in waitlisting rates in ETC areas relative to

the comparison areas. Growth in waitlisting likely requires less provider investment than growth in home dialysis, which may account for the apparently different early finding for home dialysis. We find no early evidence of a change in rates of living donor transplants, which represent the other focus of the transplant-related incentives. Key steps for growth in living donor transplants depend on patient activation and donor support, which may require more time to develop. Instead, there is evidence of an increase under the ETC Model in the frequency of deceased donor transplants, which was found to be the driver of an increase in overall transplant rates among beneficiaries undergoing dialysis for ESRD. The strategy for expanding deceased donor transplantation centers on organ procurement efficiency and minimizing organ discards. These issues are a focus of the ETCLC, whose operations are not limited to ETC areas but could potentially have an impact under the model in conjunction with any changes in waitlisting in ETC areas.

Finally, there was no early impact of the model on key forms of utilization which are relatively common among beneficiaries with ESRD, including acute care hospitalizations, outpatient ED visits, and hospital readmissions. Similarly, DiD analyses indicate no change in overall Medicare payments among dialysis patients due to the ETC Model, with total Medicare payments PBPM in the ETC and comparison areas continuing to increase over time. We note that since the payment amounts in ETC areas do not reflect the additional payments made to model participants through the HDPA (i.e., of three percent where applicable), these results suggest that the model was not budget neutral overall in its first year. We also observed no impacts on measures of in-center HD patient experience of care due to the model. More generally, there was no early evidence of adverse unintended impacts of the model, which will continue to be an important consideration for the evaluation.

The impacts of the ETC Model may continue to evolve for multiple reasons. Participating providers may benefit from having additional time to develop, implement, and test strategies to grow home dialysis programs or further promote waitlisting and access to transplantation. Perceptions of model incentives and refinements to the initial incentives in subsequent years will also be important to consider when evaluating future impacts. First, the PPA did not affect Medicare payments to participants until July 2022, at which point the financial impact of the model may become more visible and concrete. Relatedly, there could be a growing impact of the PPA-related incentives over time based on the increasingly wider range of payment adjustments throughout the intervention period. In addition, the introduction of the Health Equity Incentive in the second year of the model strengthens incentives to encourage home dialysis and transplantation among beneficiaries who are underserved.

Moving forward, it will also be important to account for possible effects of the related Kidney Care Choices (KCC) Model which began January 1, 2022. Based on areas of overlap between the ETC and KCC Models with regard to both certain model goals (e.g., involving both transplantation and home dialysis) and in participation (i.e., for providers participating in both models), effects of the two models could be mutually reinforcing and also represent potential confounders that will need to be considered in CY 2022 forward. 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 (e.g., 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

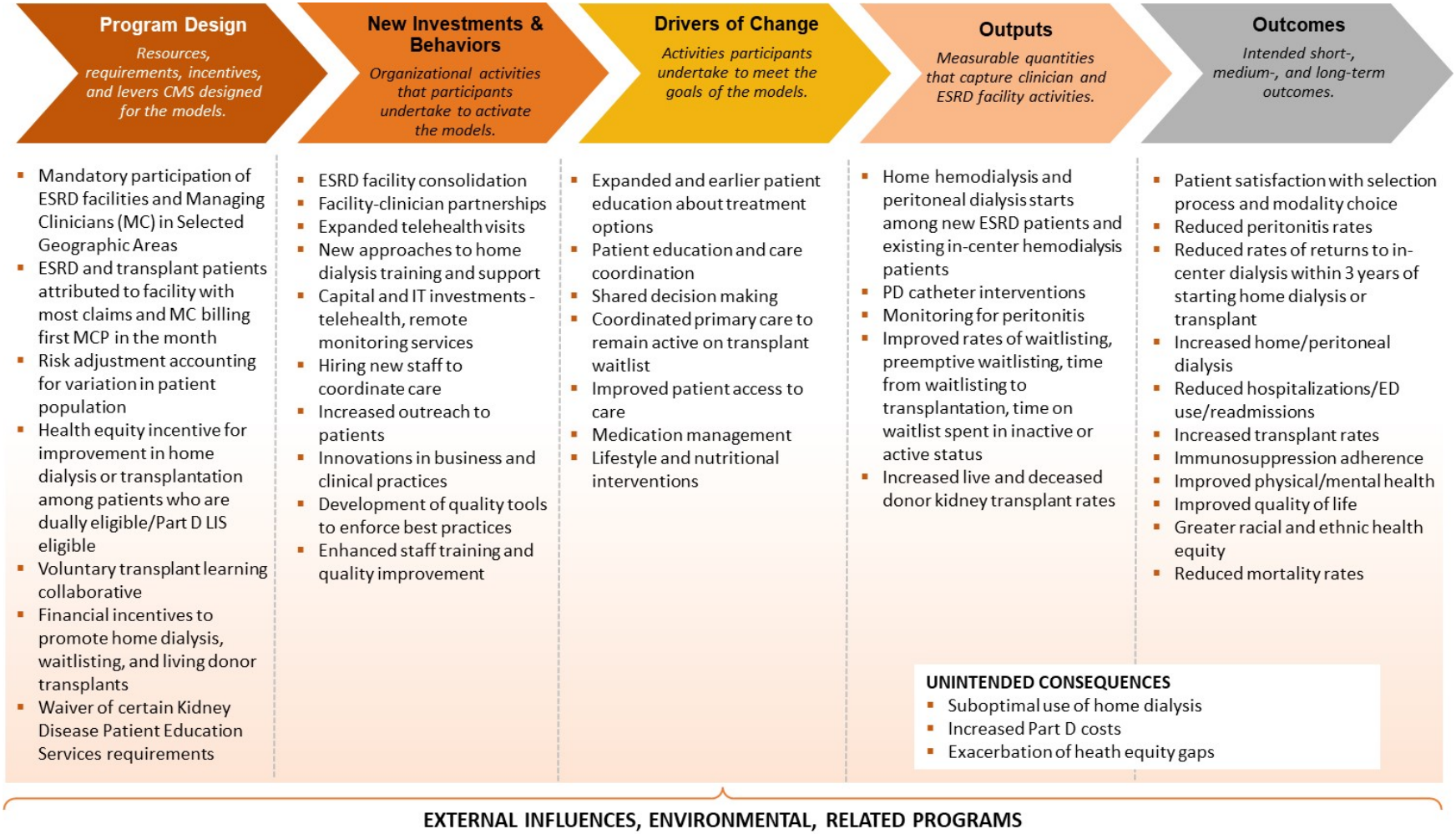
and establishing incentives for optimal ESRD starts. In addition, under the Kidney Care First option of the KCC Model, the MCP amount is increased to standardize Medicare payments for nephrology services for home dialysis and in-center dialysis patients. Such areas of model overlap will need to be considered in examining impacts of the ETC Model in year two as well as in subsequent years.

In future annual reports, we will continue to address the RQs that were the focus of this first report. For some RQs, we plan to expand our analyses by examining additional patient outcomes of interest such as mortality and by incorporating qualitative data and additional quantitative data for analysis. In future reports, we will also be addressing additional RQs involving other impacts of the model. Below is a list of several broad RQs that are planned for upcoming annual reports:

- How do participating ESRD facilities and Managing Clinicians respond to the ETC Model?
- Does the ETC Model affect QoL for beneficiaries?
- Does the ETC Model have implications for health equity?

To help address the evaluation RQs and inform specific areas of primary and secondary data collection and analysis, we incorporated a patient-centric approach as part of our ETC and KCC evaluation activities. We convened a PAG in October 2022. The goal of the PAG meetings was to capture patient perspectives on the ETC and KCC models. There were a total of eighteen patient participants. Members reflected the range of experience based on dialysis modality, being a transplant recipient (including pre-emptive transplant recipients) or living with late-stage CKD. The discussions and feedback from the PAG better positions us to understand what is meaningful to patients from their perspective and experiences, and, for example, what they think is important to ask participants about approaches to care delivery, and ways dialysis and transplant care and patient experiences can be improved for people with kidney disease. The list above is not comprehensive but is intended to reflect some of the additional RQs that are being prioritized in the nearer term as part of this evaluation.

Appendix A: ETC Evaluation Logic Model



Program Design. The logic model begins with design features including incentives and specific interventions which are the catalysts for achieving model goals. The primary design features of the ETC Model include financial incentives to promote home dialysis and kidney transplantation, randomized selection of HRRs for inclusion in the model and mandatory participation of ESRD facilities and Managing Clinicians, and the introduction of a Health Equity Incentive starting in the second year of the model.

Our evaluation of the ETC Model is being carried out in conjunction with an evaluation of the KCC Model, which is a separate model also being tested by CMS under the authority of CMMI. The KCC Model is a voluntary model that is intended to reduce the cost of care and improve the QoC for patients with CKD Stage 4 or 5 or with ESRD. Among the more specific aims of the KCC Model are to delay the onset of dialysis and encourage kidney transplantation. The KCC Model went into effect January 1, 2022.

Since there is some overlap in the goals of the ETC and KCC Models and some ESRD facilities and Managing Clinicians located in the Selected Geographic Areas may also have elected to participate in the KCC Model, it will be important to understand and account for possible effects of the KCC Model as part of our evaluation of the ETC Model, as the evaluation progresses.

New investments and behaviors. In response to the specific incentives and other features of the ETC Model, we anticipate that ETC Model participants will make investments to improve patient education regarding kidney replacement treatment options, enhance the treatment selection process, and transform the home dialysis training process. These investments will drive changes in patient decision making about treatment options and promote successful use of home dialysis.

Drivers of change. The investments that ETC participants make, in turn, allow them to initiate activities and actions that result in changes in how resources are used, what information is gathered and communicated, and how care is delivered. For example, potential drivers of change under the ETC Model include activities that promote patient education about treatment options, access to care, shared decision making, and coordination among ESRD providers.

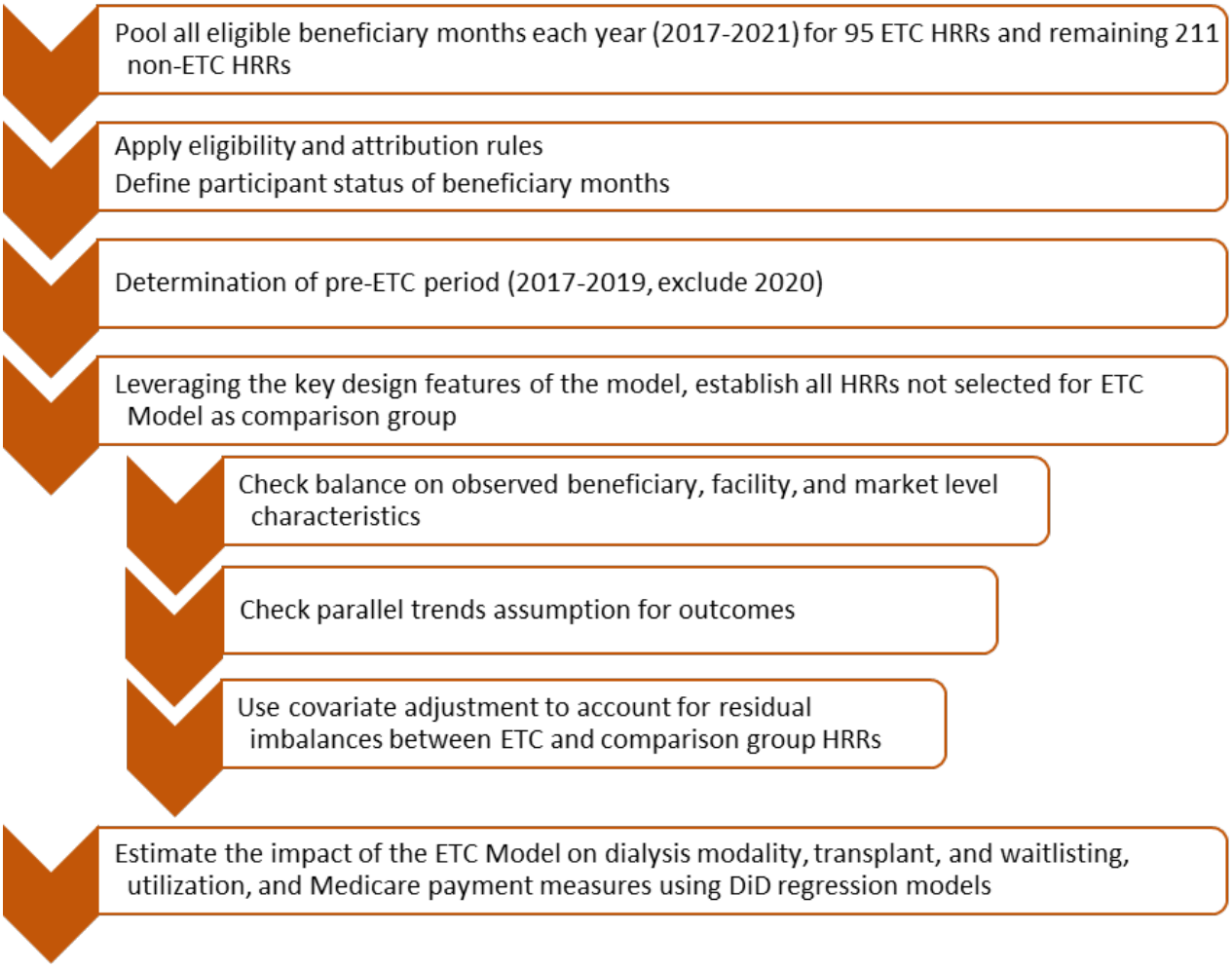
Outputs. Effects of the drivers of change are captured in intermediate outcome measures. Intermediate outcomes generally reflect processes of care or activities that are antecedents to attaining other model goals, such as rates of home dialysis, waitlisting, and transplantation, rates of transition from home dialysis to in-center HD, and clinical process quality measures.

Outcomes. Outputs are linked to short-, medium- and long-term outcomes that reflect goals of the ETC Model, including improved patient QoL, improvements in other patient outcomes, and lower overall Medicare payments.

Appendix B: Difference-in-Differences Approach

We used a DiD framework to compare changes in outcome measures observed over time in the Selected Geographic Areas (the ETC areas) relative to those in the comparison group, comprised of HRRs in the Comparison Geographic Areas (the comparison areas), as the basis for evaluating the effects of the ETC Model. The differential change in the outcome over time for patients in the ETC areas relative to those in the comparison areas represents the estimated effect of the ETC Model. The DiD framework offers a quasi-experimental design that can address many threats to validity, and rests on the critical assumption that, in the absence of the ETC Model, the outcome measures in the two groups would have changed in a parallel manner over time. **Exhibit B-1** shows how the DiD approach was implemented.

Exhibit B-1. DiD Implementation Steps



B.1. Data Sources and Outcome Measures

The data used to construct our analytic files underlying the DiD analyses are shown in **Exhibit B-2**.

Exhibit B-2. Data Sources Used for the ETC Model Evaluation

Data Source Name	Date Range*	Data Contents	Use
Medicare FFS Claims and Enrollment Data; Housed in Chronic Conditions Warehouse	January 2016 – December 2021	Medicare Parts A &B claims and beneficiary and enrollment information (Master Beneficiary Summary File, Enrollment Data Base, Common Medicare Environment), including beneficiary unique identifier, address, date of birth/death, sex, race, age, and Medicare enrollment status	Used to identify ESRD beneficiaries meeting model eligibility criteria, attribute beneficiaries to ESRD facilities/ managing clinicians, identify pre-emptive living donor transplant beneficiaries, create payment, utilization, and quality outcome measures, identify beneficiary demographic characteristics, and beneficiary eligibility for inclusion in the denominator for each of the outcome measures
EQRS	January 2017 – December 2021	Information on all ESRD patients treated at Medicare-certified ESRD facilities, including patient and facility characteristics (e.g., CMS Forms 2728, 2746, and 2744), patient attribution to ESRD facilities, dialysis modality and setting, and clinical quality measures	Used to obtain patient demographic and medical information extracted from the CMS ESRD Medical Evidence Report form (CMS-2728), facility information from Annual Facility Survey (AFS). Data used for comparison group selection, risk adjustment, stratification variables, quality measures, and health equity analyses
Kidney and Transplant Waitlisting Data from SRTR	January 2017 – December 2021	Listing and removal date for kidney/kidney pancreas waitlist, start and end date for waitlist status period, transplant date and organ type	Used to create outcome measures such as waitlisting rate (active/inactive), transplant among dialysis patients and living donor transplant among all patients (dialysis patients and pre-emptive transplant).
AHRF	2019	County-level data on population, environment, geography, health care facilities, and health care professionals	Used for descriptive analysis of ETC and comparison group market characteristics (predictors/characteristics were included in the comparison group selection modeling)
Master Data Management	2017 – 2021	Provider- and beneficiary level information on participation in CMMI payment demonstration programs	Used to identify providers who are aligned with CEC model, NGACO and Medicare Shared Savings Program
ICH CAHPS Survey	Spring 2017 – Fall 2021	Patient experience with in-center HD care	Used to assess patient experience among in-center dialysis patients

Data Source Name	Date Range*	Data Contents	Use
Medicare Data on Provider Practice and Specialty National Plan and Provider Enumeration System	2017 – 2021	Information on provider's name, gender, age, ZIP code, specialty (taxonomy) and practice address.	Used to identify managing clinician characteristics for assessing balance
The ZIP Code File-SAS	2017 – 2021	ZIP codes and Core-Based Statistical Areas (CBSAs)	Used to link ZIP codes to counties, CBSA

Note: * As discussed in detail below, we drop 2020 data from our analyses.

The dialysis modality, transplant, waitlisting, utilization, and Medicare payment measures evaluated in this report using a DiD methodology are defined in **Exhibit B-3** (see **Exhibits C-1** and **C-2** for the facility survey wave-level patient experience of care measures).

Exhibit B-3. Outcome Measures Used to Evaluate the ETC Model

Outcomes		Description of Outcomes
Dialysis Modality Measures (%)	Home Dialysis	Monthly flag set to 1 if the most used dialysis service for the beneficiary during a given month (i.e., primary modality) was home HD services, and 0 otherwise. Primary modality was determined as the dialysis service with the highest monthly count, and the prior month's primary modality was used in the case of a tie. If prior month was not resolvable, ties were decided among modalities in the following order: home HD, self-administered in-center HD, nocturnal dialysis, and in-center HD. Determination of individual modalities is described more below.
	Peritoneal Dialysis	Monthly flag set to 1 if monthly count of either Continuous Cycling Peritoneal Dialysis (CCPD) or Continuous Ambulatory Peritoneal Dialysis (CAPD) services were greater than zero, and 0 otherwise. Home CCPD was based on outpatient ESRD facility claims with revenue center lines 0851 (CCPD outpatient-CCPD/composite or other rate), Home CAPD was based on outpatient ESRD facility claims with revenue center lines 0841 (CAPD outpatient-CAPD/composite or other rate), and other peritoneal dialysis was based on outpatient ESRD facility claims with revenue center lines 0831 (Peritoneal dialysis outpatient or home-peritoneal-composite or other rate). Count of services was based on individual revenue center lines with these revenue center codes and condition code 74 (Home) and/or 76 (Backup in-facility dialysis). Services were counted in the month of the claim from date.
	Home HD	Monthly flag set to 1 if monthly count of home HD services were greater than zero, and 0 otherwise. Home HD was based on outpatient ESRD facility claims with revenue center lines 0821 (HD outpatient or home dialysis-HD-composite or other rate) or 0881 (Miscellaneous dialysis-ultrafiltration). Count of services was based on individual revenue center lines with these revenue center codes and condition code 74 (Home) and/or 76 (Backup in-facility dialysis). Services were counted in the month of the claim from date.
	In-Center HD	Monthly flag set to 1 if monthly count of in-center HD services were greater than zero, and 0 otherwise. In-center HD was based on outpatient ESRD facility claims with revenue center lines 0821 (HD outpatient or home dialysis-HD-composite or other rate) or 0881 (Miscellaneous dialysis-ultrafiltration). Count of services was based on individual revenue center lines with these revenue center codes and condition code 71 (Full care in unit or transient). Services were counted in the month of the claim from date.
	In-Center Self-Administered Dialysis	Monthly flag set to 1 if monthly count of self-administered in-center HD services were greater than zero, and 0 otherwise. Self-administered in-center HD was based on outpatient ESRD facility claims with revenue center lines 0821 (HD outpatient or home dialysis-HD- composite or other rate) or 0881 (Miscellaneous dialysis-ultrafiltration). Count of services was based on individual revenue center lines with these revenue center codes and condition code 72 (self-care in unit). Services were counted in the month of the claim from date.
	Nocturnal HD	Monthly flag set to 1 if monthly count of nocturnal dialysis services were greater than zero, and 0 otherwise. Nocturnal dialysis was based on outpatient ESRD facility claims with revenue center lines 0821 (HD outpatient or home dialysis-HD-composite or other rate) or 0881 (Miscellaneous dialysis-ultrafiltration) and Healthcare Common Procedure Code modifier code UJ (Services provided at night) in any modifier field on the revenue center line. Count of services was based on individual revenue center lines with these revenue center codes and condition code 71 (full care in unit or transient). Services were counted in the month of the claim from date.
	Home Dialysis Training	Monthly indicator of self-care training. Self-care training was based on outpatient ESRD facility claims with any dialysis revenue center line (i.e., 0821, 0831, 0841, 0851, 0881) and condition code 73 (self-care training). Month was based on the month of the claim from date.

Outcomes		Description of Outcomes
Waitlisting (%)	Overall	Monthly flag set to 1 if beneficiary is waitlisted in the SRTR at the end of the month, and 0 otherwise. Analyses of this outcome were limited to beneficiaries less than 75 years old, with age calculated annually based on beneficiary date of birth at the end of the CY.
	Active Status	Monthly flag set to 1 if beneficiary is waitlisted with active status (i.e., waitlist status is not 4099, 4999, 5099, or 5999) in the SRTR at the end of the month, and 0 otherwise. Analyses of this outcome were limited to beneficiaries less than 75 years old, with age calculated annually based on beneficiary date of birth at the end of the CY.
	Inactive Status	Monthly flag set to 1 if beneficiary is waitlisted with inactive status (i.e., waitlist status is 4099, 4999, 5099, or 5999) in the SRTR at the end of the month, and 0 otherwise. Analyses of this outcome were limited to beneficiaries less than 75 years old, with age calculated annually based on beneficiary date of birth at the end of the CY.
Transplant (per 1,000 Beneficiary Months)	Total[1]	Monthly flag set to 1 if beneficiary received a living or deceased donor transplant during the month. Analyses of this outcome were limited to beneficiaries less than 75 years old, with age calculated annually based on beneficiary date of birth at the end of the CY.
	Deceased Donor[1]	Monthly flag set to 1 if beneficiary received a deceased donor transplant during the month. Analyses of this outcome were limited to beneficiaries less than 75 years old, with age calculated annually based on beneficiary date of birth at the end of the CY.
	Living Donor[1]	Monthly flag set to 1 if beneficiary received a living donor transplant during the month. Analyses of this outcome were limited to beneficiaries less than 75 years old, with age calculated annually based on beneficiary date of birth at the end of the CY.
	Living Donor (among Dialysis Patients and Pre-emptive Transplant Recipients)	Monthly flag set to 1 if beneficiary received a living donor transplant during the month. Analyses of this outcome were limited to beneficiaries less than 75 years old, with age calculated annually based on beneficiary date of birth at the end of the CY. Beneficiary months for pre-dialysis patients were included for analyses of this outcome.
Utilization (%)	Acute Care Hospitalizations	Monthly indicator set to 1 if at least one inpatient acute care hospitalization admission stay occurred. Individual hospitalization claims were combined into stays. The earliest claim from date from claims in the stay was used as the stay from date. The latest claim thru date from claims in the stay was used as the stay thru date. The admission stay was counted in the month of the stay from date.
	Readmission	Monthly indicator set to 1 if and inpatient acute care hospitalizations unplanned readmission stay occurred. This measure counts hospital admission stays that were not identified as a planned admission (i.e., unplanned), when they occurred within 30 days after a previous hospitalization index admission stay. The 30-day window was based on the stay from date on the readmission stay relative to the stay thru date on a preceding index admission stay. Planned/unplanned admissions were guided by CMS' Hospital-Wide Readmissions measure specifications.
	OP ED Use	Monthly indicator set to 1 if an outpatient ED claims/visits (i.e., did not result in inpatient hospitalization) occurred. Based on Part B Institutional claims that have a claim line with a revenue center code starting with 045. ED visits are counted in the month of the claim thru date.

Outcomes		Description of Outcomes
Medicare Payments (PPPM)	Total Parts A & B	Monthly beneficiary sum of total Medicare Parts A & B actual (i.e., CMS payments only) standardized amounts, winsorized at the 99th percentile. Payments are counted in the month of the claim from date for all Part A claims (i.e., hospitalization payments, LTCH, IRF, and other payments). Payments are counted in the month of the first expense date for all Part B institutional claims (e.g., hospital outpatient and dialysis) and non-institutional claims (e.g., Evaluation and Management (E/M) services, Part B covered drugs, durable medical equipment, etc.).
	Total Part A	Monthly beneficiary sum of total Part A actual (i.e., CMS payments only) standardized amounts, winsorized at the 99th percentile. Payments are counted in the month of the claim from date for all Part A claims (i.e., hospitalization payments, LTCH, IRF, and other payments).
	Part A Acute Care Hospitalization	Monthly beneficiary sum of Part A actual (i.e., CMS payments only) hospitalization standardized amounts, winsorized at the 99th percentile. Includes claim type 60 (inpatient) where 3rd digit of CMS Certification Number (CCN)=0 (inpatient prospective payment system or 3rd/4th digit of CCN=13 (critical access hospital).
	Part A LTCH and IRF	Monthly beneficiary sum of Part A Actual (i.e., CMS payments only) select institutional care (i.e., IRF and LTCH) standardized amounts, winsorized at the 99th percentile.
	Other Part A	Monthly beneficiary sum of Part A Actual (i.e., CMS payments only) home health standardized amounts, winsorized at the 99th percentile.
	Total Part B	Monthly beneficiary sum of total Part B actual (i.e., CMS payments only) standardized amounts, winsorized at the 99th percentile. Payments are counted in the month of the first expense date for all Part B institutional claims (e.g., hospital outpatient, and dialysis) and non-institutional claims (e.g., E/M services, Part B covered drugs, durable medical equipment, etc.).
	Part B Dialysis	Monthly beneficiary sum of Part B Actual (i.e., CMS payments only) total dialysis standardized amounts, winsorized at the 99th percentile.
	Other Part B	Monthly beneficiary sum of total Part B Actual (i.e., CMS payments only) standardized amounts, excluding total dialysis payments and winsorized at the 99th percentile.

Note: We also examine facility survey-wave level measures of patient experience among in-center dialysis patients (see Appendix C). Home dialysis: peritoneal dialysis or home HD. Dialysis modality indicators are not mutually exclusive (i.e., a beneficiary may have more than one modality in a month). Waitlisting and transplant measures are restricted to beneficiaries ages < 75 years. 1Among dialysis patients.

B.2. Beneficiary Attribution and Eligibility

We applied a series of inclusion/exclusion criteria, (**Exhibit B-4**), per the ETC Model Final Rule to restrict the sample of FFS Medicare beneficiaries to include only eligible beneficiary months with either an attributed ESRD facility or Managing Clinician (**Exhibits B-5** and **B-6**).[21] We applied these criteria to all beneficiary months from 2017-2021 for Medicare FFS beneficiaries that had:

1. At least one non-AKI outpatient ESRD facility claim
2. And/or an MCP claim
3. And/or a living donor kidney transplant claim

For each beneficiary, eligibility criteria was evaluated monthly. Among eligible and attributed beneficiary months, we determined ETC treatment status (participant and non-participant) based on the zip code of the attributed ESRD facility reported on the AFS as well as on the Medicare claims (i.e., whether the zip code was located in an ETC HRR). For the measure living donor transplant (dialysis and pre-emptive) that includes pre-emptive transplants we had to define the treatment status using geographic location of the Managing Clinician. Since these transplants mostly occur before the beneficiary is under the care of an ESRD facility, we used the attributed Managing Clinician's zip code (obtained from National Plan and Provider Enumeration System data source) to define treatment status of the beneficiary for the given month. Only the month when the beneficiary received pre-emptive transplant was attributed to the numerator of the measure.

[21] Centers for Medicare & Medicaid Services. September 29, 2020. Medicare Program; Specialty Care Models To Improve Quality of Care and Reduce Expenditures. 42 CFR Part 512 [CMS–5527–F] RIN 0938–AT89, Vol. 85, No. 189 Fed. Reg., 61114-61381.

Exhibit B-4. Monthly Eligibility Criteria

- **ESRD Specific: Eligibility criteria are evaluated monthly for each ESRD beneficiary, defined as a beneficiary who meets either of the following:**
  - Is receiving dialysis or other services for ESRD, up to and including the month in which the beneficiary receives a kidney transplant.
  - Has already received a kidney transplant and has a non-AKI dialysis or MCP claim –
    - At least 12 months after the beneficiary's latest transplant date; or
    - Less than 12 months after the beneficiary's latest transplant date and has a kidney transplant failure diagnosis code documented on any Medicare claim.
- **Pre-emptive Living Donor Transplant Specific:** Beneficiaries are eligible to be included in the model if they have a living donor kidney transplant claim, where in the prior six months the beneficiaries must not have had an outpatient ESRD facility claim nor MCP service.
- **Inclusion criteria:**
  - FFS: Beneficiary must have FFS coverage in the month.
  - Medicare enrollment: Beneficiary must be enrolled in Medicare Parts A & B, or Medicare Part B only.
  - Age at least 18 years: Beneficiary must be at least 18 years of age prior to the first day of the month.
  - U.S.: Beneficiary residence zip code must be within U.S. (excluding U.S. territories) at any time in the month.
- **Exclusion criteria:**
  - AKI: Beneficiary must not have an outpatient ESRD facility claim denoting dialysis for AKI in the month.
  - NF: Beneficiary must not receive dialysis in an NF or skilled nursing facility (SNF), nor reside in a NF or SNF.
  - Dementia: Beneficiary must not have a diagnosis code for dementia in the current or preceding 12 months.
  - Hospice: Beneficiary must not be in hospice in the month.
  - Kidney transplant: A beneficiary was not eligible in the 12 months after the month of transplant if no transplant failure was reported.

Exhibit B-5. Attribution Definition (ESRD)

- **Beneficiary attribution criteria are evaluated monthly for each beneficiary.**
  - A beneficiary can be attributed to only one ESRD facility and only one Managing Clinician each month.
  - The claim service date is used for attribution.
- **Attribution to ESRD facilities:**
  - Attribution is determined for each month based on outpatient ESRD facility claims.
  - For beneficiaries treated at multiple facilities in a month, we selected the facility with the largest count of dialysis services in the month (based on counts of revenue center lines).
  - If there is more than one facility with the same count of dialysis services during the month, we selected the facility with the earliest dialysis service date.
  - If there is more than one facility with the same count of dialysis services and the same earliest service date, we selected the facility with the earliest (lowest) claim ID.
- **Attribution to managing clinicians:**
  - Attribution is determined for each month based on MCP claims.
  - For beneficiaries with multiple clinicians billing an MCP claim in a month, we selected the clinician with the earliest service date.
  - If there are multiple clinicians with an MCP claim and the same earliest service date during the month, we selected the clinician with the earliest (lowest) claim ID.

Exhibit B-6. Attribution Definition (CKD)

- **Attribution to a Managing Clinician:**
  - Attribution was applied yearly, in the year of the transplant up to and including the month of the transplant.
  - Pre-emptive living donor transplant attribution to a clinician was based on a count of services (based on counts of lines from carrier claims and outpatient facility claims) in the year of the transplant, up to and including the month of transplant.
  - If there are multiple clinicians, the clinician with the most services was selected; additional ties were broken using the most recent service and the lowest claim ID.

B.3. Pre-ETC Period Determination

With the ETC Model starting in January 2021, ideally the years immediately prior to 2021 would be included in defining the pre-ETC period. However, in 2020 there was both the onset of the COVID-19 PHE (March 2020) as well as the publication of the ETC Model final rule in September 2020 which included the announcement of HRRs selected for inclusion in the model.[22] In light of potential differential impacts of COVID-19 PHE in ETC and comparison regions as well as the possibility of a preemptive responses among ETC participants, we excluded 2020 from the study and defined the pre-ETC period as January 2017-December 2019, as shown in the timeline below (**Exhibit B-7**).

Exhibit B-7. ETC Timeline

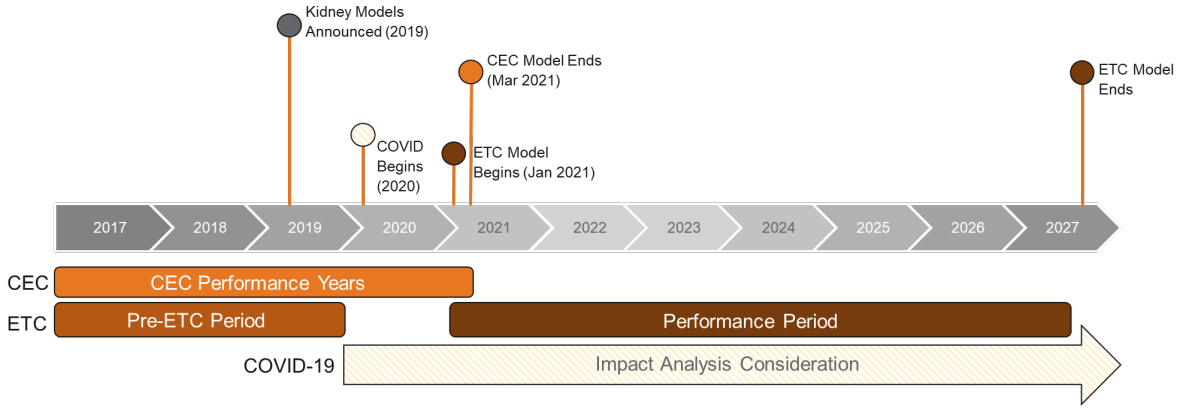
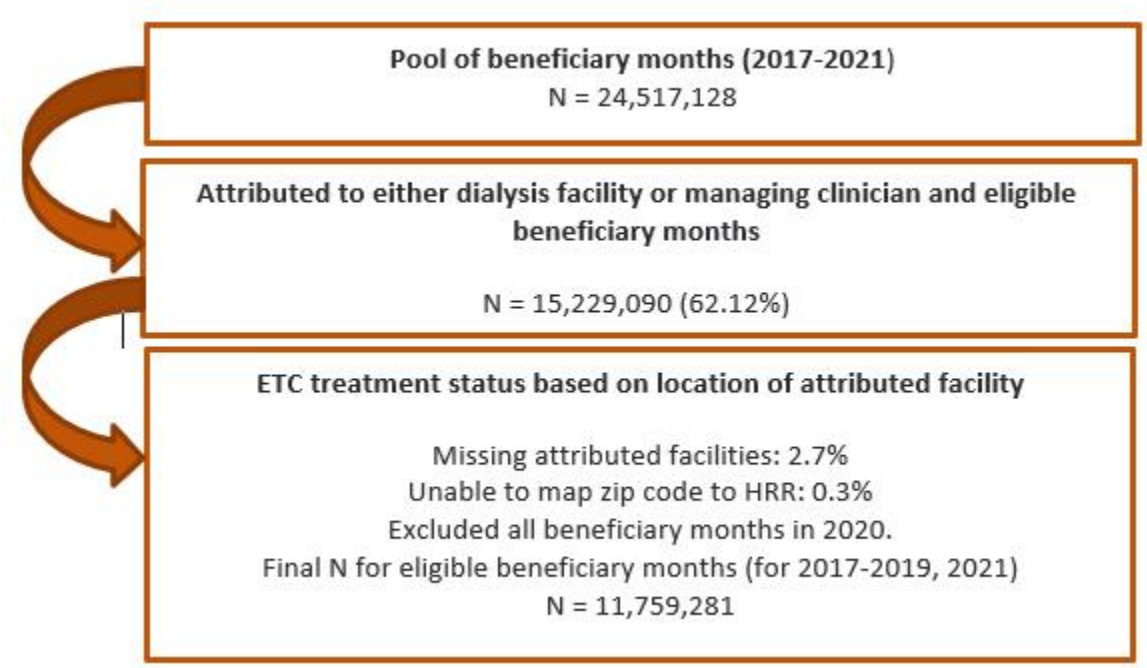


Exhibit B-8 below shows how we derived our final sample and **Exhibit B-9** reports the size of the final sample for the ETC and comparison groups.

[22] Centers for Medicare & Medicaid Services. September 29, 2020. Medicare Program; Specialty Care Models To Improve Quality of Care and Reduce Expenditures. 42 CFR Part 512 [CMS–5527–F] RIN 0938–AT89, Vol. 85, No. 189 Fed. Reg., 61114-61381.

Exhibit B-8. Flow Chart of ETC Cohort Construction



Note: Pre-emptive living donor transplant was set to zero for all other measures except living donor transplant (dialysis and pre-emptive).

Exhibit B-9. Characteristics of ETC and Comparison Areas

Characteristic	ETC		Comparison	
	Pre-ETC	2021	Pre-ETC	2021
Number of HRRs	95	95	211	211
Number of ESRD Facilities	2,514	2,519	5,228	5,250
Number of Managing Clinicians	6,656	4,749	9,544	7,746
Number of Unique Beneficiaries	171,240	99,699	336,396	194,288
Number of Patient Months	3,116,915	836,098	6,167,668	1,638,600

Note: Pre-ETC period is CY 2017-2019.

B.4. Comparison Group Assessment

The mandatory participation of the ESRD facilities and the Managing Clinicians in the Selected Geographic Areas helped to guard against selection bias, inherent in voluntary opt-in initiatives and demonstrations. Since the Selected Geographic Areas were selected at random, with the addition of Maryland HRRs, it is unlikely that the participants belonging to the HRRs selected for the ETC Model will differ substantially in observed and unobservable characteristics from the patients in the Comparison Geographic Areas.[23] We leveraged these features of the model to determine a comparison group credibly representing the counterfactual that would address the

[23] As noted in the Final Rule, CMS also included all HRRs that had at least 20 percent of ZIP Codes in Maryland. (Ibid.).

question "*What would have happened in the selected geographic areas in the absence of the ETC Model?"*

Based on the design of the model and other assessment criteria discussed below, we established a comparison group comprised of all HRRs not selected for the ETC Model. The steps that were followed in the selection of the appropriate comparison group for the ETC Model are explained below:

1. We assessed balance in the pre-ETC period between the Selected Geographic Areas (ETC areas) and the Comparison Geographic Areas (comparison areas) on outcomes of interest and patient, provider, and market characteristics. Balance across characteristics and limiting observed differences in the two populations would help prevent us from erroneously inferring effects of the ETC Model that are, in fact, a result of differences in the underlying populations.
2. We compared pre-ETC trends in key outcomes for the Selected Geographic Areas (ETC areas) and the Comparison Geographic Areas (comparison areas). A strong pattern of non-parallel trends across key outcomes could raise concerns that the Comparison Geographic Areas do not represent a valid counterfactual for identifying effects of the ETC Model in a DiD framework.

B.4.1. Assessing Balance between the Selected and Comparison Geographic Areas

We assessed balance at the HRR-level (i.e., unit of randomization), ESRD facility-level, and patient month-level (i.e., unit of analysis for DiD) by calculating SMDs on patient, facility, and market characteristics between the ETC and non-ETC regions:

$$\text{SMD} = (\mu_1 - \mu_2)/\sqrt{(\sigma_1^2 + \sigma_2^2)/2}$$

We compared SMDs against a standard threshold value of 0.2 to understand the extent of any differences between the ETC and non-ETC regions.

We assessed balance on the following list of factors:

- Patient characteristics:
  - Age, sex, race, ethnicity, duration of ESRD, indicators of socio-economic status (dual eligibility for Medicare and Medicaid), cause of ESRD, Body Mass Index (BMI) at incidence, original reason of Medicare entitlement, comorbid conditions, alignment with other CMMI models
- Facility characteristics:
  - Facility ownership status (large dialysis organization, other dialysis organization, independent), for-profit status, facility size, geographic region, rural-urban status
- Market characteristics:
  - Demographic characteristics of general Medicare population (e.g., age, race, ethnicity), poverty rate, educational attainment, MA penetration, numbers of hospitals and physicians per 100,000 population

We also examined balance between the ETC areas (excluding four Maryland HRRs) and the comparison areas to examine if the degree of imbalance on factors between ETC and comparison areas was driven by the non-random inclusion of Maryland HRRs in the model.

The SMDs for characteristics assessed are displayed in **Exhibits B-10 – B-12**. Of the 138 characteristics assessed, only five had a SMD greater than 0.2.

Exhibit B-10. Means and SMDs for Patient Characteristics at Patient Month-Level

Characteristic		ETC 2017-2019 N =3,116,915		ETC without Maryland 2017-2019 N = 2,856,296		Non-ETC 2017-2019 N = 6,167,668		SMD (ETC vs. non-ETC)	SMD (ETC without Maryland vs. non-ETC)
		Mean	SD	Mean	SD	Mean	SD		
Patient Characteristics	**Age, Continuous (Years)**	61.7	14.2	61.6	14.2	62.0	14.2	-0.02	-0.03
	Age, Categorical								
	18 - <25 Years	0.69%	8.3%	0.72%	8.4%	0.65%	8.0%	0.005	0.01
	25 - <35 Years	4.0%	19.5%	4.0%	19.7%	3.8%	19.1%	0.01	0.01
	35 - <45 Years	9.0%	28.6%	9.1%	28.7%	8.8%	28.3%	0.01	0.01
	45 - <55 Years	18.1%	38.5%	18.2%	38.6%	17.7%	38.2%	0.01	0.01
	55 - <65 Years	25.6%	43.6%	25.6%	43.7%	25.9%	43.8%	-0.01	-0.01
	65 - <75 Years	25.7%	43.7%	25.5%	43.6%	25.7%	43.7%	-0.001	-0.01
	75 Years & Over	17.0%	37.6%	16.9%	37.5%	17.4%	37.9%	-0.01	-0.01
	Female	43.2%	49.5%	43.1%	49.5%	42.9%	49.5%	0.01	0.003
	Ethnicity (Hispanic)	11.1%	31.4%	11.8%	32.3%	17.5%	38.0%	-0.18	-0.16
	Race								
	Black or African American	39.4%	48.9%	36.9%	48.3%	34.2%	47.4%	0.11	0.06
	Non-Hispanic White	53.0%	49.9%	55.2%	49.7%	57.9%	49.4%	-0.10	-0.06
	Asian	3.3%	17.8%	3.3%	17.9%	4.8%	21.4%	-0.08	-0.08
	Native Hawaiian/Pacific Islander	1.1%	10.3%	1.1%	10.5%	1.3%	11.3%	-0.02	-0.02
	American Indian/Alaska Native	2.7%	16.2%	2.9%	16.8%	1.0%	10.1%	0.12	0.14
	Other	0.57%	7.5%	0.57%	7.5%	0.75%	8.6%	-0.02	-0.02
	BMI, Categorical								
	<18.5	2.7%	16.1%	2.6%	16.0%	2.7%	16.1%	0.000	-0.003
	18.5- <25	23.0%	42.1%	22.9%	42.0%	23.8%	42.6%	-0.02	-0.02
	25- <30	27.1%	44.5%	27.1%	44.5%	27.2%	44.5%	-0.003	-0.003
	30- <35	20.1%	40.0%	20.1%	40.1%	19.7%	39.8%	0.01	0.01
	35- <40	12.2%	32.7%	12.3%	32.8%	12.1%	32.7%	0.002	0.004
	40 or greater	13.0%	33.6%	13.0%	33.6%	12.4%	32.9%	0.02	0.02
	Missing	2.0%	14.0%	1.9%	13.7%	2.0%	14.0%	-0.001	-0.01

Characteristic		ETC 2017-2019 N =3,116,915		ETC without Maryland 2017-2019 N = 2,856,296		Non-ETC 2017-2019 N = 6,167,668		SMD (ETC vs. non-ETC)	SMD (ETC without Maryland vs. non-ETC)
		Mean	SD	Mean	SD	Mean	SD		
Patient Characteristics (cont'd)	**ESRD Vintage, Continuous (Years)**	5.2	5.0	5.2	5.0	5.2	5.0	0.01	0.003
	ESRD Vintage, Categorical								
	<6 Months	8.2%	27.5%	8.2%	27.5%	8.4%	27.7%	-0.01	-0.01
	6 Months - <1 Year	7.3%	26.0%	7.4%	26.1%	7.4%	26.1%	-0.003	-0.001
	1 - <2 Years	13.5%	34.2%	13.6%	34.2%	13.5%	34.2%	-0.001	0.002
	2 - <3 Years	12.7%	33.3%	12.7%	33.3%	12.6%	33.2%	0.001	0.002
	4 - <7 Years	28.0%	44.9%	28.0%	44.9%	28.1%	45.0%	-0.002	-0.002
	7 - <10 Years	16.4%	37.0%	16.4%	37.0%	16.5%	37.1%	-0.004	-0.004
	10 Years and Over	13.9%	34.6%	13.8%	34.5%	13.5%	34.1%	0.01	0.01
	Dual Medicare/Medicaid Enrollment (Full or Partial Benefits)	47.2%	49.9%	47.7%	49.9%	48.6%	50.0%	-0.03	-0.02
	Part D Benefit Enrollment	81.6%	38.7%	82.0%	38.4%	81.9%	38.5%	-0.01	0.003
	Part D LIS (Where Enrolled in Part D Benefits)	67.8%	46.7%	68.0%	46.7%	69.2%	46.2%	-0.03	-0.03
	Medicare Shared Savings Program	22.3%	41.6%	22.1%	41.5%	22.3%	41.6%	-0.001	-0.004
	Alternative Payment Models								
	CEC	20.3%	40.2%	20.6%	40.4%	12.4%	32.9%	**0.22**	**0.22**
	NGACO	2.9%	16.9%	3.1%	17.4%	3.5%	18.4%	-0.03	-0.02
	Original Medicare Entitlement								
	ESRD and Disability	19.1%	39.3%	19.5%	39.6%	18.6%	38.9%	0.01	0.02
	ESRD	31.7%	46.5%	32.1%	46.7%	32.1%	46.7%	-0.01	0.00
	Disability	21.3%	41.0%	21.0%	40.7%	20.8%	40.6%	0.01	0.01
	Old Age	27.9%	44.8%	27.5%	44.6%	28.5%	45.2%	-0.01	-0.02

Characteristic		ETC 2017-2019 N =3,116,915		ETC without Maryland 2017-2019 N = 2,856,296		Non-ETC 2017-2019 N = 6,167,668		SMD (ETC vs. non-ETC)	SMD (ETC without Maryland vs. non-ETC)
		Mean	SD	Mean	SD	Mean	SD		
Comorbidities	**Acute Myocardial Infarction**	3.5%	18.5%	3.5%	18.5%	3.8%	19.0%	-0.01	-0.01
	Alzheimer's Disease	0.04%	2.0%	0.04%	2.0%	0.04%	2.1%	-0.002	-0.001
	Asthma	10.4%	30.5%	10.2%	30.3%	10.4%	30.5%	0.0003	-0.005
	Atrial Fibrillation and Flutter	20.1%	40.1%	20.1%	40.1%	20.5%	40.4%	-0.01	-0.01
	Benign Prostatic Hyperplasia	9.1%	28.8%	9.1%	28.8%	9.1%	28.8%	0.001	0.0004
	Cancer, Any	10.2%	30.2%	10.0%	30.0%	10.0%	30.0%	0.006	0.002
	Cancer, Breast	2.1%	14.3%	2.0%	14.1%	2.0%	14.1%	0.004	-0.001
	Cancer, Colorectal	1.7%	12.8%	1.7%	12.7%	1.7%	12.7%	0.0001	0.000
	Cancer, Endometrial	0.49%	7.0%	0.49%	7.0%	0.48%	6.9%	0.001	0.001
	Cancer, Lung	0.72%	8.5%	0.73%	8.5%	0.74%	8.6%	-0.003	-0.002
	Cancer, Prostate	3.0%	17.0%	2.9%	16.9%	3.0%	17.2%	-0.003	-0.01
	Cancer, Urologic	3.2%	17.7%	3.2%	17.7%	3.0%	17.0%	0.02	0.02
	Cataract	17.2%	37.7%	17.1%	37.7%	17.2%	37.8%	-0.001	-0.003
	Chronic Obstructive Pulmonary Disease	21.7%	41.2%	21.8%	41.3%	21.9%	41.4%	-0.004	-0.002
	Depression, Bipolar, or Other Depressive Mood Disorders	21.8%	41.3%	22.1%	41.5%	21.4%	41.0%	0.01	0.02
	Diabetes	65.2%	47.6%	65.3%	47.6%	66.7%	47.1%	-0.03	-0.03
	Glaucoma	13.2%	33.9%	12.9%	33.6%	13.3%	33.9%	-0.001	-0.01
	Congestive Heart Failure	45.1%	49.8%	44.9%	49.7%	46.1%	49.8%	-0.02	-0.02
	Hip/Pelvic Fracture	0.87%	9.3%	0.89%	9.4%	0.94%	9.7%	-0.01	-0.01
	Hyperlipidemia	69.7%	46.0%	69.7%	46.0%	69.6%	46.0%	0.002	0.002
	Hypertension	92.7%	25.9%	92.6%	26.1%	92.8%	25.8%	-0.002	-0.01
	Hypothyroidism	18.9%	39.2%	19.3%	39.4%	19.7%	39.8%	-0.02	-0.01
	Ischemic Heart Disease	42.1%	49.4%	42.0%	49.4%	44.0%	49.6%	-0.04	-0.04
	Non-Alzheimer's Dementia	1.5%	12.1%	1.5%	12.0%	1.5%	12.3%	-0.005	-0.01
	Osteoporosis with or without Pathological Fracture	4.4%	20.4%	4.4%	20.6%	4.7%	21.2%	-0.02	-0.01
	Pneumonia	12.6%	33.2%	12.6%	33.1%	12.8%	33.4%	-0.01	-0.01
	Parkinson's Disease and Secondary Parkinsonism	0.53%	7.2%	0.54%	7.3%	0.61%	7.8%	-0.01	-0.01
	Rheumatoid Arthritis/Osteoarthritis	28.9%	45.3%	28.9%	45.3%	28.9%	45.3%	-0.0003	-0.0001
	Stroke/Transient Ischemic Attack	8.3%	27.6%	8.2%	27.4%	8.4%	27.7%	-0.003	-0.01

Characteristic		ETC 2017-2019 N =3,116,915		ETC without Maryland 2017-2019 N = 2,856,296		Non-ETC 2017-2019 N = 6,167,668		SMD (ETC vs. non-ETC)	SMD (ETC without Maryland vs. non-ETC)
		Mean	SD	Mean	SD	Mean	SD		
Health Conditions at Start of Dialysis (Data Source: EQRS 2728 form)	**Primary Cause of ESRD, Categorical**								
	Diabetes	42.9%	49.5%	43.5%	49.6%	44.5%	49.7%	-0.03	-0.02
	Glomerulonephritis	11.4%	31.8%	11.6%	32.0%	11.0%	31.2%	0.01	0.02
	Hypertension	31.4%	46.4%	30.6%	46.1%	30.0%	45.8%	0.03	0.01
	Other	14.3%	35.0%	14.4%	35.1%	14.5%	35.2%	-0.005	-0.002
	Diabetes	51.4%	50.0%	51.9%	50.0%	52.5%	49.9%	-0.02	-0.01
	Congestive Heart Failure	21.6%	41.1%	21.8%	41.3%	21.7%	41.2%	-0.004	0.001
	Atherosclerotic Heart Disease	10.2%	30.3%	10.5%	30.7%	10.0%	29.9%	0.01	0.02
	Other Cardiac Disease	13.0%	33.7%	13.4%	34.1%	13.0%	33.7%	0.0002	0.01
	Cerebrovascular Disease, CVA, TIA	5.8%	23.4%	5.9%	23.5%	5.8%	23.5%	-0.002	0.002
	Peripheral Vascular Disease	7.4%	26.1%	7.6%	26.5%	6.9%	25.4%	0.02	0.03
	Chronic Obstructive Pulmonary Disease	5.4%	22.6%	5.5%	22.8%	5.3%	22.5%	0.002	0.01
	Tobacco Use (Current Smoker)	6.5%	24.7%	6.7%	25.0%	6.2%	24.1%	0.01	0.02
	Malignant Neoplasm, Cancer	4.6%	20.9%	4.7%	21.1%	4.6%	20.9%	-0.001	0.003
	Alcohol Dependence	1.2%	10.7%	1.2%	10.9%	1.1%	10.4%	0.01	0.01
	Drug Dependence	1.3%	11.1%	1.3%	11.2%	1.1%	10.5%	0.01	0.01
	Inability to Ambulate	2.4%	15.4%	2.5%	15.7%	2.6%	15.8%	-0.01	-0.003
	Inability to Transfer	0.97%	9.8%	0.99%	9.9%	1.0%	10.2%	-0.01	-0.01
	Patient Months under Care of Nephrologist Prior to ESRD Therapy								
	Not under Care of Nephrologist prior to ESRD	20.8%	40.6%	20.7%	40.5%	21.3%	41.0%	-0.01	-0.01
	Unknown If under Care of Nephrologist	18.2%	38.6%	17.8%	38.2%	19.3%	39.5%	-0.03	-0.04
	< 6 Months under Care	12.4%	33.0%	12.3%	32.8%	12.5%	33.1%	-0.004	-0.01
	6 - <12 Months under Care	19.1%	39.3%	19.1%	39.3%	18.3%	38.7%	0.02	0.02
	12 Months or Longer under Care	29.4%	45.6%	30.1%	45.9%	28.6%	45.2%	0.02	0.03
	Prior Employment Status (Employed Full or Part-Time)	24.7%	43.1%	24.7%	43.1%	24.6%	43.1%	0.003	0.003
	Current Employment Status (Employed Full or Part-Time)	15.5%	36.2%	15.3%	36.0%	15.2%	35.9%	0.01	0.003

Note: SD = standard deviation. CVA = Cerebrovascular Accident. TIA = Transient Ischemic Attack. Shading indicates a SMD > 0.2.

Exhibit B-11. Means and SMDs for Facility Characteristics at Facility-Level

Characteristic		ETC 2017-2019 N=2514		ETC without Maryland 2017-2019 N=2311		Non-ETC 2017-2019 N=5228		SMD for 2017-2019 (ETC vs. Non- ETC)	SMD for 2017-2019 (ETC without Maryland vs. Non-ETC)
		Mean	SD	Mean	SD	Mean	SD		
Facility Characteristics from AFS	**Number of HD Stations**	17.4	8.1	17.3	8.2	17.5	8.6	-0.01	-0.02
	For-Profit	89.2%	31.0%	89.2%	31.1%	87.3%	33.3%	0.06	0.06
	Facility Chain/Ownership:								
	DaVita	36.9%	48.3%	35.9%	48.0%	39.2%	48.8%	-0.05	-0.07
	Fresenius Medical Care	38.8%	48.7%	39.5%	48.9%	34.6%	47.6%	0.09	0.10
	Independent/Non-Chain For-Profit	3.6%	18.5%	3.6%	18.6%	5.4%	22.7%	-0.09	-0.09
	Other For-Profit	10.7%	30.9%	10.7%	31.0%	8.7%	28.2%	0.07	0.07
	Non-Profit	10.0%	30.0%	10.4%	30.5%	12.1%	32.6%	-0.07	-0.05
	Facility Size:								
	<=50	36.8%	48.2%	37.6%	48.5%	39.3%	48.8%	-0.05	-0.03
	>50 and <=75	21.2%	40.9%	21.9%	41.3%	21.8%	41.3%	-0.02	0.001
	>75 and <=100	18.1%	38.5%	17.1%	37.7%	17.1%	37.6%	0.03	0.001
	>100	24.0%	42.7%	23.4%	42.3%	21.8%	41.3%	0.05	0.04
	Provides In-Center HD Service	94.8%	22.1%	94.9%	22.0%	92.7%	26.0%	0.09	0.09
	Provides Peritoneal Dialysis Service	50.6%	50.0%	50.2%	50.0%	54.2%	49.8%	-0.07	-0.08
	Provides Home HD Training Service	28.8%	45.3%	29.2%	45.5%	30.4%	46.0%	-0.04	-0.03
	Facility has Shift after 5 p.m.	16.6%	37.2%	16.7%	37.3%	16.7%	37.3%	-0.001	0.001
	Total In-Center Dialysis Patients	57.4	42.8	57.5	43.2	59.0	44.7	-0.04	-0.03
	Total Home Dialysis Patients	7.6	15.2	7.7	15.4	8.1	16.5	-0.03	-0.02
	Total Patients Receiving Care at End of Survey Period	65.0	47.5	65.2	48.1	67.1	48.6	-0.04	-0.04

Characteristic		ETC 2017-2019 N=2514		ETC without Maryland 2017-2019 N=2311		Non-ETC 2017-2019 N=5228		SMD for 2017-2019 (ETC vs. Non- ETC)	SMD for 2017-2019 (ETC without Maryland vs. Non-ETC)
		Mean	SD	Mean	SD	Mean	SD		
Facility Location Characteristics	**Facility Region**								
	Northeast	14.7%	35.4%	16.0%	36.6%	13.3%	33.9%	0.04	0.08
	Midwest	20.2%	40.2%	22.0%	41.4%	21.3%	40.9%	-0.03	0.02
	South	47.3%	49.9%	42.6%	49.5%	45.2%	49.8%	0.04	-0.05
	West	17.9%	38.3%	19.4%	39.6%	20.3%	40.2%	-0.06	-0.02
	Facility RUCC								
	Metro	83.1%	37.5%	81.8%	38.6%	83.4%	37.2%	-0.01	-0.04
	Urban	16.3%	37.0%	17.5%	38.0%	15.9%	36.6%	0.01	0.04
	Rural	0.64%	8.0%	0.69%	8.3%	0.69%	8.3%	-0.007	0.0004

Note: Shading indicates a SMD > 0.2. Data based on EQRS. Facility attributes averaged for each group.

Exhibit B-12. Means and SMDs for Market Characteristics at HRR Level

Characteristic		ETC 2017-2019 N=95		ETC without Maryland 2017-2019 N=91		Non-ETC 2017-2019 N=211		SMD for 2017-2019 (ETC vs. Non-ETC)	SMD for 2017-2019 (ETC without Maryland vs. Non-ETC
		Mean	SD	Mean	SD	Mean	SD		
Market Characteristics	**Race**								
	Asian	2.6%	2.4%	2.5%	2.3%	3.6%	5.3%	**-0.24**	**-0.27**
	Non-Hispanic Black	12.2%	13.1%	11.6%	13.0%	9.1%	9.6%	**0.27**	**0.21**
	Hispanic	9.9%	10.5%	9.9%	10.7%	14.1%	15.0%	**-0.32**	**-0.32**
	Native Hawaiian/ Pacific Islander	0.17%	0.25%	0.17%	0.26%	0.21%	0.74%	-0.07	-0.07
	Non-Hispanic White	70.4%	15.8%	71.1%	15.4%	68.8%	18.9%	0.10	0.14
	American Indian/ Alaskan Native	2.2%	4.3%	2.2%	4.4%	1.6%	2.8%	0.15	0.17
	Persons > 25 Years Old with Less than High School Diploma	8.9%	2.9%	8.9%	2.9%	9.4%	3.7%	-0.14	-0.13
	MA Penetration	31.1%	12.9%	31.9%	12.5%	33.7%	11.5%	**-0.21**	-0.15
	Poverty	13.4%	4.0%	13.5%	4.0%	13.0%	3.6%	0.09	0.13
	Median Age, 2010	38.9	3.3	38.9	3.4	38.4	3.1	0.16	0.15
	Market Level Capacity per 100,000 Population								
	Number of Short-Term General Hospitals	2.4	1.5	2.5	1.5	2.5	1.8	-0.05	-0.02
	Number of LTCHs	0.11	0.24	0.10	0.23	0.12	0.35	-0.01	-0.04
	Number of Short-Term General Hospitals with HD	0.38	0.36	0.38	0.37	0.42	0.45	-0.09	-0.08
	Number of Non-Federal Transplant (i.e., Transplant Surgeons)	0.03	0.06	0.03	0.06	0.04	0.11	-0.15	-0.16
	Number of Non-Federal PCP, Patient Care	67.1	18.5	66.6	18.5	66.6	18.9	0.03	0.00
	Number of Non-Federal PCP, Hospital Resident	6.0	4.9	5.9	4.9	6.3	5.6	-0.05	-0.07
	ADI	59.0	11.8	59.6	11.6	58.7	12.6	0.02	0.07
	Percent of ACO Beneficiaries	30%	14%	30%	14%	29%	13%	0.12	0.13
	Percent of CEC Beneficiaries	0.1%	0.2%	0.1%	0.2%	0.1%	0.2%	0.16	0.16

Note: Shading indicates a SMD > 0.2. County level data based on publicly available AHRF. County-level market characteristics aggregated to HRR using zip code-county crosswalks. HRR market attributes averages for each group. [1]ADI national percentile rankings based on the University of Wisconsin's publicly available values (https://www.neighborhoodatlas.medicine.wisc.edu/).

B.4.2. Examining Parallel Trends in Key Outcomes

The validity of the DiD estimator hinges on the fact that change in outcomes experienced in the comparison areas is an accurate counterfactual for the change that would have occurred in the ETC areas in the absence of the ETC Model. A key assumption of a DiD design is that changes in outcomes from the pre-ETC period to CY would have been similar in the ETC and comparison group HRRs absent the ETC Model. We test the assumption of parallel trends across the pre-ETC years by comparing the ETC group's trend in the pre-ETC period against the trend in the comparison group for all outcomes. We examined and tested for parallel trends in three ways:

1) **Falsification models (placebo test).** We tested for differential changes in impact measures between the ETC and comparison areas between the first two years of the pre-ETC period (i.e., 2017-2018) and the last year of the pre-ETC period (i.e., 2019) as a "placebo test." That is, we applied the exact same risk-adjusted DiD specification while assigning 2017-2018 as the pre-ETC period and falsely assigning 2019 as the post-intervention time period and computed a DiD estimate for 2019 (see **Exhibit B-18**). Such estimated effects for the ETC Model in 2019 should be null since the model was not implemented until 2021. DiD estimates that are statistically different from zero ($p < 0.10$) means we rejected the parallel trends assumption (i.e., suggesting that there is lack of parallel trends in the outcomes for the two groups over the pre-ETC period). Results of the falsification tests are shown in **Exhibit B-13**.
2) **Plots of pre-ETC period trends in outcomes.** We compared annual trends in outcomes between ETC and non-ETC groups. We calculated the difference between ETC and non-ETC groups in means of the unadjusted and risk-adjusted outcome values (the DiD models are adjusted for a list of patient-, facility-, and market-level characteristics) across the pre-ETC period (2017-2019) (see **Exhibit B-18)**. Upward or downward sloping lines during the pre-ETC period indicate a lack of parallel trends, as differences between the ETC and non-ETC groups become larger or smaller during the pre-ETC period. A comparison of unadjusted and risk adjusted trend lines also helped in determining whether risk adjustment improved the degree of balance (i.e., satisfy the parallel trends assumption) between the two groups during the pre-ETC period. Plots depicting trends in the difference in yearly means for select outcomes between ETC and comparison areas are shown in **Exhibit B-14**.
3) **Dynamic trend test.** We also tested an alternative method for the parallel trends test commonly referred to as a trend test. In this specification, for the pre-ETC years (2017-2019), in addition to having individual time fixed effects, each individual pre-ETC time indicator was interacted with the treatment indicator. To assess parallel trends, we examined the statistical significance of the coefficient corresponding to the time and treatment dummy interaction term at 0.10 level of significance. If the outcome trends between the ETC and comparison groups are the same prior to the start of the ETC Model, then the interaction coefficient should be near zero and not statistically significant (i.e., the difference in trends is not significantly different between the two groups in the pre-ETC period). Like other tests, this parallel trend test for the interaction terms also adjusted for the covariate list of patient, provider and market level characteristics (see **Exhibit B-18**). We also estimated a Joint F-Test to determine whether all the pre-ETC interaction terms were jointly equal to zero. Results of the trend tests are discussed below in **Exhibit B-15**.

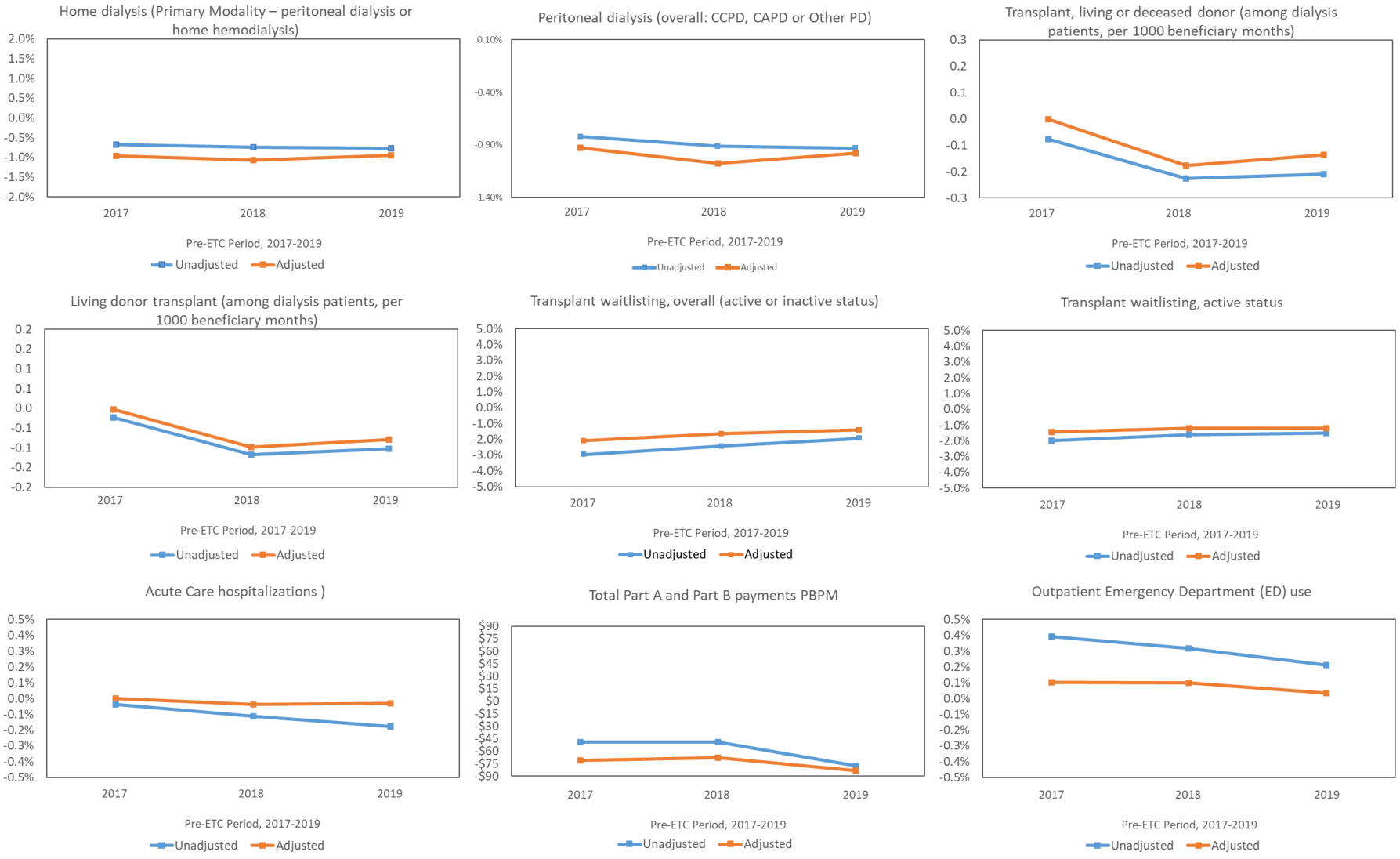
Results of the three parallel trends tests highlight that all first annual report outcomes passed statistical tests implying that there was no meaningful difference in trends between the ETC and comparison group during the pre-ETC period.

Exhibit B-13. Assessing Parallel Trends: Falsification Test Results

Outcomes		Adjusted Model				
		DiD Falsification[a]	SE	p-value	90% CI Lower	90% CI Upper
Dialysis Modality Measures (%)	**Home Dialysis**	0.07	0.16	0.68	-0.20	0.33
	Peritoneal Dialysis	0.02	0.14	0.87	-0.21	0.26
	Home HD	0.05	0.06	0.47	-0.06	0.15
	In-Center HD	-0.07	0.16	0.69	-0.33	0.20
	In-Center Self-Dialysis	0.004	0.01	0.73	-0.02	0.03
	Nocturnal HD	0.003	0.04	0.94	-0.07	0.06
	Home Dialysis Training	0.02	0.02	0.37	-0.02	0.06
Waitlisting (%)	**Overall**	0.44	0.31	0.16	-0.07	0.96
	Active Status	0.11	0.25	0.67	-0.31	0.53
	Inactive Status	0.34	0.24	0.17	-0.07	0.74
Transplant (per 1,000 Patient Months)	**Total[1]**	-0.05	0.15	0.73	-0.30	0.20
	Deceased Donor[1]	-0.02	0.14	0.87	-0.26	0.21
	Living Donor[1]	-0.03	0.04	0.49	-0.10	0.04
	Living Donor (Dialysis and Pre-Emptive)	-0.03	0.04	0.51	-0.09	0.04
Utilization (%)	**Acute Care Hospitalization[2]**	-0.01	0.06	0.86	-0.12	0.09
	Readmission	-0.22	0.26	0.41	-0.65	0.22
	Outpatient ED Use[2]	-0.07	0.09	0.45	0.00	0.00
Medicare Payments (PPPM)	**Total Parts A & B**	-$14	$17	0.41	-$42	$14
	Total Part A[3]	-$8	$15	0.61	-$33	$18
	Acute Care Hospitalization[3]	-$4	$8	0.62	-$16	$9
	Part A LTCH, IRF[3]	-$1	$2	0.64	-$5	$3
	Other Part A[3]	-$1	$1	0.50	-$3	$1
	Total Part B	-$3	$12	0.81	-$23	$17
	Part B Dialysis	-$1	$8	0.89	-$15	$12
	Other Part B	-$2	$9	0.84	-$17	$13

Note: Transplant and waitlisting measures restricted to patients less than 75 years old. [a] *Represents the estimated effect of the ETC Model in 2019 (before the Model was implemented)* [1]Among dialysis patients. [2] One or more during the month. [3] Estimates obtained from a Two-part model. *Primary modality - peritoneal or home HD); Dialysis modality indicators are not mutually exclusive (i.e., a beneficiary may have more than one modality in a month).

Exhibit B-14. Trends in the Difference in Outcomes between ETC and Comparison Areas, Unadjusted and Adjusted



Note: Shows difference in outcome (ETC minus comparison areas). Upward or downward sloping lines indicate lack of parallel trends. Adjusted for a set of patient, facility and market characteristics listed in **Exhibit B-18.**

Exhibit B-15. Assessing Parallel Trends: Dynamic Trend Test for Outcome Measures

Domain	Measure and Year	Joint Test p-value
Dialysis Modality Measures	**Home Dialysis***	0.52
	Peritoneal Dialysis	0.36
	Home HD	0.77
	In-Center HD	0.38
	In-Center Self-Dialysis	0.18
	Nocturnal HD	0.47
	Home Dialysis Training	0.57
Waitlisting	**Overall**	0.19
	Active Status	0.34
	Inactive Status	0.39
Transplant (per 1,000 Patient Months)	**Total**[2]	0.52
	Deceased Donor[2]	0.84
	Living Donor[2]	0.16
	Living Donor (among dialysis patients and pre-emptive transplant recipients)	0.15
Utilization	**Acute Care Hospitalization**[1]	0.86
	Readmission	0.19
	Outpatient ED use[1]	0.72
Medicare Payments (PPM)	**Total Parts A & B**	0.55
	Total Part A[3]	0.87
	Part A Acute Care Hospitalization[3]	0.61
	Part A LTCH, IRF[3]	0.18
	Other Part A[3]	0.37
	Total Part B	0.42
	Part B Dialysis	0.67
	Other Part B	0.51

Notes: Transplant and waitlisting measures restricted to patients less than 75 years old. [1] One or more during the month. [2]Among dialysis patients. [3]Estimates obtained from a Two-part model. *Primary modality – peritoneal dialysis or home HD; dialysis modality indicators are not mutually exclusive (i.e., a patient may have more than one modality reported in a month).

B.5. DiD Regression Model and Estimated ETC Impacts

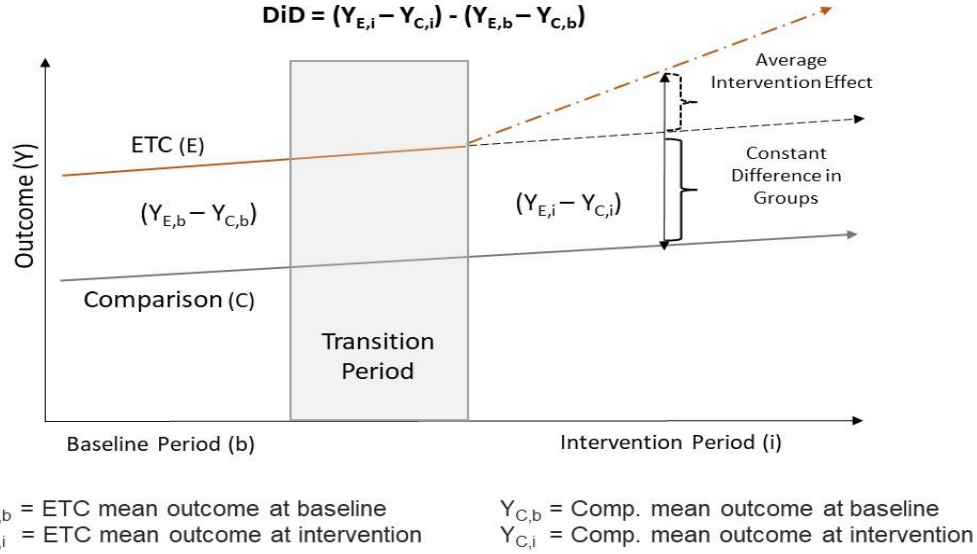
The DiD framework quantifies the impact of the ETC Model by comparing changes in outcomes for the ETC population before and after the start of the ETC Model with changes in outcomes for the comparison population before and after the start of the ETC Model. The DiD framework by design controls for unobserved, time-varying changes that are common to all patients (i.e., cyclical, or seasonal trends or broader changes in the health system), as well as time-invariant, unmeasured differences between ETC and comparison group markets and patient populations. To the extent that the distribution of observed covariates is similar across the ETC and comparison groups, we can be confident that differences in outcomes across groups are attributable to the ETC intervention rather than pre-existing differences between patients in the ETC and comparison areas.

The basic DiD estimate can be expressed as the difference in outcomes between the ETC and comparison groups in the intervention period and subtracting the difference in outcomes between

the two groups in the pre-ETC period, as shown in **Exhibit B-16**. $Y_{E,i}$ is the mean outcome for the ETC group during the intervention period, $Y_{C,i}$ is the mean outcome for the comparison group during the intervention period, $Y_{E,b}$ is the mean outcome for the ETC group during the pre-ETC period, and $Y_{C,b}$ is the mean outcome for the comparison group during the pre-ETC period.

The DiD model assumes that if the ETC Model did not exist, the two groups would continue to follow the same parallel trends during the intervention period (shown by the black dotted (E) and grey line (C) during the intervention period (i), Therefore, any observed difference in outcomes between the pre-ETC period –$Y_{E,b}$ - $Y_{C,b}$) and intervention period –$Y_{E,i}$ - $Y_{C,i}$) is driven by the ETC Model. Thus, the resulting DiD estimate of the average intervention effect is ($Y_{E,i}$ - $Y_{C,i}$) – ($Y_{E,b}$ - $Y_{C,b}$)

Exhibit B-16. Illustration of DiD Model



We used repeated cross-sectional regression models for estimating the effects of the ETC Model on patient outcomes for 2021, the first year of the model. DiD modeling was performed at the patient month-level.

Defining each patient i in time t, identifying the treatment units (patients) with an indicator variable $Treat_i$ (1, 0 indicator (1 = eligible patients belonging to ETC selected HRRs, 0 = eligible patients belonging to comparison group HRRs), identifying the CYs with an indicator variable $Post_t$, and identifying a vector of covariates as P_{Cov} (as needed; to adjust for residual imbalance despite randomization), the DiD estimator for outcome Y is implemented as:

$$Y_{i,t} = \alpha_0 + \alpha_1 Treat_i + \beta_1 Post_t + \delta_1 Treat_i * Post_t + \omega P_{Cov} + +\epsilon_{i,t}$$

Coefficients as described above.

- The coefficient α_1 is the average difference between the ETC and comparison group over the pre-ETC period.
- The coefficient β_1 captures changes in the ETC and comparison groups between the pre-ETC period and CY.

- The coefficient δ_1 is the DiD effect in 2021. In a linear model, this can be interpreted as the regression adjusted average difference in CY 2021 between ETC patients and comparison patients.

Two-part Model. Four of the eight Medicare payment (PBPM) measures were estimated using a two-part model because they were highly right skewed with a substantial point mass (> 85%) at zero. In the two-part model for these measures, for the first part we fitted a logit model for the probability of observing a nonzero versus zero outcome, and for the second part a generalized linear model with a log link for the positive outcomes. Impact estimates, including predicted baseline and CY levels, were adjusted to account for the nonzero cross partial resulting from nonlinearity.[24]

Computation of standard errors. We clustered standard errors at the HRR-level to account for intra-cluster correlation among facilities operating within the same HRR. Clustering at the HRR level, which is the unit of randomization, will also account for the correlation among patients receiving services from the same ESRD facility/ same Managing Clinician. Given that the ETC Model effect is analyzed at the national level and all facilities are nested within HRRs, accounting for HRR clusters protects against the potential underestimation of standard errors, thereby minimizing the risk that we make false positive inferences about the effect of the ETC Model. Given that there is a possibility of within HRR cross facility correlation of the regressors and errors, ignoring this correlation (for example, by clustering at facility level) could lead to incorrect inference.

B.5.1. Covariate Adjustments

Covariates and estimated coefficients (ωP_{Cov}) in the equation accounted for differential factors across the treatment and comparison group which improved the precision of impact estimates and net out effects of any observed differences in characteristics between the two groups that arose by chance despite randomization. Key criteria that were considered in selecting factors for covariate adjustment include the following:

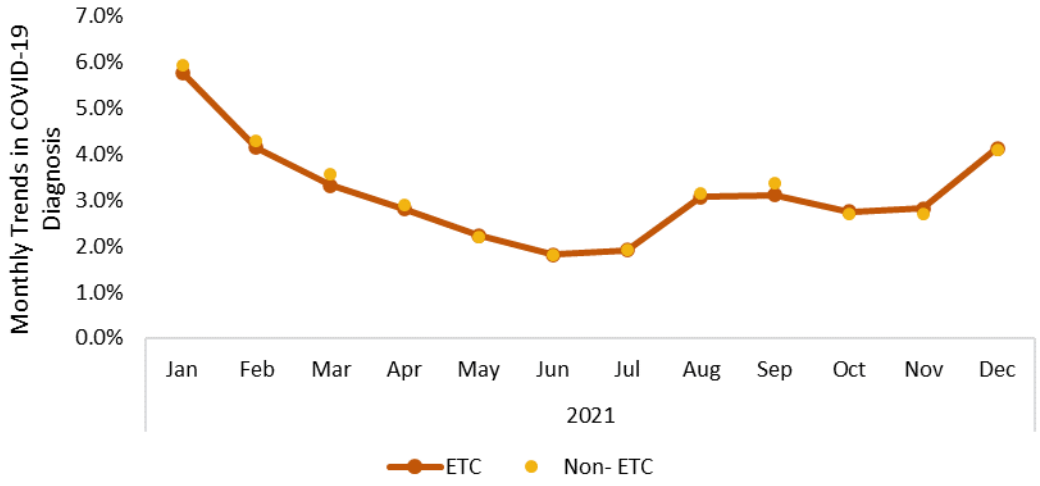
- **Relationship with impact measures of interest**. Factors found to have a relatively strong relationship with impact measures of interest were given greater emphasis for covariate adjustment in impact analyses, provided they also satisfy other criteria.
- **Degree of imbalance between ETC and comparison groups**. Covariate adjustments for selected patient and facility characteristics, and market-level characteristics will be used to address any observed lack of balance during the pre-ETC period.
- **Differential trends between ETC and comparison groups prior to model performance years.** Factors exhibiting such trends may be both exogenous to the ETC Model and pose a greater risk of introducing bias should their pre-ETC trends extend into the performance period. The extent of this risk also depends on other criteria, such as the strength of their relationship with the impact measures. Adjustment for such factors may help to satisfy the parallel trends assumption of our DiD approach.

[24] Karaca-Mandic, Pinar, Edward C. Norton, and Bryan Dowd. "Interaction terms in nonlinear models." Health services research 47.1pt1 (2012): 255-274.

- **Potential endogeneity.** We sought to avoid selection of factors that were endogenous to the ETC Model. For example, adjustment for clinical characteristics of patients influenced by the QoC provided by ESRD facilities and Managing Clinicians may lead to biased estimates of the effects of ETC Model. To minimize this risk, we used caution when selecting factors. We restricted the list to include health care status indicators either at the start of ESRD or to include conditions that would not be influenced by the quality of dialysis care (i.e., ESRD providers would not have influence over the prevalence of these conditions, like cancer), provided these conditions also had a pattern of strong relationship with outcomes.
- **Potential sources of confounders that emerge during the intervention.** There may be factors that did not contribute to a lack of balance during the pre-ETC period but represent potential sources of confounding after the start of the model. A particular concern is the COVID-19 PHE that continued in 2021, which may not uniformly affect the ETC and comparison groups. We discuss this in detail below.

The COVID-19 PHE may influence outcomes of interest either based on individual patients who are infected with COVID-19 or through community-level COVID-19 rates that strain local health system resources. If the COVID-19 PHE affected the outcomes of interest in the ETC areas differently than those in the comparison areas, then the estimates of the impact of the ETC Model during 2021 may be biased. For these reasons, we examined both patient COVID-19 diagnoses reported in the claims data and county-level COVID-19 data (e.g., county level COVID-19 incidence rates) for assessment of balance and potential covariate adjustment.[25] As shown in **Exhibit B-17**, we did not find evidence to suggest that COVID-19 had a markedly different impact on patients in ETC and comparison group HRRs; overall, we observed relatively similar trends in the percentage of patient months with an initial COVID-19 diagnosis in the two groups throughout 2021.

Exhibit B-17. Trends in Monthly COVID-19 in ETC and Comparison Areas during 2021



Nevertheless, to account for potential confounding due to the COVID-19 PHE on utilization in the ETC Model, we included one county-level and four patient month-level risk-adjustment

[25] USAFacts (2023) https://usafacts.org/

variables (see **Exhibit B-18**). They are: (1) county-month-level rates of incidence of COVID-19 diagnoses;[25] (2) four patient month-level variables that indicate a COVID-19 diagnosis found in claims data: during the month; within the last 30 days; within the last 31-60 days, and within the last 61-90 days.

There are limitations of the available COVID-19 data which are important to consider. For instance, claims data will not capture all COVID-19 infections (e.g., due to home testing), such that there may be unmeasured differences between the ETC and the comparison group. Another potential limitation is that the availability of vaccines during the intervention may alter the relationship between reported COVID-19 diagnoses and patient outcomes over time, which may not occur uniformly in both ETC and comparison areas if vaccine use and availability differ between these two groups. To address this, we conducted additional analyses to examine the sensitivity of impact estimates to COVID-19 covariate adjustments. **Exhibit B-20** shows the difference in impact estimates of outcomes measures with and without COVID-19 adjustments.

The list of factors based on characteristics of patients, facilities and markets that were used for covariate adjustments in the DiD model specification are shown in **Exhibit B-18**. By using a multivariate regression, we were able to adjust for observed characteristics of patients influencing the outcome, which may not be differenced out by the DiD design.[26]

[26] One important factor involves participation in the KCC Model, which may differ between the ETC and comparison areas. However, since the KCC Model was underway starting in January 2022, we did not adjust for it in this report, which evaluates the impact of the ETC Model only through its first year (i.e., CY 2021).

Exhibit B-18. Covariate Adjustments Included in the DiD Models

Patient-Level	Facility-Level	Market-Level
▪ Age categories* ▪ Female ▪ Hispanic Ethnicity ▪ Race categories* ▪ BMI at ESRD incidence ▪ ESRD vintage categories* (i.e., time on dialysis) ▪ Indicator for dual eligible status (monthly) ▪ Indicator Original Reason for Entitlement Code: age, disabled, ESRD, ESRD and Disabled ▪ Indicator for primary cause of ESRD: diabetes, glomerulonephritis, hypertension, other ▪ Indicators for comorbidities: Cancer (annual), acute myocardial infarction I, diabetes, pneumonia, rheumatoid arthritis ▪ Indicators of health status at incidence of ESRD: Atherosclerotic Heart Disease, Peripheral Vascular Disease, other cardiac disease, Congestive Heart Failure, Chronic Obstructive Pulmonary Disease, tobacco user, alcohol and drug dependence, inability to ambulate and transfer, prior employment status. ▪ Indicators for alignment with: CEC, NGACO, Medicare Shared Savings Program ▪ Pre-ESRD nephrology care ▪ Indicators for presence of COVID-19: during the month, within the last 30 days, 31-60 days, 61-90 days)[1]	▪ Census Region Indicator: North, East South, West ▪ Rural Urban Indicator: Metro, Urban, Rural ▪ Facility chain/ownership indicator categories* ▪ Facility patient count (annual)	▪ Poverty indicator ▪ Education attainment[2] ▪ CBSA MA penetration (annual) ▪ CBSA geographic rate of primary care providers per 10,000 population (annual) ▪ ADI ▪ Percent of ACO beneficiaries in the market ▪ Percent of CEC beneficiaries in the market ▪ County level COVID-19 incidence rate

Note: * Age categories: 18-25 years, 25-35 years, 35-45 years, 45-55 years, 55-65 years, 65-75 years, > 75 years. Race categories: White, African American, Asian, Native Hawaiian/Pacific Islander, American Indian/Alaska Native, Other/Unknown Race. Patient race data were obtained from EQRS Form 2728 and supplemented by RTI race from the claims. Time on dialysis categories: <6 months, 6 -12 months, 1-2 years, 2-3 years, 3-6 years, 6-10,10 years and higher. Facility chain/ownership categories: Fresenius, DaVita, independent for profit, other for profit, non-profit, missing/unknown chain. [1] COVID-19 indicators not applicable for checking pre-ETC trends. [2] Percent of persons in the facility county of residence who are ages 25 years and older with less than a high school diploma.

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B.5.2. Unadjusted Means and Impact Estimates for All Outcomes

Exhibit B-19. Unadjusted Means of Outcome Measures Used to Evaluate the ETC Model

Outcomes		ETC		Comparison Group	
		Pre-ETC	CY 2021	Pre-ETC	CY 2021
		N = 3,116,915	N = 836,098	N = 6,167,668	N = 1,638,600
Dialysis Modality Measures (%)	**Home Dialysis**	12.0%	14.8%	12.7%	15.5%
	Peritoneal Dialysis	10.0%	12.0%	10.9%	12.9%
	Home HD	2.3%	3.2%	2.1%	2.9%
	In-center HD	88.1%	85.3%	87.3%	84.6%
	In-center Self-Dialysis	0.04%	0.03%	0.09%	0.05%
	Nocturnal HD	0.37%	0.22%	0.43%	0.27%
	Home Dialysis Training	0.75%	0.91%	0.77%	0.86%
Waitlisting (%)	**Overall**	18.9%	18.5%	21.3%	19.9%
	Active Status	11.9%	10.9%	13.6%	12.1%
	Inactive Status	7.0%	7.6%	7.7%	7.8%
Transplant (per 1000 Patient Months)	**Total** [1]	3.8	4.9	3.9	4.7
	Deceased Donor[1]	3.2	4.3	3.3	4.0
	Living Donor[1]	0.57	0.57	0.65	0.63
	Living Donor (among Dialysis Patients and Pre-emptive Transplant recipients)	0.68	0.74	0.75	0.75
Utilization (%)	**Acute Care Hospitalization**	9.7%	9.3%	9.8%	9.4%
	Readmission	29.9%	29.2%	29.9%	29.8%
	Outpatient ED Use	11.4%	9.7%	11.1%	9.6%
Medicare Payments (PPPM)	**Total Parts A & B**	$5,677	$6,006	$5,734	$6,084
	Total Part A	$1,581	$1,702	$1,652	$1,786
	Part A Acute Care Hospitalization	$1,361	$1,463	$1,400	$1,508
	Part A LTCH, IRF	$101	$110	$120	$135
	Other Part A	$120	$137	$133	$153
	Total Part B	$4,136	$4,344	$4,136	$4,351
	Part B Dialysis	$2,899	$2,972	$2,882	$2,957
	Other Part B	$1,238	$1,372	$1,253	$1,395

Notes: Home dialysis: peritoneal dialysis or home HD. Dialysis modality indicators are not mutually exclusive (i.e., a patient may have more than one modality in a month). Waitlisting and transplant measures are restricted to patients ages < 75 years. 1 Among dialysis patients.

Exhibit B-20. Comparison of ETC Model Impact Estimates with and without Adjustments for COVID-19 Covariates

Outcomes		Model with COVID Adjusters		Model without COVID Adjusters	
		DiD Estimate	p-value	DiD Estimate	p-value
Dialysis Modality Measures	**Home Dialysis***	-0.11	0.63	-0.11	0.63
	Peritoneal Dialysis	-0.13	0.53	-0.13	0.53
	Home HD	0.01	0.91	0.01	0.91
	In-Center HD	0.10	0.67	0.10	0.68
	In-Center Self-Dialysis	0.02	0.51	0.02	0.51
	Nocturnal HD	-0.01	0.78	-0.02	0.77
	Home Dialysis Training	0.07**	0.02	0.07**	0.02
Waitlisting	**Overall**	0.83*	0.10	0.83	0.10
	Active Status	0.41	0.33	0.42	0.33
	Inactive Status	0.42	0.20	0.42	0.21
Transplant (per 1,000 Patient Months)	**Total1[1]**	0.37*	0.08	0.37*	0.08
	Deceased Donor[1]	0.37*	0.07	0.37*	0.07
	Living Donor[1]	0.004	0.93	0.003	0.94
	Living Donor (among Dialysis Patients and Pre-emptive Transplant Recipients)	0.005	0.91	0.004	0.92
Utilization	**Acute Care Hospitalization [2]**	0.07	0.44	0.07	0.48
	Readmission	-0.50	0.10	-0.50	0.10
	Outpatient ED use [2]	-0.13	0.22	-0.14	0.21
Medicare Payments (PPPM)	**Total Parts A & B**	$10	0.67	$13	0.58
	Total Part A[3]	-$7	0.78	-$6	0.82
	Part A Acute Care Hospitalization[3]	-$5	0.68	-$5	0.68
	Part A LTCH, IRF[3]	-$8**	0.01	-$7**	0.013
	Other Part A[3]	-$2	0.42	-$2	0.36
	Total Part B	$5	0.73	$6	0.69
	Part B Dialysis	$2	0.82	$2	0.82
	Other Part B	$7	0.59	$8	0.55

Notes: Transplant and waitlisting measures restricted to patients less than 75 years old. [1] Among dialysis patients. [2] One or more during the month.[3]Estimates obtained from a two-part model. *Primary modality - peritoneal dialysis or home HD); dialysis modality indicators are not mutually exclusive (i.e., a patient may have more than one modality reported in a month). Significance of the DiD impact estimates is indicated for each outcome where * implies significance at the 10 percent level, ** at the five percent level, and *** at the one percent level assuming a two-tailed test. ¥ indicates that this outcome measure did not satisfy the parallel trend assumption between the ETC and the comparison group in the pre-ETC period, a critical assumption required for an unbiased DiD estimate (none indicated).

Appendix C: In-Center Hemodialysis Consumer Assessment of Healthcare Providers Survey Analysis Supplement

C.1. Data Sources

We used the ICH CAHPS survey data for 2017-2019 (pre-ETC) and CY 2021 (ETC) to assess the impact of the ETC Model on patients' self-reported experiences with in-center HD. For our analyses, we used facility-survey wave level ICH CAHPS data from CMS.

As part of CMS's ESRD Quality Incentive Program, all Medicare-certified in-center ESRD facilities that do not qualify for an exemption from participating in the ICH CAHPS survey must contract with an approved ICH CAHPS survey vendor to administer the survey twice each year: once in the spring (April-early July) and once in the fall (October-early January).[27] The survey is fielded to a sample of the facility's HD patients at least 18 years old who have received outpatient HD for at least three months at the ESRD facility, drawing from patients who received in-center dialysis in October through December of the previous year for the spring survey, and April through June of the current year for the fall survey.[28] Results are publicly reported on CMS' Care Compare site and updated each April and October.

In spring 2020, CMS also issued an Extraordinary Circumstances Exception (ECE) due to the COVID-19 PHE.[29] During the ECE, facilities were not required to conduct the spring 2020 wave of the ICH CAHPS so that facilities could instead allocate resources to patient care and safeguard the safety of their staff.[30] Given the ECE and the COVID-19 PHE's potential effect on response rates for the fall wave, we excluded 2020 ICH CAHPS data from our analyses.

C.2. Description of the In-Center Hemodialysis Consumer Assessment of Healthcare Providers Survey Measures

We analyzed six In-Center HD Patient Experience of Care publicly reported ICH CAHPS measures are derived from 35 ICH CAHPS survey questions. The three global rating measures are each derived from a single ICH CAHPS question and reflects the percentage of respondents who reported a score of nine or 10 on a scale of zero (worst) to 10 (best) (see **Exhibit C-1**). The three composite measures are derived from multiple ICH CAHPS questions and reflect the percentage of respondents who reported the most favorable ratings (see **Exhibit C-2**).[31] The six measures are adjusted for survey mode and several patient-mix factors by the ICH CAHPS Data

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[27] CMS (February 2023). *ICH CAHPS Survey: Survey Administration and Specifications Manual Version 11.0.* https://ichcahps.org/Portals/0/SurveyMaterials/ICH_SurveyAdminManual.pdf.

[28] Additional criteria for determining ICH CAHPS survey eligibility for in-center dialysis patients include not using hospice services or living in a long-term facility.

[29] CMS (2020). *End-Stage Renal Disease Quality Incentive Program (ESRD QIP) Frequently Asked Questions: Exceptions for Dialysis Facilities Affected by COVID-19*. https://www.cms.gov/files/document/covid-qip-esrd-faqs.pdf.

[30] CMS (2020). *End-Stage Renal Disease Quality Incentive Program (ESRD QIP) Frequently Asked Questions: Exceptions for Dialysis Facilities Affected by COVID-19*. https://www.cms.gov/files/document/covid-qip-esrd-faqs.pdf.

[31] CMS (2022). *Patient-Mix Coefficients and Star Ratings for the In-Center Hemodialysis CAHPS (ICH CAHPS) Survey Results Publicly Reported in October 2022.* https://ichcahps.org/Portals/0/PublicReporting/ICHCAHPS_PublicReportingCoefficients_Spring2021Fall2021.pdf.

Center contractor, including overall health; overall mental health; heart disease; difficulty hearing; visually impaired; difficulty concentrating, remembering, or making decisions; difficult dressing/bathing; age; sex; education; language other than English spoken at home; whether or not someone helped complete the survey; number of years on dialysis.[32]

Exhibit C-1. In-Center HD Patient Experience of Care Global Rating Measures and their Corresponding ICH CAHPS Questions

Global Measure	ICH CAHPS Question	Interpretation
Rating of Kidney Doctors **This corresponds to the following measure reported on CMS' Care Compare website: "Patients who gave their kidney doctors a rating of 9 or 10 on a scale of 0 to 10"**	Q8: Using any number from 0 to 10, where 0 is the worst kidney doctors possible and 10 is the best kidney doctors possible, what number would you use to rate the kidney doctors you have now?	This global measure reflects the percentage of patients who gave a score of 9 or 10 on a scale of 0 (worst possible) to 10 (best possible).
Rating of Dialysis Center Staff **This corresponds to the following measure reported on CMS' Care Compare website: "Patients who gave the dialysis center staff a rating of 9 or 10 on a scale of 0 to 10"**	Q32: Using any number from 0 to 10, where 0 is the worst dialysis center staff possible and 10 is the best dialysis center staff possible, what number would you use to rate your dialysis center staff?	This global measure reflects the percentage of patients who gave a score of 9 or 10 on a scale of 0 (worst possible) to 10 (best possible).
Rating of Dialysis Center **This corresponds to the following measure reported on CMS' Care Compare website: "Patients who gave the dialysis center a rating of 9 or 10 on a scale of 0 to 10"**	Q35: Using any number from 0 to 10, where 0 is the worst dialysis center possible and 10 is the best dialysis center possible, what number would you use to rate this dialysis center?	This global measure reflects the percentage of patients who gave a score of 9 or 10 on a scale of 0 (worst possible) to 10 (best possible).

Source: CMS (February 2023). *ICH CAHPS Survey: Survey Administration and Specifications Manual Version 11.0.* https://ichcahps.org/Portals/0/SurveyMaterials/ICH_SurveyAdminManual.pdf.

[32] CMS (2022). *Patient-Mix Coefficients and Star Ratings for the In-Center Hemodialysis CAHPS (ICH CAHPS) Survey Results Publicly Reported in October 2022.* https://ichcahps.org/Portals/0/PublicReporting/ICHCAHPS_PublicReportingCoefficients_Spring2021Fall2021.pdf.

Exhibit C-2. In-Center HD Patient Experience of Care Composite Measures and their Corresponding ICH CAHPS Questions

Composite Measure	ICH CAHPS Questions	Interpretation of Measure
Nephrologists' Communication and Caring This corresponds to the following measure reported on CMS' Care Compare website: "Patients who reported that kidney doctors "always" communicated well and cared for them as a person"	Q3: In the last 3 months, how often did your kidney doctors listen carefully to you?	This composite measure reflects the percentage of patients who provided the most favorable ratings to the corresponding six ICH CAHPS questions.
	Q4: In the last 3 months, how often did your kidney doctors explain things in a way that was easy for you to understand?	
	Q5: In the last 3 months, how often did your kidney doctors show respect for what you had to say?	
	Q6: In the last 3 months, how often did your kidney doctors spend enough time with you?	
	Q7: In the last 3 months, how often did you feel your kidney doctors really cared about you as a person?	
	Q9: Do your kidney doctors seem informed and up to date about the health care you receive from other doctors?	
Quality of Dialysis Center Care and Operations This corresponds to the following measure reported on CMS' Care Compare website: "Patients who reported that dialysis center staff "always" communicated well, kept patients as comfortable and pain-free as possible, behaved in a professional manner, and kept the center clean"	Q10: In the last 3 months, how often did the dialysis center staff listen carefully to you?	This composite measure reflects the percentage of patients who provided the most favorable ratings to the corresponding 17 ICH CAHPS questions.
	Q11: In the last 3 months, how often did the dialysis center staff explain things in a way that was easy for you to understand?	
	Q12: In the last 3 months, how often did the dialysis center staff show respect for what you had to say?	
	Q13: In the last 3 months, how often did the dialysis center staff spend enough time with you?	
	Q14: In the last 3 months, how often did you feel the dialysis center staff really cared about you as a person?	
	Q15: In the last 3 months, how often did dialysis center staff make you as comfortable as possible during dialysis?	
	Q16: In the last 3 months, did dialysis center staff keep information about you and your health as private as possible from other patients?	
	Q17: In the last 3 months, did you feel comfortable asking the dialysis center staff everything you wanted about dialysis care?	
	Q21: In the last 3 months, how often did dialysis center staff insert your needles with as little pain as possible?	
	Q22: In the last 3 months, how often did dialysis center staff check you as closely as you wanted while you were on the dialysis machine?	
	Q24: In the last 3 months, how often was the dialysis center staff able to manage problems during your dialysis?	
	Q25: In the last 3 months, how often did dialysis center staff behave in a professional manner?	
	Q26: In the last 3 months, did dialysis center staff talk to you about what you should eat and drink?	
	Q27: In the last 3 months, how often did dialysis center staff explain blood test results in a way that was easy to understand?	
	Q33: In the last 3 months, when you arrived on time, how often did you get put on the dialysis machine within 15 minutes of your appointment or shift time?	
	Q34: In the last 3 months, how often was the dialysis center as clean as it could be?	
	Q43: In the last 12 months, how often were you satisfied with the way they handled these problems?	

Composite Measure	ICH CAHPS Questions	Interpretation of Measure
Providing Information to Patients This corresponds to the following measure reported on CMS' Care Compare website: "Patients who reported that YES their kidney doctors and dialysis center staff gave them the information they needed to take care of their health"	Q19: The dialysis center staff can connect you to the dialysis machine through a graft, fistula, or catheter. Do you know how to take care of your graft, fistula, or catheter?	This composite measure reflects the percentage of patients who provided the most favorable ratings to the corresponding nine ICH CAHPS questions.
	Q28: As a patient you have certain rights. For example, you have the right to be treated with respect and the right to privacy. Did this dialysis center ever give you any written information about your rights as a patient?	
	Q29: Did dialysis center staff at this center ever review your rights as a patient with you?	
	Q30: Has dialysis center staff ever told you what to do if you experience a health problem at home?	
	Q31: Has any dialysis center staff ever told you how to get off the machine if there is an emergency at the center?	
	Q36: You can treat kidney disease with dialysis at a center, a kidney transplant, or with dialysis at home. In the last 12 months, did your kidney doctors or dialysis center staff talk to you as much as you wanted about which treatment is right for you?	
	Q38: In the last 12 months, has a doctor or dialysis center staff explained to you why you are not eligible for a kidney transplant?	
	Q39: Peritoneal dialysis is dialysis given through the belly and is usually done at home. In the last 12 months, did either your kidney doctors or dialysis center staff talk to you about peritoneal dialysis?	
	Q40: In the last 12 months, were you as involved as much as you wanted in choosing the treatment for kidney disease that is right for you?	

C.3. Study Populations

We defined our population as patients who responded to the ICH CAHPS survey and dialyzed at ESRD facilities located in ETC HRRs (i.e., the ETC group) and in non-ETC HRRs (i.e., the comparison group). CMS does not report ICH CAHPS data for facilities with fewer than 30 completed surveys in the two most recent survey periods and also suppresses ICH CAHPS data for facilities that have fewer than 10 completed surveys.[33] Similarly, ESRD facilities that served 29 or fewer survey-eligible patients in the previous year are not required to participate in the ICH CAHPS survey. These exemptions and suppressions translated to approximately 60 percent of ESRD is facilities having ICH CAHPS in the pre-ETC (2017-2019) period with similar declining shares between the ETC and the comparison group (see **Exhibit C-3**). For the first CY of the ETC Model, the share of ESRD facilities with ICH CAHPS data decreased even further, with just 46 to 47 percent of facilities having ICH CAHPS data in the spring 2021 wave and only 28 to 31 percent in the fall 2021 wave. The percent of facilities with ICH CAHPS data was similar between the ETC and the comparison group, with a small but consistently larger share among comparison facilities (e.g., 63 percent versus 67 percent for the spring 2017 wave).

The ICH CAHPS response rates of surveyed patients also decreased in the sample, dropping from 33 percent in the spring 2017 to 29 percent in spring 2019, to a low of 20 percent in fall 2021, the most recent wave in our sample (see **Exhibit C-3**). These declines reflect dramatic

[33] CMS (February 2023). *ICH CAHPS Survey: Survey Administration and Specifications Manual Version 11.0.* https://ichcahps.org/Portals/0/SurveyMaterials/ICH_SurveyAdminManual.pdf.

differences between the earliest and latest waves in terms of the number of facilities (4,309 vs. 2,172) and of completed surveys (98,134 vs. 34,735; see **Exhibit C-3**).

Exhibit C-3. Characteristics of ESRD Facilities Used in the ICH CAHPS Analyses

Characteristic	Pre-ETC												Post-ETC			
	2017 Spring		2017 Fall		2018 Spring		2018 Fall		2019 Spring		2019 Fall		2021 Spring		2021 Fall	
	ETC	Non-ETC	ETC	Non-ETC	ETC	Non-ETC	ETC	Non-ETC	ETC	Non-ETC	ETC	Non-ETC	ETC	Non-ETC	ETC	Non-ETC
ESRD Facilities*	2,175	4,403	2,175	4,403	2,268	4,637	2,268	4,637	2,337	4,777	2,337	4,777	2,390	4,897	2,390	4,897
ESRD Facilities with ICH CAHPS Data	1,378	2,931	1,345	2,815	1,267	2,697	1,336	2,822	1,325	2,771	1,314	2,748	1,090	2,313	675	1,497
Percent with ICH CAHPS Data	63%	67%	62%	64%	56%	58%	59%	61%	57%	58%	56%	58%	46%	47%	28%	31%
Number of ICH CAHPS Sampled Patients across Facilities	92,426	203,692	91,583	198,910	84,057	183,288	88,733	192,550	89,714	195,014	88,419	193,044	74,868	164,600	54,025	122,654
ICH CAHPS Survey Responses across Facilities	30,766	67,368	28,418	62,181	25,897	56,491	27,387	59,331	26,030	56,104	25,090	53,627	19,074	41,818	10,702	24,033
Response Rate	33.3%	33.1%	31.0%	31.3%	30.8%	30.8%	30.9%	30.8%	29.0%	28.8%	28.4%	27.8%	25.5%	25.4%	19.8%	19.6%

Note: *Reflects total number of ESRD facilities with adult patients who are attributed and eligible for the ETC Model and are not missing ETC status. All ETC and comparison group HRRs are represented in the ICH CAHPS sample (not shown).

C.4. Analytic Methods

C.4.1. Assessing Balance of the ICH CAHPS Sample

For our facility survey wave-level analysis, we used the six survey-waves: spring 2017-fall 2019 for our pre-ETC period and the spring 2021-fall 2021 waves for the post-ETC period. We assessed the balance of the facilities included in the ICH CAHPS analysis by calculating SMDs for key characteristics and using a standard threshold value of 0.2 to understand the extent of any differences between the ETC and comparison group HRRs (see **Section B.3**). Broadly, ETC and comparison groups were well balanced across facility-, patient-, and market-level characteristics that were used as covariates (discussed below) in the analyses (see **Exhibit C-4**) as well as across other key patient and facility characteristics (see **Exhibit C-5**). The exceptions included higher rates of CEC participation among facilities in the ETC group (e.g., 80 percent for the ETC group and 68 percent for comparison group in 2021), and a lower percent of patients who are Hispanic among ETC facilities (e.g., 11 percent and 19 percent, respectively, in 2021; see **Exhibit C-4**).

We weighted each observation by the number of survey respondents at the corresponding facility. Similar to the other analyses in this report, we clustered standard errors at the HRR level (see **Section B.4**) Our DiD analyses included 30,312 facility-survey wave observations for 5,355 unique ESRD facilities.

Exhibit C-4. Annual Means (and Standard Errors) for Covariates Used in the ICH CAHPS Analyses

Characteristic	Pre-ETC			CY 2021		
	ETC	Comparison	SMD	ETC	Comparison	SMD
Number of Facilities	4,419	9,266	N/A	1,126	2,396	N/A
Number of Surveys per Wave						
Spring	3,970	8,399	N/A	1,086	2,309	N/A
Fall	3,995	8,385	N/A	674	1,494	N/A
Census Region (% in Each Region)						
Northeast	15.3 (36.0)	14.3 (35.0)	.03	17.5 (38.0)	16.1 (36.7)	.04
South	49.3 (50)	44.7 (49.7)	.09	46.0 (49.9)	40.3 (49.1)	.12
Midwest	16.9 (37.5)	18 (38.4)	-.03	16.3 (36.9)	17.4 (37.9)	-.03
West	18.4 (38.8)	23 (42.1)	-.11	20.2 (40.3)	26.3 (44.0)	-.14
Number of Patients at ESRD Facility	534,932	1,166,498	N/A	128,467	286,722	N/A
Hospital-Owned (%)	2.5 (15.5)	2.2 (14.8)	.01	2.7 (16.1)	2.8 (16.4)	-.01

Characteristic	Pre-ETC			CY 2021		
	ETC	Comparison	SMD	ETC	Comparison	SMD
Facility Chain/Ownership (%)						
DaVita	38.1 (48.6)	41.2 (49.2)	-.06	34.8 (47.7)	38.4 (48.6)	-.07
Fresenius	41.8 (49.3)	37.2 (48.3)	.10	45.1 (49.8)	37.7 (48.5)	.15
Independent/Non-Chain For-Profit	1.8 (13.2)	2.9 (16.9)	-.08	1.7 (12.9)	3.6 (18.7)	-.12
Other For-Profit	10.8 (31)	8.9 (28.5)	.06	10.0 (30.1)	9.1 (28.8)	.03
Non-Profit	7.6 (26.5)	9.7 (29.6)	-.08	8.3 (27.7)	11.1 (31.5)	-.09
Facility RUCC (%)						
Metro	84.1 (36.5)	86.3 (34.3)	-.06	86.2 (34.5)	89.3 (30.9)	-.09
Urban	15.5 (36.2)	13.4 (34.0)	.06	13.5 (34.2)	10.5 (30.6)	.09
Rural	0.4 (6.0)	0.3 (5.5)	.01	0.3 (5.2)	0.2 (4.6)	.01
Medicare Shared Savings Program	99.1 (9.4)	99.3 (8.5)	-.02	99.0 (9.8)	99.3 (8.4)	-.03
APMs (%)						
CEC	77.4 (41.8)	67.0 (47.0)	.23	79.9 (40.1)	68.3 (46.5)	.27*
NGACO	56.5 (49.6)	57.2 (49.5)	-.01	57.8 (49.4)	60.8 (48.8)	-.06
COVID-19 Incidence Rate	0 (0)	0 (0)		102.4 (73.3)	87.9 (119.1)	.15
ADI	59.9 (20.4)	56.4 (23.2)	.16	58.1 (20.9)	53.9 (23.8)	.19
Dually Eligible for Medicare and Medicaid %	46.7 (15.6)	48.6 (17)	-.12	46.2 (15.6)	49.2 (17.6)	-.18
Patient Race (%)						
Black or African American	39.4 (30.4)	34.1 (29.0)	.18	38.7 (30.1)	33.2 (28.4)	.19
Non-Hispanic White	53.6 (28.8)	58.5 (28.0)	-.17	54.0 (28.4)	58.3 (27.4)	-.16
Asian	3.2 (5.7)	4.6 (9.3)	-.18	3.4 (5.9)	5.4 (10.4)	-.24*
Native Hawaiian/ Pacific Islander	1.0 (2.8)	1.3 (4.1)	-.07	1.1 (2.7)	1.5 (4.5)	-.11
American Indian/Alaska Native	2.2 (10.3)	0.8 (4.4)	.18	2.2 (9.9)	0.7 (4.2)	.19
Other/Unknown Race	0.6 (1.0)	0.8 (1.3)	-.16	0.6 (1.1)	0.8 (1.4)	-.18
Patient Hispanic Ethnicity (%)	10.7 (16.4)	17.6 (22.7)	-.35	11.3 (17.0)	19.0 (23.1)	-.38*

Notes: Pre-ETC includes spring 2017-fall 2019 survey waves. CY 2021 includes spring 2021-fall 2021 survey waves. Patient characteristics reflect overall patient population derived from the Medicare administrative

data. * Indicates SMD exceeds the 0.2 threshold, suggesting a meaningful difference between the ETC and the comparison group.

Exhibit C-5. Annual Means (and Standard Errors) for Selected Characteristics of ESRD Facilities Used in ICH CAHPS Analyses

Characteristic	Pre-ETC			CY 2021		
	ETC	Comparison Group	SMD	ETC	Comparison Group	SMD
Number of Facilities	4,419	9,266	N/A	1,126	2,396	N/A
Offer Home Dialysis (%)	41.9 (49.4)	45.1 (49.8)	-.06	44.8 (49.8)	47.0 (49.9)	-.04
Average Age of Patients (Years)	62.2 (3.7)	62.4 (3.7)	-.06	62.4 (3.7)	62.5 (3.7)	-.05
LIS patients (%)	54.2 (15.6)	55.9 (16.6)	-.11	53.5 (15.6)	56.1 (17.0)	-.16
Maryland						
Facilities (%)	8.1	0.0	N/A	9.2	0.0	N/A
Patients (%)*	4.3	0.0	N/A	5.6	0.0	N/A

Notes: Pre-ETC includes spring 2017-fall 2019 survey waves. CY 2021 includes spring 2021-fall 2021 survey waves. Patient characteristics reflect overall patient population derived from the Medicare administrative data. Patient characteristics reflect overall patient population derived from Medicare administrative data. * Reflects the percent of ICH CAHPS surveys used in the analyses that are from ESRD facilities in Maryland.

C.4.2. DiD Approach for the ICH CAHPS Analysis

We used a DiD framework to compare changes in the six measures observed over time for patients dialyzing at facilities located in the ETC areas, compared to patients dialyzing at facilities in the comparison group. While the facility-wave data are risk adjusted for patient characteristics, as described above, our DiD analyses included the following covariates summarized at the ESRD facility level to control for potential differences between the ETC and comparison groups (as discussed in **Section B.1**, patient characteristics reflect overall patient population derived from the Medicare administrative data):

- Survey wave
- Census region of the ESRD facility
- ESRD facility size (i.e., number of patients)
- Hospital-ownership of the ESRD facility
- Chain/ownership of the ESRD facility
- Rural/urban location of the ESRD facility
- ESRD facility's participation in selected APMs
- ESRD facility's county level yearly average COVID-19 incidence rate
- ADI for the location of the ESRD facility
- Percent of ESRD facility's patients who are dually eligible for Medicare and Medicaid
- Percent of ESRD facility's patient race and ethnicity

C.4.3. Assessing Parallel Trends: Dynamic Trends Test

We also estimated a joint F-Test to determine whether all the pre-ETC interaction terms were jointly equal to zero for the in-center HD patient experience of care measures. The joint F-Test examines the parallel trend assumption by testing whether there is a significant treatment effect at all time points prior to the initiation of intervention (i.e., the six survey waves in the pre-ETC period (spring 2017 –fall 2019)). We tested for a treatment effect in all survey waves in the pre-ETC period using spring 2019 as the reference and applied the same risk-adjusted DiD specification discussed in the previous section. If there are differential estimates that are jointly statistically different from zero ($p < 0.1$), it would suggest that there is lack of parallel trends in the outcomes for the two groups over the pre-ETC period. None of the six patient experience of care measures were statistically different from zero (see **Exhibit C-6**), suggesting the parallel trends assumption was upheld.

Exhibit C-6. Assessing Parallel Trends: DiD Estimates for ICH Patient Experience of Care Measures

Measures		Model Estimates					Joint Test p-value
		Spring 2017	Fall 2017	Spring 2018	Fall 2018	Fall 2019	
Patient Experience of Care	Rating of Kidney Doctors	0.28	0.22	0.10	-0.16	0.30	0.87
	Rating of Dialysis Center Staff	0.40	-0.13	-0.60	-0.31	-0.39	0.55
	Rating of Dialysis Center	0.35	-0.09	-0.23	-0.37	0.08	0.70
	Nephrologists' Communication and Caring	0.24	0.12	0.16	-0.04	0.12	0.96
	Quality of Dialysis Center Care and Operations	0.02	-0.22	-0.46	-0.37	-0.001	0.47
	Providing Information to Patients	0.10	0.38	-0.02	0.15	-0.23	0.14

Notes: This analysis includes spring 2017-fall 2019 ICH CAHPS surveys. To examine the parallel trend assumption, we tested for a treatment effect in all pre-ETC survey waves and used spring 2019 survey wave as the reference.

C.4.4. DiD Findings

As noted in the main report, we found no impact on any of the six in-center HD patient experience of care measures for the first CY of the ETC Model. **Exhibit C-7** complements the DiD findings presented in the main report with additional information on adjusted means for each measure and the associated percent change for each measure. Our DiD results were also robust to sensitivity analyses that restricted to the subgroup of ESRD facilities (3,006) that had ICH CAHPS data in both the pre-ETC and post-ETC periods (see **Exhibit C-8**).

Exhibit C-7. Impact of the ETC Model on ICH Patient Experience of Care Measures for CY 2021

Measures		ETC		Comparison Group		Model Estimates				% Relative Change
		Pre-ETC Mean	CY 2021 Mean	Pre-ETC Mean	CY 2021 Mean	DiD	p-value	Lower 90% CI	Upper 90% CI	
Patient Experience of Care	Rating of Kidney Doctors	59.5%	60.1%	60.7%	61.3%	-0.01	0.98	-0.86	0.83	-0.02%
	Rating of Dialysis Center Staff	62.5%	63.8%	63.1%	65.0%	-0.66	0.19	-1.5	0.16	-1.1%
	Rating of Dialysis Center	67.6%	68.3%	68.2%	69.2%	-0.28	0.58	-1.1	0.54	-0.41%
	Nephrologists' Communication and Caring	67.3%	67.0%	67.9%	67.5%	0.11	0.78	-0.51	0.72	0.16%
	Quality of Dialysis Center Care and Operations	62.6%	63.0%	63.1%	63.7%	-0.23	0.54	-0.78	0.36	-0.36%
	Providing Information to Patients	80.2%	79.9%	80.5%	80.2%	-0.04	0.86	-0.39	0.31	-0.05%

Notes: Sample size = 30,312 facility-survey wave observations. Pre-ETC includes spring 2017-fall 2019 survey waves. CY 2021 includes spring 2021-fall 2021 survey waves. Values reflected weighted adjusted measure values.

Exhibit C-8. Sensitivity Analysis: Impact of the ETC Model on ICH Patient Experience of Care Measures for CY 2021 Among Subset of Facilities with ICH CAHPS Data in Both Pre-ETC Period and CY 2021

Measures		ETC		Comparison Group		Model Estimates				% Relative Change
		Pre-ETC Mean	CY 2021 Mean	Pre-ETC Mean	CY 2021 Mean	DiD	p-value	Lower 90% CI	Upper 90% CI	
Patient Experience of Care	Rating of Kidney Doctors	59.1%	60.4%	60.6%	61.7%	0.23	0.64	-0.58	1.0	0.39%
	Rating of Dialysis Center Staff	62.3%	62.7%	63.0%	64.0%	-0.55	0.23	-1.30	0.20	-0.89%
	Rating of Dialysis Center	67.3%	67.4%	68.1%	68.3%	-0.15	0.75	-0.88	0.59	-0.22%
	Nephrologists' Communication and Caring	67.0%	67.4%	67.8%	67.7%	0.37	0.30	-0.22	1.0	0.55%
	Quality of Dialysis Center Care and Operations	62.3%	62.4%	62.9%	63.2%	-0.20	0.55	-0.76	0.36	-0.32%
	Providing Information to Patients	80.1%	79.7%	80.3%	79.8%	0.15	0.47	-0.20	0.51	0.19%

Notes: Sample size = 22,251 facility-survey wave observations among 3,006 unique ESRD facilities that have ICH CAHPS data in both the pre-ETC and CY 2021 periods. Pre-ETC includes spring 2017-fall 2019 survey waves. CY 2021 includes spring 2021-fall 2021 survey waves. Values reflected weighted adjusted measure values.

Appendix D: Power Calculation Methodology

The sensitivity of a model to detect difference between the treatment and comparison group is measured by statistical power. In this section, we describe our power calculation methodology, which is to determine the smallest detectable difference, given the fixed sample size and other parameters. We set the level of Type I error (false positive, i.e., falsely concluding that model has an effect when it does not) at an acceptable level of 0.1 and computed power under this specification.

Clustered designs are common in DiD framework and hence we first calculated intra-cluster correlation coefficient (ICC) and then computed the design effect using the equation.

$$Design\ Effect = 1 + (m-1) * ICC$$

where *m* is the average cluster size. The design effect is essentially the variance inflation ratio because it is the ratio of the variance of an estimate in a cluster design to the variance computer under the assumption of simple random sampling.[34]

We conducted power calculations for two main outcomes: home dialysis and overall transplant waitlisting. Using a two-tailed test at 0.1 level of significance, the evaluation has 80% power to detect a minimum effect size of 1.8 percentage points difference for home dialysis and a 2.0 percentage points difference for the transplant waitlisting measure.

[34] Sandra M Eldridge, Deborah Ashby and Sally Kerry. Sample size for cluster randomized trials: effect of coefficient of variation of cluster size and analysis method. Int. J. Epidemiol. (October 2006) 35 (5): 1292-1300.