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# End-Stage Renal Disease Treatment Choices (ETC) Model

## *Second Annual Evaluation Report*

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### *January 2024*


### *The Lewin Group*

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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 |
| AR | annual report |
| 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 |
| DDD | difference-in-difference-in-differences |
| ECE | extraordinary circumstance exception |
| ED | emergency department |
| EHR | electronic health record |
| E/M | Evaluation and Management |
| EQRS | End-Stage Renal Disease Quality Reporting System |
| ESRD | end-stage renal disease |
| ETC | ESRD Treatment Choices |
| 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 |

| Acronym | Definition |
|---|---|
| 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 |
| 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.

CMS designed the ETC Model to include approximately 30 percent of Hospital Referral Regions (HRRs) in the United States (U.S.). These HRRs were selected at random using a 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 implementation of the ETC Model, 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. ETC Participant performance is based on levels of home dialysis use, waitlisting for a deceased donor transplant, living donor transplantation, and, for certain ETC Participants, pre-emptive transplantation, among FFS beneficiaries in their care. Effective January 1, 2022, the model also included health equity provisions that were intended to reduce disparities 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. 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 2022 to promote health equity by reducing disparities in home dialysis and transplantation have implications for the care of beneficiary groups who have historically been underserved. To achieve these goals, this evaluation 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. This second annual evaluation report examines impacts of the ETC Model during calendar years (CYs) 2021 and 2022, which correspond to the first three Measurement Years (MYs) of the model.[2]

The ETC Model introduced two distinct types of financial incentives to encourage greater use of home dialysis and transplantation. First, starting on January 1, 2021, rates of home dialysis use, transplant waitlisting, and pre-emptive and living donor transplantation among attributed beneficiaries were used to determine the PPA for participating ESRD facilities and Managing Clinicians. The PPA was applied to Medicare payments to ESRD facilities and Managing Clinicians starting on July 1, 2022. The initial PPAs ranged from up to a five percent reduction to

[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.

[2] MY1 covered the time period from January 1, 2021, to December 31, 2021, MY2 covered the time period from July 1, 2021 to June 30, 2022, and MY3 covered the time period from January 1, 2022, to December 31, 2022.

up to a four percent increase to certain Medicare payments subject to adjustment. The maximum positive and negative payment adjustments increase over the course of the model.

Second, ESRD facilities and Managing Clinicians were eligible to receive a positive Home Dialysis Payment Adjustment (HDPA) 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 and represented a three percent adjustment during CY 2021 and a two percent adjustment during CY 2022.

CMS also adopted two health equity provisions involving changes to the calculation of the PPA that were effective on January 1, 2022. First, CMS introduced a Health Equity Incentive that enables ETC Participants to earn more favorable PPAs when demonstrating significant improvement in rates of home dialysis or transplantation among beneficiaries who were dually eligible or who were enrolled in a Part D plan and recipients of the Part D Low Income Subsidy (LIS). In addition, CMS assessed rates of home dialysis and transplantation among ETC Participants separately based on whether dually eligible and Part D LIS beneficiaries comprised less than half versus half or more of their attributed beneficiaries.

This second annual report (AR2) examines impacts of the ETC Model through 2022, reflecting the first two years of experience with the model and the first year in which the model's health equity provisions were in effect. This report uses a combination of quantitative and qualitative data to inform conclusions about impacts of the model. We report findings from semi-structured interviews with participating ESRD facilities and Managing Clinicians regarding their experience implementing the model, strategies they have employed, and challenges they have faced. As with the first annual report (AR1), outcomes for quantitative analyses include the use of home dialysis, waitlisting for a kidney transplant, living donor and deceased donor transplantation, utilization of services, Medicare Parts A & B payments, and in-center hemodialysis (HD) patient experience of care. In AR2, we incorporated additional outcomes, including mortality, measures of infections and other potential complications of ESRD treatment, and Part D spending. We examined whether there were cumulative impacts of the model during the combined 2021-2022 period and also examined impacts separately in each year. We also conducted initial analyses of the potential implications of the model for health equity by comparing impacts observed among underserved populations relative to other patients. Future annual reports will incorporate analyses of additional patient-reported data on quality of life (QoL) as well as experience of care for patients using a home dialysis modality.

## ES.2. Overview of Findings

Through the first two calendar years of the model, there was no evidence of an impact of the ETC Model on the use of home dialysis modalities, transplant waitlisting, and living donor transplantation, which are the direct targets of the model's payment adjustments (see **Exhibit ES-1**) for a summary of the evaluation findings). While home dialysis use continued to grow nationally, there was no evidence of faster growth in home dialysis use in the areas selected for the ETC Model (that is, Selected Geographic Areas or ETC areas) relative to a comparison group of HRRs not selected for the ETC Model (that is, Comparison Geographic Areas or comparison areas). For details regarding cumulative impact estimates for home dialysis and other measures, see **Exhibit 11** in **Section 4.3**. There was evidence of an increase in home dialysis training under the ETC Model for the combined CY 2021 – CY 2022 period, which reflects an

early increase in home dialysis training in CY 2021 that was not sustained in CY 2022. Based on data for CY 2021, the ETC Model resulted in an estimated 546 additional patient months with home dialysis training in ETC areas during the first year of the model, which corresponds to a 10 percent increase over pre-ETC home dialysis training rates (see **Exhibit 13** and **Appendix B, Exhibit B-21** for yearly impact estimates). It will be important to continue to examine the frequency of home dialysis training in future years of the model and assess whether there are subsequent changes in the extent to which patients successfully transition to a home dialysis modality.

For transplant-related measures, there was no evidence of a change in waitlisting rates in ETC areas relative to comparison areas based on the combined CY 2021 – CY 2022 data. There was evidence of an increase in transplant rates under the ETC Model for the combined CY 2021 – CY 2022 period, though this finding reflects relative growth in CY 2021 that was not sustained in CY 2022. The impact estimate for the first year of the model corresponds to an estimated 225 additional kidney transplants in ETC areas in CY 2021, which represents a 10 percent increase over pre-ETC transplant rates (see **Exhibit 16** and **Appendix B, Exhibit B-21** for yearly impact estimates). This observed growth in overall transplants is attributed to growth in deceased donor transplants. Through the first two years of the model, there was no impact on living donor transplant rates.

## Exhibit ES-1. Summary of Cumulative Evaluation Findings, CY 2021 – CY 2022

| Domain | Outcome | Cumulative ETC Model Impact, 2021-2022 |
|---|---|---|
| **Dialysis Modality Measures** | Home Dialysis | |
| | Peritoneal Dialysis | |
| | Home Hemodialysis | |
| | In-Center HD^ | |
| | In-Center Hemodialysis | |
| | In-Center Self-Dialysis | |
| | Nocturnal Hemodialysis | |
| | Home Dialysis Training | ↑ |
| **Transplantation** | Overall Waitlisting | |
| | Active Status | |
| | Inactive Status | |
| | Overall Transplants | ↑ |
| | Deceased Donor | ↑ |
| | Living Donor | |
| | Living Donor (Dialysis and Pre-emptive) | |
| **Utilization** | Acute Care Hospitalization | |
| | Readmission | |
| | Outpatient ED Use | ↓ |
| **Medicare Payments** | Total Parts A & B | |
| | Total Part A | |
| | Part A Acute Care Hospitalization | |
| | Part A LTCH and IRF | |
| | Other Part A | |
| | Total Part B | |
| | Part B Dialysis | |
| | Other Part B | |
| | Part D | |
| **Quality** | Peritonitis | |
| | Vascular Infection | |
| | Hospitalizations with Vascular Access Complications | |
| | Hospitalizations with ESRD Complications | |
| | Mortality | No Impact[1] |
| **In-Center HD Patient Experience of Care** | Rating of Kidney Doctors | |
| | Rating of Dialysis Center Staff | |
| | Rating of Dialysis Center | |
| | Nephrologists' Communication and Caring | |
| | Quality of Dialysis Center Care and Operations | |
| | Providing Information to Patients | |

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

Arrow indicates the direction of the statistically significant cumulative impact estimate. Detailed impact estimates for each outcome are included in the body of the report. ^In-center HD includes in-center hemodialysis, in-center self-dialysis, and in-center nocturnal dialysis. [1]The post-ETC and pre-ETC hazard ratios of mortality obtained from risk-adjusted Cox proportional hazards model were similar.

There were no major shifts in overall Medicare payments or utilization of acute care services through the first two years of the model. There was 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, in overall Part A or Part B payments PPPM, or in Part D payments PPPM. There was also no impact of the model on overall acute care hospitalizations or hospital readmissions. There was evidence of a decline in outpatient ED use in ETC areas relative to comparison areas of 0.17 percentage points ($p<0.1$), which corresponds to a 1.5 percent decline in 2021-2022 relative to pre-ETC levels. While the impact estimates were positive for each of the model's first two years, only the impact estimate for the second year was statistically significant (see **Exhibit 17** and **Appendix B, Exhibit B-21** for details).

With respect to other patient outcomes, there was no evidence during 2021-2022 of an impact on QoC based on measures of dialysis-related infections and other potential treatment complications among dialysis patients as well as patient mortality. There was also no early impact of the model on measures of in-center HD patient experience of care.

For AR2, we carried out semi-structured interviews with samples of ESRD facilities and Managing Clinicians to gain insights on the perspectives and experience of ETC Participants in implementing the model. Overall, the interviews with participating ESRD facilities and Managing Clinicians did not indicate a major shift in behavior in direct response to the model's incentives, which is in alignment with the quantitative findings. The responses of interview participants suggest that ETC Model implementation primarily represents a continuation of prior efforts to increase home dialysis and transplantation.

Given the specific nature of the model's health equity provisions, we assessed whether impacts differed for dually eligible beneficiaries or recipients of the Part D LIS. We also compared model impacts across racial and ethnic groups. The results of these analyses did not indicate an overall pattern of differential impacts of the model across patient subgroups for home dialysis use, waitlisting, transplantation, or other outcomes.[3] Instead, there was a pattern of differences across subgroups in home dialysis use, waitlisting, and transplantation that predated the start of the ETC Model and largely persisted through CY 2022.

## ES.3. Discussion

Through the first two years of the ETC Model, the findings of quantitative and qualitative analyses provided limited evidence of an impact of the model on changes in care involving home dialysis and transplantation, no pattern of differential impacts among underserved populations that would indicate early implications of the model for health equity, and no early evidence of unintended impacts. The cumulative findings for CY 2021 and CY 2022 include no evidence of an increase in the use of home dialysis modalities in ETC areas relative to the comparison group. While there was evidence that the model resulted in a modest increase in home dialysis training in the first year of the model, this impact was not sustained in the second year and did not appear to translate to a subsequent increase in the use of home dialysis.

[3] Other outcomes for health equity analyses included acute care hospitalizations, hospital readmissions, peritonitis among PD patients, and Total Medicare Parts A & B payments PPPM.

With respect to transplantation, there was no evidence of an impact of the model on either waitlisting rates or living donor transplant rates, which are both a specific focus of the ETC Model incentive structure. There was evidence of faster growth in overall transplant rates in ETC areas relative to comparison areas that reflects increased rates of deceased donor transplants. However, this evidence was limited to the first year of the model and was not accompanied by an increase in waitlisting rates which would presumably be the mechanism through which the model would affect the frequency of deceased donor transplants. We therefore conclude that the initial relative growth in deceased donor transplants and overall transplants in ETC areas that was limited to CY 2021 is not likely to be the result of ETC Model incentives.

While the evaluation findings in this report are based on two years of experience with the model, we caution that it is still too early to form conclusions about possible longer-term impacts of the model. ETC Participants may continue to adapt their practices and learn from ongoing efforts to encourage use of home dialysis and transplantation as successful options for patients. This may be important in a context where ESRD facilities and Managing Clinicians identify a wide range of potential barriers to home dialysis and transplantation that may vary substantially from patient to patient. In certain respects, the ETC Model was also maturing during its second year, when there were two important new milestones: the health equity provisions of the model were effective on January 1, 2022, and the initial PPAs were applied to some payments to facilities and Managing Clinicians effective July 1, 2022. More time will be needed to determine the eventual intended and unintended effects of the model's performance incentives and payment adjustments.

There are both qualitative and quantitative data suggesting a recent focus on alternatives to in-center HD that is not solely due to the ETC Model. During interviews, ETC Participants noted preexisting efforts to encourage home dialysis and transplant options among patients that were not initiated specifically in response to the model. Such efforts may not be limited to ETC areas. As a possible indication of broader changes in practice, the use of home dialysis continued to expand in both the ETC and comparison areas after the start of the ETC Model. This reflected 6.8 percent growth in ETC areas between the first half of 2021 and the second half of 2022 (from 14.7 percent to 15.7 percent of dialysis patient months) and 5.8 percent growth in comparison areas (from 15.4 to 16.3 percent). To the extent that any changes made among ETC Participants in response to the model are incremental relative to changes that are not limited to ETC areas, more time may be needed to observe their effects.

An important focus for future work involves the collection and analysis of additional patient-reported data which will involve both quantitative and qualitative methods. In a future report, patient-reported data will be used to examine patient QoL, experience of care for home dialysis patients, and patient perspectives on the modality selection process. In addition, it should be noted that the ETC and KCC Models were being implemented concurrently starting in CY 2022. Given the overlap in certain ETC and KCC Model goals (for instance, transplantation) and in participation (that is, 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. This will be explored in a future AR.

# 1. Introduction

The Centers for Medicare & Medicaid Services (CMS) launched the End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model on January 1, 2021. The ETC Model is intended to encourage greater use of home dialysis and kidney transplantation, while reducing Medicare expenditures and preserving or enhancing quality of care (QoC) for patients with ESRD. In addition, starting in the second year of the model, January 1, 2022, the model design was amended to 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 patient groups who have historically been underserved.

This evaluation employs a mixed methods research design that incorporates both quantitative and qualitative data. CMS administrative data and data from patient surveys will be used to conduct quantitative impact analyses. In addition, throughout the evaluation, we will be collecting and analyzing qualitative data through interviews with both ETC Participants and beneficiaries to provide context for the quantitative findings and to inform future quantitative analyses.

This second annual report (AR2) assesses the impacts of the ETC Model during the first two years of the model (CYs 2021 and 2022). A combination of quantitative and qualitative data are used to inform conclusions about early impacts of the model. Using data collected through semi-structured interviews with participating ESRD facilities and Managing Clinicians, we describe the experience of ETC Participants in implementing the model. In examining potential impacts of the model, key outcomes of interest include use of home dialysis, waitlisting for a kidney transplant, living donor and deceased donor transplantation, utilization of services, Medicare payments, QoC, and patient experience of care. We also assess whether the model has implications for health equity by comparing impacts observed among underserved populations relative to other beneficiaries.

## 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.).[4] 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.

[4] 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.

Managing Clinicians include nephrologists and other qualified practitioners who furnish and bill ESRD-related physician services under the Medicare Monthly Capitation Payment (MCP). The ETC Model incentives take the form of adjustments to the Medicare payment amounts that participating ESRD facilities and Managing Clinicians would otherwise receive for providing care to patients with Medicare fee-for-service (FFS) coverage.

The ETC Model was accompanied by a waiver of certain requirements that clinicians had to fulfill in order 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 provisions. Each of these features is discussed 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 where 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 is in effect for the first three years of the ETC Model (CYs 2021-2023), 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, transplant waitlisting, and living donor transplant rates. The numerator for the home dialysis rate is calculated as the number of beneficiary years for attributed beneficiaries who received dialysis at home during the Measurement Year (MY) plus one half the number of beneficiary years for attributed beneficiaries who received in-center self-dialysis plus (starting in MY3) one half the number of beneficiary years for attributed beneficiaries who received nocturnal in-center dialysis. The denominator for the home dialysis rate is calculated as the number of beneficiary years for attributed beneficiaries who received in-center or home dialysis during the MY. For ESRD facilities, both the home dialysis rate and the transplant rate (discussed below) are aggregated to the ESRD facility's aggregation group, which includes all ESRD facilities owned by the same legal entity that are located in the same HRR.

The transplant rate is the sum of the transplant waitlist rate and the living donor transplant rate among attributed beneficiaries who were less than 75 years of age. The transplant waitlist rate is calculated as the number of beneficiary years during the MY for which attributed beneficiaries were on the kidney transplant waitlist divided by the total number of attributed beneficiary years during the MY. The living donor transplant rate is calculated as the number of beneficiary years during the MY for which attributed beneficiaries received living donor transplants divided by the total number of attributed beneficiary years during the MY. In calculating the transplant waitlist rate for Managing Clinicians, attributed beneficiaries include both ESRD beneficiaries receiving in-center or home dialysis and beneficiaries who received a pre-emptive living donor transplant (that is, prior to starting dialysis).

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. Achievement scores are calculated for each Participant based on their performance during the 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 during a Benchmark Year (BY). 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 period during which performance was assessed, 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 was 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 PPAs could have implications for both home dialysis and transplantation among beneficiaries starting in 2021 and continuing in subsequent years of the model. The range of potential PPAs increases over time for both facilities and Managing Clinicians. Starting in the fourth year of the model (CY 2024, which corresponds to PPA Period 7), there is a larger potential negative payment adjustment for ESRD 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 (Measurement Years 1-2) (cms.gov)

**Health equity provisions.** The model was amended in the second year (CY 2022) to include provisions that are intended to promote greater equity in home dialysis and transplantation among beneficiaries with ESRD.[5] First, starting with MY3, which began on January 1, 2022, the PPA achievement benchmarks were stratified based on the percentage of attributed beneficiary years during the MY for FFS beneficiaries who were dually eligible for Medicare and Medicaid or who were eligible for the Part D LIS . This change was made in recognition of the historically lower home dialysis and transplant rates among patients with lower socioeconomic status, among other patient characteristics.[6,7,8]

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 achieved sufficient improvement in home dialysis and transplant rates among attributed beneficiaries who were dually eligible for Medicare and Medicaid or Part D LIS recipients. Additional details about these health equity provisions are provided in **Appendix B, Section B.6**. Together, these two refinements to the original ETC Model design that went into effect starting in CY 2022 represent novel features of a health care payment model that were designed to promote health equity.

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5 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.

6 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.

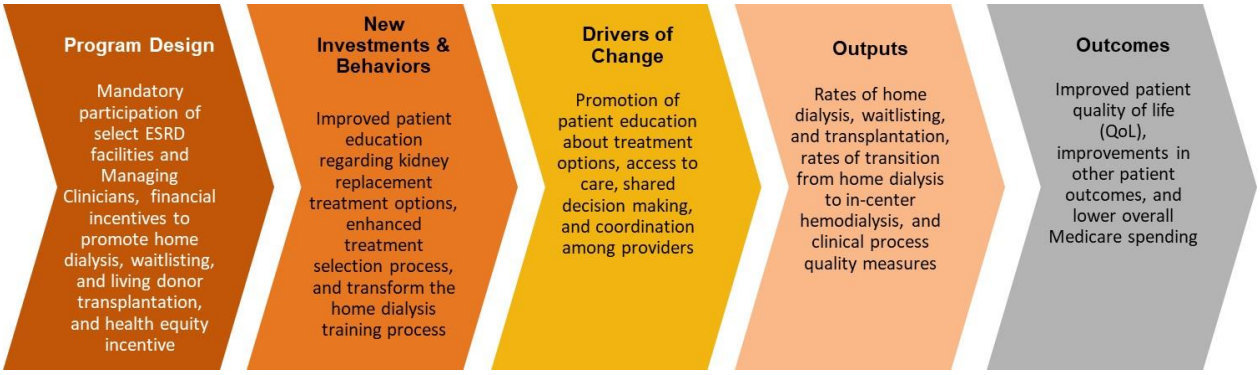
7 Patzer RE, McClellan WM. Influence of race, ethnicity, and socioeconomic status on kidney disease. Nat Rev Nephrol 2012 Sep;8(9):533-541.

8 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. 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 AR2 are discussed below.

**Exhibit 2. ETC Logic Model (Abbreviated)**




### 1.2.1. Who Participates in the ETC Model?

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

### 1.2.2. How Do Participating ESRD Facilities and Managing Clinicians Implement the ETC Model?

As part of this mixed methods evaluation of the impact of the ETC Model, we conducted semi-structured interviews with a sample of ESRD facilities and a sample of Managing Clinicians located in the selected ETC HRRs. There were multiple goals in collecting and analyzing data based on these interviews: to understand how the two types of ETC Model Participants are implementing the model; to provide context for the quantitative findings; to help inform conclusions about ETC Model impacts; and to potentially inform future data collection and analyses. In conducting these interviews during the spring/summer of 2023, we inquired about changes that participating ESRD facilities and Managing Clinicians made in response to the model's incentives, strategies that they employed, and perceived barriers and facilitators of change under the model. To ensure that the interviews captured diverse perspectives, we selected respondents that were heterogeneous based on geographic location and other criteria.

In this report, the qualitative data that were collected through these interviews were used to address specific research questions about how ESRD facilities and Managing Clinicians are implementing the ETC Model. The qualitative findings from these interviews were then integrated with findings from quantitative analyses to help address other research questions about the impacts of the ETC Model (as discussed further below).

### 1.2.3. What Were the Impacts of the ETC Model?

We used quantitative data to examine 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 first assessed whether the model's design to encourage home dialysis, transplant waitlisting, and transplantation affected the use of these renal replacement therapies. Given the model's incentives, changes in the use of these renal replacement therapies are of interest as potential outcomes that are most directly affected by the model. Increased use of home dialysis and/or transplantation are also the primary mechanisms by which any impacts on other outcomes of interest such as QoC, QoL, patient experience of care, and cost of care would be expected. For AR2, we examined potential impacts of the model separately in each of the first two years of the model and also examined whether there are cumulative impacts observed during the combined 2021-2022 period.

In evaluating a range of outcomes which are discussed further below, the results of quantitative analyses are integrated with the qualitative findings from interviews with ESRD facility staff and Managing Clinicians. These interviews yielded insights about the perspectives of model participants and about their responses to the model that were used to help interpret the estimated model impacts based on the quantitative data.

**Dialysis modality.** Home dialysis is a major focus of the model design as well as the evaluation, as the level of home dialysis use among attributed beneficiaries determines the HDPA and also constitutes 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 may serve as a potential indicator of future home dialysis use as well as the future performance of participants. As such, we examined whether the model is associated with a change in how frequently beneficiaries with ESRD undergo training for home dialysis.

It is also possible that any early effects of the model on home dialysis use will be more likely to occur among certain subgroups of beneficiaries. We explored this possibility by examining impacts among beneficiary subgroups defined based on duration of ESRD, beneficiary age, and whether the beneficiary was treated at an ESRD facility with an established home dialysis program.

**Waitlisting and transplantation.** The other major aspect of performance measurement under the ETC Model, kidney transplantation, has two dimensions: waitlisting for a deceased donor transplant, and living donor transplantation.[9] Starting in CY 2021, the performance of participating

[9] 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

ESRD facilities and Managing Clinicians along these dimensions would determine their future PPAs, with the initial payment adjustments being applied in July 2022. We therefore examined whether there is evidence of changes in transplant-related events in the first two years 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. A change in waitlisting of patients in active status may be more likely to have implications for quality of care and patient outcomes. Therefore, in addition to examining whether the ETC Model is associated with changes in overall waitlisting rates, we also separately examined rates of active and inactive waitlisting for a transplant.

**Utilization and Medicare payments.** Changes in the use of home dialysis or transplantation could have important implications for service utilization more broadly as well as overall Medicare payments for beneficiaries with FFS coverage. Patterns in utilization and Medicare payments may differ with the use of home dialysis and transplantation compared to in-center HD or in the event they are affected by any changes in QoC (as discussed further below). We therefore examined changes in major types of utilization that may also be important indicators of both quality and efficiency, including overall acute care hospitalizations, outpatient emergency department (ED) visits, and hospital readmissions. In addition to examining overall Medicare Parts A & B payments among FFS beneficiaries with ESRD, we also examined major components of Part A & B payments as potential drivers of any changes in overall payments as well as Part D payments for beneficiaries enrolled in a stand-alone Part D plan.

**Quality of care.** Changing patterns in home dialysis and transplantation could have important implications for QoC. There is potential for the effects of the model to be either positive or negative with respect to specific aspects of quality. For example, there is potential for the ETC Model to enhance quality of care by encouraging greater consideration of home dialysis modalities and transplantation which may have benefits for some patients, and by establishing incentives to reduce the frequency of treatment complications that might limit the long-term use of home dialysis modalities. Alternatively, a potential unintended consequence of the model is that it could encourage inappropriate use of home dialysis modalities in ways that result in more frequent treatment complications and increased mortality.

This report examines several indicators of QoC that capture both important patient outcomes and potential complications of ESRD treatment. Mortality is examined as an important outcome for assessment of model impacts, given the high mortality risk for patients with ESRD undergoing dialysis. Other QoC indicators include measures of dialysis-related infections and other potential treatment complications. These measures include peritonitis infections in PD patients, vascular infections in HD patients, hospitalizations with vascular access complications, and hospitalizations with ESRD complications.

beneficiaries undergoing dialysis for ESRD, performance under the PPA is calculated based on living donor transplants only.

**Patient experience of care.** There is 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 there are no data on home dialysis patient experience of care already being collected through existing surveys regularly fielded by CMS to Medicare beneficiaries, we will be fielding a patient experience of care survey in 2024 for patients using a home dialysis modality so that these data can be analyzed for future reports. There is also potential, however, for the model to have either positive or negative implications for the experience of patients undergoing in-center HD, which continues to be the predominant renal replacement therapy. For example, if the model encourages 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 account for these possibilities, we continue to examine measures of in-center HD patient experience using data routinely collected using the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) survey.

### *1.2.4. Did the ETC Model Have Implications for Health Equity?*

AR2 also includes an initial assessment of whether the ETC Model has implications for health equity among beneficiaries with ESRD. Potential impacts on health equity are especially pertinent starting in CY 2022, when ETC Model refinements promoting greater health equity first went into effect. The ETC health equity provisions include both the adoption of stratified achievement benchmarks for home dialysis and transplant rates based on dual eligible/Part D LIS status and the introduction of the Health Equity Incentive to reward ETC Participants for higher levels of improvement for underserved beneficiaries. Even in the context of these model refinements promoting health equity, it is also important to consider the risk that any preexisting disparities could persist or even widen over time under the model due to ongoing barriers in access to home dialysis and transplantation that may be pronounced for underserved populations. As such, there is a need to understand both the potential benefits and the potential risks of the ETC Model with regard to health equity.

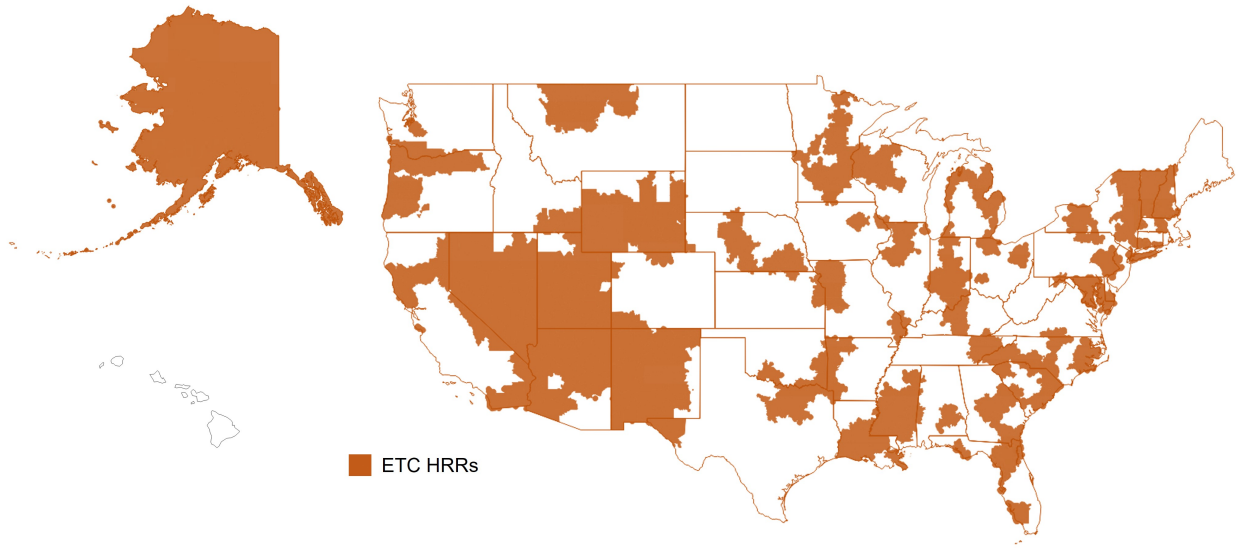
With this motivation, we examined whether the impacts of the ETC Model during CY 2021 and CY 2022 differed for historically underserved populations. This included the populations targeted by the model's incentives (dually eligible beneficiaries, beneficiaries enrolled in Part D plans who are recipients of the Part D LIS), and racial and ethnic minority groups. We both estimated impacts for these beneficiary subgroups and assessed whether they differed from those observed for corresponding reference populations. In addition to assessing the relative impacts of the model on the use of home dialysis, waitlisting, and transplantation, other selected indicators of utilization and quality of care were also considered.

## 2. Who Participates in the ETC Model?

The selection process for the ETC Model resulted in the inclusion of 95 HRRs in the ETC 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 ETC areas are geographically distributed throughout the U.S. (see **Exhibit 3**). The ETC areas include 40 states, and the Comparison Geographic Areas include 43 states. Seven states fall entirely in the ETC areas, 10 states fall entirely in the comparison areas, and 33 states are split. All Medicare certified ESRD facilities and Managing Clinicians in the ETC areas are required to participate in the ETC Model.

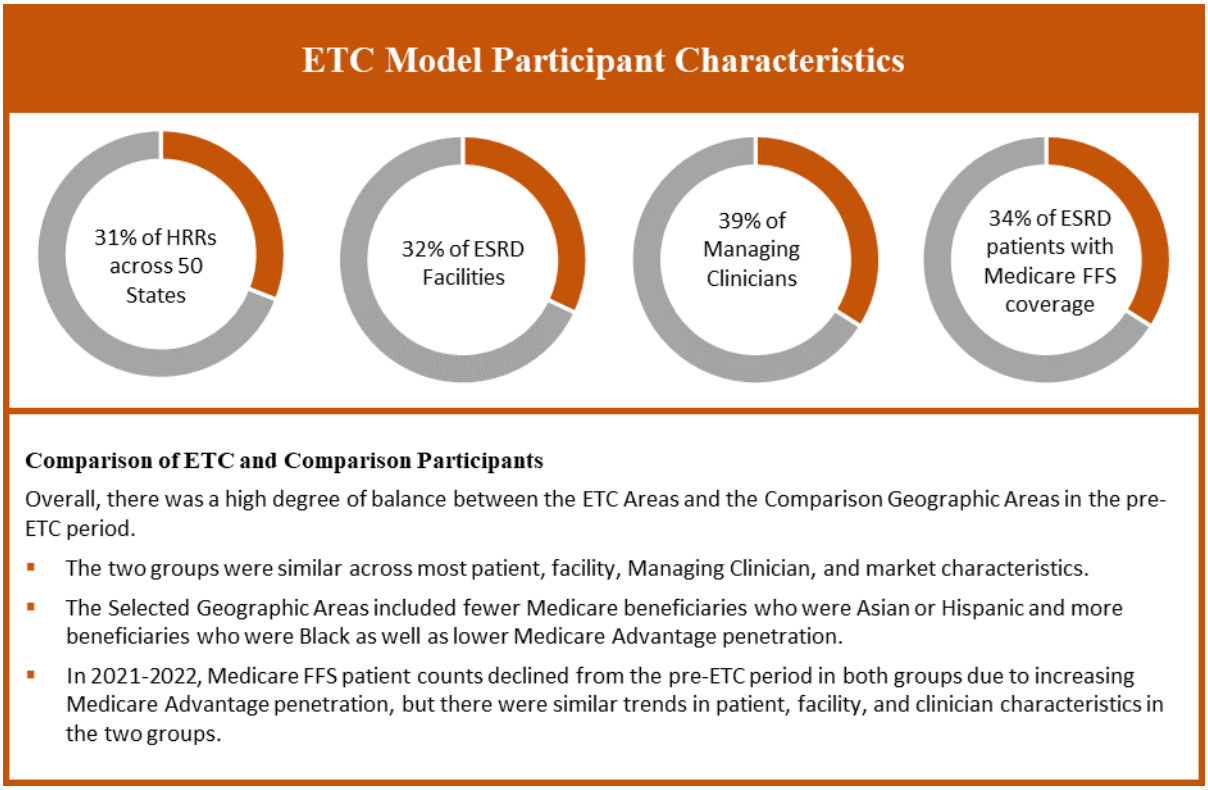
In this section, we describe the characteristics of patients, ESRD facilities, Managing Clinicians, and HRRs in the ETC Model. By examining and evaluating the balance of these multiple characteristics in the Selected and Comparison Geographic Areas we provide context for the development of the comparison group. We also present the characteristics of the patients, facilities, and Managing Clinicians during the initial two-year period of the model (2021-2022) for both the Selected and Comparison Geographic Areas.

**Exhibit 3. Map of ETC HRRs**



## 2.1. Key Findings

**Exhibit 4. Characteristics of ETC Model Participants, 2021 – 2022**




**Notes:** ETC Model participant characteristics were calculated based on 2021-2022 data.

## 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 2017-2022. All months where the patient had either a chronic dialysis claim at an outpatient ESRD facility, an 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 2017-2022 Medicare claims, transplant, and waitlisting outcomes from 2017-2022 Scientific Registry of Transplant Recipients (SRTR) files[10], facility-level characteristics from the 2017-2022 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.

[10] 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.

We considered 2017-2019 as the pre-ETC period and excluded 2020 from the study (see **Appendix B, Section B.3**).

We examined patient-, ESRD facility-, Managing Clinician-, and market-level characteristics of the 95 ETC HRRs compared with the 211 comparison HRRs. We assessed balance at three levels: HRR-, facility-, and patient-month level. As a measure of assessing balance, we computed standardized mean differences (SMD) and compared the absolute value against a threshold of 0.2 to identify any imbalance between the two groups (see **Appendix B, Exhibits B-11-B-14**). Furthermore, we examined trends and balance on the same factors in the post-ETC period between the two groups to assess changes in case-mix or any other patient- and facility-level attributes between the two groups. This was done to inform whether the increasing enrollment of patients with ESRD in Medicare Advantage (MA) plans may have led to differences between the two groups in the underlying FFS cohort.

## 2.3. Results

### *2.3.1. Characteristics of ETC Participants*

**ESRD facilities.** Outpatient ESRD facilities located in the ETC areas are designated as ETC Participants. Facilities located in the Comparison Geographic Areas comprise the comparison group (hereafter referred to as comparison areas). In **Exhibit 5** 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 share 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. There was balance (SMD < 0.2) in the percentage of facilities distributed across these four regions between the two groups (see **Appendix B, Exhibit B-12**). Of note for the ETC Model, ESRD facilities in both groups that provided PD and home HD ranged between 50 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 for facility characteristics is included in **Appendix B, Exhibit B-12**.

In the post-ETC period (2021-2022), the total number of facilities increased slightly in both groups from the pre-ETC period. There was a noticeable shift in facility patient volume based on the number of Medicare FFS patients in the post-ETC period compared to pre-ETC period. The proportion of facilities with fewer than 75 annual Medicare FFS patients increased from 58 to 76 percent in the ETC group and from 61 to 79 percent in the comparison group. With the number of facilities increasing over time, total patients receiving care per facility declined marginally in both groups. In general, facilities exhibited similar trends in both the ETC and comparison groups with a slight decline in total patients receiving care in both groups. However, the total number of home dialysis patients that include Medicare FFS, MA, and other insured patients, increased in

both groups between the pre-ETC and post-ETC periods. Consequently, the average number of in-center dialysis patients decreased in both groups.

**Exhibit 5. ESRD Facility Characteristics by ETC Participant Status for 2017 – 2019 (Pre-ETC) and 2021 – 2022 (Post-ETC) Periods**

| Variable | ETC Mean | | Comparison Mean | |
|---|---|---|---|---|
| | Pre-ETC | Post-ETC | Pre-ETC | Post-ETC |
| | N = 2,512 | N = 2,564 | N = 5,227 | N = 5,330 |
| **Number of HD Stations** | 17.4 | 17.3 | 17.5 | 17.5 |
| **Facility Ownership** | | | | |
| DaVita | 37.2% | 36.8% | 39.3% | 39.5% |
| Fresenius | 39.0% | 38.7% | 34.9% | 34.7% |
| Independent/Non-Chain For-Profit | 3.5% | 4.1% | 5.1% | 5.5% |
| Other For-Profit | 10.6% | 11.4% | 8.5% | 9.0% |
| Non-Profit | 9.8% | 9.0% | 12.2% | 11.3% |
| **Facility Patient Volume (Medicare FFS Patients) *** | | | | |
| <=50 | 36.7% | 49.8% | 39.3% | 52.4% |
| >50 and <=75 | 21.2% | 25.7% | 21.8% | 26.7% |
| >75 and <=100 | 18.0% | 13.6% | 17.1% | 12.2% |
| >100 | 24.0% | 10.9% | 21.8% | 8.7% |
| **In-Center HD Service Provided** | 94.8% | 94.3% | 92.9% | 93.2% |
| **Peritoneal Dialysis Service Provided** | 50.1% | 49.8% | 54.0% | 53.7% |
| **Home HD Training Service Provided** | 28.7% | 28.5% | 30.3% | 30.1% |
| **Facility Has Shift after 5:00 p.m.** | 16.2% | 15.4% | 16.6% | 15.9% |
| **Total In-Center Dialysis Patients** | 57.4 | 54.0 | 59.0 | 55.2 |
| **Total Home Dialysis Patients** | 7.6 | 9.7 | 8.1 | 10.0 |
| **Total Patients Receiving any Dialysis Care[1]** | 65.0 | 63.7 | 67.1 | 65.2 |
| **Facility Region** | | | | |
| Northeast | 14.6% | 15.0% | 13.3% | 13.6% |
| Midwest | 20.3% | 19.6% | 21.2% | 20.5% |
| South | 47.3% | 47.5% | 45.2% | 44.9% |
| West | 17.8% | 17.9% | 20.3% | 21.0% |
| **Facility RUCC** | | | | |
| Metro | 83.0% | 83.2% | 83.4% | 84.3% |
| Urban | 16.3% | 16.1% | 15.9% | 15.1% |
| Rural | 0.64% | 0.70% | 0.69% | 0.66% |

**Notes:** Pre-ETC period= 2017-2019. Post-ETC period =2021-2022. RUCC= Rural-Urban Continuum Code. *Facility volume is based on number of unique Medicare FFS patients treated in a year. Facility attributes were averaged, with equal weight given to all facilities in each group. [1]Obtained from the CMS 2744 form, this corresponds to the total number of patients receiving any dialysis in any setting at the end of the survey period.

**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 in ETC areas. The ETC areas include 39 percent of Medicare Managing Clinicians. Displayed in **Exhibit 6** are select average characteristics of Managing Clinicians during the pre-ETC and post-ETC periods. In terms of clinical specialty, there was overall balance between ETC and comparison clinicians for both periods. The predominant clinician specialty was nephrology. Nurse Practitioners and Physician Assistants accounted for approximately 15 percent of claims for

the MCP. Nurse Practitioners and Physician Assistants who submit dialysis MCP claims are often employed by nephrology practices. On average, ETC clinicians treated fewer Hispanic patients than comparison clinicians, and the SMD is just above the threshold of the balance criteria for both periods (absolute value slightly > 0.2), (see **Appendix B, Exhibit B-13**). Similar differences for Hispanic patients were seen at the HRR and patient levels (see **Exhibits 7** and **8**). Even though the average number of patients treated per month decreased, the percentage of patients using PD and home dialysis slightly increased in the post-ETC period compared to pre-ETC period. This pattern was evident in both groups.

**Exhibit 6. Managing Clinician Characteristics by ETC Participant Status for 2017 – 2019 (Pre-ETC) and 2021 – 2022 (Post-ETC) Periods**

| Characteristic | ETC | | Comparison | |
|---|---|---|---|---|
| | Pre-ETC | Post-ETC | Pre-ETC | Post-ETC |
| | N = 6,650 | N = 5,656 | N = 9,539 | N = 8,796 |
| | Mean | Mean | Mean | Mean |
| **Demographics** | | | | |
| Mean Age | 48.7 | 49.3 | 49.7 | 50.4 |
| Male | 64.7% | 60.6% | 65.8% | 62.3% |
| **Specialty** | | | | |
| Nephrology | 75.3% | 72.1% | 74.3% | 71.2% |
| Nurse Practitioner | 11.9% | 14.2% | 10.6% | 12.7% |
| Internal Medicine | 8.0% | 7.2% | 9.3% | 8.7% |
| Physician Assistant | 2.1% | 2.3% | 2.2% | 2.4% |
| Certified Clinical Nurse Specialist | 0.11% | 0.04% | 0.23% | 0.20% |
| Other | 2.5% | 4.2% | 3.3% | 4.9% |
| **Average Patient Volume and Characteristics** | | | | |
| Number of Dialysis Patients per Month | 28.6 | 20.3 | 28.3 | 19.9 |
| Average Age | 61.4 | 62.28 | 61.8 | 63.2 |
| Male | 56.8% | 57.3% | 57.1% | 57.8% |
| White | 44.6% | 46.8% | 43.6% | 45.6% |
| Black/African American | 37.2% | 34.5% | 32.7% | 30.5% |
| Asian | 3.8% | 4.2% | 5.1% | 5.5% |
| American Indian/Alaska Native | 1.8% | 1.8% | 0.89% | 0.9% |
| Hispanic | 11.2% | 11.2% | 16.3% | 15.8% |
| Dually Eligible for Medicare and Medicaid | 47.2% | 45.5% | 48.3% | 47.0% |
| **Average Number of Patients Treated per Month by Dialysis Modality** | | | | |
| In-Center HD | 25.4 | 17.4 | 25.0 | 17.0 |
| Peritoneal Dialysis | 2.6 | 2.3 | 2.8 | 2.4 |
| Home HD | 0.54 | 0.59 | 0.51 | 0.52 |
| Other | 0.01 | 0.01 | 0.01 | 0.01 |

| Characteristic | ETC | | Comparison | |
|---|---|---|---|---|
| | Pre-ETC | Post-ETC | Pre-ETC | Post-ETC |
| | N = 6,650 | N = 5,656 | N = 9,539 | N = 8,796 |
| | Mean | Mean | Mean | Mean |
| **Percent of Patients Treated per Month by Dialysis Modality** | | | | |
| In-Center HD | 88.5% | 86.0% | 87.2% | 84.7% |
| Peritoneal Dialysis | 9.6% | 11.1% | 10.8% | 12.4% |
| Home HD | 1.9% | 2.8% | 2.0% | 2.8% |
| Other | 0.05% | 0.07% | 0.06% | 0.08% |

**Notes**: Results displayed are based on yearly averages and cover years 2017-2019 for the Pre-ETC period and years 2021-2022 for the Post-ETC period.

### 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 7**). Comparing SMD against the 0.2 threshold value, the ETC areas had 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 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-14**.

**Exhibit 7. Market (HRR)-Level Characteristics by ETC Status, 2017 – 2019 (Pre-ETC)**

| Characteristic | | ETC Mean | Comparison Mean |
|---|---|---|---|
| | | N=95 | N=211 |
| **Demographic Characteristics** | Median Age, 2010 | 38.8 | 38.4 |
| | Asian | 2.7% | 3.6% |
| | Non-Hispanic Black | 12.3% | 9.1% |
| | Hispanic | 10.1% | 14.1% |
| | Native Hawaiian/Pacific Islander | 0.17% | 0.21% |
| | Non-Hispanic White | 70.2% | 68.8% |
| | American Indian/Alaskan Native | 2.1% | 1.6% |
| | Persons above Age 25 without a High School Diploma | 8.9% | 9.3% |
| | MA Penetration | 31.1 | 33.7 |
| | Poverty | 13.3% | 13.0% |
| **Market Level Capacity (Number per 100,000 Population)** | Short-Term General Hospitals | 3.3 | 3.7 |
| | LTCH | 0.3 | 0.2 |
| | Short-Term General Hospitals with HD | 1.3 | 1.4 |
| | Non-Federal Transplant (that is, Transplant Surgeons) | 0.3 | 0.4 |
| | Non-Federal PCP, Patient Care | 288.9 | 331.9 |
| | Non-Federal PCP, Hospital Resident | 41.5 | 45.0 |

| Characteristic | | ETC Mean | Comparison Mean |
|---|---|---|---|
| | | N=95 | N=211 |
| Market Characteristics | ADI[1] | 60.6 | 59.9 |
| | ACO Beneficiaries (%) | 31.0% | 28.9% |
| | Comprehensive ESRD Care (CEC) Beneficiaries (%) | 0.14% | 0.09% |
| | Kidney Care Choice (KCC) Beneficiaries* (%) | 0.37% | 0.30% |

**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. *Only for 2022.

### 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 and do not meet a set of defined exclusion criteria. 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 (for example, due to events such as transplantation and death), and emergence of ineligibility criteria (for instance, nursing home placement, dementia diagnosis, hospice placement). Thus, the unit of analysis for most analyses for the ETC Model evaluation is the patient month (see **Appendix B,** Section B.2).[11] **Exhibit 8** displays select characteristics for 171,205 ETC patients and 336,281 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.

There were declines over time in the number of FFS patients and patient months that likely reflect increasing enrollment of patients with ESRD in MA plans. Effective January 1, 2021, Medicare beneficiaries with ESRD were no longer restricted from enrolling in MA plans as a result of the 21st Century Cures Act. There was a decline in the number of patient months from 3,085,142 in 2017 to 2,116,988 in 2022. This translated to a 26% decline in ETC FFS patients from 115,971 in 2017 to 86,139 in 2022 and a 27% decline in comparison FFS patients from 229,962 in 2017 to 167,176 in 2022.

Overall, in the pre-ETC period, 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. The 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 8**). We observed a slight imbalance for alignment with the CEC Model (20 percent of

[11] The exceptions involve analyses of mortality which employ patient-level time to event models and analyses of in-center hemodialysis patient experience of care which are based on facility-level data from the ICH-CAHPS survey. These analyses are described further in Section 4.

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-11**).

In the 2021-2022 period, we observed comparable changes in both groups relative to the pre-ETC period. These changes included a decrease in the percentage of Black patients and those eligible for both Medicaid and Medicare (dually eligible) and recipients of the Part D LIS. There was also an increase in the percentage of beneficiaries receiving nephrology care prior to ESRD, particularly those under care between 6 to 12 months, for both groups. In the ETC group, a larger percentage of patient months were found to be aligned with a clinician participating in the KCC Model compared to the comparison group. This pattern was similar during the pre-ETC period where the ETC group had a larger percentage of patient months aligned with clinicians who later volunteered to participate in the KCC Model in 2022 than the comparison group.

**Exhibit 8. Patient Characteristics by ETC Status, for 2017 – 2019 (Pre-ETC) and 2021 – 2022 (Post-ETC) Periods**

| Characteristic | | ETC Mean | | Comparison Mean | |
|---|---|---|---|---|---|
| | | Pre-ETC | Post-ETC | Pre-ETC | Post-ETC |
| | | N = 3,116,658 | N = 1,550,586 | N = 6,165,640 | N = 3,034,722 |
| Patient Characteristics | Mean Age | 61.7 | 63.1 | 62.0 | 63.3 |
| | Median Age | 63.0 | 65.0 | 63.0 | 65.0 |
| | Female | 43.2% | 42.5% | 42.9% | 42.1% |
| | Race/Ethnicity[1] | | | | |
| | Hispanic | 11.1% | 11.0% | 17.5% | 17.4% |
| | Non-Hispanic Black or African American | 39.2% | 34.6% | 33.8% | 29.2% |
| | Non-Hispanic White | 42.6% | 46.1% | 41.4% | 44.7% |
| | Non-Hispanic Asian | 3.2% | 3.9% | 4.7% | 5.8% |
| | Non-Hispanic Native Hawaiian/ Pacific Islander | 0.94% | 1.0% | 1.2% | 1.3% |
| | Non-Hispanic American Indian/ Alaska Native | 2.6% | 2.9% | 1.0% | 1.1% |
| | Non-Hispanic Other | 0.35% | 0.50% | 0.41% | 0.53% |
| | Time from Start of ESRD (Years) | 5.2 | 5.4 | 5.2 | 5.4 |
| | Dually Eligible for Medicare and Medicaid (Full or Partial Benefits) | 47.2% | 45.3% | 48.6% | 47.4% |
| | Part D Benefit Enrollment | 81.6% | 78.8% | 81.9% | 79.5% |
| | Part D LIS (among Part D Enrollees) | 67.8% | 62.4% | 69.2% | 63.9% |
| | Medicare Shared Savings Program | 22.3% | 21.0% | 22.3% | 25.0% |
| | Alternative Payment Models (APMs) | | | | |
| | CEC | 20.3% | 3.4% | 12.4% | 1.6% |
| | KCC* | 30.5% | 31.6% | 22.0% | 23.2% |
| | NGACO | 2.9% | 1.2% | 3.5% | 1.1% |

| Characteristic | | ETC Mean | | Comparison Mean | |
|---|---|---|---|---|---|
| | | Pre-ETC | Post-ETC | Pre-ETC | Post-ETC |
| | | N = 3,116,658 | N = 1,550,586 | N = 6,165,640 | N = 3,034,722 |
| Health Conditions at Start of Dialysis (Data Source: EQRS 2728 form) | **Primary Cause of ESRD** | | | | |
| | Diabetes | 42.9% | 41.8% | 44.6% | 43.2% |
| | Glomerulonephritis | 11.5% | 11.2% | 11.0% | 10.4% |
| | Hypertension | 31.4% | 30.9% | 30.1% | 29.8% |
| | Other | 14.1% | 16.1% | 14.3% | 16.5% |
| | **Health Status at Start of ESRD** | | | | |
| | Diabetes | 51.3% | 52.3% | 52.4% | 53.5% |
| | Congestive Heart Failure | 21.5% | 20.7% | 21.7% | 20.8% |
| | Atherosclerotic Heart Disease | 10.2% | 9.2% | 9.9% | 9.1% |
| | **Nephrologist Care Prior to ESRD Therapy** | | | | |
| | Less than 6 Months | 19.1% | 19.4% | 18.3% | 18.8% |
| | 6 - <12 Months | 29.2% | 32.1% | 28.3% | 31.0% |
| | 12 Months or Longer | 18.5% | 17.2% | 19.6% | 17.8% |
| | Not under Care of Nephrologist Prior to ESRD | 20.8% | 17.4% | 21.3% | 18.2% |
| | Unknown | 12.4% | 14.0% | 12.5% | 14.1% |

**Note:** Pre-ETC = 2017-2019 Post-ETC period =2021-2022. NGACO = Next Generation ACO2. A patient may contribute up to 12 observation per year to this patient-month summary. [1]Race and ethnicity are mutually exclusive categories based primarily on patient-reported race and ethnicity from the CMS ESRD Medical Evidence Form. *In the pre-ETC period, this shows the percent of patient months aligned with a clinician who eventually volunteered for the KCC Model that was implemented in 2022.

## 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 health care demonstration models and help assure that the study will yield findings that are representative and scalable. In fact, the selection process yielded a geographically broad and diverse selected sample (see **Exhibit 5**). Overall, ETC and comparison areas were reasonably balanced. Of the 168 characteristics assessed at the market, facility, managing clinician and patient level, only seven had a SMD greater than 0.2.

The market characteristics of the ETC areas were generally comparable to the comparison areas. There was imbalance in Asian, Black, and Hispanic populations at the market level as judged by the SMD (see **Exhibit 7**). However, these factors were better balanced at the Managing Clinician and patient month-levels, probably due to larger sampling units (see **Exhibit 6** and **Exhibit 8**). The ETC areas had a lower level of MA penetration among the general Medicare population (see **Exhibit 7**). The ETC Model excludes patients enrolled in MA plans and focuses on enrollees in the traditional Medicare FFS program.

ESRD facilities and Managing Clinicians showed balance between the ETC and comparison groups across all measured characteristics (see **Exhibit 5** and **Exhibit 6**). Similarly, nearly all patient characteristics summarized at the patient-month level were balanced (see **Exhibit 8**). 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.

Although the overall level of balance between the ETC and comparison groups was high, the model evaluation will adjust for multiple market, facility, Managing Clinician, and patient characteristics including, but not restricted to, those that are not completely balanced.

There was a decline between the pre-ETC and post-ETC periods in the number of eligible FFS patients and FFS patient months in both the ETC and comparison groups. It is likely that this decline reflects an increase in enrollment of patients with ESRD in MA plans. Although we also observe certain shifts in patient case-mix between the pre-ETC and post-ETC periods, such as a decrease in the percent of Black, dually eligible, and Part D LIS patients and an increase in average age, they occurred similarly in both groups (SMD < 0.2; see **Appendix B, Exhibit B-11**). As a result, there was still overall balance in demographic and clinical characteristics between the two groups in the post-ETC period (see **Appendix B, Exhibits B-11 – B-13**). However, these observations raise the possibility that the case-mix of the ETC sample could continue to shift over time if patients who opt for MA during the ETC intervention period differ from those with traditional Medicare coverage. Therefore, it will be important to continue to assess balance in patient characteristics and monitor MA enrollment trends for each year of the ETC Model.

## 3. How Do Participating ESRD Facilities and Managing Clinicians Implement the ETC Model?

This section summarizes the findings of semi-structured interviews that The Lewin Team conducted between March and July of 2023 with a sample of ESRD facilities and a sample of Managing Clinicians located in ETC areas. We inquired about changes that participating facilities and Managing Clinicians made in response to the ETC Model, strategies they employed, perceived barriers to home dialysis and transplantation, and other topics related to model implementation.

In some cases, providers commented upon topics that may be examined from the patient perspective as well. We note that providers' perceptions do not replace the voice of patients. Where relevant, we have included input from patients via the Patient Advisory Group (PAG), which the Lewin Team convened in October 2022 to provide patient perspectives on the ETC and KCC Models. Future reports will include direct patient experience based on forthcoming interviews and surveys focusing on patient quality of life and barriers to home dialysis and transplantation.

## 3.1. Key Findings

**Exhibit 9. Participant Implementation Strategies to Increase Home Dialysis and Transplantation**


## 3.2. Methods

Between March and July of 2023, we conducted 33 semi-structured telephone and video interviews with ESRD facility personnel (n=20) and Managing Clinicians (n=13). The interviews focused on the following research topics related to model implementation: 1) who is participating in the ETC Model; 2) how they are implementing the ETC Model; 3) the extent to which participants have adequate resources to encourage and educate patients; 4) responses to the model, including ways in which care provision may have changed; 5) the impact of the ETC Model on reducing disparities in ESRD outcomes; 6) how concurrent and past participation in other CMS models impacts ETC implementation; and 7) perceived unintended consequences. These data complement our quantitative data collection efforts on related topics.

Both samples were diversified to ensure that a range of views were represented. The facility sample was selected to include diversity in census-defined geographic region, type of dialysis offered (in-center HD only and both home and in-center), percent of dual beneficiaries served, ETC Model performance, and facilities with and without affiliation to a large dialysis organization (LDO). The Managing Clinician sample was selected to include diversity in geographic region and model performance. Please see **Appendices F** and **G** for further detail on methods, sample selection, and sample characteristics.

## 3.3. Results

Overall, the interviews conducted with ESRD facility staff and Managing Clinicians suggest that ETC Model implementation primarily represents a continuation of prior efforts to increase home dialysis and transplantation; for some, due to prior participation in CEC or concurrent participation in KCC. The majority of participants reported that they had not observed negative unintended consequences of the model, including no reports of inappropriate use of modality to avoid incurring model penalties. This section includes descriptions of model implementation strategies and participant strategies to address barriers to model implementation.

### *3.3.1. Model Implementation Strategies*

ESRD facilities described a number of changes during the model period to increase home dialysis and transplant. Some of these were directly attributed to the model, while some participants did not know the motivation for changes because they were initiated at the corporate level. This likely reflects the fact that ESRD facility staff do not typically have access to information about the rationale for system-level practice changes. Managing Clinicians, by contrast, are more likely than ESRD facility personnel to have access to such information. Managing Clinicians attributed some changes in transplant processes to the ETC Model but did not directly attribute strategies for patient engagement to the model. While participants agreed with model goals, they were typically motivated by improving patient care as opposed to by the model's financial incentives. Here we focus on changes that took place during the ETC Model period that are consistent with model goals, and either were, or might have been, in response to the model.

#### *3.3.1.1. Enhanced Existing Staff Efforts*

Interview participants from most facilities reported that they did not hire new staff in response to the ETC Model. More commonly, facilities enhanced existing staff efforts to increase home dialysis and transplant. Many facilities in the sample had champions for home dialysis to educate patients and help them overcome barriers. Many staff at ESRD facilities reported having regional educators who spoke with patients about modality options. All but one of these facilities were affiliated with LDOs. Most ESRD facilities do not use the ETC Model reports from CMS to inform care they provide under the model, though several participants from LDO facilities said that they are used at the corporate level.

One participant from a dialysis facility emphasized the value of having staff dedicated to educating patients about the option of receiving a kidney transplant and facilitating the referral. Their LDO made the decision to place transplant responsibilities under the exclusive purview of the social worker instead of the clinic manager and nurses. This was described as effective because the social worker can focus on transplant whereas other staff had competing priorities. The participant thought this staffing model change was likely in response to the model.

#### 3.3.1.2. Enhanced Patient Education About Modality Options

Multiple facilities affiliated with the same LDO mentioned that they now have a virtual transitional care program comprised of a series of online classes. A facility administrator said that this program is part of the response to the ETC Model. A reported advantage of this virtual program is that it is supported by a well-trained regional team that can focus on patient education about modality whereas in-center staff have multiple roles and priorities. One LDO facility added a section on home dialysis modalities to its quarterly patient education during the model period. Another LDO facility's corporate office started a new practice called "modality charting" whereby each month nurses must document that patients are aware of their options.

> *"…for any patients that are new to dialysis that come to us, we register them, and it is an online class. So we provide an iPad for them. And then they have modality educators that are teaching them kind of in a virtual classroom setting. It's usually about two weeks, six sessions, one every single day that they come for the first two weeks, which then kind of gives them an introduction to dialysis, and then tells them about the different modality choices that they have, so that they can make a more educated decision. And then once that is done, there is home nurses that, ideally, will go in and check to make sure that they don't have any more questions, and then to make a determination of what modality is going to be best for them."*
>
> – Facility Administrator

Most participants from ESRD facilities felt that they had the resources needed to encourage and educate patients, especially those affiliated with an LDO. One participant noticed that in the last two years there has been a big push from her LDO to move people to home dialysis. Her facility has received many communication materials (for example, posters, flyers, buttons) to give to patients that encourage this modality.

> *"[Our LDO] has a whole gamut of—so this is a global company. They're huge. They have a whole gamut of written and audiovisual-type materials. They have a patient website. So I mean, there's a lot. There's a lot available to the patient… I feel [our LDO] has a ton of materials. And we are better equipped now, I think, than we were before as a city-owned entity."*
>
> – Head Nurse

A social worker from a non-LDO said there is a high incidence of patients who "crash into dialysis" in her area due to poor access to care. Such patients have had an urgent, unplanned start to dialysis and have had little to no care from a nephrologist prior to starting dialysis.[12] This participant went on to describe the positive impact of having a designated educator at the facility who has increasingly worked with nephrologists during the ETC Model period to educate patients who know in advance that their kidneys are failing. According to the interview participant, they now see more nephrologists refer patients to home dialysis as an initial modality instead of starting them on in-center dialysis with the intention to transfer them to home dialysis later.

The responses from ESRD facility staff and Managing Clinicians suggested they deliver comprehensive patient education about home dialysis and transplantation, in contrast with the

[12] Molnar, A.O., Hiremath, S., Brown, P.A. et al. Risk factors for unplanned and crash dialysis starts: a protocol for a systematic review and meta-analysis. Syst Rev 5, 117 (2016). https://doi.org/10.1186/s13643-016-0297-2

findings from the PAG. The PAG indicated that patients do not receive sufficient education about alternatives to in-center dialysis, both in terms of timeliness of learning about treatment options and quality of education.

#### 3.3.1.3. Continued Focus on Home Dialysis

About half of the ESRD facilities in the interview sample conducted staff trainings to inform staff about the ETC Model. One participant said that the model has "heightened awareness" among staff about home dialysis as a treatment option. Other facilities held trainings on increasing home dialysis and transplantation that were not specifically tied to the ETC Model. In addition to requiring that model information be posted at the facility per ETC Model regulations, several LDO facilities distributed of information about the ETC Model during staff meetings and introduced new topics (for instance, urgent-start PD, or urgent initiation of PD in incident dialysis patients) to regional education sessions held for Managing Clinicians.

One participant from an ESRD facility said that their LDO developed new EHR technology to support home dialysis. It now has a platform that enables home dialysis patients to look at their labs, medication list, order PD supplies, enter their vital signs, and message staff with non-urgent requests. This innovation came from company leadership and while the participant thought that the LDO had probably thought about implementing this platform before the model began, they think that the model made it a priority. Another facility participant said that their LDO has increased internal corporate goals around home dialysis during the ETC Model period.

Most ESRD facilities in our interview sample that offered home dialysis (n=10) did not make capacity changes during the model period, though there were a few facilities in the sample that added to their capacity. A non-LDO facility started a PD program in response to the ETC Model. They modified their existing HHD training room to accommodate PD training. Another LDO facility planned to modify its training space in response to staffing shortages by replacing an internal wall with a moveable divider to create a space where a single nurse could efficiently offer training to a group of patients on home dialysis.

#### 3.3.1.4. Improved Transplant Referral Process

Almost half of ESRD facilities in the sample described changes to their transplant referral practices supporting the required medical evaluation work-up, which requires extensive testing and coordination of multiple appointments. These changes primarily focused on improving communication between the ESRD facility and transplant center and between the patient and transplant center. For instance, one participant described a new pilot program by their LDO to reduce communication barriers, the development of which they credited to the ETC Model. Their social workers have calls with the transplant center to go over the list of active patients so that they can circle back to them if there is a missing test or outstanding paperwork. Other facilities now have expedited processes to send information to transplant centers once patients have been referred by a physician. For example, one ESRD facility participant said that due to the ETC Model, there is a new electronic transmission process to submit records for patients who the doctor has identified are eligible for transplant. Multiple facilities also have improved processes to ensure that patients review materials sent to them by the transplant center and return evaluation paperwork.

> *"The other thing we do is fax…There's a referral form that the transplant centers mail to the patients. And sometimes, the patients say they don't get it. …[The transplant center sends] me a copy of it so I can give it to the patient in person and say, "Here, do this for the center. And when you're finished with it, give it back to me, and I'll make sure that I fax it to them so we know they get it" because that was a big lack of communication. So that's another strategy."*
>
> *– Social Worker*

Most Managing Clinicians described efforts to improve documentation and tracking in order to promote early referral for transplant. A "watch list" of patients who would likely enter ESRD in the near future was a common practice. Early identification and frequent monitoring meant patients were referred to transplant clinics for evaluation prior to starting dialysis. There was also more check-in with these patients after referrals had been made. Clinicians also emphasized the quality of data being tracked. Accurate and complete documentation in EHRs allowed staff and navigators to provide timely follow-up care and ensure patients were following up on referrals and completing initial evaluations and workups. One clinician described their previous process for referring patients to transplant clinics as verbal orders to a nurse, often while passing by in the hallway. The nurse would then provide patients with transplant applications; however this did not necessarily result in patients completing the applications. After the ETC Model began, this process changed to include a referral order in the EHR that allowed nurses to track and follow up with patients from the point of referral through a successful transplant. In contrast to the reported efforts to increase communication and timeliness for kidney transplantation, PAG findings indicated that patients experience insufficient communication with nephrologists and facilities regarding the necessary steps and process for completing transplant evaluations.

### 3.3.2. Participant Strategies to Address Barriers to Model Implementation

This section provides a summary of participant level barriers to model implementation as well as participant strategies to address these barriers. While participants did not report making changes to increase health equity nor did they have changes planned, they continued to try to meet the needs of underserved patients to the best of their ability.

Nearly all Managing Clinicians in the sample felt that many factors beyond their control limited increased adoption of home modalities and transplantation (for instance, comorbidities, lack of support system). This was particularly the case among clinicians in private practice and those serving smaller or rural populations. They emphasized concerns for the long-term financial sustainability of their practices due to the model's financial penalties. Several felt that the model's goals were unattainable for their populations and would result in penalties that would be "devastating" for small clinician practices that could be eventually forced to close.

Managing Clinicians perceived the primary barrier to model implementation at the provider level was shortages of staff trained in home dialysis. They reported that the nationwide health care workforce shortage following the pandemic has made it difficult to retain and hire nurses, especially those trained in home modalities. To scale up home dialysis utilization, nurses must have experience with home modalities. Though clinicians generally supported the practice of cross-training nurses to combat these shortages, they also noted the difficulty in training nurses while caring for full and complex patient panels.

**Incentives not motivating.** Some staff from both facilities and Managing Clinician practices were unaware of incentives. Managing Clinicians that were aware of the model incentives reported that the incentives did not typically serve as a motivating factor to achieve model goals. Instead, they were motivated by giving their patients the best care possible. Additionally, some Managing Clinicians reported ethical concerns with the connection between financial gain and patient care or well-being. One ESRD facility participant said that the incentives were more motivating at the corporate level at their LDO, however, corporate LDO staff were not part of this interview sample. Additionally, a participant from a non-LDO facility said that the number of patients attributed to the model was not sufficient to create worthwhile incentives for the facility.

> *"…we are going to make these investments regardless of the model per se or financial incentives from the model. What is challenging, however, is that the number of patients who are eligible for the model relative to our new patients is very small. So the vast majority of new patients are either on a Medicare Advantage Plan or a Managed Care Plan. And as a result of that, all of the work that we are doing… is not resulting in a payoff from the model… That's probably the biggest challenge with financial success in this model is that the pool of Medicare primary patients, it's decreasing."*
>
> – Special Project Staff

**Lack of care partner support**. Similar to findings from the PAG, facility staff and Managing Clinicians said that lack of care partner support is a common barrier to home dialysis. This is particularly problematic among older patients who may live alone, or with a partner who is physically unable to help. All clinicians recognized the need for patients to have someone available to move and set up supplies and provide emotional support. We will be conducting interviews with care partners later in the evaluation.

#### 3.3.2.1. Strategies to Address Barriers to Home Dialysis

**Addressed space constraints.** Participants from both dialysis facilities and clinician practices reported that inadequate space in the home to accommodate supplies was a frequent barrier to in-home treatment. This is a particular concern for patients residing in urban areas, in multi-generational households, and with insufficient income. A few facility staff and Managing Clinicians interviewed said they implemented home visits during which they tried to find ways to address limited space, such as by clearing out or re-organizing a room and stacking supplies in creative ways. Another reported strategy was to send smaller shipments of supplies to patients. In addition to limited space, some patients are experiencing homelessness and thus home dialysis is not an option for them. Social workers helped to connect patients with resources to find permanent housing.

#### 3.3.2.2. Strategies to Address Barriers to Transplantation

Both Managing Clinicians and ESRD facility staff identified transportation to transplant appointments as a common barrier. Social workers from facilities tried to work with patients to arrange transportation. Clinicians said that they struggled to overcome these logistical barriers and support these patients to successfully undergo transplantation.

According to interview participants, transportation barriers can be particularly problematic among low-income populations. They also noted that transportation is a particular challenge in rural locations where the transplant center may be far away. For example, one facility is located on a

Native American Indian reservation and one of the transplant centers that they work with is five to six hours away. Staff at the facility help patients with transportation or locate a place to stay for transplant appointments. One Managing Clinician reported that their practice opened a transplant clinic to see patients in rural areas of their state every two to four weeks to improve clinic access and transplantation rates.

#### *3.3.2.3. Strategies to Address Communication Barriers*

Participants reported multiple communications barriers when seeking to increase home dialysis and transplant. Low health literacy can contribute to barriers in understanding diagnoses and misconceptions about dialysis and transplantation. When facilities do not have staff to communicate in languages other than English, there can be additional barriers. Facilities reported that they try to provide materials in languages other than English and sometimes ask family members to translate. Participants also mentioned that print materials present challenges for low literacy and illiterate patients. In response, staff prioritized verbal education. For example, one participant described how they have been tailoring training to a patient with a low education level.

> "There's a gentleman we're training here…his educational level is minimal…I don't think he finished high school, definitely. And when he talks, it's very hard to understand kind of where his understanding is. But he's done well the first days of training because we've taken an approach of-- we're not giving him things to read. We're walking him through it. We're verbally teaching him. We're talking back, hands-on approach."
>
> – Social Worker

## 3.4. Discussion

Overall, the interviews conducted with ESRD facility staff and Managing Clinicians suggest that they have not substantially changed practices directly in response to the ETC Model, though many of their practices align with ETC Model goals. Often their current efforts to increase home dialysis and transplantation build upon prior efforts that were already underway before the model began. In some cases, these efforts were due to prior participation in CEC or influenced by concurrent participation in KCC. For example, participants typically reported enhancing efforts among current staff to support increased home dialysis and transplant rather than hiring new staff. These findings suggest that for most participants, the model does not represent a paradigm shift in how ESRD facilities and Managing Clinicians provide care. These findings are consistent with our quantitative results, which do not indicate an increase in home dialysis and transplant waitlisting among patients in ETC areas relative to the comparison group.

Among Managing Clinicians, the most prominent provider-level barrier was a shortage in nursing staff with the appropriate training to initiate patients on home dialysis. Because they are limited in their capacity to overcome staffing shortages, clinicians felt the best way to address these barriers was through early intervention with patients with chronic kidney disease to slow progression or prevent the need for dialysis or transplantation. Similarly, PAG participants also emphasized a greater need for early intervention in chronic kidney disease.

Participants identified barriers for home dialysis and transplant that were at the system-level, provider level and patient level. There is a need for a greater understanding of current patient

perspectives on the modality selection process and of their perceived barriers to home dialysis and transplantation. We plan to conduct interviews with patients to gain additional insights on these issues later in this evaluation.

## 4. What Were the Impacts of the ETC Model?

This section summarizes quantitative findings of the impact of the ETC Model on dialysis modality, transplant waitlisting, kidney transplantation, utilization, Medicare payments, quality of care, and in-center HD patient experience of care over the first two years of the model, 2021-2022. New in this report, we also examined five measures of QoC: peritonitis among PD patients, vascular infections among HD patients, hospitalizations with vascular complications, hospitalizations with ESRD complications, and mortality.

## 4.1. Key Findings

**Exhibit 10. Summary of Cumulative Evaluation Findings, CY 2021 – CY 2022**

| Domain | Outcome | Cumulative ETC Model Impact, 2021-2022 |
|---|---|---|
| **Dialysis Modality Measures** | Home Dialysis | |
| | Peritoneal Dialysis | |
| | Home Hemodialysis | |
| | In-Center HD^ | |
| | In-Center Hemodialysis | |
| | In-Center Self-Dialysis | |
| | Nocturnal Hemodialysis | |
| | Home Dialysis Training | ↑ |
| **Transplantation** | Overall Waitlisting | |
| | Active Status | |
| | Inactive Status | |
| | Overall Transplants | ↑ |
| | Deceased Donor | ↑ |
| | Living Donor | |
| | Living Donor (Dialysis and Pre-emptive) | |
| **Utilization** | Acute Care Hospitalization | |
| | Readmission | |
| | Outpatient ED Use | ↓ |
| **Medicare Payments** | Total Parts A & B | |
| | Total Part A | |
| | Part A Acute Care Hospitalization | |
| | Part A LTCH and IRF | |
| | Other Part A | |
| | Total Part B | |
| | Part B Dialysis | |
| | Other Part B | |
| | Part D | |
| **Quality** | Peritonitis | |
| | Vascular Infection | |
| | Hospitalizations with Vascular Access Complications | |
| | Hospitalizations with ESRD Complications | |
| | Mortality | No Impact[1] |
| **In-Center HD Patient Experience of Care** | Rating of Kidney Doctors | |
| | Rating of Dialysis Center Staff | |
| | Rating of Dialysis Center | |
| | Nephrologists' Communication and Caring | |
| | Quality of Dialysis Center Care and Operations | |
| | Providing Information to Patients | |

## 4.2. 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.[13] 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 (that is, consisting of HRRs not selected for the model). Descriptive analyses of balance showed similarity in the majority of patient-, facility-, clinician- and market-level characteristics between the 95 ETC HRRs and all 211 comparison HRRs (see **Appendix B, Exhibits B-11 – B-14).**

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 and the concurrent announcement of HRRs selected for inclusion in the model. Considering potential differential impacts of COVID-19 PHE in the ETC and comparison areas as well as the possibility of pre-emptive responses among ETC Participants once the model was finalized and the selected ETC areas were announced, we excluded 2020 from the study period and defined the pre-ETC period as January 2017-December 2019.

We produced DiD impact estimates for the first two years of the model CY 2021 and CY 2022, based on a patient-month level analytic file created using Medicare enrollment and claims data along with EQRS, facility-level, transplant registry and market data sources. We also calculated aggregate (cumulative) estimates (CY 2021-2022) as the weighted average of the yearly DiD estimates, weighted by the number of participant (ETC) intervention patient months in each year. DiD modeling was performed at the patient month level. We adjusted for patient, facility, and market level characteristics in DiD models (see **Appendix B, Exhibit B-19**) to account for potential confounders and residual imbalance that existed between the two groups despite randomization. Notably, we controlled for participation of ETC Managing Clinicians in the KCC Model (implemented in January 2022). Given the overlapping goals of the ETC and KCC Models, we controlled for participation of Managing Clinicians in the KCC Model in the DiD analyses.

Details on 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, approaches used to test the parallel trends assumption, and unadjusted means of outcome measures and impact estimates are included in **Appendix B**.

[13] We applied inclusion/exclusion criteria (from the ETC Model Final Rule and the 2022 ESRD PPS) to restrict the sample to include only eligible patients in a given month with either an attributed ESRD facility or Managing Clinician.

For 2021-2022, 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 2021-2022 but still adjusted for patient- and county-level COVID-19 indicators to account for potential confounding (see **Appendix B, Exhibit B-18**).

We assessed whether the impact of the ETC model is heterogeneous among different subgroups of interest using a difference-in-difference-in-differences (DDD) model, adjusting for the same set of patient, facility, and market level risk-adjusters as in the DiD model (see **Appendix B, Exhibit B-19**). The DDD model allowed us to estimate the impact of the ETC Model on subgroups of interest and formally test whether the impact differs from that of a reference subgroup using a common set of risk adjusters.

We evaluated mortality as time-to-event using the Cox proportional hazards model. We used an intent-to-treat approach that included all patient time at risk and deaths following initial ETC attribution and eligibility. Models were adjusted for the full range of patient, facility, and market characteristics used for the DiD analyses. Mortality risk was evaluated separately in the pre-ETC period (2017-2019) and the ETC intervention period (2021-2022 for this report). Details on mortality analyses are included in **Appendix D.**

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 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) and post-ETC (spring 2021-fall 2022 survey waves) periods. Facilities included in the ICH CAHPS analysis correspond to approximately 60 percent of facilities included in the overall analytic sample in the pre-ETC period and 28 to 54 percent in the post-ETC period (that is, CY 2021-2022; see **Appendix E-3**). Of the 4,476 ESRD facilities with ICH CAHPS data in the post-ETC period, 77 percent (3,451 facilities; 1,115 from ETC areas and 2,336 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 were 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 E, Exhibits E-5** and **E-6**). The six ICH CAHPS-based measures were adjusted for several patient-mix factors and survey mode and for a subset of the patient, facility, and market characteristics (see **Appendix E,** Section E.4). We estimated a DiD model that produced impact estimates for CY 2021, CY 2022, and cumulatively post-ETC, based on spring and fall 2021-2022 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 E.**

In AR2, we used a combination of qualitative findings regarding model implementation by ESRD facility and Managing Clinician participants with quantitative findings based on analyses of secondary data to make inferences about model impacts.

## 4.3. Results

The analytic sample included 230,793 patients in the ETC areas and 450,512 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 11**).

**Exhibit 11. 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<br>▪ Percent of patients receiving peritoneal dialysis in a given month<br>▪ Percent of patients receiving home HD in a given month<br>▪ Percent of patients receiving in-center HD (in-center hemodialysis or self-administered dialysis or nocturnal) in a given month<br>▪ Percent of patients receiving in-center hemodialysis in a given month<br>▪ Percent of patients receiving in-center self-administered dialysis in a given month<br>▪ Percent of patients receiving nocturnal HD in a given month<br>▪ Percent of patients receiving home dialysis training in a given month |
| **Transplant Waitlisting** | ▪ Percent of eligible patients on the transplant waitlist in a given month - Overall<br>▪ Percent of eligible patients on the transplant waitlist in a given month - Active status<br>▪ 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<br>▪ Percent of patients receiving a deceased donor[1] kidney transplant in a given month<br>▪ Percent of patients receiving a living donor[1] kidney transplant in a given month<br>▪ 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<br>▪ Percent of patients with a hospital readmission in a given month<br>▪ Percent of patients with at least one outpatient ED visit in a given month |
| **Standardized Medicare Payments** | ▪ Total Parts A & B payments PPPM<br>▪ Total Part A payments PPPM<br>▪ Part A acute care hospitalization payments PPPM<br>▪ Part A LTCH and Inpatient Rehabilitation Facility (IRF) payments PPPM<br>▪ Other Part A payments PPPM<br>▪ Total Part B payments PPPM<br>▪ Part B dialysis payments PPPM<br>▪ Other Part B payments PPPM<br>▪ Part D payments PPPM |

| Domain | Evaluation Measure |
|---|---|
| **QoC** | ▪ Percent of PD patients with at least one diagnosis of peritonitis in a given month<br>▪ Percent of HD patients with at least one vascular infection in a given month<br>▪ Percent of patients with at least one hospitalization with a non-infectious vascular access complication in a given month<br>▪ Percent of patients with at least one ESRD-related hospitalization in a given month<br>▪ Mortality |
| **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)<br>▪ Rating of Dialysis Center Staff: Percent of patients who gave the dialysis center staff a rating of 9 or 10 (0 to 10 scale)<br>▪ Rating of Dialysis Center: Percent of patients who gave the dialysis center a rating of 9 or 10 (0 to 10 scale)<br>▪ Nephrologists' Communication and Caring: Percent of patients who reported that kidney doctors "always" communicated well and cared for them as a person (responses: always, sometimes, rarely, never).<br>▪ Quality of Dialysis Center and Operations: 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 (responses: always, sometimes, rarely, never).<br>▪ Providing Information to Patients: 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 (responses: yes, no). |

**Notes:** All measures were analyzed at the patient month-level except for the hospital readmission measure which was analyzed at the index discharge level and the ICH CAHPS measures which were analyzed at the facility survey-wave level. Mortality rate is expressed as death per 100 patient years and analyzed as a time to event model. Transplant and waitlisting measures were restricted to patients less than 75 years old. Dialysis modality indicators except home dialysis training are mutually exclusive (primary modality in a patient-month). Home dialysis: peritoneal dialysis or home HD. In- center HD includes in-center hemodialysis, in-center self-dialysis and nocturnal.[1] Among dialysis patients.[2] Among dialysis patients and pre-dialysis pre-emptive transplant patients.[3] See **Appendix E, Exhibit E-2** for a complete description of the ICH CAHPS items included in these composite measures.

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 considering 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 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 cumulative DiD analyses is provided in **Exhibit 12**. For each impact measure, we report mean adjusted values in both the pre-ETC period (CYs 2017-2019) and in the post-ETC period (CYs 2021-2022), the cumulative DiD estimate with a 90 percent confidence interval (CI), and the estimated impact expressed relative to the pre-ETC level (that is, 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 12**: dialysis modality measures, waitlisting, transplantation, utilization, Medicare spending, QoC, and in-center HD patient experience of care.

## Exhibit 12. Estimated Impacts of the ETC Model for CY 2021 – CY 2022

| Outcomes | | ETC | | Comparison | | Model Estimates | | | % Relative Change[1] |
|---|---|---|---|---|---|---|---|---|---|
| | | Pre-ETC Mean | Post-ETC Mean[#] | Pre-ETC Mean | Post-ETC Mean | DiD | Lower 90% CI | Upper 90% CI | |
| Dialysis Modality Measure[2] (%) | **Home Dialysis** | 11.8% | 14.9% | 12.8% | 16.0% | -0.07 | -0.46 | 0.32 | -0.59% |
| | Peritoneal Dialysis | 9.8% | 11.9% | 10.8% | 13.0% | -0.13 | -0.48 | 0.21 | -1.4% |
| | Home HD | 2.1% | 3.0% | 2.1% | 3.0% | 0.06 | -0.14 | 0.27 | 3.1% |
| | **In-Center HD** | 88.1% | 84.9% | 87.1% | 83.9% | 0.07 | -0.32 | 0.46 | 0.08% |
| | In-Center Hemodialysis | 87.8% | 84.8% | 86.7% | 83.6% | 0.03 | -0.39 | 0.44 | 0.03% |
| | In-Center Self-Dialysis | 0.03% | 0.01% | 0.09% | 0.04% | 0.03 | -0.03 | 0.09 | 111.7% |
| | Nocturnal HD | 0.29% | 0.16% | 0.33% | 0.19% | 0.01 | -0.07 | 0.08 | 2.6% |
| | **Home Dialysis Training** | 0.70% | 0.84% | 0.73% | 0.81% | 0.05** | 0.01 | 0.10 | 7.7% |
| Waitlisting[3] (%) | **Overall** | 19.4% | 18.9% | 21.1% | 19.9% | 0.80 | -0.08 | 1.7 | 4.1% |
| | Active Status | 12.2% | 11.1% | 13.4% | 11.9% | 0.42 | -0.36 | 1.2 | 3.5% |
| | Inactive Status | 7.2% | 7.8% | 7.7% | 7.9% | 0.38 | -0.22 | 0.98 | 5.3% |
| Transplant[3] (per 1,000 Patient Months) | **Total (among Dialysis Patients)** | 3.9 | 5.4 | 3.8 | 4.9 | 0.38* | 0.06 | 0.69 | 9.7% |
| | Deceased Donor[4] | 3.3 | 4.8 | 3.2 | 4.3 | 0.36* | 0.05 | 0.67 | 11.1% |
| | Living Donor[4] | 0.60 | 0.59 | 0.64 | 0.61 | 0.01 | -0.04 | 0.07 | 2.3% |
| | **Living Donor (Dialysis and Pre-emptive)[5]** | 0.60 | 0.59 | 0.64 | 0.61 | 0.01 | -0.05 | 0.07 | 2.2% |
| Utilization (%) | **Acute Care Hospitalization** | 10.0% | 9.2% | 9.9% | 9.0% | 0.05 | -0.11 | 0.21 | 0.52% |
| | **Readmission** | 30.1% | 29.1% | 30.0% | 29.2% | -0.22 | -0.70 | 0.27 | -0.72% |
| | **Outpatient ED Use** | 11.3% | 9.5% | 11.2% | 9.5% | -0.17* | -0.33 | -0.01 | -1.5% |
| Medicare Payments (PPPM) | **Total Parts A & B** | $5,704 | $6,015 | $5,760 | $6,055 | $16 | -$26 | $57 | 0.28% |
| | Total Part A[6] | $1,647 | $1,705 | $1,681 | $1,730 | $9 | -$35 | $53 | 0.56% |
| | Part A Acute Care Hospitalization[6] | $1,413 | $1,458 | $1,421 | $1,453 | $13 | -$3 | $29 | 0.92% |
| | Part A LTCH, IRF[6] | $104 | $121 | $120 | $135 | $2 | -$2 | $6 | 1.9% |
| | Other Part A[6] | $128 | $142 | $135 | $151 | -$2 | -$5 | $2 | -1.3% |
| | Total Part B | $4,117 | $4,344 | $4,153 | $4,370 | $10 | -$11 | $31 | 0.24% |
| | Part B Dialysis | $2,879 | $2,985 | $2,886 | $2,990 | $2 | -$9 | $13 | 0.06% |
| | Other Part B | $1,238 | $1,359 | $1,267 | $1,379 | $8 | -$10 | $26 | 0.66% |
| | **Total Part D** | $873 | $806 | $899 | $831 | $0.2 | -$19 | $19 | 0.02% |
| Quality (%) | **Peritonitis[7]** | 4.3% | 4.4% | 4.2% | 4.4% | -0.08 | -0.35 | 0.20 | -1.8% |
| | **Vascular Infection[8]** | 0.97% | 0.89% | 1.0% | 0.92% | 0.03 | -0.03 | 0.08 | 2.6% |
| | **Hospitalizations with Vascular Access Complications** | 0.79% | 0.84% | 0.81% | 0.86% | 0.01 | -0.02 | 0.04 | 1.0% |
| | **Hospitalizations with ESRD Complications** | 0.85% | 0.81% | 0.79% | 0.77% | -0.02 | -0.06 | 0.02 | -2.5% |

| Outcomes | | ETC | | Comparison | | Model Estimates | | | % Relative Change[1] |
|---|---|---|---|---|---|---|---|---|---|
| | | Pre-ETC Mean | Post-ETC Mean[#] | Pre-ETC Mean | Post-ETC Mean | DiD | Lower 90% CI | Upper 90% CI | |
| Patient Experience of Care | Rating of Kidney Doctors | 59.5% | 59.3% | 60.7% | 60.5% | 0.10 | -0.61 | 0.81 | 0.16% |
| | Rating of Dialysis Center Staff | 62.7% | 63.8% | 63.1% | 64.2% | 0.06 | -0.65 | 0.77 | 0.09% |
| | Rating of Dialysis Center | 67.8% | 68.4% | 68.3% | 68.6% | 0.18 | -0.56 | 0.92 | 0.26% |
| | Nephrologists' Communication and Caring[9] | 67.3% | 67.0% | 67.8% | 67.1% | 0.46 | -0.07 | 0.99 | 0.68% |
| | Quality of Dialysis Center Care and Operations[9] | 62.7% | 63.3% | 63.1% | 63.6% | 0.24 | -0.26 | 0.74 | 0.38% |
| | Providing Information to Patients[9] | 80.2% | 79.5% | 80.5% | 79.5% | 0.26 | -0.09 | 0.61 | 0.32% |

**Notes:** A summary of the results of the Pre-ETC period includes CY 2017 – CY 2019. Pre-ETC and Post-ETC (CY 2021-2022) means were adjusted for patient, facility, and market characteristics. [1]Relative change based on cumulative DiD estimate (before rounding). 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. [2]Dialysis modality indicators except for home dialysis training are mutually exclusive (primary modality in a patient-month). Home dialysis: peritoneal dialysis or home HD. In- center HD includes in-center hemodialysis, in-center self-dialysis and nocturnal. [3]Transplant and waitlisting measures restricted to patients less than 75 years old. [4]Among dialysis patients. [5]Among dialysis patients and pre-emptive transplant recipients. [6]Estimates obtained from a two-part model. [7]Among PD patients. [8]Among HD patients. [9]See **Appendix E**, **Exhibit E-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.

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

A major goal of the ETC Model is to promote patient education and choice in the dialysis modality selection process with the expectation of growth in home dialysis modalities and decreased reliance on in-center HD. The major home dialysis modalities include PD and home HD. The ETC Model started on January 1, 2021. Beginning in 2022, the ETC Model also awarded partial credit to model participants for in-center self- administered HD and in-center nocturnal dialysis on the grounds that these modalities promote self-care. For the first three calendar 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. Participants are also eligible for the PPA, a positive or negative payment based on home dialysis and transplant performance. The initial PPAs were determined by performance in the first model year and were applied starting in July 2022.

The estimated impact of the ETC Model on home dialysis through the first two years of the model is shown in **Exhibit 13**. Home dialysis grew steadily in the ETC group from 11.8 percent of dialysis patients in the pre-ETC period to 14.7 percent in 2021 and 15.1 percent in 2022 (all values adjusted for case-mix). Home dialysis showed a similar growth pattern in the comparison group (12.8% to 15.8% to 16.2%). The DiD estimate was small and not statistically significant in CY 2021 (-0.10), CY 2022 (-0.03) and cumulatively during CYs 2021-2022 (-0.07). Both PD and HHD grew at similar rates in the ETC and comparison groups with small, non-significant DiD estimates. There was a commensurate fall in in-center HD (excluding self-care and nocturnal center dialysis) in each year of similar magnitude in ETC areas and comparison groups.

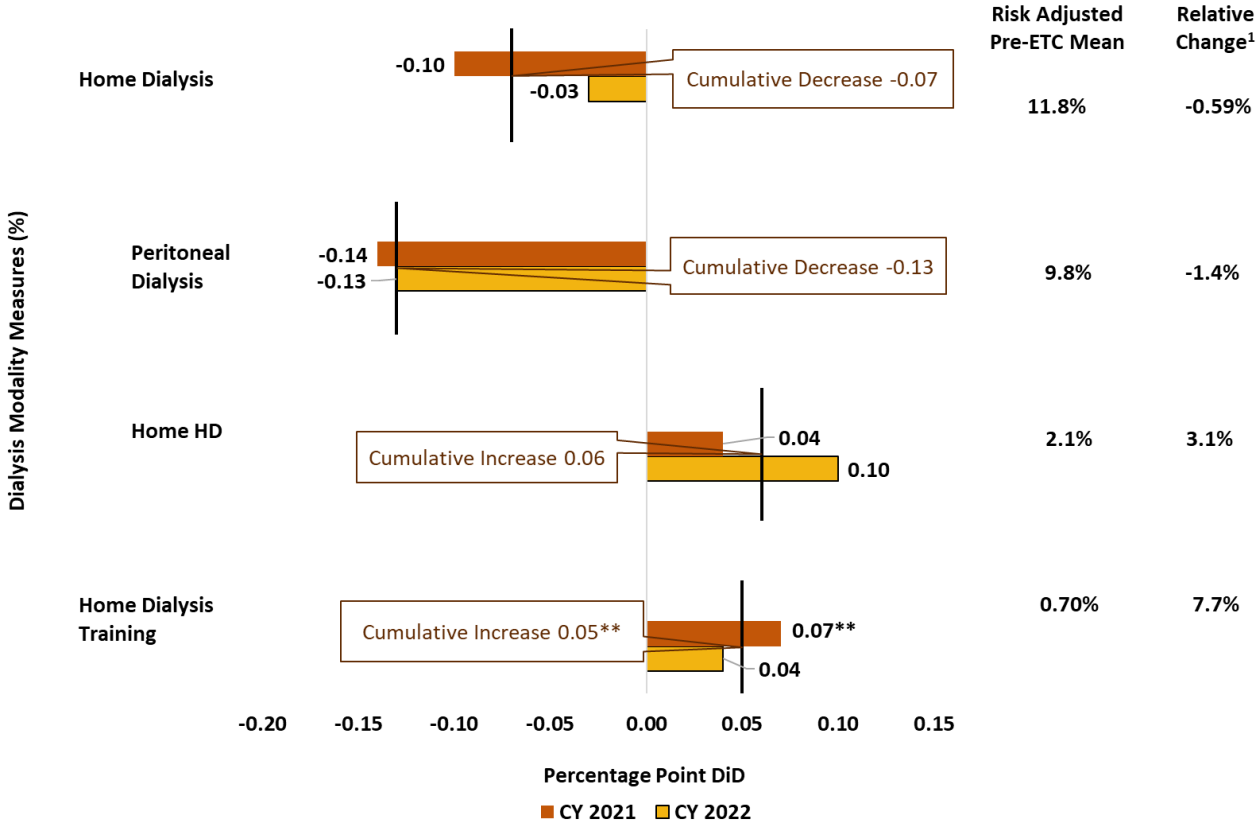
The cumulative two-year DiD estimate was statistically significant, indicating a 0.05 percentage point increase in home dialysis training in ETC areas relative to the comparison group (see **Exhibit 13**). The percentage of patient months engaged in home dialysis training increased faster in the ETC group (0.70% to 0.84%) than the comparison group (0.73% to 0.80%) in the first year of the model, yielding a statistically significant DiD estimate of 0.07 percentage points during CY 2021. This difference was initially viewed as a potential early signal of home dialysis expansion. Slightly faster growth was also seen in the second year of the model but the DiD estimate (0.04) was smaller and not statistically significant. However, if the differential growth was driven by the model's financial incentives, we would have expected faster growth in CY 2022 as home dialysis resources and the ETC financial incentives expanded. In-center self-dialysis and nocturnal center dialysis were used by a small percentage of patients with no noticeable group growth differences despite the ETC Model incentives (see **Exhibit 14**).

We examined the possibility of an early signal of increased home dialysis attributable to the ETC Model by focusing on specific segments of the beneficiary and facility population. We hypothesized that early expansion of home dialysis might focus initially on new patients with ESRD, younger patients with ESRD and dialysis facilities with an established home dialysis program. Although patients may start home dialysis at any time after reaching ESRD, they are most amenable at the start of ESRD whereas patients who settle into in-center HD tend not to switch to home dialysis. Using a DDD model, we examined home dialysis penetration among patients in the initial 90 days of ESRD, which largely captures the start of dialysis, with subgroups of patients with varying time on dialysis (90 days to one year, one to five years, and greater than five years; see **Appendix B, Section B.6**).

Results of the DDD analysis indicated no difference in the change in home dialysis use in this early window (0-90 days) between the ETC and comparison groups, with a non-significant DiD for this patient subgroup and non-significant DDD estimates when comparing subgroups (see **Appendix B, Exhibit B-29**). We also reasoned that home dialysis expansion might start with younger patients, who tend to gravitate to home dialysis. Again, there was no evidence of an impact of the model on home dialysis use among younger age groups. Finally, we reasoned that home dialysis expansion might start in facilities with established home dialysis programs that presumably had the infrastructure and staff in place to support further expansion. Once again, the DDD analysis revealed a non-significant DiD estimate for this subgroup of facilities (see **Appendix B, Exhibit B-30**).

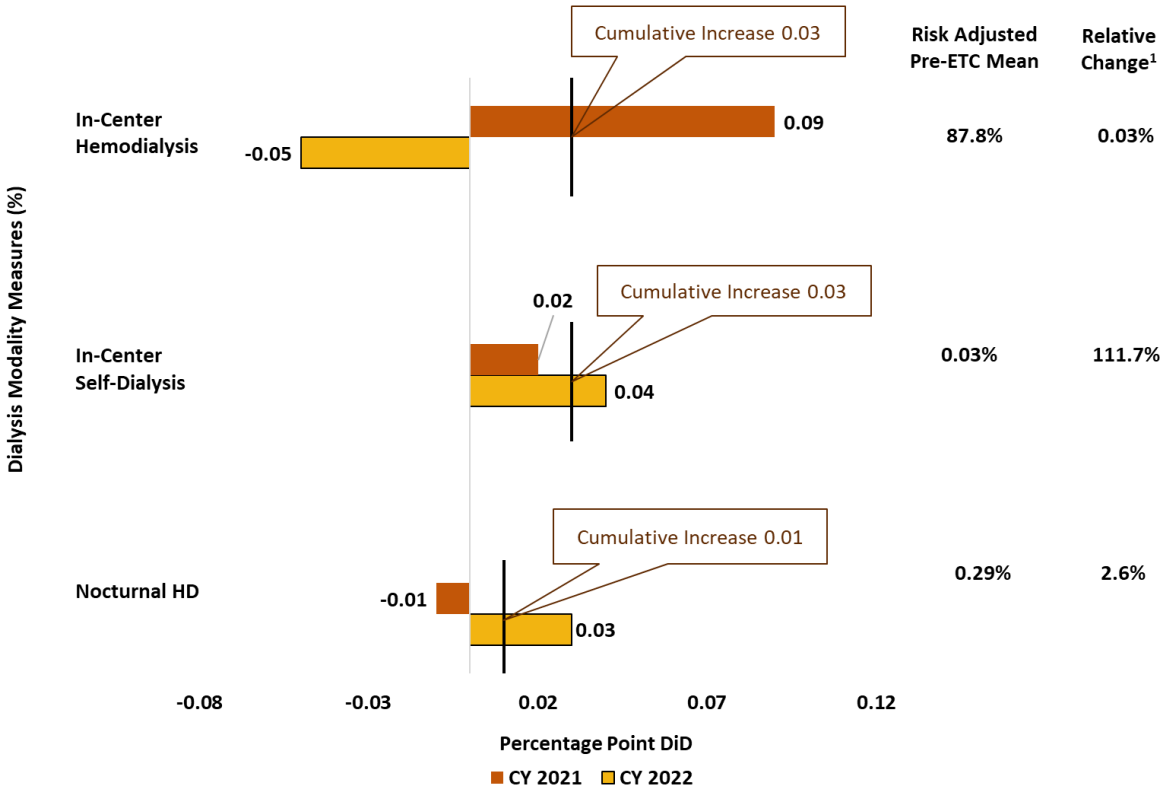
As of the second year of the model, the percentage of patients treated with home dialysis increased steadily by approximately 0.4 percentage points/year, continuing an upward trend that started in 2010. However, the ETC Model incentives to providers do not appear to have stimulated additional home dialysis growth in ETC areas relative to the comparison areas thus far.

**Exhibit 13. DiD Impact Estimates for Home 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 and CY 2022 with the pre-ETC period relative to the same difference over time for patients in the comparison group. Cumulative DiD estimate is a weighted average of the yearly DiD estimates (see **Appendix B,** Section B.5). Significance of the DiD impact estimates is indicated for each outcome where * implies significance at the 10 percent level, ** at the five percent level, and *** at the one percent level assuming a two-tailed test. All dialysis modality measures except for home dialysis training are based on primary modality in a patient month and are mutually exclusive. Home dialysis: peritoneal dialysis or home HD. In- center HD includes in-center hemodialysis, in-center self-dialysis and nocturnal. [1]Relative change based on Cumulative (CY 2021 + CY 2022) DiD estimate (before rounding).

**Exhibit 14. DiD Impact Estimates for In-Center 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 and CY 2022 with the pre-ETC period relative to the same difference over time for patients in the comparison group. Cumulative DiD estimate is a weighted average of the yearly DiD estimates (see **Appendix B,** Section B.5). Significance of the DiD impact estimates is indicated for each outcome where * implies significance at the 10 percent level, ** at the five percent level, and *** at the one percent level assuming a two-tailed test. All dialysis modality measures except for home dialysis training are based on primary modality in a patient month and are mutually exclusive. Home dialysis: peritoneal dialysis or home HD. In- center HD includes in-center hemodialysis, in-center self-dialysis and nocturnal. [1]Relative change based on Cumulative (CY 2021 + CY 2022) DiD estimate (before rounding).

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

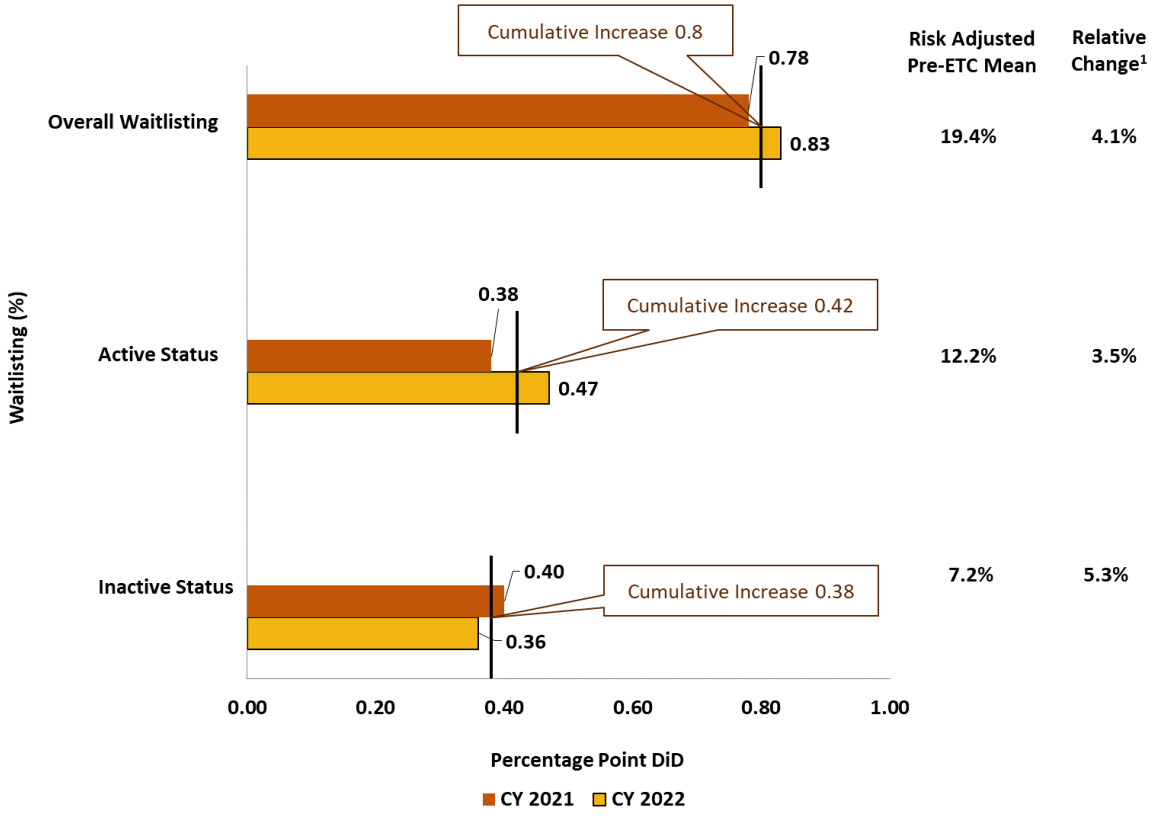
The ETC Model incentivizes dialysis providers to guide more patients to kidney transplantation. Important early steps in the transplant process include referral to a transplant center and placement on the transplant waitlist. Patients who have been evaluated and meet the criteria for a transplant are usually added to the waitlist in active status, meaning they qualify to receive a kidney transplant if a suitable organ becomes available. Patients who develop a medical complication or other temporary contraindication to transplant may be 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 outcome measure for the ETC Model and as such we examined overall, active and inactive waitlist status trends. The ETC Model waitlist and transplant rates are restricted to patients less than age 75 years.

Estimates of ETC Model impacts on transplant waitlisting are shown in. The overall percentage of patients waitlisted (active + inactive) declined from the pre-ETC period through CY 2021 and

then stabilized in CY 2022 (ETC: 19.4% to 18.9% to 19.0%; Comparison: 21.1% to 19.8% to 19.9%). The DiD estimates for CYs 2021-2022 combined (0.80 percentage points), CY 2021 (0.78 percentage points), and CY 2022 (0.83) showed a favorable but not statistically significant effect for the ETC group. The percentage of patients in active waitlist status declined in each performance year for both ETC and comparison groups. The DiD estimate was positive (that is, favorable to ETC group) but not statistically significant for any period. The percentage of patients in inactive waitlist status showed a mostly upward trend for both the ETC and comparison groups. However, the changes were similar for both groups and the DiD estimates were not statistically significant.

The decline in active waitlisting preceded the start of the ETC Model. As of the second year, the ETC Model has not had a measurable impact on transplant waitlisting.

**Exhibit 15. 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 and CY 2022 with the pre-ETC period relative to the same difference over time for patients in the comparison group. Cumulative DiD estimate is a weighted average of the yearly DiD estimates (see **Appendix B,** Section B.5). Significance of the DiD impact estimates is indicated for each outcome where * implies significance at the 10 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. [1]Relative change based on Cumulative (CY 2021 + CY 2022) DiD estimate (before rounding).

### 4.3.3. 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. Managing Clinicians are also incentivized to increase preemptive transplants among patients with chronic kidney disease (pre-dialysis). The rationale holds that dialysis providers play an important role in helping their patients understand and facilitate living donor organ donations. In contrast, there is not an explicit incentive to increase deceased donor organ transplantation, although 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.[14] As with waitlisting, the ETC Model evaluates transplant rates for dialysis patients under the age of 75, in addition to the general model exclusions described in **Appendix B, Exhibit B-4**.

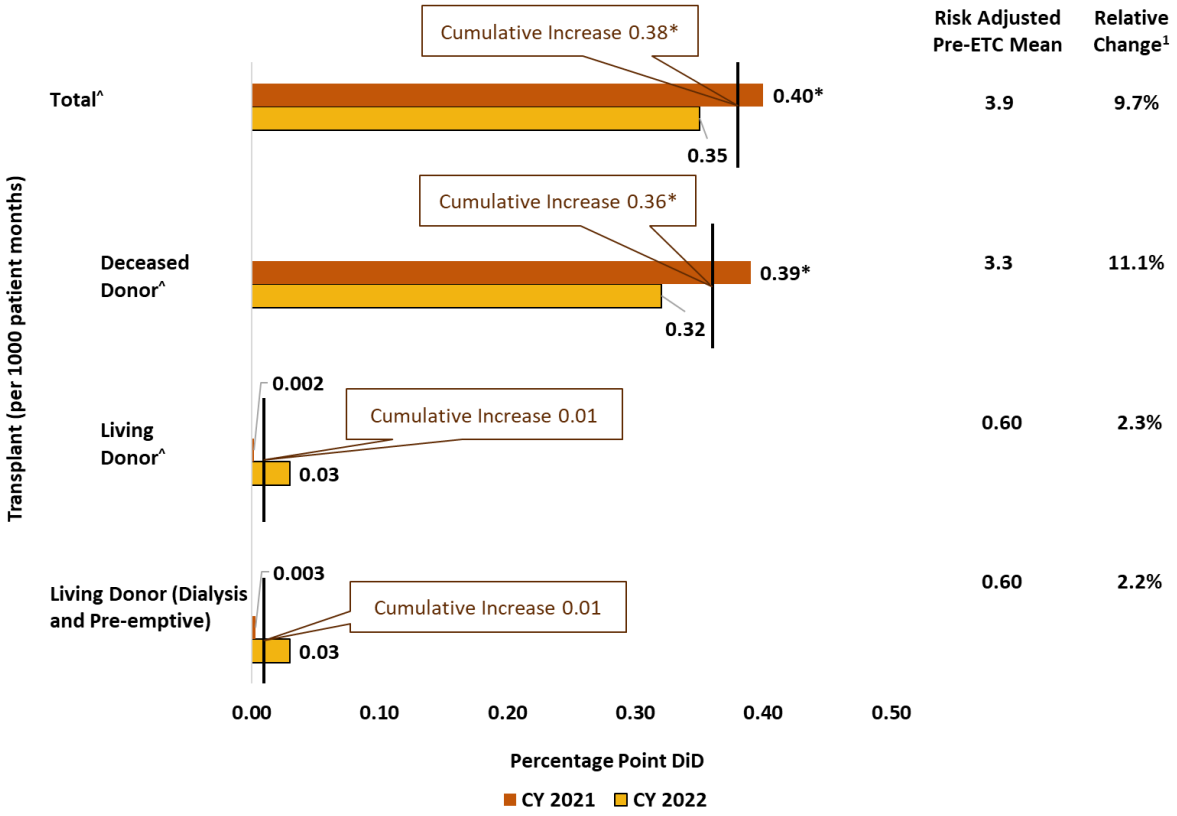
Estimates of ETC Model impacts on kidney transplantation are shown in **Exhibit 16**. The total transplant rate (per 1,000 patient-months) increased in the ETC group from 3.9 in the pre-ETC period to 5.1 in CY 2021 and 5.7 in CY 2022. The total transplant rate for the comparison group increased from 3.8 to 4.7 to 5.3 for the corresponding periods. The cumulative DiD estimate of 0.38 transplants/1000 patient months for the combined 2021-2022 period was statistically significant. The rate of growth in transplant rates was significantly faster for the ETC group in CY 2021 (DiD=0.40). The rate of growth was also faster for the ETC group in CY 2022 (DiD=0.35) but the difference was not statistically significant. We estimated that the higher rate of transplantation represents approximately 225 additional transplants in ETC areas in CY 2021.

This pattern for the total transplant rate was largely driven by deceased donor transplants, which grew in both the ETC (3.3 to 4.5 to 5.1) and comparison (3.2 to 4.1 to 4.7) groups. As with total transplants, the DiD estimate for deceased donor transplants was statistically significant cumulatively (0.36) and for CY 2021 (0.39) but not for CY 2022 (0.32). Although the ETC Model provides specific incentives to expand living donor transplantation, the living donor transplant rate did not increase in the first two years of the model for either group, regardless of whether pre-emptive living donor transplants were excluded or included in the rate calculation. The DiD estimates for living donor transplantation showed small and non-significant differences between the ETC and comparison group.

The faster growth in total and deceased donor transplants in 2021 is potentially attributable to ETC Model incentives. However, it is important to remember that the ETC Model does not explicitly incentivize deceased donor transplants. Furthermore, an attributable ETC Model effect would be expected to operate through a statistically significant increase in waitlisting rates in the ETC group relative to the comparison group, which we do not observe, and to strengthen over time with increasing financial incentives and maturation of dialysis provider infrastructure to support transplantation. We anticipate that the impact attribution will be clarified as the ETC Model continues.

[14] 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.

**Exhibit 16. 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 and CY 2022 with the pre-ETC period relative to the same difference over time for patients in the comparison group. Cumulative DiD estimate is a weighted average of the yearly DiD estimates (see **Appendix B,** Section B.5) Significance of the DiD impact estimates is indicated for each outcome where * implies significance at the 10 percent level, ** at the five percent level, and *** at the one percent level assuming a two-tailed test. ^Among dialysis patients. Waitlisting and transplant measures are restricted to patients with age <75 years. [1]Relative change based on Cumulative (CY 2021 + CY 2022) DiD estimate (before rounding).

### *4.3.4. 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 for utilization of services among dialysis patients. 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.

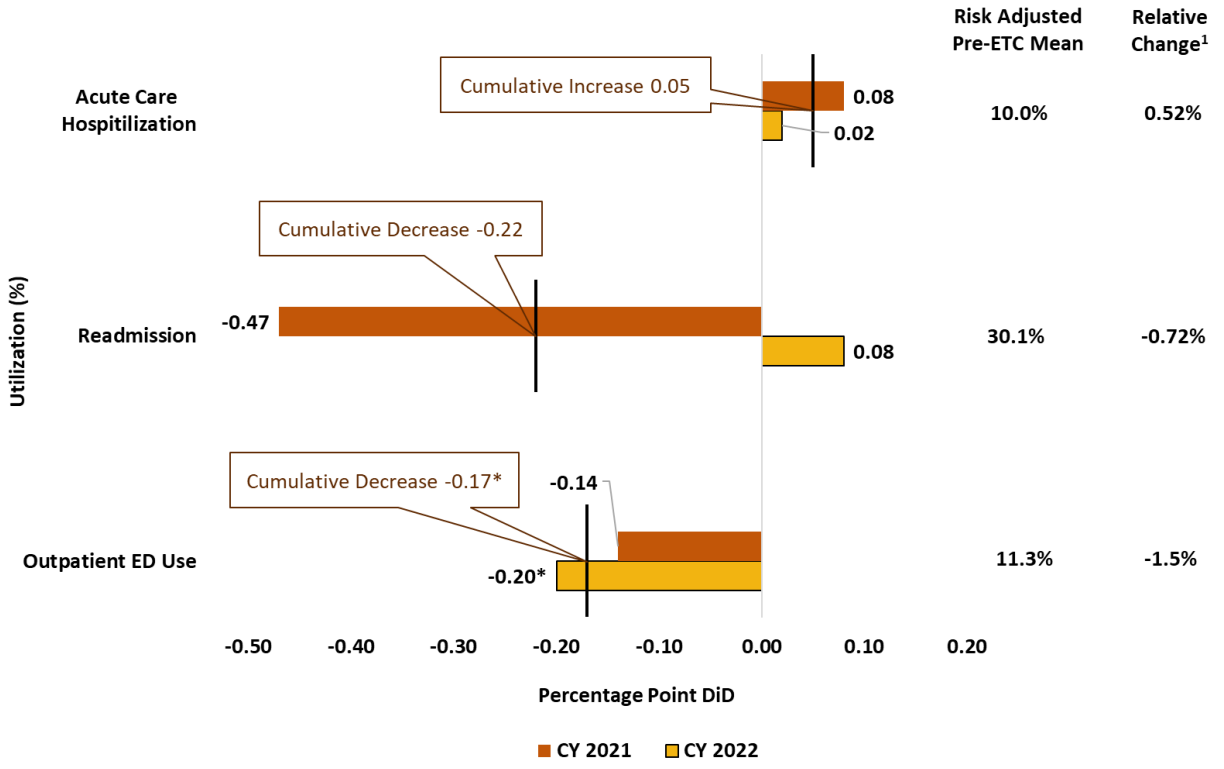
In this report, we examined three key measures of utilization among dialysis patients: acute care hospitalizations, outpatient ED visits, and hospital readmissions. Each of these types of utilization is common among dialysis patients and reflect a need for care for acute conditions that may be avoidable in some cases. Analyses of utilization measures, which possibly are sensitive to the

choice of dialysis modality, will provide insights into the mechanisms by which the model affects the overall cost of care for dialysis patients. 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 the first two years of the model for both ETC Participants and the comparison group. The rate of decline was similar for both groups for acute care hospitalizations and readmissions, such that impact estimates indicate no change in utilization patterns for these two measures during the first two years of the ETC Model (see **Exhibit 17**). However, there was evidence of a slightly faster decline in outpatient ED use in the ETC group. When combining data for the two year-period, the cumulative impact estimate is negative and statistically significant (-0.17 percentage points), translating to a 1.5 percent decline relative to the pre-ETC level of outpatient ED use. The DiD estimate for ED use was negative in both years but statistically significant only for CY 2022, indicating a relative decline of -0.20 percentage points (see **Appendix B, Exhibit B-21**). This DiD estimate translates to a 1.8 percent decline relative to a pre-ETC average of 11.3 percent.

The relatively high rate of ED use among dialysis patients may indicate opportunities for intervention and improved management of patients with ESRD. If the ETC Model leads to a greater level of engagement with patients about their treatment and what is and isn't working well, there may be potential to prevent certain ED visits that would have otherwise occurred. We will continue to evaluate potential impacts on the use of these acute care services as the model evolves.

**Exhibit 17. Cumulative 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 and CY 2022 with the pre-ETC period relative to the same difference over time for patients in the comparison group. Cumulative DiD estimate is a weighted average of the yearly

DiD estimates (see **Appendix B,** Section B.5). Significance of the DiD impact estimates is indicated for each outcome where * implies significance at the 10 percent level, ** at the five percent level, and *** at the one percent level assuming a two-tailed test. [1]Relative change based on Cumulative (CY 2021 + CY 2022) DiD estimate (before rounding).

### 4.3.5. 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. The evolving patterns of modality use and associated changes in QoC could have implications for utilization, potentially influencing Medicare payments. Because ETC Participants face financial incentives to increase use of home dialysis and transplantation, and in the process, also improve certain aspects of patient care (for instance, through a greater focus on patient education, consideration of patient perspectives, shared decision-making, and encouraging the successful longer-term use of home dialysis), there may be potential for quality-enhancing care changes implemented by providers to affect forms of utilization and, in turn, Medicare spending. In addition to changes in the types and volume of services being provided, changes in the intensity of care may also impact 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.[15] This measure reflects average Medicare payments across patients with FFS coverage in a given month for all Parts A & B services.[16] We also separately examined major components of Part A and Part B payments to identify the source(s) of any observed overall changes in payments. We defined separate payment categories for Part A and Part B services, and defined categories for several distinct payment components under Part A and Part B, including payments for acute care hospitalizations as well as for 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 86 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 and CY 2022 and the PPA applied during CY 2022. New for this report, we examined potential impacts on Part D spending (a measure of drug costs) for FFS beneficiaries enrolled in a stand-alone Part D plan.

Medicare payments PPPM increased over time in both the ETC and comparison groups overall and for Parts A & B services (see **Exhibit 18**). The growth in overall payments is relatively similar in the two groups, reflecting a seven percent increase in total Medicare payments PPPM between the pre-ETC period and the first two years of the model (CY 2021-CY 2022).

ETC Model impacts on Medicare payments are shown in **Exhibits 18 – 20**. The impact estimates for total, total Part A, and total Part B payments PPPM are relatively small and not statistically

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

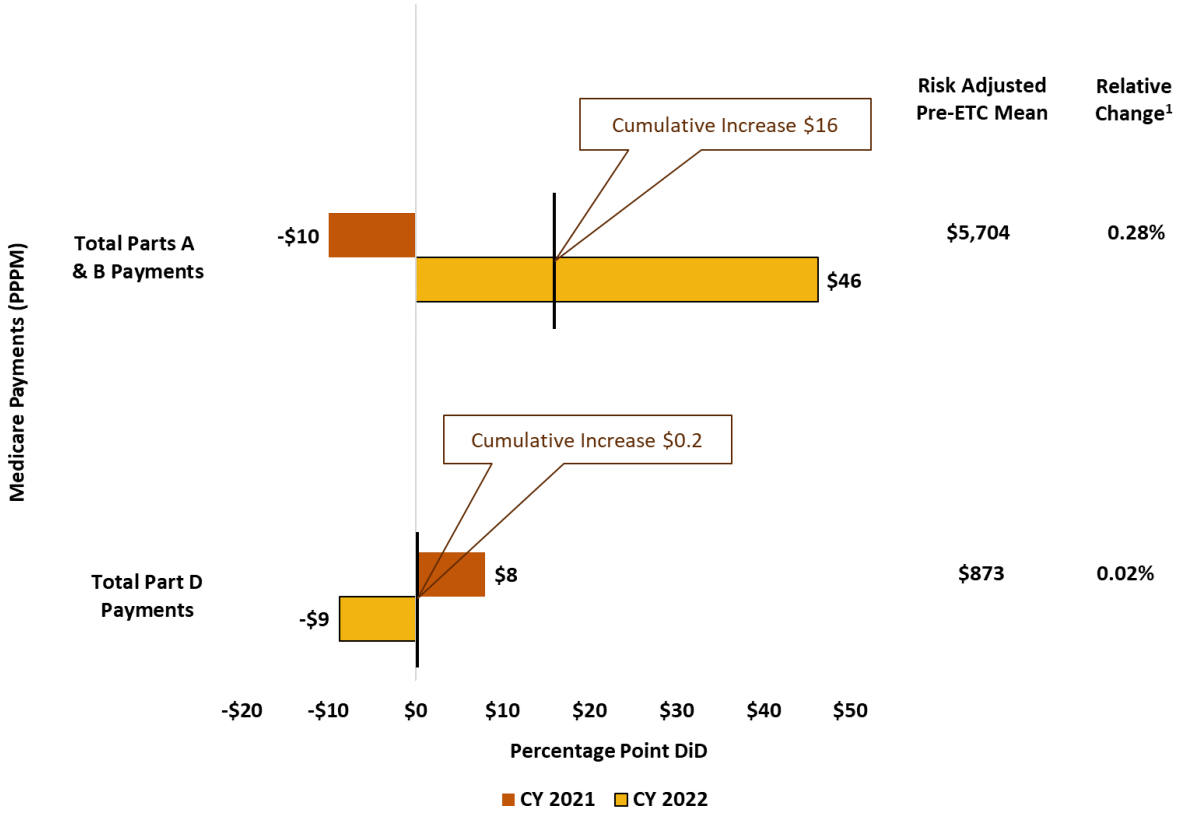
[16] Measures of payments do not include model incentive payments in the form of either the HDPA (upward adjustment only) or the PPA (starting July 2022; upward or downward adjustment), and as such are used to assess gross savings and not net savings which would incorporate costs of the model.

significant, suggesting the ETC Model did not reduce Medicare payments in ETC areas relative to the comparison group over the two-year period.

Similarly, none of the cumulative impact estimates for components of Medicare Parts A & B payments were statistically significant. The only payment category with a statistically significant yearly impact estimate involves Medicare payments to LTCHs and IRFs. The CY 2021 DiD estimate indicates $7 PPPM lower average payments to LTCHs and IRFs, whereas the CY 2022 estimate corresponds to $12 PPPM higher payments in ETC areas relative to the comparison group. The two-year cumulative estimate, however, is small and not statistically significant. This payment category constitutes a small portion (<0.2 percent) of 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 changes in payments (see **Exhibit 19** and **Appendix B, Exhibit B-21).**

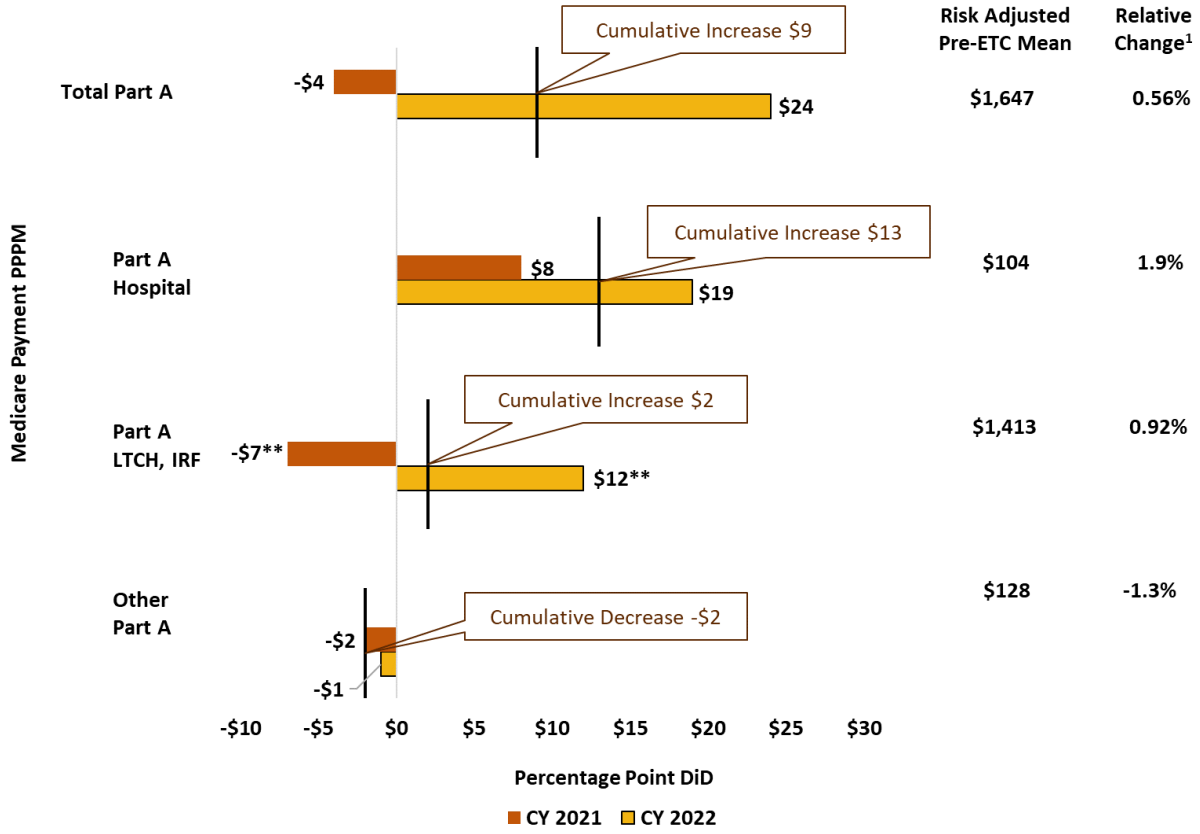
Between the pre-ETC and the post-ETC period, there was a decline in Part D payments PPPM in both the ETC and comparison areas (see **Appendix B, Exhibit B-20**). The DiD analysis indicates that the decline in Part D spending among patients enrolled in Part D was not statistically different between the two groups (see **Exhibit 18** and **Appendix B, Exhibit B-21**).

**Exhibit 18. DiD Impact Estimates for Medicare Parts A & B and Part D Payments PPPM**



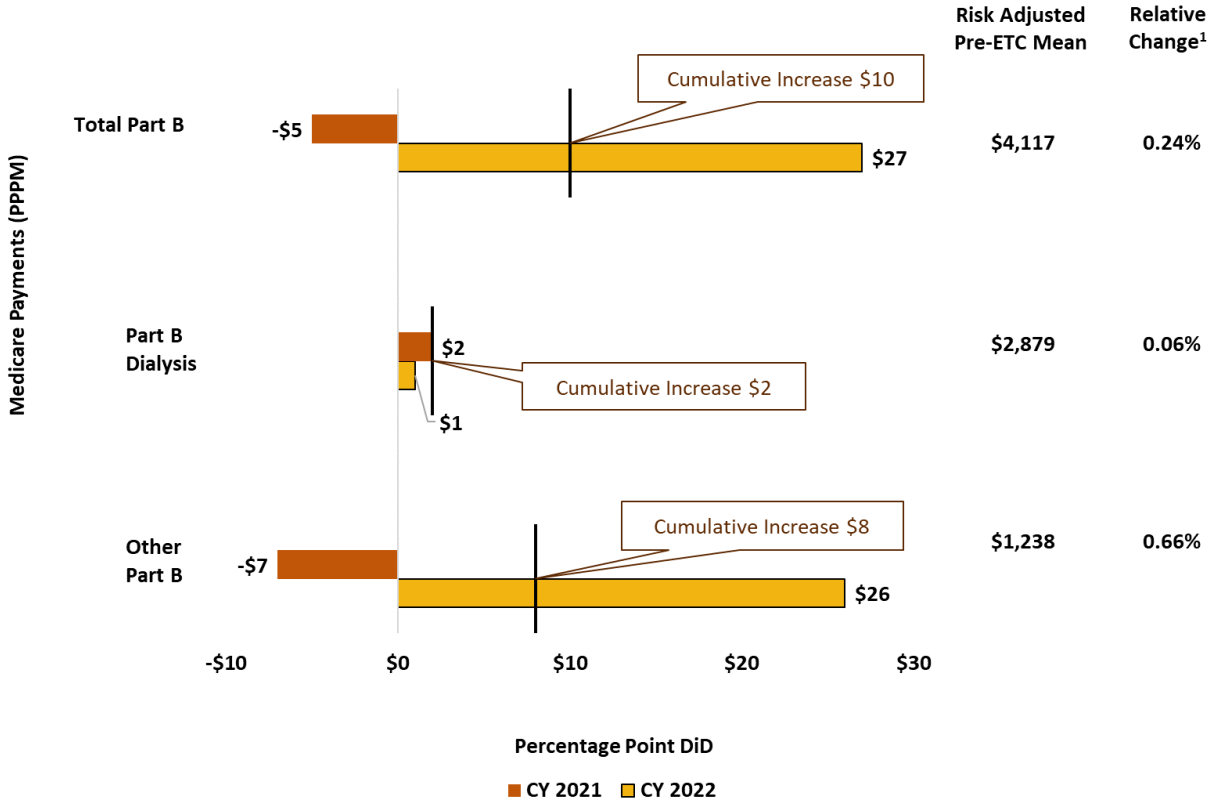

**Notes:** Pre-ETC period is CY 2017-CY 2019. Each impact estimate is based on a DiD model and reflects the difference in the risk-adjusted mean outcome for patients in the ETC areas for CY 2021 and CY 2022 with the pre-ETC period relative to the same difference over time for patients in the comparison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

## Exhibit 19. DiD Impact Estimates for Medicare Part A 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 and CY 2022 with the pre-ETC period relative to the same difference over time for patients in the comparison group. Cumulative DiD estimate is a weighted average of the yearly DiD estimates (see **Appendix B,** Section B.5). Significance of the DiD impact estimates is indicated for each outcome where * implies significance at the 10 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). [1]Relative change based on Cumulative (CY 2021 + CY 2022) DiD estimate (before rounding).

**Exhibit 20. DiD Impact Estimates for Medicare Part B 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 and CY 2022 with the pre-ETC period relative to the same difference over time for patients in the comparison group. Cumulative DiD estimate is a weighted average of the yearly DiD estimates (see **Appendix B,** Section B.5). Significance of the DiD impact estimates is indicated for each outcome where * implies significance at the 10 percent level, ** at the five percent level, and *** at the one percent level assuming a two-tailed test. [#]Relative change based on Cumulative (CY 2021 + CY 2022) DiD estimate.

We also analyzed the frequency of ESRD facility claims for Transitional Drug Add-on Payment Adjustment (TDAPA) and Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES). TDAPA and TPNIES provide extra payments to ESRD facilities for newly developed drugs, supplies and equipment that are temporarily paid outside the bundled prospective payment to ESRD facilities. The frequency of claims for TDAPA and TPNIES items were balanced for facilities located in the ETC and comparison areas in both the pre-ETC and post-ETC periods. Claims for calcimimetic agents (cinacalcet and etelcalcitide) were relatively frequent in the pre-ETC period (2017-2019) compared to the post-ETC period but showed similar trends in both groups. There was no evidence of group differences in facility billing for items covered by TDAPA or TPNIES that would have potential implications for the ETC Model evaluation. Descriptive tables and additional details are included in **Appendix B,** Section B.7.

### *4.3.6. What Was the Impact of the ETC Model on Quality of Care?*

This section addresses the impact of the ETC Model on several indicators that are potentially linked to quality of care including peritonitis, vascular infections, hospitalizations with non-infectious vascular access complications, hospitalizations with ESRD-related complications, and mortality.

**Peritonitis**. Peritonitis is a major infectious complication of PD related to the presence within the peritoneal cavity of a foreign-body dialysis catheter and peritoneal fluid. Although PD patients are trained in sterile fluid exchange techniques, the catheter provides a portal of entry for pathogens, especially bacteria. Peritonitis typically presents with acute abdominal pain, cloudy peritoneal fluid and signs of systemic toxicity such as fever. Symptoms typically respond to antibiotic therapy. A typical peritonitis episode involving the symptom phase and treatment spans a 1-to-2-week timeframe. However, some patients experience complications including disruptively severe symptoms, treatment resistance, recurrence, and others. Peritonitis is a frequent contributing factor when patients decide to discontinue PD in favor of ICHD. Dialysis providers influence peritonitis risk in a variety of ways including training effectiveness and treatment protocols. Peritonitis avoidance is a major goal in the management of PD patients. The ETC Model emphasizes expansion of home dialysis, which is dominated by PD. It is possible that increased provider focus on PD could lead to improved QoC as revealed by lower rates of peritonitis and associated services. On the other hand, efforts to expand PD could result in changes to patient case-mix that could adversely affect peritonitis risk.

We restricted the peritonitis evaluation to patient months associated with PD treatment. Peritonitis risk was quantified as the percentage of patient months with a submitted claim (inpatient, outpatient, carrier) containing a peritonitis diagnosis code. A single episode of peritonitis may generate multiple claims and diagnosis codes. Approximately 4.4% of patient months were associated with a peritonitis claim. The rate was similar in the pre-ETC (2017-2019) and ETC intervention (2021-2022) periods for both the ETC and comparison groups (see **Appendix B**, **Exhibit B-20**). The DiD analysis found no statistically significant group difference either cumulatively during 2021-2022 or during either of the two years (see **Exhibit 21**). As of the second year of the model, there was no evidence that the ETC Model influenced PD-associated peritonitis rates.

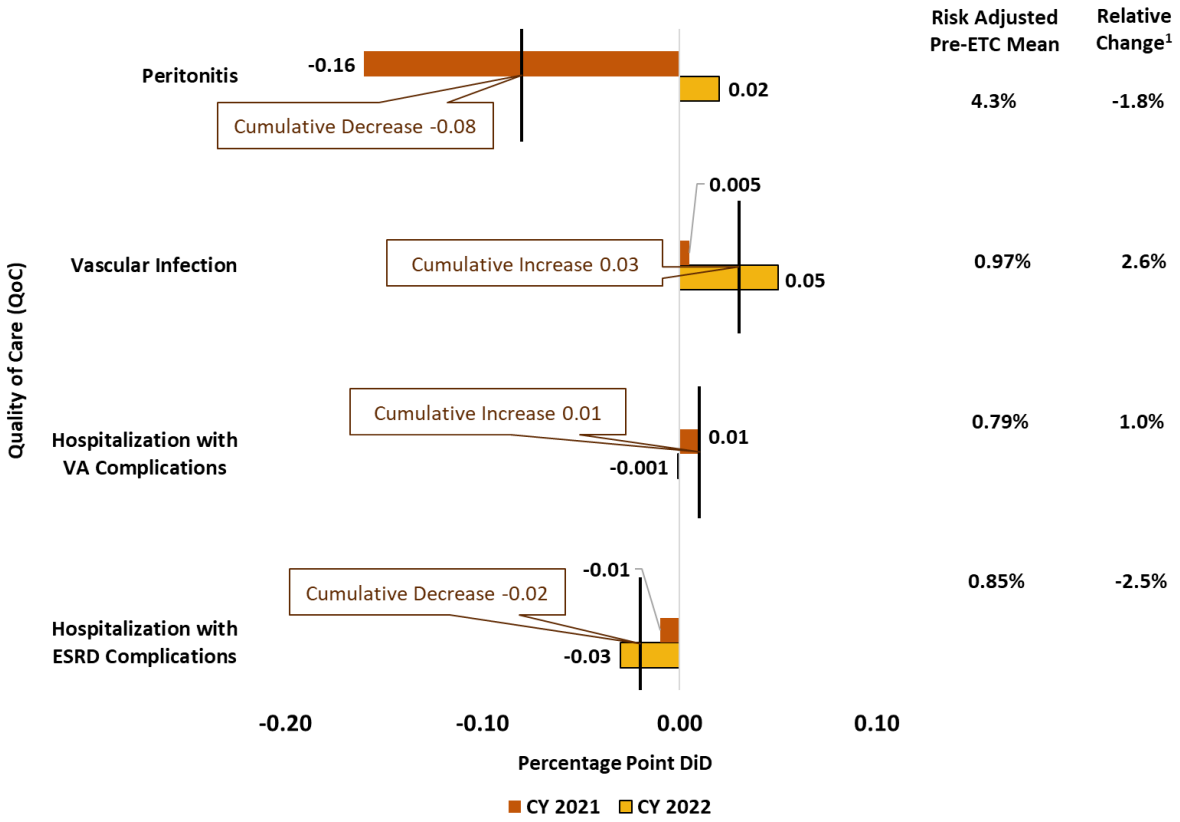
**Vascular infections.** The frequency of vascular infections are related to QoC. Vascular infections in dialysis patients are usually related to hemodialysis vascular access devices. Among the available options, the infection risk is lowest for native VA fistula followed by synthetic vascular grafts and indwelling catheters. Dialysis providers strongly influence vascular device selection, particularly the use of catheters. Infection risk is also influenced by facilities through sterile technique adherence and needling skill when connecting the patient to the dialysis machine. In general, the frequency of vascular infections was lower in the first two years of the model than the pre-ETC period but with no statistically significant difference in the change over time between the ETC and comparison groups (see **Exhibit 21** and **Appendix B, Exhibits B-20** and **B-21**).

**Hospitalizations with vascular complications.** We also examined the frequency of hospitalizations related to non-infectious vascular complications such as thrombosis. The rate of these complications is potentially influenced by ESRD facility procedures involved in connecting the patient to the dialysis machine. In general, the incidence of vascular access complications was higher following the start of the model than in the pre-ETC period. However, the magnitude and direction of the change was similar in the ETC and comparison groups, resulting in a very small, non-significant DiD estimate (see **Exhibit 21**).

**ESRD-related hospitalizations.** ESRD-related hospitalizations arise from conditions that dialysis attempts to prevent such as fluid overload and hyperkalemia. Although many patient and

environmental factors are involved, dialysis provider performance plays a role in the rate of this complication. For example, more frequent assessment of patient "dry weight" could prevent some hospitalizations related to fluid overload. In general, there was a stable to falling rate in this measure of ESRD complications in both the ETC and comparison groups, yielding a small and non-significant DiD estimate (see **Exhibit 21**).

**Exhibit 21. DiD Impact Estimates for Quality of Care (QoC) 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 and CY 2022 with the pre-ETC period relative to the same difference over time for patients in the comparison group. Cumulative DiD estimate is a weighted average of the yearly DiD estimates (see **Appendix B,** Section B.5) Significance of the DiD impact estimates is indicated for each outcome where * implies significance at the 10 percent level, ** at the five percent level, and *** at the one percent level assuming a two-tailed test. Peritonitis measure is among PD patients. Vascular infection measure is among HD patients. [1]Relative change based on Cumulative (CY 2021 + CY 2022) DiD estimate (before rounding).

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

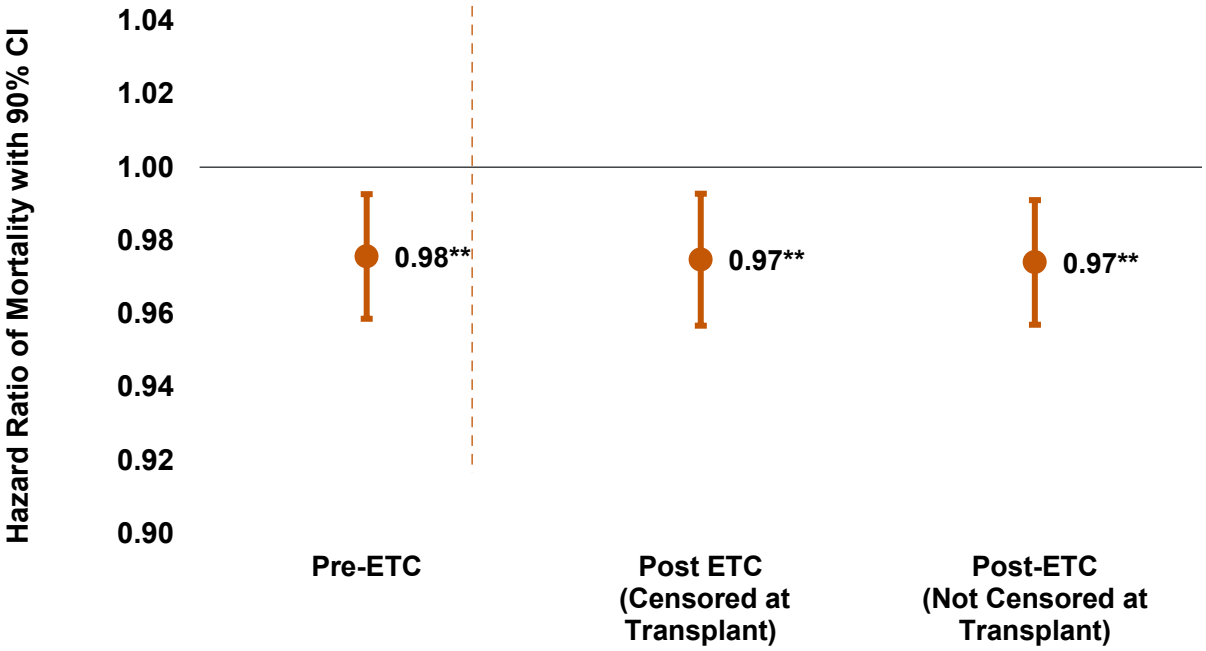
Several observational studies have attempted to compare mortality by dialysis modality. The unadjusted mortality rates are typically lower for home dialysis patients compared to in-center dialysis patients. However, these differences are thought to result, at least in part, from selection bias: home dialysis patients tend to be younger and healthier than in-center patients. There is no

convincing evidence of consistent modality-related differences in mortality after adjustment for patient case mix.[17] Thus, we would not necessarily expect the ETC Model to influence mortality due to home dialysis expansion per se. However, there has been concern about a potential adverse impact of home dialysis expansion associated with changes to patient case-mix. Indeed, CMS monitors the facility standardized mortality and hospitalization ratios (SMR, SHR) for unintended model consequences. The ETC Model also promotes expansion of kidney transplantation. Unlike dialysis modality, there is convincing evidence that transplantation confers a survival advantage. Therefore, a careful evaluation of mortality is justified by the potential impact of the ETC Model on modality case-mix and transplantation events.

Based on a Cox proportional hazards model with adjustments for patient, facility, and market characteristics, patients in ETC areas experienced a small (hazard ratio, HR=0.98) but statistically significant survival advantage during the pre-ETC period (see **Exhibit 22**). A survival advantage of approximately the same magnitude (HR=0.97) and statistical significance was also found for the ETC intervention period, both without and with censoring for transplantation. An analysis of trends in unadjusted death rates revealed increasing mortality for both groups with rates remaining somewhat lower in the ETC group relative to the comparison group during 2017-2022 (see **Appendix D, Exhibit D-1**). The lack of a meaningful difference between the pre-ETC and post-ETC mortality risk indicates that the ETC Model had no effect on mortality – neither protective nor detrimental. The lack of a difference between the two approaches for censoring time at risk indicates that the ETC Model did not stimulate additional transplants sufficient to influence overall survival over the current two-year intervention period (consistent with the ETC transplant findings described in **Section 4.3.3**). The small survival advantage in the ETC group over the comparison group could indicate unmeasured group differences in patient case mix, provider quality, or reporting. In conclusion, we find no evidence of a positive or negative impact on patient survival during the first two years of the ETC Model.

[17] A useful summary can be found in: Perl, J., E. A. Brown, C. T. Chan, C. Couchoud, S. J. Davies, R. Kazancioglu, S. Klarenbach, A. Liew, D. E. Weiner, M. Cheung, M. Jadoul, W. C. Winkelmayer, M. E. Wilkie and P. for Conference (2023). "Home dialysis: conclusions from a Kidney Disease: Improving Global Outcomes (KDIGO) Controversies Conference." Kidney Int 103(5): 842-858.

**Exhibit 22. Risk-adjusted Hazard Ratio of Mortality**




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

### *4.3.7. 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 which we are currently undertaking and will be presented in a subsequent annual report. 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. Like the first annual report (AR1), we use existing ICH CAHPS survey data in our analyses 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 in-center dialyzing patients, we used "top-box" scores, reflecting the highest level of satisfaction (for example, the percent who gave a rating of nine or 10 on a zero to 10 scale) for six measures derived from the ICH CAHPS survey: rating of kidney doctors (global); rating of dialysis center staff (global); rating of dialysis

center (global); nephrologists' communication and caring (composite); quality of dialysis center care and operations (composite); and providing information to patients (composite) (see **Appendix E**). 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 shares between the ETC and comparison groups (see **Appendix E.3**). In the first year of the ETC Model, the share of ESRD facilities with ICH CAHPS data decreased further, with just 47 percent of facilities having ICH CAHPS data in the ETC group and 49 percent in the comparison group. However, the share of ESRD facilities with ICH CAHPS data rebounded slightly in the second year of the model, with 57 percent in both the ETC and comparison groups. Survey response rates also increased in the second year of the model, which partly reflected the increase from 2021 to 2022 in terms of the number of ESRD facilities with ICH CAHPS data (3,530 vs. 4,091, respectively) and of completed surveys (95,643 vs. 122,027, respectively). 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.

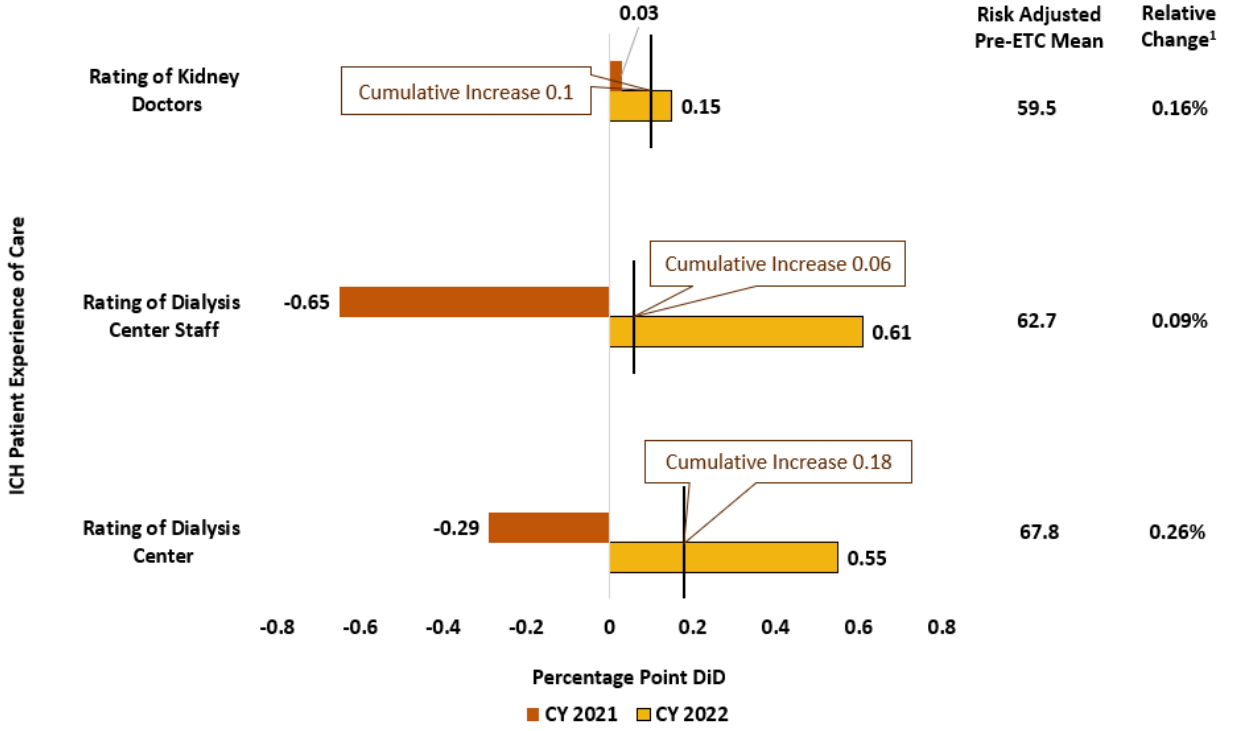
Similar to our previously reported findings,[18] relative to the comparison group, we found no statistically significant impact of the ETC Model on any of the six in-center HD patient experience measures in the post-ETC period, cumulatively or for the individual CY year (see **Exhibits 23** and **24**).[19] A limitation of the analysis was that the sample was based on all patients with ESRD receiving in-center HD at the facility (including patients not covered by the Medicare FFS program) rather than restricting solely to patients attributed to the ETC Model.

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 (that is, those undergoing dialysis at home).

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

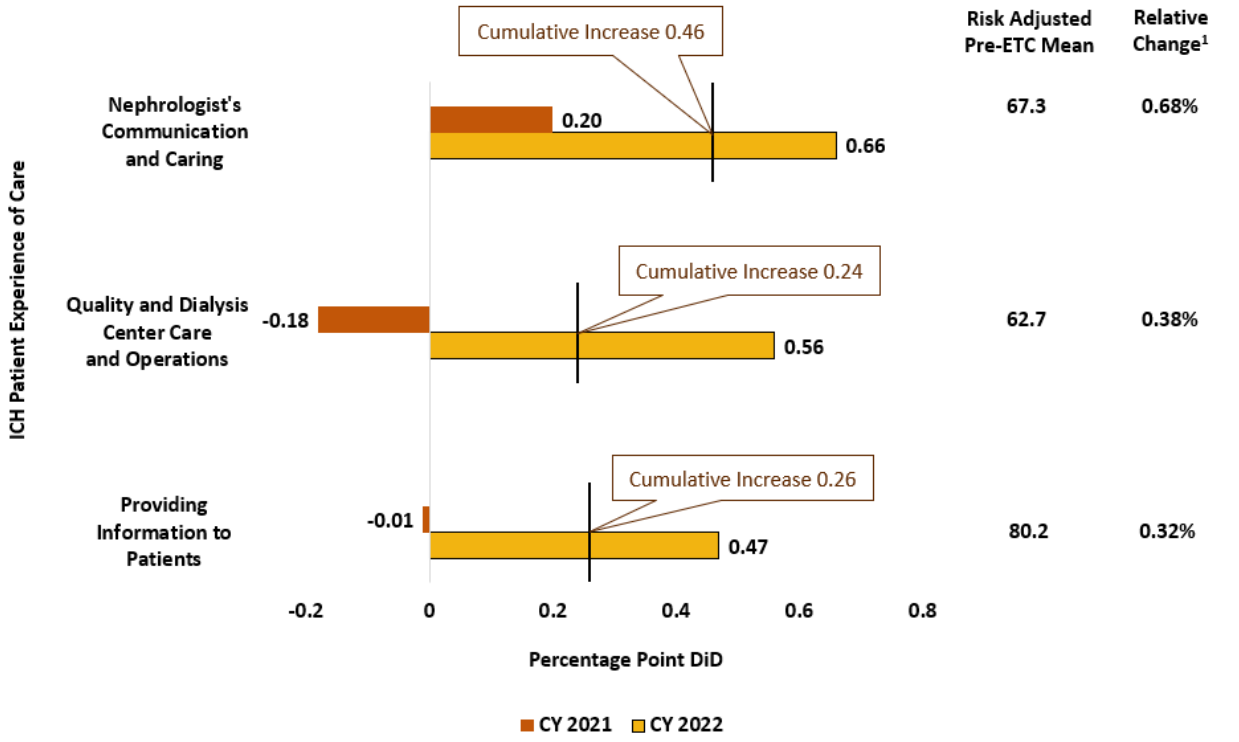
[19] Findings were similar based on DiD analyses that were limited to a subset of facilities with available ICH CAHPS data in both the pre-ETC and post-ETC periods (see **Appendix E**, **Exhibit E-9**).

**Exhibit 23. DiD Impact Estimates for Global 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 and CY 2022 with the pre-ETC period relative to the same difference over time for patients in the comparison group. Cumulative DiD estimate is a weighted average of the yearly DiD estimates (see **Appendix B,** Section B.5) Significance of the DiD impact estimates is indicated for each outcome where * implies significance at the 10 percent level, ** at the five percent level, and *** at the one percent level assuming a two-tailed test. 1Relative change based on Cumulative (CY 2021 + CY 2022) DiD estimate (before rounding).

**Exhibit 24. DiD Impact Estimates for Composite 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 and CY 2022 with the pre-ETC period relative to the same difference over time for patients in the comparison group. Cumulative DiD estimate is a weighted average of the yearly DiD estimates (see **Appendix B**, Section B.5) Significance of the DiD impact estimates is indicated for each outcome where * implies significance at the 10 percent level, ** at the five percent level, and *** at the one percent level assuming a two-tailed test. 1Relative change based on Cumulative (CY 2021 + CY 2022) DiD estimate (before rounding).

## 4.4. Discussion

In the U.S., in-center HD is, and has been over recent decades, 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 health care payments. Transplantation provides a clear survival advantage to patients who meet the waitlist 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. 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. Providers play an important role in facilitating patient awareness and encouragement to seek donors. 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. In short, dialysis providers are positioned to address the behavioral and organizational barriers to alternative treatment options.

As of the second calendar year of the ETC Model, we find that the ETC incentives had little impact on the key outcome measures. Although home dialysis use continued a multi-year growth trend, DiD analysis did not detect statistically significant differences in the rate of growth in ETC areas relative to the comparison group. We found a significant effect of ETC on home dialysis training in CY 2021, a potential early signal of accelerated growth. However, the home training effect was not statistically significant in CY 2022. We looked for but did not find other early signals of ETC impact on home dialysis among new dialysis patients, younger dialysis patients and patients treated in facilities with established home dialysis programs. It is possible that participating ESRD facilities and Managing Clinicians are still developing the staff and infrastructure needed to support additional growth in home dialysis.

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 and our inclusion of both patient- and county-level COVID-19 adjustments in impact analyses, we expect minimal risk of confounding in impact estimates. We will continue to monitor the potential impact of COVID-19 on ETC outcomes.

The start of the ETC Model also coincided with large-scale movement of beneficiaries from the traditional Medicare FFS program to MA plans. Prior to 2021, patients with ESRD were generally only eligible for MA if they were enrolled in plans prior to the onset of ESRD. Starting on January 1, 2021, patients with ESRD have the option of selecting MA plans. The loss of beneficiaries to MA has affected the composition of the FFS population in several aspects including age, race, dual eligibility, and other socioeconomic indicators. Thus far, the population changes have been similar for the ETC and comparison groups.

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. There was a downward trend in overall waitlisting rates (active decreased while inactive increased) in both the ETC and comparison groups. As of CY 2022, there was no difference in the rate of change in waitlisting between the two groups. The overall and active waitlist rates were falling even though dialysis providers face financial incentives to add patients to the waitlist under the ETC Model and the ESRD Quality Incentive Program (QIP).

Expansion of access to transplantation requires steps beyond waitlisting. Key steps for growth in living donor transplantation depend on patient activation and donor support. Thus far, there is no evidence of an ETC impact on living donor transplantation, regardless of whether pre-emptive

transplants are included. There was a statistically significant impact estimate for deceased donor transplants in CY 2021, but not for CY 2022. Given that the ETC Model provides no direct incentive for deceased donor transplantation and there was no observed impact on waitlisting rates, the CY 2021 result appears to have been spurious.

Interviews with a sample of ETC facilities and Managing Clinicians yielded insights that help to provide context for interpreting our quantitative findings. Interview participants identified a focus on home dialysis and transplantation that predated the ETC Model. They viewed implementation of the model as a continuation of prior efforts to increase home dialysis and transplantation rather than leading to a paradigm shift in how they provide care. While facilities did attribute certain changes to the ETC Model involving patient education and communication with transplant centers, Managing Clinicians typically did not attribute recent changes impacting treatment choices to the model. Hence, while the model may have led some ETC Participants to enhance already existing strategies or activities, it did not appear to directly result in widespread changes in their practices at this stage of the model. References to a preexisting focus on encouraging home dialysis and transplant options for patients that is independent of the model may also have implications for other findings, such as the ongoing growth in home dialysis occurring in both the ETC and comparison groups. Impacts attributable to the ETC Model would need to reflect changes that supersede existing efforts to encourage home dialysis and transplantation that are not confined to ETC areas.

Participants also identified a wide range of barriers to home dialysis and transplantation that point to the challenges and the complexity of achieving model goals. The primary barriers to home dialysis that were identified included insufficient space in the home, partner support and transportation to the training center, patient fear of performing home dialysis, and shortages of trained staff. The primary barriers related to transplantation included eligibility requirements, transportation to the transplant center, lack of social support, and patient concerns over health and finances. Participants identified strategies that they use to try to help patients overcome barriers. However, some participants indicated that many of the common barriers to home dialysis and transplantation were difficult to address or overcome with current resources.

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. 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.

Our findings indicate no evidence of the model's impact on acute care hospitalizations or hospital readmissions, despite these being significant components of total Medicare payments for this population. However, there was a favorable a reduction in outpatient ED use among ETC Participants compared to the comparison group throughout the two years of the model. This reduction was primarily driven by the decline in ED use during the second year, CY 2022. The high rate of ED use among dialysis patients presents potential opportunities for intervention and improved management of patients with ESRD. If the ETC Model enhances patient engagement regarding their treatment, there is potential to prevent certain ED visits that might have otherwise occurred. However, in the absence of measurable impacts of the model during CY 2022 on aspects

of care that relate more directly to the model's incentives, it is not clear that the relative decline in ED use in CY 2022 can be attributed to changes in practice that are related to the ETC Model. We will continue to track these and other utilization measures in future reports.

In alignment with our utilization findings, there is currently no early evidence of the model's impact on overall Medicare payments. In this report, we explored potential effects of the model on Part D spending for FFS beneficiaries enrolled in a stand-alone Part D plan. The rate of decline in Part D spending was found to be similar in both groups, indicating no significant change in spending patterns during the initial two years of the Model. This could be attributed, in part, to the absence of direct incentives under the model to reduce overall Medicare payments.

It is important to note that the Medicare payment amounts used in our analyses do not include the application of the ETC payment adjustments. This includes both the HDPA, which represented a three percent and two percent payment adjustment to ETC Participants billing Medicare for home dialysis services during CY 2021 and CY 2022, respectively, and the PPA, which reflected performance-based payment adjustments applied during the second half of CY 2022 that could be positive or negative. Therefore, these findings would only be able to capture any gross savings under the model. In a future analysis, we will account for any additional payments made through a combination of the HDPA and PPA to explore the prospect of net savings.

Changes in transplant rates like those observed in CY 2021 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.

Experience of care for in-center HD patients, based on ICH CAHPS survey data, appeared to be relatively comparable in both ETC and comparison groups. There was no impact of the model on these patient outcomes of perceived QoC. Our analyses for this report 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. To more fully address the ETC Model's impact on patient experience, we will also be surveying patients who dialyze at home and who are therefore more directly impacted by the ETC Model incentives. Analyses of these primary data collection efforts will be based on a cross-sectional survey among patients with ESRD dialyzing at home in both the ETC and comparison groups and presented in the next AR.

## 5. Did the ETC Model Have Implications for Health Equity?

This section summarizes quantitative findings regarding differential impacts of the ETC Model on subgroups of patients with ESRD based on dual eligibility, Part D LIS status, and race and ethnicity. We examined impacts on home dialysis use, transplant waitlisting, overall kidney transplants, living donor kidney transplants, and selected measures of utilization, quality, and Medicare payments in CY 2021 and CY 2022.

## 5.1 Key Findings

**Exhibit 25. Assessment of Differential ETC Model Impacts among Patient Subgroups, CY 2021 – CY 2022**

| Measure | Patient Subgroup | Differential ETC Model Impact by Patient Subgroup[1] |
|---|---|---|
| **Home Dialysis**  | Dually Eligible (Ref: No) | |
| | Yes | |
| | Part D LIS Recipient (Ref: No) | |
| | Yes | |
| | Race/Ethnicity (Ref: White Non-Hispanic) | |
| | Hispanic | |
| | Black[2] | ↓ |
| | Other race[2] | |
| **Waitlisting**  | Dually Eligible (Ref: No) | |
| | Yes | |
| | Part D LIS Recipient (Ref: No) | |
| | Yes | |
| | Race/Ethnicity (Ref: White Non-Hispanic) | |
| | Hispanic | # |
| | Black[2] | |
| | Other race[2] | |
| **Transplantation**  | Dually Eligible (Ref: No) | |
| | Yes | ↓ |
| | Part D LIS Recipient (Ref: No) | |
| | Yes | |
| | Race/Ethnicity (Ref: White Non-Hispanic) | |
| | Hispanic | |
| | Black[2] | |
| | Other race[2] | |

**Key:** **Favorable change relative to reference subgroup at p<0.10** | **Unfavorable change relative to reference subgroup at p<0.10** | **No change relative to reference subgroup**

[1]Based on DDD models that tested for differences in cumulative ETC Model impacts between each subgroup and the reference subgroup when adjusting for patient, facility, and market characteristics. Arrow indicates the direction of the statistically significant DDD estimate. Detailed impact estimates are presented later in this chapter.
[2]Indicates race among non-Hispanic patients. #Due to evidence of non-parallel trends during the pre-ETC period, results from a DDD model indicating a favorable trend in waitlisting among Hispanic patients in ETC areas (relative to comparison areas) likely reflects pre-ETC trends rather than an impact of the ETC Model.

## 5.2 Methods

We specified difference-in-difference-in-differences (DDD) models to assess whether the implications of the model during CY 2021-CY 2022 differed among patients with ESRD based on characteristics that are reflected in the health equity provisions of the ETC Model (dual eligibility and Part D LIS status, as well as race and ethnicity). These models allowed us to compare and test for differences in impact estimates (that is, DiD estimates) among patient subgroups. In specifying these tests, we supplemented the interactions of ETC group and post-ETC indicators in our standard DiD models with a third interaction involving the patient subgroup of interest.

Analyses of ETC Model impacts for dually eligible patients included those with full Medicaid benefits, which is consistent with the definition of dual eligibility used for the ETC Model health y equity provisions.[20] Analyses of impacts by Part D LIS status were limited to patients enrolled in a Part D plan. There was a high level of overlap between dual eligibility and Part D LIS status; among dually eligible patients in ETC areas who were enrolled in a Part D plan, 99.7 percent were also recipients of the Part D LIS, while only 42.4 percent of non-dually eligible patients in ETC areas were recipients of the Part D LIS (see **Appendix B, Exhibit B-22**). Among Medicare beneficiaries without ESRD, only 28.3 percent are recipients of the Part D LIS.[21] As with the impact analyses presented in **Section 4**, patient race and ethnicity were based primarily on data reported on the CMS ESRD Medical Evidence Form, which collects patient-reported race and ethnicity data for individuals with ESRD. Racial and ethnic minorities were more likely to be dually eligible and recipients of the Part D LIS (see **Appendix B, Exhibits B-23** and **B-24**).

For the health equity analyses, we examined a subset of impact measures that were either highly relevant to the design of the model, potentially important indicators of patient well-being or resource use, or reflect past evidence of disparities. These impact measures included home dialysis use, waitlisting, overall transplantation, living donor transplantation, acute care hospitalization, hospital readmission, peritonitis among patients using PD, and Medicare Parts A & Part B payments PPPM.

The primary analyses were adjusted for the same set of patient, facility, and market characteristics as the overall impact analyses described in **Section 4**. This approach allowed us to account for the same potential confounders when estimating impacts for specific subgroups of patients while also being able to directly relate the results to those of our overall impact analyses. However, since one of our objectives is to evaluate whether the ETC Model has had an impact on disparities, we also explored whether the results of these analyses are sensitive to the risk adjustment approach that is used. A potential disadvantage of using a more fully adjusted model to assess disparities is that it may include adjustments for factors (such as socioeconomic indicators) that are sources of disparities between subgroups that we would want to capture. For example, when controlling for dual eligibility when comparing ETC Model impacts by race and ethnicity, we are estimating

[20] 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.

[21] United States Renal Data System. 2022 *USRDS Annual Data Report: Epidemiology of kidney disease in the United States.* National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2022.

differences between racial and ethnic groups that are not related to dual eligibility and testing whether these differences change due to the ETC Model.

To explore whether our findings are sensitive to the risk adjustment approach that is used, we also performed similar DDD analyses using a more parsimonious set of factors as covariates that are largely measured at the onset of ESRD and may be associated with patient outcomes but would not be expected to strongly reflect disparities in ESRD patient care. These factors included patient age, sex, primary cause of ESRD, comorbidities reported at onset of ESRD, body mass index at onset of ESRD, and duration of ESRD. These analyses included no adjustments for other patient characteristics or for any facility or market characteristics.

For further details regarding our analytic approach for the health equity analyses and tests of the parallel trends assumption for the subgroups of interest for these analyses, see **Appendix B, Section B.6**.

## 5.3 Results

Approximately one third of patients were dually eligible and approximately two thirds of patients enrolled in a Part D plan were recipients of the Part D LIS (see **Appendix B, Exhibit B-11** for details). Through the first two years of the ETC Model, there was no evidence of differential effects on home dialysis use based on either dual eligibility or receipt of the Part D LIS (see **Exhibit 26**). Prior to the start of the ETC Model, there was lower use of home dialysis among both dually eligible patients and Part D LIS recipients in ETC areas, which are 4.4 and 5.4 percentage points lower compared to patients who were not dually eligible and not recipients of the Part D LIS, respectively (see **Exhibit 26**). However, these gaps appeared to remain relatively stable over time, as indicated by the not statistically significant DDD estimates for these subgroups.

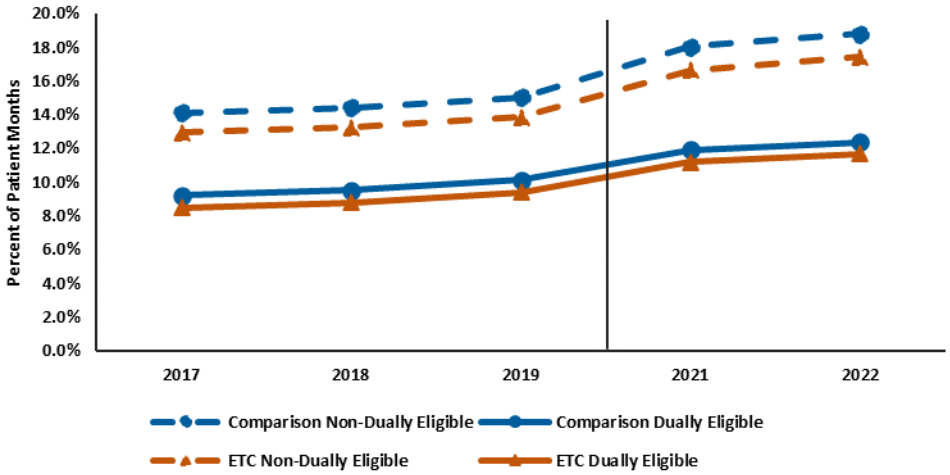
**Exhibit 26. Health Equity DDD Model Impact Estimates for Home Dialysis Use, CY 2021 – CY 2022**

| Patient Subgroup | | Cumulative DiD[1] | % Relative Change | DDD[1] (vs. Ref group) | Pre-ETC Gap in ETC areas (vs. Ref group) | % Change in Pre-ETC Gap |
|---|---|---|---|---|---|---|
| Dually Eligible[2] | Yes | 0.02 | 0.24% | 0.23 | -4.4% | -5.2% |
| | No (Ref) | -0.21 | -1.6% | - | - | - |
| Part D LIS Recipient | Yes | -0.10 | -1.1% | 0.01 | -5.4% | -0.14% |
| | No (Ref) | -0.11 | -0.74% | - | - | - |
| Race and Ethnicity | Hispanic[3] | 0.14 | 1.4% | -0.25 | -4.1% | 6.1% |
| | Black[4] | -0.38 | -4.5% | -0.78* | -6.1% | 12.7% |
| | Other race[4] | -0.93 | -8.4% | -1.3 | -3.7% | 35.6% |
| | White (Ref)[4] | 0.39 | 2.7% | - | - | - |

**Notes:** Ref corresponds to reference subgroup. Results are based on DDD models of cumulative impacts in CY 2021 and CY 2022, with adjustment for patient, facility, and market characteristics. DDD estimates correspond to the relative impact of the ETC Model for the patient subgroup relative to the reference subgroup. The pre-ETC period includes CY 2017 – CY 2019. The pre-ETC gap in ETC areas corresponds to the difference in pre-ETC means between the patient subgroup and the reference subgroup while adjusting for patient, facility, and market characteristics. Analyses of Part D LIS recipients are limited to patients enrolled in Part D. [1]Corresponds to percentage point change. [2]Includes dually eligible beneficiaries with full Medicaid benefits. [3]Among Hispanic patients, race was reported as White for 94.1% of patient months, Black for 1.9%, and Other race for 4.0%. [4]Indicates race among non-Hispanic patients. *Indicates statistical significance of DiD or DDD estimate at p-value <0.1.

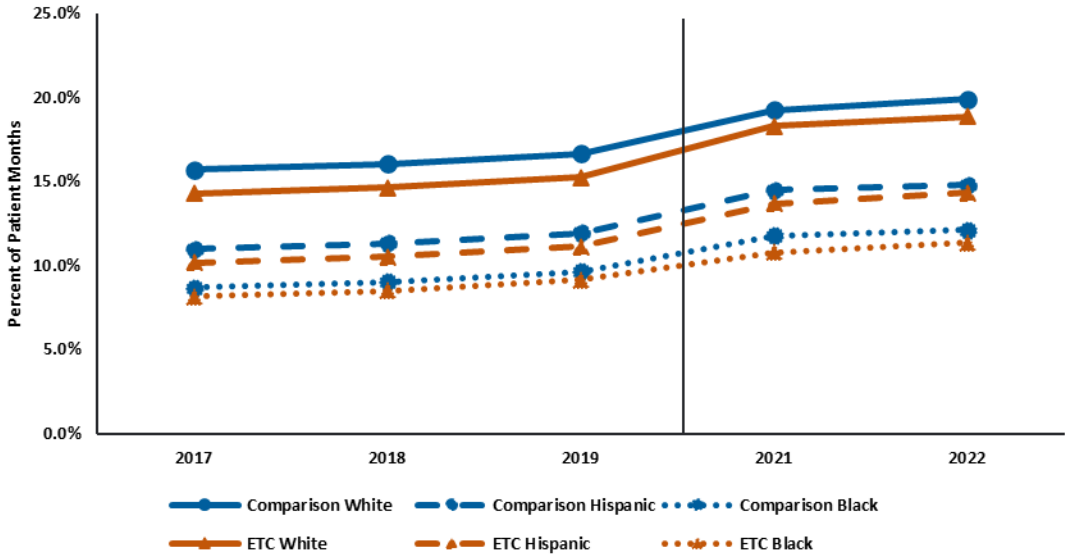
To evaluate relative trends among patient subgroups separately in the ETC and comparison areas, we also utilized plots of risk-adjusted trends in home dialysis use. As illustrated in **Exhibit 27**, there were similar upward trends in home dialysis use among dually eligible and non-dually eligible patients in both ETC and comparison areas.

**Exhibit 27. Adjusted Trends in Home Dialysis Use by Patient Dual Eligibility, for ETC and Comparison Areas, CY 2017 – CY 2022**




We performed similar analyses by patient race and ethnicity. In the ETC and comparison areas during the pre-ETC and post-ETC periods, approximately 41 to 46 percent of patients were White non-Hispanic, 29 to 39 percent were Black non-Hispanic, 11 to 18 percent were Hispanic, and 7 to 9 percent were Other race non-Hispanic (see **Appendix B, Exhibit B-11** for details). There was growth in home dialysis use across racial and ethnic subgroups in both ETC and comparison areas. These trends are shown in **Exhibit 28** for Black non-Hispanic, Hispanic, and White non-Hispanic patients. Results from the DDD model indicate that the gap between Black and White non-Hispanic patients, which was 6.1 percentage points during the pre-ETC period, was 0.78 percentage points larger under the ETC Model (see **Exhibit 26**). Home dialysis use continued to be lower for Black non-Hispanic patients in both ETC and comparison areas. The gaps in home dialysis use for Hispanic and Other race patients relative to White non-Hispanic patients appeared to be relatively stable through the first two years of the model, based on not statistically significant DDD estimates for these race/ethnicity subgroups (see **Exhibit 26**).

**Exhibit 28. Adjusted Trends in Home Dialysis Use by Patient Race and Ethnicity, for ETC and Comparison Areas, CY 2017 – CY 2022**




There was no pattern of the ETC Model affecting waitlisting rates differently for historically underserved groups (see **Exhibit 29**). Both DDD estimates and subgroup-specific cumulative DiD estimates were generally not statistically significant. The only exception was for Hispanic patients, for whom there was an increase in waitlisting rates in ETC areas relative to the comparison areas. However, when testing the parallel trends assumption of the model, there was evidence of nonparallel pre-ETC trends for the Hispanic patient subgroup indicating that the relative gains in waitlisting for Hispanic patients began prior to the implementation of the ETC Model. We therefore caution against attributing the measured improvement in waitlisting for Hispanic patients in **Exhibit 29** to the ETC Model.

**Exhibit 29. Health Equity DDD Model Impact Estimates for Waitlisting, CY 2021 – CY 2022**

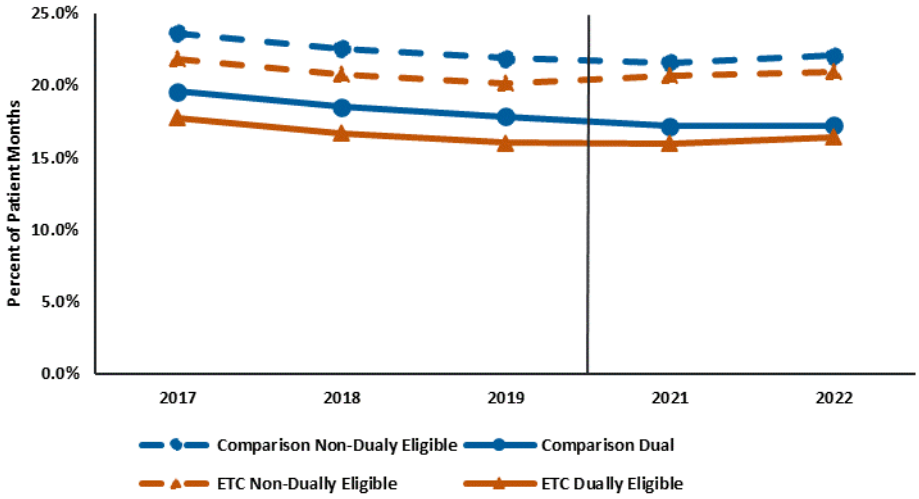
| Patient Subgroup | | Cumulative DiD[1] | % Relative Change | DDD[1] (vs. Ref group) | Pre-ETC Gap in ETC areas (vs. Ref group) | % Change in Pre-ETC Gap |
|---|---|---|---|---|---|---|
| Dually Eligible[2] | Yes | 0.82 | 4.9% | 0.06 | -4.1% | -1.5% |
| | No (Ref) | 0.76 | 3.6% | - | - | - |
| Part D LIS Recipient | Yes | 0.85 | 5.2% | 0.13 | -6.3% | -2.1% |
| | No (Ref) | 0.72 | 3.2% | - | - | - |
| Race and Ethnicity | Hispanic | 2.0** | 10.3% | 1.3*^ | 1.9% | 67.6% |
| | Black[3] | 0.40 | 2.0% | -0.35 | 2.0% | -17.7% |
| | Other race[3] | -0.51 | -2.4% | -1.3 | 3.7% | -34.0% |
| | White (Ref)[3] | 0.75 | 4.2% | - | - | - |

**Notes:** Ref corresponds to reference subgroup. Results are based on DDD models of cumulative impacts in CY 2021 and CY 2022, with adjustment for patient, facility, and market characteristics. DDD estimates correspond to the relative impact of the ETC Model for the patient subgroup relative to the reference subgroup. The pre-ETC period includes CY 2017 – CY 2019. The pre-ETC gap in ETC areas corresponds to the difference in pre-ETC means between the patient subgroup and the reference subgroup while adjusting for patient, facility, and market characteristics. Analyses of Part D LIS recipients are limited to patients enrolled in Part D. [1]Corresponds to percentage point change. [2]Includes dually eligible beneficiaries with full Medicaid benefits. [3]Indicates race among non-Hispanic patients. *Indicates statistical significance of DiD or DDD estimate

at p-value <0.1. **Indicates statistical significance of DiD or DDD estimate at p-value <0.05. ^Based on evidence of non-parallel trends during the pre-ETC period, this DDD estimate likely reflects relative pre-ETC trends.

With no clear impact of the ETC Model on waitlisting rates among patient subgroups, the observed gaps in waitlisting that predated the ETC Model largely persisted during the first two years of the model. For example, risk-adjusted waitlisting rates remained approximately five percentage points lower for dually eligible patients than non-dually eligible patients, in both ETC and comparison areas (see **Exhibit 30**). For all four patient groups, waitlisting rates declined somewhat between 2017 and 2019, and then stabilized or increased slightly in 2021-2022. Based on the figures, it appears that waitlisting rates were converging somewhat between the ETC and comparison areas in the post-intervention period, but as shown in **Exhibit 30** the dually eligible and non-dually eligible subgroup DiD estimates were not statistically significant.

**Exhibit 30. Adjusted Trends in Waitlisting by Patient Dual Eligibility, for ETC and Comparison Areas, CY 2017 – CY 2022**




Given the goals of the ETC Model to encourage both greater use of kidney transplantation and greater equity in transplantation, we examined potential impacts of the model on overall rates of transplantation among underserved patients, including both deceased donor and living donor transplants. Having observed an overall increase in transplant rates in ETC areas relative to comparison areas (as described in Section 4.3.3, there were also increases among some patient subgroups. The overall results reflected relative growth in transplant rates among patients who are not dually eligible, not recipients of the Part D LIS, Hispanic, and White non-Hispanic (see **Exhibit 31**). These increases did not appear to be driven by relative gains in waitlisting among these subgroups, based on the results for waitlisting described above. As with the overall results, the relative growth in transplants among these subgroups may not relate directly to the ETC Model incentives, as discussed in Section 4).

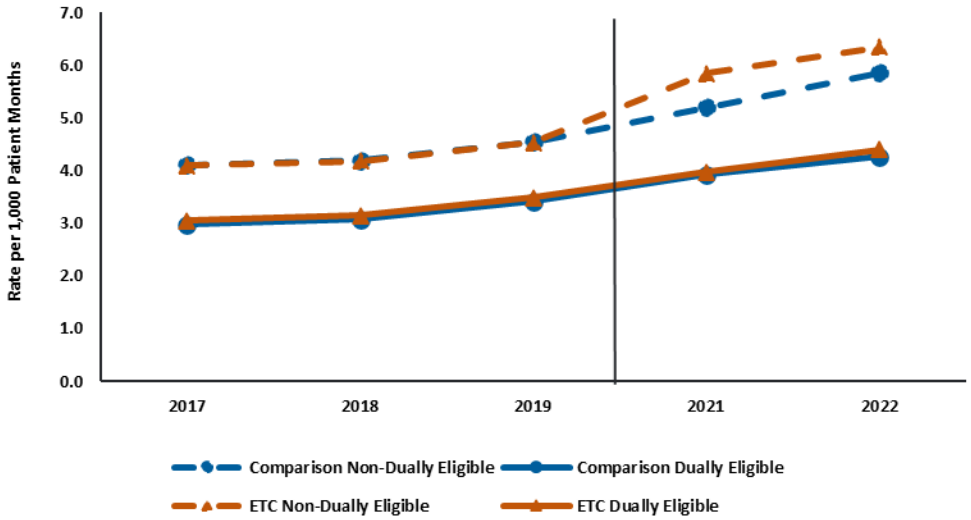
**Exhibit 31. Health Equity DDD Model Impact Estimates for Transplantation, CY 2021 – CY 2022**

| Patient Subgroup | | Cumulative DiD[1] | % Relative Change | DDD[1] (vs. Ref group) | Pre-ETC Gap in ETC areas (vs. Ref group)[1] | % Change in Pre-ETC Gap |
|---|---|---|---|---|---|---|
| Dually Eligible[2] | Yes | 0.02 | 0.6% | -0.57** | -1.0 | 54.4% |
| | No (Ref) | 0.59** | 13.7% | - | - | - |
| Part D LIS Recipient | Yes | 0.16 | 5.3% | -0.27 | -1.7 | 16.2% |
| | No (Ref) | 0.44* | 9.2% | - | - | - |
| Race and Ethnicity | Hispanic | 0.77** | 17.6% | 0.47 | 0.34 | 137.7% |
| | Black[3] | 0.21 | 6.0% | -0.10 | -0.64 | 15.3% |
| | Other race[3] | 0.58 | 13.7% | 0.27 | 0.15 | 176.9% |
| | White (Ref)[3] | 0.30* | 7.5% | - | - | - |

**Notes:** Ref corresponds to reference subgroup. Results are based on DDD models of cumulative impacts in CY 2021 and CY 2022, with adjustment for patient, facility, and market characteristics. DDD estimates correspond to the relative impact of the ETC Model for the patient subgroup relative to the reference subgroup. The pre-ETC period includes CY 2017 – CY 2019. The pre-ETC gap in ETC areas corresponds to the difference in pre-ETC means between the patient subgroup and the reference subgroup while adjusting for patient, facility, and market characteristics. Analyses of Part D LIS recipients are limited to patients enrolled in Part D. [1]Corresponds to transplants per 1,000 patient months. [2]Includes dually eligible beneficiaries with full Medicaid benefits. [3]Indicates race among non-Hispanic patients. *Indicates statistical significance of DiD or DDD estimate at p-value <0.1. **Indicates statistical significance of DiD or DDD estimate at p-value <0.05.

The increase in transplant rates among non-dually eligible patients was statistically different from the change for dually eligible patients and adds to the pre-existing gap in transplant rates based on dual eligibility (see **Exhibit 31**). There was growth in risk-adjusted transplant rates over time among both dually eligible and non-dually eligible patients, in both ETC and comparison areas (see **Exhibit 32**). However, during the first two years of the model, there was a somewhat steeper rate of growth among non-dually eligible patients in ETC areas that was not occurring to the same degree in the comparison areas, which led to a widening of the gap in transplant rates by dual eligibility in ETC areas. Based on the model's incentives, changes in waitlisting represent the mechanism by which any changes in deceased donor transplant rates would be expected. Since there were no relative gains in waitlisting for non-dually eligible patients due to the ETC Model, the widening gap in overall rates of transplantation (including both deceased donor and living donor transplants) may not be a consequence of the model.

**Exhibit 32. Adjusted Trends in Transplant Rates by Patient Dual Eligibility, for ETC and Comparison Areas, CY 2017 – CY 2022**




While changes in overall transplant rates among underserved patients are of interest given the goal of the ETC Model to encourage both greater use of kidney transplantation overall and greater equity in transplantation, we also examined changes in living donor transplant rates given the nature of the ETC Model incentives which focus specifically on waitlisting and living donor transplantation. Similar to the overall impact analyses, there was no evidence that the model led to a change in living donor transplant rates among patient subgroups (see **Exhibit 33**). There was a gain for non-dually eligible patients relative to dually eligible patients (see **Exhibit 33**), which is similar to the pattern observed above for overall transplants. However, unlike overall transplant rates, this result did not reflect growth in living donor transplants among non-dually eligible patients in ETC areas relative to the comparison areas, since the DiD estimate for non-dually eligible patients was not statistically significant (see **Exhibit 33**).

**Exhibit 33. Health Equity DDD Model Impact Estimates for Living Donor Transplantation, CY 2021 – CY 2022**

| Patient Subgroup | | Cumulative DiD[1] | % Relative Change | DDD[1] (vs. Ref group) | Pre-ETC Gap in ETC areas (vs. Ref group)[1] | % Change in Pre-ETC Gap |
|---|---|---|---|---|---|---|
| Dually Eligible[2] | Yes | -0.06 | -13.0% | -0.12* | -0.3 | 46.1% |
| | No (Ref) | 0.06 | 8.5% | - | - | - |
| Part D LIS Recipient | Yes | -0.02 | -4.2% | -0.11 | -0.4 | 30.7% |
| | No (Ref) | 0.09 | 11.8% | - | - | - |
| Race and Ethnicity | Hispanic | 0.08 | 11.6% | 0.12 | -0.14 | -89.0% |
| | Black[3] | 0.04 | 12.5% | 0.09 | -0.47 | -18.9% |
| | Other race[3] | 0.08 | 16.4% | 0.12 | -0.36 | -33.5% |
| | White (Ref)[3] | -0.04 | -5.4% | - | - | - |

**Notes:** Ref corresponds to reference subgroup. Results are based on DDD models of cumulative impacts in CY 2021 and CY 2022, with adjustment for patient, facility, and market characteristics. DDD estimates correspond to the relative impact of the ETC Model for the patient subgroup relative to the reference subgroup. The pre-ETC period includes CY 2017 – CY 2019. The pre-ETC gap in ETC areas corresponds to the difference in pre-ETC means between the patient subgroup and the reference subgroup while adjusting for patient, facility, and market characteristics. Analyses of Part D LIS recipients are limited to

patients enrolled in Part D. [1]Corresponds to transplants per 1,000 patient months. [2]Includes dually eligible beneficiaries with full Medicaid benefits. [3]Indicates race among non-Hispanic patients. *Indicates statistical significance of DiD or DDD estimate at p-value <0.1.

In considering whether the ETC Model has implications for health equity, it is important to consider other important outcomes among patients with ESRD beyond those aspects of ESRD care that relate directly to the model's incentives. We therefore also examined changes in measures of acute care hospitalizations, readmissions, peritonitis among PD patients, and total Medicare Parts A & B payments PPPM. Broadly, there was not a pattern of the ETC Model leading to differential changes in these measures for underserved patients. DDD estimates were generally not statistically significant across patient subgroups (see **Appendix B, Exhibits B-25 – B-28**, for detailed results). The exceptions do not indicate a pattern of differential impacts across either subgroups or measures. The DDD models pointed to a smaller decline in acute care hospitalizations for Part D LIS recipients and a relative increase in readmissions and Medicare payments PPPM for patients with Other race under the model. Other DDD estimates were not statistically significant for these measures. Overall, the results of these analyses do not suggest an important shift in utilization, quality, or Medicare spending for underserved patients relative to other patients due to the ETC Model.

While the analyses presented in this section examined cumulative impacts of the model during its first two years, we also explored whether the observed impacts appeared to shift between the first year of the model and the second year when the health equity provisions went into effect. However, the overall patterns described above in the relative impacts by patient subgroup were generally similar when examining impacts during each year.

From the perspective of evaluating disparities, we also explored analyses with a limited set of covariates to avoid controlling for factors that may be sources of disparities in ESRD patient care. Adjustments were limited to age, sex, duration of ESRD, and clinical conditions at onset of ESRD. The results of the DDD models described above were generally not sensitive to the use of a more parsimonious risk adjustment approach. There were two instances where the statistical significance of a cumulative DDD estimate for home dialysis use, waitlisting, overall transplantation, or living donor transplantation changed with the limited risk adjustments: for home dialysis use, the DDD estimate for Black non-Hispanic patients was no longer statistically significant; and for waitlisting, the DDD estimate for Hispanic patients was no longer statistically significant.

## 5.4 Discussion

In our initial analyses of the potential implications of the ETC Model for health equity, we did not observe a pattern of changes in ESRD patient care and outcomes that would suggest historically underserved populations are experiencing either disproportionate gains or losses under the model. Our comparisons of patient subgroups defined based on dual eligibility, receipt of the Part D LIS, and race and ethnicity did not indicate a differential impact of the model across most subgroups and measures. There was instead a pattern of pre-existing differences among subgroups that had so far largely persisted. This pattern included lower use of home dialysis among dually eligible, Part D LIS, Hispanic, and Black non-Hispanic patients. This pattern also included lower waitlisting and transplant rates among dually eligible and Part D LIS beneficiaries. These analyses reflect experience from the first two years of the model and from the first year in which the model's health equity provisions were in effect.

It will be important to consider the implications of the ETC Model for health equity throughout this evaluation, for multiple reasons. Through changes in how the performance of ETC Participants is measured with respect to dually eligible patients and Part D LIS recipients starting in CY 2022, the model also established incentives that are designed to promote greater equity in home dialysis and transplantation. In the context of incentives to encourage overall greater use of home dialysis and transplantation, however, a potential unintended consequence is that there could be smaller gains under the model for underserved populations. Factors that have historically represented barriers to home dialysis and transplantation for underserved populations could also limit gains under the model for some patients and lead to widening inequities in care.

There were preexisting gaps in home dialysis use based on both indicators of patient SES as well as race and ethnicity that largely persisted during the first two years of the model. This includes a 4 to 6 percentage point lower use of home dialysis among dually eligible patients and Part D LIS recipients, a 4 to 5 percentage point gap for Hispanic patients, and a 6 to 7 percentage point gap for Black patients (both relative to White non-Hispanic patients). With the ETC health equity provisions in place during the second year of the model, there was no evidence of accelerated growth in home dialysis use among these historically underserved groups in ETC areas. More time may be needed for ETC Participants to mobilize greater staff time and resources towards home dialysis programs in ways that begin to address longstanding inequities.

Persistent gaps in home dialysis use may also indicate the nature of some of the challenges in overcoming barriers to the use of home dialysis, which may, in some cases, contribute to inequities in home dialysis use. Among the barriers to home dialysis that were identified by ESRD facility staff and Managing Clinicians during the semi-structured interviews that were conducted during 2023 (see **Section 3**), respondents referred to a lack of space in the home to perform home dialysis or store supplies and a lack of transportation to a training facility. Previous studies have found PD to be more commonly used among patients who had family support or were not living alone.[22, 23, 24] For some patients, there may be barriers to the use of home dialysis that are not readily within the control of ESRD providers or more difficult to overcome.

Through the second year of the model and the first year in which the model's health equity provisions were in effect, there was no evidence of relative gains in either waitlisting or transplantation for underserved populations that would mitigate pre-existing inequities. Lower waitlisting and transplant rates among dually eligible patients and Part D LIS recipients that predated the ETC Model largely persisted. Our interviews with facilities and Managing Clinicians identified some barriers to transplantation that are likely to be more common for underserved populations, and particularly for patients with limited financial resources. Some facilities and Managing Clinicians referred to strategies that they have employed to address such barriers, including engaging patient navigators to provide education, and assisting patients with transportation issues. The results of our analyses do not suggest that such efforts have led to

[22] Stack AG. 2002. Determinants of modality selection among incident US dialysis patients: Results from a national study. J Am Soc Nephrol 13(5): 1279–1287.

[23] Oliver MJ, Garg AX, Blake PG, Johnson JF, Verrelli M, Zacharias JM, Pandeya S, Quinn RR. 2010. Impact of contraindications, barriers to self-care and support on incident peritoneal dialysis utilization. Nephrol Dial Transplant 25(8): 2737–2744.

[24] Prakash S, Perzynski AT, Austin PC, Wu CF, Lawless ME, Paterson JM, Quinn RR, Sehgal AR, Oliver MJ. 2013. Neighborhood socioeconomic status and barriers to peritoneal dialysis: A mixed methods study." Clin J Am Soc Nephrol 8:1741–1749.

targeted gains in overall waitlisting rates or transplant rates among patients with lower incomes, as indicated by dual eligibility and Part D LIS status.

Input obtained from patients for this evaluation also provided insights on potentially important barriers to home dialysis and transplantation that may have implications for health equity. Through the PAG that the Lewin Team convened to provide patient perspectives on the ETC and KCC Models, a lack of sufficient education on dialysis and transplant modalities to support patient decision making about their treatment was identified by PAG members as a common theme. In addition, concerns were raised from PAG members about the need for additional follow-up with patients after referral for transplant evaluation. These patient perspectives point to a need for additional information and support regarding treatment options which could be more acute for underserved patients.

Some facility and Managing Clinician respondents referred to practices that they are using to increase uptake of both home dialysis and transplantation which may be especially beneficial for underserved patients. However, as discussed in **Section 3**, neither facility staff nor Managing Clinicians typically identified changes they had made to increase health equity specifically in response to the ETC Model. Instead, some facility respondents referred to relevant strategies that were already in place or focusing more generally on trying to meet the needs of underserved populations. Similarly, Managing Clinician respondents did not point to practices that were specifically designed to improve health equity under the model, and instead focused on ensuring that options were offered to all patients.

The insights provided by samples of ETC Participants align with our quantitative findings to date which do not provide early evidence of changes in practice specifically in response to the model's health equity incentives in ETC areas. Given how recent and novel the health equity provisions of the model are, and also considering the nature and range of the barriers identified by both facility and Managing Clinicians, it stands to reason that more time is needed to determine whether the model can achieve greater equity in home dialysis and transplantation. If the model has the effect of contributing to greater awareness among providers of the types of barriers facing historically underserved patients and a greater focus or success in helping patients address these barriers, there is potential for future gains in equity. Later in this evaluation, we plan to gather information from dialysis patients through interviews that may help us to better understand barriers to home dialysis and transplantation under the model from the perspective of patients, and we will consider whether such barriers may have implications for health equity.

## 6. Discussion

The ETC Model design is a randomized selection process and mandatory participation of both ESRD facilities and Managing Clinicians, which provides a strong foundation for evaluating the effects of the model. The selection process yielded a geographically broad and diverse sample for the intervention. There was a high overall level of balance between ETC areas and the areas not selected for the model (that is, Comparison Geographic Areas) on a wide range of factors. 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 HRRs not selected for the ETC Model, which leverages the random selection and mandatory design components of the 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 two years of the model in the ETC areas relative to the comparison group. The DiD approach was supported as a robust evaluation strategy based on comparisons of pre-ETC trends in outcomes between the two groups that showed parallel trends in the pre-ETC period for the vast majority of outcomes.

AR2 summarizes ETC Model results at the two-year mark for a model with a planned six- and one-half year implementation period (through June 30, 2027). The ETC Model establishes financial incentives for participating ESRD facilities and Managing Clinicians to expand home dialysis, transplant waitlisting and living donor kidney transplantation. The incentive periods and two types of payment adjustments under the model were both in effect as of July 2022, when the initial PPAs were applied and certain payments to participating ESRD facilities and Managing Clinicians were adjusted either upward or downward based on their performance on home dialysis and transplant measures. Although there was overall growth in home dialysis and transplantation, there is little evidence that ETC Model incentives are contributing to these trends.

Growth in home dialysis in the ETC and comparison groups was similar through the first two years of the model. This includes recent growth for both PD and HHD. While there was a higher rate of growth in the frequency of home dialysis training in the first year of the model, which might suggest an early signal of a model impact on home dialysis use, this higher rate of growth did not continue into the model's second year and did not translate into subsequent differential growth in home dialysis use. In exploring other potential early indicators of an ETC Model impact, there was no evidence of accelerated growth in home dialysis use in ETC areas among patients and facilities for whom early gains may have occurred more readily, including new dialysis patients, younger dialysis patients, or patients treated at facilities with larger, established home dialysis programs.

Our ETC Model findings cover the years from 2017 through 2022. In fact, home dialysis has been growing at a slow but steady rate since 2010, following a long period of decline. The start of the current growth phase coincides with the introduction of the current Medicare ESRD prospective payment system, which eliminated some of the financial incentives that favored in-center hemodialysis. The overall growth rate of approximately 0.5 percentage points/year reflects patient availability and provider capacity. Further, the expansion of home dialysis capacity requires time to grow infrastructure, especially nursing and medical staff with the training and level of interest needed for a successful program. Given the clinical complexity of the patient population and the need for development of home dialysis infrastructure, it is too early to form conclusions about the long-term effects of the ETC Model incentives in driving further home dialysis expansion.

With respect to transplantation, there was also no evidence through the first two years of the model of an impact on either waitlisting rates or living donor transplant rates, which are both a specific focus of the ETC Model incentive structure. There was evidence of faster growth in overall transplant rates in ETC areas relative to comparison areas that reflects increased rates of deceased donor transplants. However, this growth was concentrated in the first year of the model and was not accompanied by an increase in waitlisting rates which would presumably be the mechanism through which the model would affect the frequency of deceased donor transplants. In addition, an attributable ETC Model effect would be expected to strengthen over time with increasing financial incentives and further development of dialysis provider infrastructure and partnerships to support transplantation. For now, we conclude that the initial relative growth in deceased donor transplants and overall transplants in ETC areas that was limited to CY 2021 is not likely to be a result of the ETC Model incentives. It is expected that impacts related to transplantation will be clarified as implementation of the model continues.

For AR2, we gained insights on the perspectives and experience of ETC Participants in implementing the model that also provide context for interpreting results of the quantitative analyses. Our semi-structured interviews with samples of facilities and Managing Clinician participating in the ETC Model did not indicate a major shift in behavior in response to the model's incentives. Facility staff attributed certain types of changes to the model that included enhancing patient education and communication with transplant centers. In contrast, Managing Clinicians did not typically attribute specific changes to the model. During interviews, facilities and Managing Clinicians also identified some strategies to address barriers to home dialysis and transplantation. These qualitative findings align with our quantitative findings, which do not provide evidence of the effects of widespread, early changes in practices that are specific to ETC Participants.

Together, the quantitative and qualitative data also suggest a growing emphasis on home dialysis and transplant options that predated or may have been independent of the ETC Model. There was recent growth in home dialysis and transplant rates in both ETC and comparison areas through the first two years of the model. In interviews, ETC Participants described robust patient engagement efforts to inform patients of dialysis modality and transplant options, with most patient engagement and education strategies predating model implementation. If the ETC Model is being perceived as part of a broader movement to place greater emphasis on facilitating home dialysis and transplantation as successful options for patients, this may be a signal that we may not expect changes in practice to be confined to ETC areas. A limitation of this study is that the perspectives of facilities and clinicians outside the ETC areas are not known since they were not included in the interviews.

In the context of these findings related to home dialysis and transplantation, there was also no pattern of changes in key utilization and payment outcomes. There were no model impacts on either acute care hospitalizations or hospital readmissions, which are both relatively common among patients with ESRD. There was a relative decline in outpatient ED use in ETC areas relative to the comparison areas in the second year of the model only; whether this pattern continues in subsequent years of the model will be the subject of a future analysis. As in AR1, DiD analyses continue to indicate no change in overall Medicare payments among dialysis patients due to the ETC Model. Since the payment amounts in ETC areas do not reflect the additional payments made to model participants through a combination of the HDPA (in both CY 2021 and CY 2022) and the

PPA (latter half of CY 2022 only), these results suggest that the model was not budget neutral overall in its first two years. In future analyses, we will account for effects of the HDPA and the PPA to provide a more complete assessment of the budgetary impact of the model. As a new analysis for this report, we explored whether there were changes in potential indicators of dialysis patient QoC that involve a range of clinical complications and other important patient outcomes, and found no measurable impact of the model. More generally, there was no early evidence of adverse unintended impacts of the model, which will continue to be an important area of focus for the evaluation.

In exploring whether there were early impacts of the model's health equity provisions which were in effect starting in CY 2022, there was not a strong pattern of differential impacts of the model on home dialysis use, waitlisting, and transplantation involving historically underserved populations. Our analyses do not suggest that underserved groups were systematically at either an advantage or a disadvantage under the ETC Model during its first two years. Instead, there was a pattern of preexisting gaps in home dialysis or transplantation among patients based on dual eligibility, Part D LIS status, and race and ethnicity that largely persisted during the first two years of the model. Among the potential barriers to home dialysis and transplantation that were identified by facilities and Managing Clinicians during interviews and by patients participating in the Patient Advisory Group, many barriers were more prevalent among underserved patients. Given how recent and novel the health equity provisions of the model are, and the barriers that may have contributed to past inequities in home dialysis and transplantation, it is reasonable to expect that more time will be needed to determine whether gains in equity can be achieved under the model.

While the evaluation findings in this report are based on two years of experience with the model, we caution that it is still early to form conclusions about possible longer-term impacts of the model. ETC Participants may continue to adapt their practices and learn from ongoing efforts to encourage use of home dialysis and transplantation as successful options for patients. This may be important in a context where facilities and Managing Clinicians identify a wide range of barriers to home dialysis and transplantation that may vary substantially from patient to patient. Also, the second year of the model included key milestones, as the health equity provisions of the model went into effect starting on January 1, 2022, and the initial PPAs were applied to certain payments to facilities and Managing Clinicians starting on July 1, 2022. Responses to the model may evolve as these incentives and payment adjustments are in effect for a longer period of time and as the PPA penalties and bonuses mature.

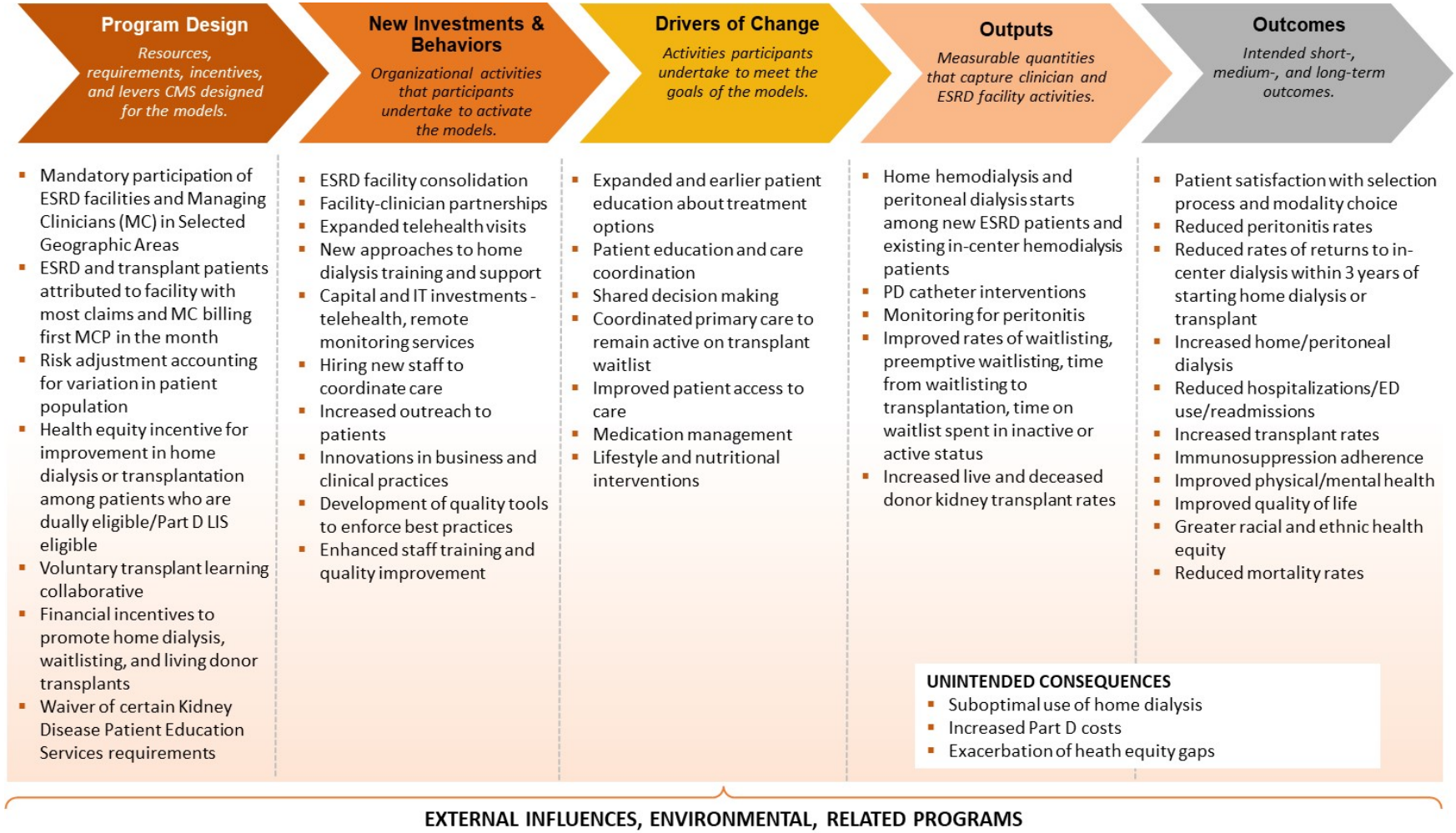
There is also a need to consider the role of external events that may influence key ETC outcome measures. First, the ETC Model started in CY 2021, one year after the start of the COVID-19 public health emergency (PHE). There may be differential effects of the COVID-19 PHE on ETC Model outcomes which will be important to monitor. Thus far, there were similar overall rates of COVID-19 infections in the two groups through CY 2022. As in AR1, the DiD analyses continue to include patient- and county-level adjustments for COVID-19 infections. However, based on the effect of these adjustments, there was no evidence that the COVID-19 PHE influenced or modified the ETC Model impact estimates. At the same time, it is important to recognize that model impacts observed during the COVID-19 PHE may be different from what might otherwise have occurred in the absence of the COVID-19 PHE. It will be important to 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 in subsequent years of the model. In addition, due to growing enrollment of

beneficiaries with ESRD in MA plans, there is also a need to continue to monitor potential changes in the FFS population eligible for the ETC Model. While there were similar changes in the size and composition of the ETC eligible FFS population in the ETC and comparison groups through the model's first two years, diverging trends between the two groups in future years could have implications for the evaluation.

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

Future ARs will continue to examine impacts of the ETC Model on aspects of dialysis modality use, transplant waitlisting, and transplantation which are the target of the model's incentives, as well as on utilization of services, Medicare payments, and indicators of QoC among patients with ESRD. There will continue to be a need to assess the potential implications of the model for health equity. It will also be a priority to incorporate additional patient-reported data using both quantitative and qualitative methods. These data will be used to examine topics such as patient QoL, patient perspectives on the modality selection process, and experience of care among home dialysis patients.

# 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 (that is, ETC 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 design 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.

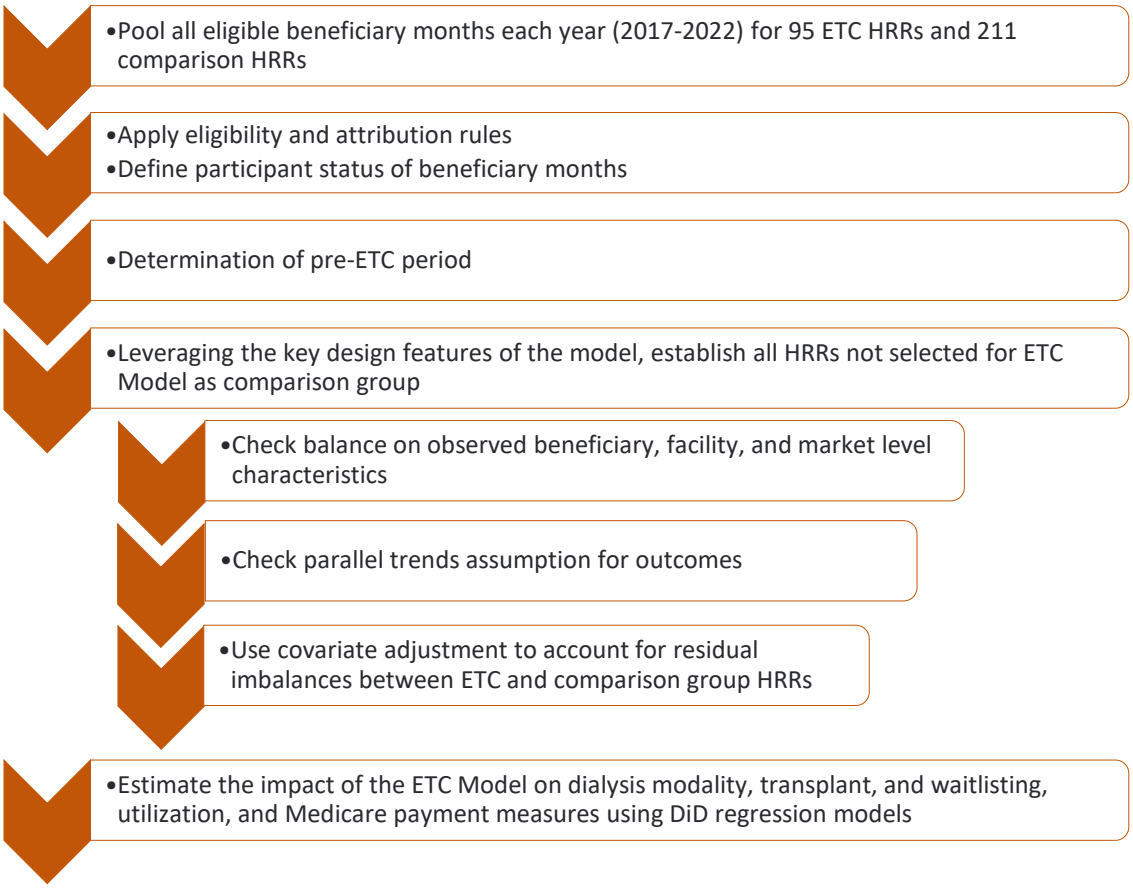
**Outputs**. Effects of the drivers of change are captured in intermediate outcome measures. Intermediate outcomes generally reflect processes of care or activities that are antecedents to attaining other model goals, such as rates of home dialysis, waitlisting, and transplantation, rates of transition 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 ETC areas relative to those in the comparison group, comprised of HRRs in the Comparison Geographic 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 2022 | 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 2022 | Information on all patients with ESRD treated at Medicare-certified ESRD facilities, including patient and facility characteristics (for example, 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 2022 | 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 – 2022 | Provider- and beneficiary level information on participation in CMMI payment demonstration programs | Used to identify providers who are aligned with CEC model, NGACO, Medicare Shared Savings Program and Kidney Care Choice Model |
| **ICH CAHPS Survey** | Spring 2017 – Fall 2022 | Patient experience with in-center HD care | Used to assess patient experience among in-center dialysis patients |
| **Medicare Data on Provider Practice and Specialty National Plan and Provider Enumeration System** | 2017 – 2022 | Information on provider's name, gender, age, ZIP code, specialty (taxonomy) and practice address. | Used to identify managing clinician characteristics for assessing balance |

| Data Source Name | Date Range* | Data Contents | Use |
|---|---|---|---|
| **The ZIP Code File-SAS** | 2017 – 2022 | ZIP codes and Core-Based Statistical Areas (CBSAs) | Used to link ZIP codes to counties, CBSA |
| **Files from KCC Implementation contractor** | 2022 | PY 2022 Q2 list contains unduplicated NPI participating in KCC model | Used to indicate whether the managing clinician a KCC participant or not |

**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 **Exhibit E-1** and **Exhibit E-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 (that is, primary modality) was home dialysis services, and 0 otherwise. Home Dialysis is defined as any of the following dialysis: Home Peritoneal Dialysis (PD) or Home Hemodialysis (HD). Determination of individual modalities is described more below. |
| | Home PD | Monthly flag set to 1 if the most used dialysis service for the beneficiary during a given month (that is, primary modality) was home PD, 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. Home PD was defined as monthly count of either Continuous Cycling Peritoneal Dialysis (CCPD) or Continuous Ambulatory Peritoneal Dialysis (CAPD) services were greater than zero. 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 the most used dialysis service for the beneficiary during a given month (that is, primary modality) was home HD, 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. 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. |

| Outcomes | | Description of Outcomes |
|---|---|---|
| **Dialysis Modality Measures (%) (cont.)** | In-Center HD | Monthly flag set to 1 if the most used dialysis service for the beneficiary during a given month (that is, primary modality) was in center dialysis services, and 0 otherwise. In Center HD was defined as any of the following dialysis: In-Center Hemodialysis, In-Center Self-Administered Dialysis and Nocturnal HD. Determination of individual modalities is described more below. |
| | In-Center Hemodialysis | Monthly flag set to 1 if the most used dialysis service for the beneficiary during a given month (that is, primary modality) was in-center HD, 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. 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 the most used dialysis service for the beneficiary during a given month (that is, primary modality) was self-administered in-center HD, 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. 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 the most used dialysis service for the beneficiary during a given month (that is, primary modality) was nocturnal dialysis, 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. 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 (that is, 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 was 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 was waitlisted with active status (that is, 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 was waitlisted with inactive status (that is, 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 (that is, 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 (that is, 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 were 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 (that is, CMS payments only) standardized amounts, winsorized at the 99th percentile. Payments were counted in the month of the claim from date for all Part A claims (that is, hospitalization payments, LTCH, IRF, and other payments). Payments were counted in the month of the first expense date for all Part B institutional claims (for example, hospital outpatient and dialysis) and non-institutional claims (for example, 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 (that is, CMS payments only) standardized amounts, winsorized at the 99th percentile. Payments were counted in the month of the claim from date for all Part A claims (that is, hospitalization payments, LTCH, IRF, and other payments). |
| | Part A Acute Care Hospitalization | Monthly beneficiary sum of Part A actual (that is, 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 (that is, CMS payments only) select institutional care (that is, IRF and LTCH) standardized amounts, winsorized at the 99th percentile. |
| | Other Part A | Monthly beneficiary sum of Part A Actual (that is, CMS payments only) home health standardized amounts, winsorized at the 99th percentile. |
| | Total Part B | Monthly beneficiary sum of total Part B actual (that is, CMS payments only) standardized amounts, winsorized at the 99th percentile. Payments were counted in the month of the first expense date for all Part B institutional claims (for example, hospital outpatient, and dialysis) and non-institutional claims (for example, E/M services, Part B covered drugs, durable medical equipment, etc.). |
| | Part B Dialysis | Monthly beneficiary sum of Part B Actual (that is, CMS payments only) total dialysis standardized amounts, winsorized at the 99th percentile. |
| | Other Part B | Monthly beneficiary sum of total Part B Actual (that is, CMS payments only) standardized amounts, excluding total dialysis payments and winsorized at the 99th percentile. |
| | Total Part D | Monthly beneficiary sum of Part D drug costs, winsorized at the 99th percentile. Payments were counted in the month of the line 1st expense date. |
| **Quality** | Peritonitis | Monthly flag set to 1 if beneficiary is diagnosed peritonitis, and 0 otherwise. Analysis of this outcome was limited to Home PD beneficiaries as defined above. The diagnosis of peritonitis is indicated by the ICD-10 codes, including K650, K658, K659, K652, T8571XA-A, T8571XD-D, and T8571XS-S, from the CCW fee-for-service data. |
| | Vascular access infection | Monthly flag set to 1 if beneficiary is diagnosed vascular access infection, and 0 otherwise. Analysis of this outcome was limited to In-center Hemodialysis and Home HD beneficiaries as defined above. and The diagnosis is indicated by the ICD-10 codes, including T80211A, T80212A, T80218A, T80219A, and T827XXA, from the CCW fee-for-service data. |
| | Hospitalization with ESRD complications | Monthly beneficiary count of inpatient claims (claim type 60) with a principal diagnosis for an end-stage renal disease (ESRD) complication. Month was based on the claim from date. The diagnosis codes are as follows: E860, E861, E869, E875, E8770, E8779, I132, J810, J811 and I50x |

| Outcomes | | Description of Outcomes |
|---|---|---|
| **Quality (cont.)** | Hospitalization with VA complications | Monthly beneficiary count of inpatient claims (claim type 60) with a principal diagnosis for a vascular access complication. Month was based on the claim from date. The diagnosis codes are as follows: T82318A, T82319A, T82328A, T82329A , T82338A , T82339A , T82398A , T82399A , T8241XA , T8242XA , T8243XA , T8249XA , T82510A , T82511A , T82518A , T82520A , T82521A , T82528A , T82529A , T82530A , T82531A , T82538A , T82590A , T82591A , T82598A , T85611A , T85621A , T85631A , T85691A , T82818A , T82828A , T82838A , T82848A , T82858A , T82868A , and T82898A. |
| | Death | Monthly flag set to 1 if beneficiary died in the current month, and 0 otherwise. Death information was obtained from MSBF data supplemented by EQRS data (Death Notification form CMS-2746 supplemented by Patient Events, CMS-2728, Current Patient Form and Remis Patient Form from EQRS). If there was a conflict between MBSF and EQRS date, the earlier date was picked. |

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

## B.2. Beneficiary Attribution and Eligibility

We applied a series of inclusion/exclusion criteria, (see **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 (see **Exhibit B-5** and **Exhibit B-6**).[25] We applied these criteria to all beneficiary months before death from January 2017-December 2022 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 (that is, 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.

[25] 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.: Dialysis Facility 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 a Managing Clinician:**
  - 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.[26] 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 (see **Exhibit B-7**).

**Exhibit B-7. ETC Timeline**

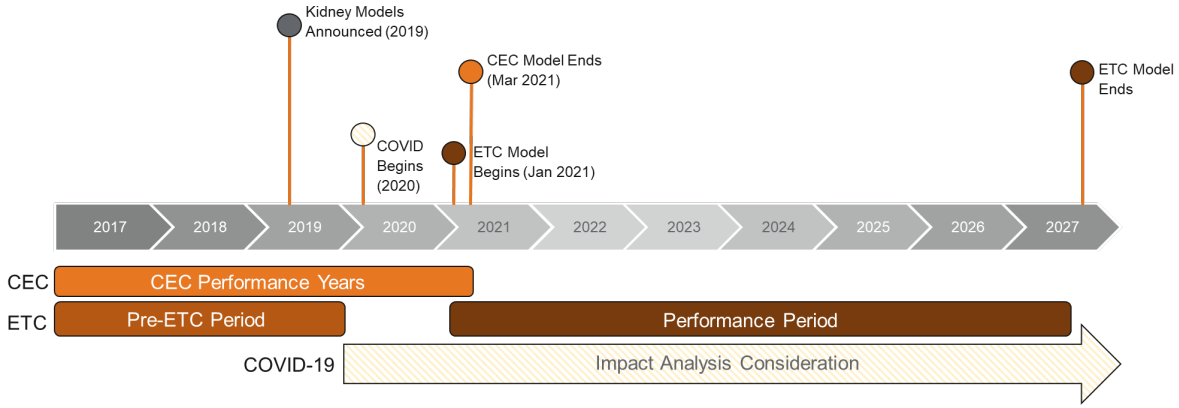
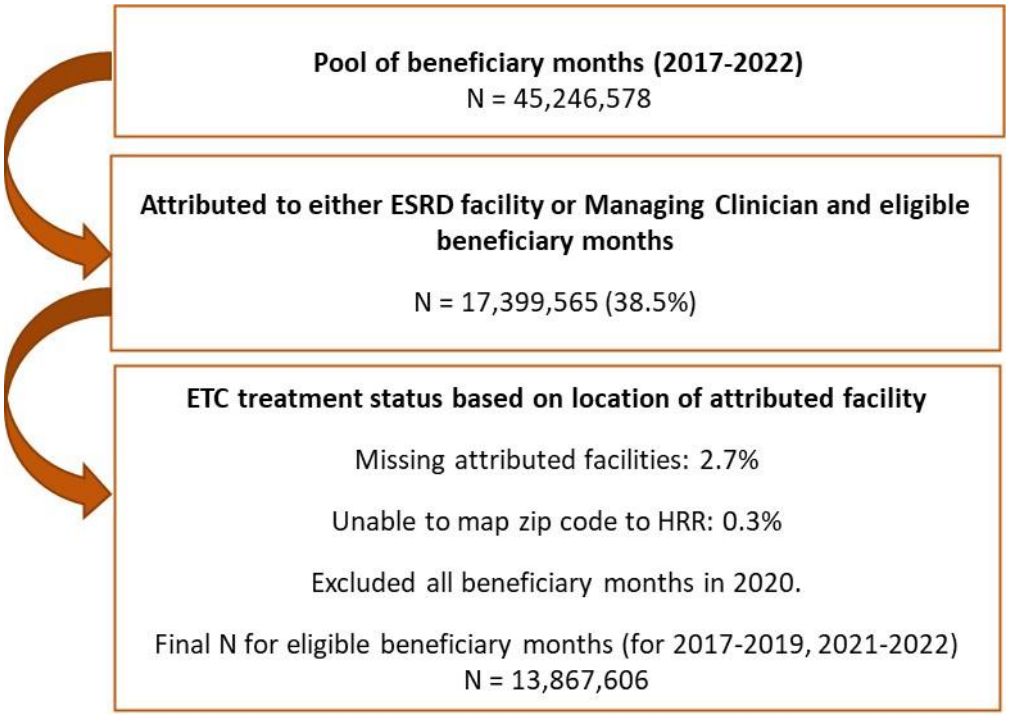



**Exhibit B-8** shows how we derived our final sample and **Exhibit B-9** – **Exhibit B-10** report the size of the final sample by pre-ETC and post-ETC periods as well as by individual years for the ETC and comparison groups, respectively.

[26] 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, Pre-ETC and Post-ETC

| Characteristic | ETC | | Comparison | |
|---|---|---|---|---|
| | Pre-ETC (2017-2019) | Post-ETC (2021-2022) | Pre-ETC (2021-2022) | Post-ETC (2021-2022) |
| Number of HRRs | 95 | 95 | 211 | 211 |
| Number of ESRD Facilities | 2,512 | 2,564 | 5,227 | 5,330 |
| Number of Managing Clinicians | 6,650 | 5,656 | 9,539 | 8,796 |
| Number of Unique Beneficiaries | 171,205 | 121,451 | 336,281 | 235,615 |
| Number of Patient Months | 3,116,658 | 1,550,586 | 6,165,640 | 3,034,722 |

**Note:** Counts of unique beneficiaries, managing clinicians, and ESRD facilities are lower for the individual year counts displayed in **Exhibit B-10** compared to the counts for the aggregate periods displayed in this exhibit as all units are not necessarily in all years.

### Exhibit B-10. Characteristics of ETC and Comparison Areas by year

| Group | Year | Number of ESRD Facilities | Number of Managing Clinicians | Number of Unique Beneficiaries | Number of Patient Months |
|---|---|---|---|---|---|
| ETC | 2017 | 2,284 | 4,753 | 115,971 | 1,031,381 |
| | 2018 | 2,382 | 4,866 | 116,584 | 1,038,338 |
| | 2019 | 2,450 | 4,956 | 117,582 | 1,046,939 |
| | 2021 | 2,517 | 4,739 | 99,516 | 834,422 |
| | 2022 | 2,497 | 4,718 | 86,139 | 716,164 |

| Group | Year | Number of ESRD Facilities | Number of Managing Clinicians | Number of Unique Beneficiaries | Number of Patient Months |
|---|---|---|---|---|---|
| Comparison | 2017 | 4,727 | 7,602 | 229,962 | 2,053,761 |
| | 2018 | 4,979 | 7,751 | 229,903 | 2,058,142 |
| | 2019 | 5,102 | 7,895 | 229,740 | 2,053,737 |
| | 2021 | 5,248 | 7,754 | 193,753 | 1,633,898 |
| | 2022 | 5,229 | 7,875 | 167,176 | 1,400,824 |

## B.4. Comparison Group Assessment

The mandatory participation of the ESRD facilities and the Managing Clinicians in the ETC areas helped to guard against selection bias, inherent in voluntary opt-in initiatives and demonstrations. Since the ETC 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.[27] We leveraged these design features of the model to determine a comparison group credibly representing the counterfactual that would address the question "*What would have happened in the ETC 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 ETC areas and the Comparison Geographic Areas (designated as 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 ETC areas and the comparison areas. A strong pattern of non-parallel trends across key outcomes could raise concerns that the comparison 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 ETC and Comparison Areas*

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

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

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

We compared SMDs against a standard threshold value of 0.2 to understand the extent of any differences between the ETC and comparison 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 (for instance, age, race, ethnicity), poverty rate, educational attainment, MA penetration, numbers of hospitals and physicians per 100,000 population

As shown in AR1, we had also examined balance between the ETC areas (excluding four Maryland HRRs) and the comparison areas and noted that the degree of imbalance on factors between ETC and comparison areas was not driven by the non-random inclusion of Maryland HRRs in the model.

The SMDs for characteristics assessed are displayed in **Exhibits B-11 – B-14**. Of the 168 characteristics assessed, only seven had a SMD greater than 0.2.

## Exhibit B-11. Means and SMDs for Patient Characteristics at Patient Month-Level

| Characteristic | | ETC | | | | Comparison | | | | SMD (ETC vs. Comparison) Pre-ETC period | SMD (ETC vs. Comparison) Post-ETC period |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Pre-ETC | | Post-ETC | | Pre-ETC | | Post-ETC | | | |
| | | N = 3,116,658 | | N = 1,550,586 | | N = 6,165,640 | | N = 3,034,722 | | | |
| | | Mean | SD | Mean | SD | Mean | SD | Mean | SD | | |
| Patient Characteristics | **Age, Continuous (Years)** | 61.7 | 14.2 | 63.1 | 14.4 | 62.0 | 14.2 | 63.3 | 14.4 | -0.02 | -0.02 |
| | **Age, Continuous (Median, years)** | 63.0 | - | 65.0 | - | 63.0 | - | 65.0 | - | - | - |
| | **Age, Categorical** | | | | | | | | | | |
| | 18 - <25 Years | 0.68% | 8.2% | 0.59% | 7.7% | 0.64% | 8.0% | 0.55% | 7.4% | 0.005 | 0.01 |
| | 25 - <35 Years | 4.0% | 19.5% | 3.8% | 19.1% | 3.8% | 19.1% | 3.7% | 18.8% | 0.01 | 0.01 |
| | 35 - <45 Years | 9.0% | 28.6% | 8.5% | 28.0% | 8.8% | 28.3% | 8.4% | 27.7% | 0.01 | 0.01 |
| | 45 - <55 Years | 18.1% | 38.5% | 15.6% | 36.3% | 17.7% | 38.2% | 15.6% | 36.3% | 0.01 | 0.001 |
| | 55 - <65 Years | 25.6% | 43.6% | 23.3% | 42.3% | 25.9% | 43.8% | 23.1% | 42.1% | -0.01 | 0.01 |
| | 65 - <75 Years | 25.7% | 43.7% | 27.9% | 44.8% | 25.7% | 43.7% | 28.2% | 45.0% | -0.001 | -0.01 |
| | 75 Years & Over | 17.0% | 37.6% | 20.2% | 40.2% | 17.4% | 37.9% | 20.6% | 40.4% | -0.01 | -0.01 |
| | **Female** | 43.2% | 49.5% | 42.5% | 49.4% | 42.9% | 49.5% | 42.1% | 49.4% | 0.01 | 0.01 |
| | **Race/Ethnicity[1]** | | | | | | | | | | |
| | Hispanic | 11.1% | 31.4% | 11.0% | 31.3% | 17.5% | 38.0% | 17.4% | 37.9% | -0.18 | -0.18 |
| | Non-Hispanic Black or African American | 39.2% | 48.8% | 34.6% | 47.6% | 33.8% | 47.3% | 29.2% | 45.4% | 0.11 | 0.12 |
| | Non-Hispanic White | 42.6% | 49.5% | 46.1% | 49.8% | 41.4% | 49.3% | 44.7% | 49.7% | 0.03 | 0.03 |
| | Non-Hispanic Asian | 3.2% | 17.6% | 3.9% | 19.2% | 4.7% | 21.3% | 5.8% | 23.4% | -0.08 | -0.09 |
| | Non- Hispanic Native Hawaiian/Pacific Islander | 0.94% | 9.6% | 1.0% | 10.0% | 1.2% | 10.8% | 1.3% | 11.2% | -0.02 | -0.02 |
| | Non- Hispanic American Indian/Alaska Native | 2.6% | 16.0% | 2.9% | 16.7% | 1.0% | 9.9% | 1.1% | 10.6% | 0.12 | 0.12 |
| | Non- Hispanic Other | 0.35% | 5.9% | 0.50% | 7.0% | 0.41% | 6.4% | 0.53% | 7.3% | -0.01 | -0.005 |
| | **BMI, Categorical** | | | | | | | | | | |
| | <18.5 | 2.1% | 14.2% | 2.0% | 13.9% | 2.1% | 14.3% | 2.0% | 14.1% | -0.002 | -0.005 |
| | 18.5- <25 | 2.7% | 16.2% | 2.7% | 16.1% | 2.7% | 16.1% | 2.6% | 16.0% | 0.001 | 0.003 |
| | 25- <30 | 22.9% | 42.0% | 22.9% | 42.0% | 23.8% | 42.6% | 23.8% | 42.6% | -0.02 | -0.02 |
| | 30- <35 | 27.1% | 44.5% | 27.2% | 44.5% | 27.2% | 44.5% | 27.4% | 44.6% | -0.003 | -0.004 |
| | 35- <40 | 20.1% | 40.1% | 20.2% | 40.2% | 19.7% | 39.8% | 19.8% | 39.9% | 0.01 | 0.01 |
| | 40 or greater | 12.2% | 32.7% | 12.3% | 32.9% | 12.1% | 32.7% | 12.1% | 32.7% | 0.002 | 0.01 |
| | Missing | 13.0% | 33.6% | 12.6% | 33.2% | 12.4% | 32.9% | 12.2% | 32.7% | 0.02 | 0.01 |

| Characteristic | | ETC | | | | Comparison | | | | SMD (ETC vs. Comparison) Pre-ETC period | SMD (ETC vs. Comparison) Post-ETC period |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Pre-ETC | | Post-ETC | | Pre-ETC | | Post-ETC | | | |
| | | N = 3,116,658 | | N = 1,550,586 | | N = 6,165,640 | | N = 3,034,722 | | | |
| | | Mean | SD | Mean | SD | Mean | SD | Mean | SD | | |
| Patient Characteristics (cont.) | **ESRD Vintage, Continuous (Years)** | 5.2 | 5.1 | 5.4 | 5.5 | 5.2 | 5.1 | 5.4 | 5.4 | 0.01 | 0.01 |
| | **ESRD Vintage, Categorical** | | | | | | | | | | |
| | <6 Months | 8.4% | 27.8% | 9.4% | 29.2% | 8.6% | 28.0% | 9.7% | 29.6% | -0.005 | -0.01 |
| | 6 Months - <1 Year | 7.3% | 26.0% | 7.3% | 26.0% | 7.3% | 26.1% | 7.4% | 26.2% | -0.002 | -0.005 |
| | 1 - <2 Years | 13.4% | 34.1% | 12.9% | 33.5% | 13.5% | 34.1% | 12.9% | 33.6% | -0.001 | -0.001 |
| | 2 - <3 Years | 12.6% | 33.2% | 12.2% | 32.7% | 12.6% | 33.2% | 12.2% | 32.7% | 0.001 | 0.000 |
| | 4 - <7 Years | 27.9% | 44.8% | 27.5% | 44.6% | 28.0% | 44.9% | 27.5% | 44.6% | -0.002 | 0.001 |
| | 7 - <10 Years | 16.4% | 37.0% | 15.9% | 36.6% | 16.5% | 37.1% | 15.9% | 36.6% | -0.004 | -0.001 |
| | 10 Years and Over | 14.0% | 34.7% | 14.8% | 35.5% | 13.5% | 34.2% | 14.3% | 35.0% | 0.01 | 0.01 |
| | **Dual Medicare/Medicaid Enrollment (Full or Partial Benefits)** | 47.2% | 49.9% | 45.3% | 49.8% | 48.6% | 50.0% | 47.4% | 49.9% | -0.03 | -0.04 |
| | **Dual Medicare/Medicaid Enrollment (Full Benefits)** | 33.3% | 47.1% | 34.8% | 47.6% | 36.5% | 48.1% | 38.8% | 48.7% | -0.07 | -0.08 |
| | **Part D Benefit Enrollment** | 81.6% | 38.7% | 78.8% | 40.9% | 81.9% | 38.5% | 79.5% | 40.3% | -0.01 | -0.02 |
| | **Part D LIS (Where Enrolled in Part D Benefits)** | 67.8% | 46.7% | 62.4% | 48.4% | 69.2% | 46.2% | 63.9% | 48.0% | -0.03 | -0.03 |
| | **Medicare Shared Savings Program** | 22.3% | 41.6% | 21.0% | 40.8% | 22.3% | 41.6% | 25.0% | 43.3% | -0.001 | -0.10 |
| | **Alternative Payment Models** | | | | | | | | | | |
| | CEC | 20.3% | 40.2% | 3.4% | 18.1% | 12.4% | 32.9% | 1.6% | 12.4% | 0.22 | 0.12 |
| | KCC* | 30.5% | 46.1% | 31.6% | 46.5% | 22.0% | 41.4% | 23.2% | 42.2% | 0.19 | 0.19 |
| | NGACO | 2.9% | 16.9% | 1.2% | 10.8% | 3.5% | 18.4% | 1.1% | 10.5% | -0.03 | 0.00 |
| | **Original Medicare Entitlement** | | | | | | | | | | |
| | ESRD and Disability | 19.1% | 39.3% | 11.3% | 31.6% | 18.6% | 38.9% | 10.8% | 31.0% | 0.01 | 0.02 |
| | ESRD | 31.7% | 46.5% | 34.8% | 47.6% | 32.1% | 46.7% | 35.1% | 47.7% | -0.01 | -0.01 |
| | Disability | 21.3% | 41.0% | 21.2% | 40.9% | 20.7% | 40.6% | 20.7% | 40.5% | 0.01 | 0.01 |
| | Old Age | 27.9% | 44.8% | 32.7% | 46.9% | 28.5% | 45.2% | 33.4% | 47.2% | -0.01 | -0.02 |

| Characteristic | | ETC | | | | Comparison | | | | SMD (ETC vs. Comparison) Pre-ETC period | SMD (ETC vs. Comparison) Post-ETC period |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Pre-ETC | | Post-ETC | | Pre-ETC | | Post-ETC | | | |
| | | N = 3,116,658 | | N = 1,550,586 | | N = 6,165,640 | | N = 3,034,722 | | | |
| | | Mean | SD | Mean | SD | Mean | SD | Mean | SD | | |
| Comorbidities | Acute Myocardial Infarction | 3.5% | 18.5% | 4.6% | 21.0% | 3.8% | 19.0% | 5.0% | 21.9% | -0.01 | -0.02 |
| | Alzheimer's Disease | 0.04% | 2.0% | 0.04% | 2.0% | 0.04% | 2.1% | 0.04% | 2.0% | -0.002 | -0.001 |
| | Asthma | 10.4% | 30.5% | 10.0% | 30.0% | 10.4% | 30.5% | 10.1% | 30.1% | 0.000 | -0.001 |
| | Atrial Fibrillation and Flutter | 20.1% | 40.1% | 22.9% | 42.0% | 20.5% | 40.4% | 23.5% | 42.4% | -0.01 | -0.01 |
| | Benign Prostatic Hyperplasia | 9.1% | 28.8% | 11.5% | 31.9% | 9.1% | 28.8% | 11.7% | 32.1% | 0.001 | -0.01 |
| | Cancer, Any | 10.2% | 30.2% | 11.5% | 31.9% | 10.0% | 30.0% | 11.2% | 31.6% | 0.01 | 0.01 |
| | Cancer, Breast | 2.1% | 14.3% | 2.4% | 15.2% | 2.0% | 14.1% | 2.3% | 15.1% | 0.004 | 0.003 |
| | Cancer, Colorectal | 1.7% | 12.7% | 1.8% | 13.1% | 1.7% | 12.7% | 1.8% | 13.3% | 0.000 | -0.003 |
| | Cancer, Endometrial | 0.49% | 7.0% | 0.53% | 7.3% | 0.48% | 6.9% | 0.55% | 7.4% | 0.001 | -0.002 |
| | Cancer, Lung | 0.72% | 8.5% | 0.91% | 9.5% | 0.74% | 8.6% | 0.87% | 9.3% | -0.003 | 0.004 |
| | Cancer, Prostate | 3.0% | 17.1% | 3.6% | 18.6% | 3.0% | 17.2% | 3.4% | 18.2% | -0.002 | 0.01 |
| | Cancer, Urologic | 3.2% | 17.7% | 3.6% | 18.6% | 3.0% | 17.0% | 3.4% | 18.2% | 0.02 | 0.01 |
| | Cataract | 17.2% | 37.7% | 18.3% | 38.7% | 17.2% | 37.8% | 18.2% | 38.6% | -0.001 | 0.003 |
| | Chronic Obstructive Pulmonary Disease | 21.7% | 41.2% | 18.9% | 39.2% | 21.9% | 41.4% | 19.2% | 39.4% | -0.004 | -0.01 |
| | Depression, Bipolar, or Other Depressive Mood Disorders | 21.8% | 41.3% | 23.5% | 42.4% | 21.4% | 41.0% | 22.9% | 42.0% | 0.01 | 0.02 |
| | Diabetes | 65.2% | 47.6% | 65.4% | 47.6% | 66.7% | 47.1% | 67.1% | 47.0% | -0.03 | -0.03 |
| | Glaucoma | 13.2% | 33.9% | 14.1% | 34.8% | 13.3% | 33.9% | 13.9% | 34.6% | -0.001 | 0.004 |
| | Congestive Heart Failure | 45.1% | 49.8% | 48.1% | 50.0% | 46.1% | 49.8% | 49.0% | 50.0% | -0.02 | -0.02 |
| | Hip/Pelvic Fracture | 0.87% | 9.3% | 1.1% | 10.3% | 0.94% | 9.7% | 1.1% | 10.5% | -0.01 | -0.004 |
| | Hyperlipidemia | 69.7% | 46.0% | 73.6% | 44.1% | 69.6% | 46.0% | 73.8% | 44.0% | 0.003 | -0.004 |
| | Hypertension | 92.7% | 25.9% | 93.3% | 25.1% | 92.8% | 25.8% | 93.2% | 25.1% | -0.002 | 0.002 |
| | Hypothyroidism | 18.9% | 39.2% | 20.1% | 40.1% | 19.7% | 39.8% | 20.7% | 40.5% | -0.02 | -0.01 |
| | Ischemic Heart Disease | 42.1% | 49.4% | 44.0% | 49.6% | 44.0% | 49.6% | 45.7% | 49.8% | -0.04 | -0.03 |
| | Non-Alzheimer's Dementia | 1.5% | 12.1% | 1.8% | 13.4% | 1.5% | 12.3% | 1.8% | 13.3% | 0.00 | 0.00 |
| | Osteoporosis with or without Pathological Fracture | 4.4% | 20.4% | 5.4% | 22.6% | 4.7% | 21.2% | 5.6% | 23.1% | -0.02 | -0.01 |
| | Pneumonia | 12.6% | 33.2% | 14.5% | 35.2% | 12.8% | 33.4% | 14.6% | 35.3% | -0.01 | -0.003 |
| | Parkinson's Disease and Secondary Parkinsonism | 0.53% | 7.3% | 0.61% | 7.8% | 0.61% | 7.8% | 0.65% | 8.0% | -0.01 | -0.004 |
| | Rheumatoid Arthritis/ Osteoarthritis | 28.9% | 45.3% | 30.4% | 46.0% | 28.9% | 45.3% | 30.3% | 46.0% | 0.000 | 0.001 |
| | Stroke/Transient Ischemic Attack | 8.3% | 27.6% | 9.2% | 28.9% | 8.4% | 27.7% | 9.0% | 28.7% | -0.003 | 0.004 |

| Characteristic | | ETC | | | | Comparison | | | | SMD (ETC vs. Comparison) Pre-ETC period | SMD (ETC vs. Comparison) Post-ETC period |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Pre-ETC | | Post-ETC | | Pre-ETC | | Post-ETC | | | |
| | | N = 3,116,658 | | N = 1,550,586 | | N = 6,165,640 | | N = 3,034,722 | | | |
| | | Mean | SD | 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% | 41.8% | 49.3% | 44.6% | 49.7% | 43.2% | 49.5% | -0.03 | -0.03 |
| | Glomerulonephritis | 11.5% | 31.9% | 11.2% | 31.5% | 11.0% | 31.3% | 10.4% | 30.5% | 0.01 | 0.03 |
| | Hypertension | 31.4% | 46.4% | 30.9% | 46.2% | 30.1% | 45.8% | 29.8% | 45.8% | 0.03 | 0.02 |
| | Other | 14.1% | 34.8% | 16.1% | 36.7% | 14.3% | 35.0% | 16.5% | 37.1% | -0.01 | -0.01 |
| | **Diabetes** | 51.3% | 50.0% | 52.3% | 49.9% | 52.4% | 49.9% | 53.5% | 49.9% | -0.02 | -0.03 |
| | **Congestive Heart Failure** | 21.5% | 41.1% | 20.7% | 40.5% | 21.7% | 41.2% | 20.8% | 40.6% | -0.004 | -0.002 |
| | **Atherosclerotic Heart Disease** | 10.2% | 30.2% | 9.2% | 29.0% | 9.9% | 29.9% | 9.1% | 28.7% | 0.01 | 0.01 |
| | **Other Cardiac Disease** | 13.0% | 33.6% | 14.3% | 35.0% | 13.0% | 33.6% | 14.4% | 35.2% | 0.000 | -0.003 |
| | **Cerebrovascular Disease, CVA, TIA** | 5.8% | 23.4% | 5.9% | 23.5% | 5.8% | 23.4% | 5.7% | 23.3% | -0.002 | 0.01 |
| | **Peripheral Vascular Disease** | 7.3% | 26.1% | 6.7% | 25.0% | 6.9% | 25.3% | 6.1% | 24.0% | 0.02 | 0.02 |
| | **Chronic Obstructive Pulmonary Disease** | 5.4% | 22.5% | 5.0% | 21.9% | 5.3% | 22.4% | 5.1% | 21.9% | 0.002 | -0.001 |
| | **Tobacco Use (Current Smoker)** | 6.5% | 24.6% | 6.0% | 23.8% | 6.2% | 24.1% | 5.8% | 23.4% | 0.01 | 0.01 |
| | **Malignant Neoplasm, Cancer** | 4.6% | 20.8% | 5.3% | 22.3% | 4.6% | 20.9% | 5.3% | 22.5% | -0.001 | -0.003 |
| | **Alcohol Dependence** | 1.2% | 10.7% | 1.1% | 10.6% | 1.1% | 10.4% | 1.1% | 10.3% | 0.01 | 0.01 |
| | **Drug Dependence** | 1.3% | 11.1% | 1.2% | 10.9% | 1.1% | 10.5% | 1.0% | 10.1% | 0.01 | 0.02 |
| | **Inability to Ambulate** | 2.4% | 15.4% | 2.6% | 15.8% | 2.6% | 15.8% | 2.7% | 16.3% | -0.01 | -0.01 |
| | **Inability to Transfer** | 1.0% | 9.8% | 1.1% | 10.2% | 1.0% | 10.1% | 1.2% | 10.7% | -0.01 | -0.01 |

| Characteristic | | ETC | | | | Comparison | | | | SMD (ETC vs. Comparison) Pre-ETC period | SMD (ETC vs. Comparison) Post-ETC period |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Pre-ETC | | Post-ETC | | Pre-ETC | | Post-ETC | | | |
| | | N = 3,116,658 | | N = 1,550,586 | | N = 6,165,640 | | N = 3,034,722 | | | |
| | | Mean | SD | Mean | SD | Mean | SD | Mean | SD | | |
| Health Conditions at Start of Dialysis (Data Source: EQRS 2728 form) | **Patient Months under Care of Nephrologist Prior to ESRD Therapy, Categorical** | | | | | | | | | | |
| | Not under Care of Nephrologist prior to ESRD | 20.8% | 40.6% | 17.4% | 37.9% | 21.3% | 40.9% | 18.2% | 38.6% | -0.01 | -0.02 |
| | Unknown If under Care of Nephrologist | 12.4% | 32.9% | 14.0% | 34.7% | 12.5% | 33.1% | 14.1% | 34.8% | -0.005 | -0.003 |
| | < 6 Months under Care | 19.1% | 39.3% | 19.4% | 39.5% | 18.3% | 38.6% | 18.8% | 39.1% | 0.02 | 0.01 |
| | 6 - <12 Months under Care | 29.2% | 45.5% | 32.1% | 46.7% | 28.3% | 45.1% | 31.0% | 46.2% | 0.02 | 0.02 |
| | 12 Months or Longer under Care | 18.5% | 38.8% | 17.2% | 37.7% | 19.6% | 39.7% | 17.8% | 38.3% | -0.03 | -0.02 |
| | **Prior Employment Status (Employed Full or Part-Time)** | 24.8% | 43.2% | 25.9% | 43.8% | 24.6% | 43.1% | 25.6% | 43.6% | 0.003 | 0.01 |
| | **Current Employment Status (Employed Full or Part-Time)** | 15.5% | 36.2% | 17.3% | 37.8% | 15.2% | 35.9% | 16.7% | 37.3% | 0.01 | 0.01 |

**Notes:** Pre-ETC = 2017-2019 Post-ETC period =2021-2022. SD = standard deviation. SMD = standardized mean difference. NGACO = Next Generation ACO. CVA = Cerebrovascular Accident. TIA = Transient Ischemic Attack. A patient may contribute up to 12 observation per year to this patient-month summary. [1]Race and ethnicity are mutually exclusive categories based primarily on patient-reported race and ethnicity from the CMS ESRD Medical Evidence Form. *In the pre-ETC period, this shows the percent of patient months aligned with a clinician who eventually volunteered for KCC model that was implemented in 2022. Shading indicates a SMD > 0.2.

## Exhibit B-12. Means and SMDs for Facility Characteristics at Facility-Level

| Characteristic | | ETC | | | | Comparison | | | | SMD (ETC vs. Comparison) Pre-ETC period | SMD (ETC vs. Comparison) Post-ETC period |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Pre-ETC N = 2,512 | | Post-ETC N = 2,564 | | Pre-ETC N = 5,227 | | Post-ETC N = 5,330 | | | |
| | | Mean | SD | 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 | 17.5 | 8.6 | -0.01 | -0.03 |
| | For-Profit | 89.2% | 31.0% | 90.6% | 29.2% | 87.3% | 33.3% | 88.9% | 31.4% | 0.06 | 0.05 |
| | Facility Ownership | | | | | | | | | | |
| | DaVita | 37.2% | 48.3% | 36.8% | 48.2% | 39.3% | 48.8% | 39.5% | 48.9% | -0.04 | -0.05 |
| | Fresenius Medical Care | 39.0% | 48.8% | 38.7% | 48.7% | 34.9% | 47.7% | 34.7% | 47.6% | 0.08 | 0.08 |
| | Independent/Non-Chain For-Profit | 3.5% | 18.3% | 4.1% | 19.8% | 5.1% | 22.1% | 5.5% | 22.9% | -0.08 | -0.07 |
| | Other For-Profit | 10.6% | 30.8% | 11.4% | 31.8% | 8.5% | 27.8% | 9.0% | 28.6% | 0.07 | 0.08 |
| | Non-Profit | 9.8% | 29.8% | 9.0% | 28.6% | 12.2% | 32.7% | 11.3% | 31.7% | -0.08 | -0.08 |
| | Facility Patient Volume (Patients)* | | | | | | | | | | |
| | <=50 | 36.7% | 48.2% | 49.8% | 50.0% | 39.3% | 48.8% | 52.4% | 49.9% | -0.05 | -0.05 |
| | >50 and <=75 | 21.2% | 40.9% | 25.7% | 43.7% | 21.8% | 41.3% | 26.7% | 44.2% | -0.01 | -0.02 |
| | >75 and <=100 | 18.0% | 38.5% | 13.6% | 34.3% | 17.1% | 37.7% | 12.2% | 32.7% | 0.02 | 0.04 |
| | >100 | 24.0% | 42.7% | 10.9% | 31.1% | 21.8% | 41.3% | 8.7% | 28.2% | 0.05 | 0.07 |
| | Provides In-Center HD Service | 94.8% | 22.2% | 94.3% | 23.1% | 92.9% | 25.6% | 93.2% | 25.2% | 0.08 | 0.05 |
| | Provides Peritoneal Dialysis Service | 50.1% | 50.0% | 49.8% | 50.0% | 54.0% | 49.8% | 53.7% | 49.9% | -0.08 | -0.08 |
| | Provides Home HD Training Service | 28.7% | 45.2% | 28.5% | 45.2% | 30.3% | 45.9% | 30.1% | 45.9% | -0.03 | -0.03 |
| | Facility has Shift after 5 p.m. | 16.2% | 36.9% | 15.4% | 36.1% | 16.6% | 37.2% | 15.9% | 36.6% | -0.01 | -0.01 |
| | Total In-Center Dialysis Patients | 57.4 | 42.7 | 54.0 | 37.7 | 59.0 | 44.7 | 55.2 | 38.8 | -0.04 | -0.03 |
| Facility Location Characteristics | Total Home Dialysis Patients | 7.6 | 15.2 | 9.7 | 18.7 | 8.1 | 16.5 | 10.0 | 20.8 | -0.03 | -0.01 |
| | Total Patients Receiving Care at End of Survey Period | 65.0 | 47.5 | 63.7 | 42.8 | 67.1 | 48.6 | 65.2 | 43.8 | -0.05 | -0.03 |
| | Facility Region | | | | | | | | | | |
| | Northeast | 14.6% | 35.4% | 15.0% | 35.7% | 13.3% | 34.0% | 13.6% | 34.2% | 0.04 | 0.04 |
| | Midwest | 20.3% | 40.2% | 19.6% | 39.7% | 21.2% | 40.9% | 20.5% | 40.4% | -0.02 | -0.02 |
| | South | 47.3% | 49.9% | 47.5% | 49.9% | 45.2% | 49.8% | 44.9% | 49.7% | 0.04 | 0.05 |
| | West | 17.8% | 38.3% | 17.9% | 38.3% | 20.3% | 40.3% | 21.0% | 40.8% | -0.06 | -0.08 |
| | Facility RUCC | | | | | | | | | | |
| | Metro | 83.0% | 37.5% | 83.2% | 37.4% | 83.4% | 37.2% | 84.3% | 36.4% | -0.01 | -0.03 |
| | Urban | 16.3% | 37.0% | 16.1% | 36.8% | 15.9% | 36.6% | 15.1% | 35.8% | 0.01 | 0.03 |
| | Rural | 0.64% | 8.0% | 0.70% | 8.4% | 0.69% | 8.3% | 0.66% | 8.1% | -0.01 | 0.01 |

**Note:** Pre-ETC period= 2017-2019. Post-ETC period =2021-2022. SD = standard deviation. SMD = standardized mean difference. RUCC= Rural-Urban Continuum Code. *Facility volume is based on number of unique Medicare FFS patients treated in a year. Facility attributes averaged, with equal weight given to all facilities in each group. Shading indicates a SMD > 0.2.

## Exhibit B-13. Means and SMDs for Managing Clinician Characteristics at Clinician-Level

| Characteristic | | ETC | | | | Comparison | | | | SMD (ETC vs. Comparison) Pre-ETC period | SMD (ETC vs. Comparison) Post-ETC period |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Pre-ETC | | Post-ETC | | Pre-ETC | | Post-ETC | | | |
| | | N = 6,650 | | N = 5,656 | | N = 9,539 | | N = 8,796 | | | |
| | | Mean | SD | Mean | SD | Mean | SD | Mean | SD | | |
| Demographics | Mean Age | 48.7 | 10.9 | 49.3 | 10.8 | 49.7 | 11.5 | 50.4 | 11.4 | -0.09 | -0.09 |
| Specialty | Male | 64.7% | 47.8% | 60.6% | 48.9% | 65.8% | 47.4% | 62.3% | 48.5% | -0.02 | -0.04 |
| | Nephrology | 75.3% | 43.1% | 72.1% | 44.8% | 74.3% | 43.7% | 71.2% | 45.3% | 0.02 | 0.02 |
| | Nurse Practitioner | 11.9% | 32.4% | 14.2% | 34.9% | 10.6% | 30.8% | 12.7% | 33.3% | 0.04 | 0.04 |
| | Internal Medicine | 8.0% | 27.2% | 7.2% | 25.8% | 9.3% | 29.1% | 8.7% | 28.1% | -0.05 | -0.06 |
| | Physician Assistant | 2.1% | 14.4% | 2.3% | 15.1% | 2.2% | 14.8% | 2.4% | 15.3% | -0.01 | -0.004 |
| | Certified Clinical Nurse Specialist | 0.11% | 3.3% | 0.04% | 2.1% | 0.23% | 4.7% | 0.20% | 4.5% | -0.03 | -0.04 |
| | Other | 2.5% | 15.7% | 4.2% | 19.9% | 3.3% | 17.8% | 4.9% | 21.5% | -0.04 | -0.03 |
| Average Patient Volume and Characteristics | Number of Dialysis Patients per Month | 28.6 | 24.8 | 20.3 | 17.5 | 28.3 | 24.5 | 19.9 | 17.0 | 0.01 | 0.02 |
| | Average Age | 61.4 | 6.9 | 62.8 | 7.3 | 61.8 | 7.2 | 63.2 | 7.3 | -0.06 | -0.05 |
| | Age >75 | 18.1% | 14.6% | 21.6% | 17.3% | 19.1% | 15.5% | 22.1% | 17.9% | -0.06 | -0.03 |
| | Male | 56.8% | 17.7% | 57.3% | 19.6% | 57.1% | 18.2% | 57.8% | 20.0% | -0.01 | -0.02 |
| | Dually Eligible for Medicare and Medicaid | 47.2% | 22.2% | 45.5% | 23.8% | 48.3% | 23.8% | 47.0% | 26.0% | -0.04 | -0.06 |
| | Cause of ESRD | 42.2% | 18.9% | 41.0% | 20.6% | 43.0% | 19.6% | 41.8% | 21.2% | -0.04 | -0.04 |

| Characteristic | | ETC | | | | Comparison | | | | SMD (ETC vs. Comparison) Pre-ETC period | SMD (ETC vs. Comparison) Post-ETC period |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Pre-ETC | | Post-ETC | | Pre-ETC | | Post-ETC | | | |
| | | N = 6,650 | | N = 5,656 | | N = 9,539 | | N = 8,796 | | | |
| | | Mean | SD | Mean | SD | Mean | SD | Mean | SD | | |
| Average Patient Volume and Characteristics (cont.) | **Race and Ethnicity** | | | | | | | | | | |
| | Hispanic | 11.2% | 17.6% | 11.2% | 17.8% | 16.3% | 22.9% | 15.8% | 22.8% | -0.25 | -0.22 |
| | Non-Hispanic White | 44.6% | 29.1% | 46.8% | 29.7% | 43.6% | 30.5% | 45.6% | 31.2% | 0.04 | 0.04 |
| | Non-Hispanic Black/ African American | 37.2% | 31.0% | 34.5% | 30.7% | 32.7% | 29.5% | 30.5% | 29.4% | 0.15 | 0.13 |
| | Non-Hispanic Asian | 3.8% | 8.7% | 4.2% | 9.6% | 5.1% | 12.3% | 5.5% | 13.0% | -0.12 | -0.11 |
| | Non-Hispanic American Indian/Alaska Native | 1.8% | 8.8% | 1.8% | 8.8% | 0.89% | 5.3% | 0.9% | 5.8% | 0.13 | 0.12 |
| | Non-Hispanic Native Hawaiian/Pacific Islander | 1.0% | 4.3% | 1.0% | 4.2% | 1.1% | 4.9% | 1.1% | 5.5% | -0.01 | -0.03 |
| | Non-Hispanic Other | 0.36% | 2.2% | 0.50% | 2.7% | 0.42% | 2.5% | 0.53% | 3.1% | -0.02 | -0.01 |
| Average Number of Patients Treated per Month by Dialysis Modality | **In-Center HD** | 25.4 | 22.6 | 17.4 | 15.6 | 25.0 | 22.4 | 17.0 | 15.1 | 0.02 | 0.03 |
| | **Peritoneal Dialysis** | 2.6 | 4.4 | 2.3 | 3.6 | 2.8 | 4.1 | 2.4 | 3.5 | -0.04 | -0.03 |
| | **Home HD** | 0.54 | 1.5 | 0.59 | 1.4 | 0.51 | 1.2 | 0.52 | 1.2 | 0.03 | 0.05 |
| | **Other** | 0.01 | 0.12 | 0.01 | 0.12 | 0.01 | 0.14 | 0.01 | 0.12 | -0.01 | -0.002 |
| Percent of Patients Treated per Month by Dialysis Modality | **In-Center HD** | 88.5% | 19.3% | 86.0% | 21.0% | 87.2% | 20.0% | 84.7% | 21.5% | 0.07 | 0.06 |
| | **Peritoneal Dialysis** | 9.6% | 17.1% | 11.1% | 18.1% | 10.8% | 18.0% | 12.4% | 18.9% | -0.07 | -0.07 |
| | **Home HD** | 1.9% | 6.6% | 2.8% | 8.4% | 2.0% | 6.9% | 2.8% | 8.2% | -0.009 | 0.002 |
| | **Other** | 0.05% | 1.2% | 0.07% | 1.2% | 0.06% | 1.1% | 0.08% | 1.3% | -0.004 | -0.01 |

**Note:** Pre-ETC period= 2017-2019. Post-ETC period =2021-2022. SD = standard deviation. SMD = standardized mean difference. Results displayed are based on yearly averages and cover years 2017-2019 for Pre-ETC and years 2021-2022 for Post-ETC. Shading indicates a SMD > 0.2.

## Exhibit B-14. Means and SMDs for Market Characteristics at HRR Level

| Characteristic | | ETC Pre-ETC N = 95 | | Comparison Pre-ETC N = 211 | | SMD (ETC vs. Comparison) Pre-ETC period |
|---|---|---|---|---|---|---|
| | | Mean | SD | Mean | SD | |
| Market Characteristics | **Race** | | | | | |
| | Asian | 2.7% | 2.4% | 3.6% | 5.3% | -0.23 |
| | Non-Hispanic Black | 12.3% | 13.1% | 9.1% | 9.5% | 0.28 |
| | Hispanic | 10.1% | 10.5% | 14.1% | 15.0% | -0.31 |
| | Native Hawaiian/ Pacific Islander | 0.17% | 0.25% | 0.21% | 0.74% | -0.07 |
| | Non-Hispanic White | 70.2% | 15.7% | 68.8% | 18.8% | 0.08 |
| | American Indian/ Alaskan Native | 2.1% | 4.2% | 1.6% | 2.8% | 0.14 |
| | **Persons > 25 Years Old with Less than High School Diploma** | 8.9% | 2.8% | 9.3% | 3.7% | -0.12 |
| | **MA Penetration** | 31.1 | 12.9 | 33.7 | 11.5 | -0.21 |
| | **Poverty** | 13.3% | 4.0% | 13.0% | 3.6% | 0.09 |
| | **Median Age, 2010** | 38.8 | 3.3 | 38.4 | 3.1 | 0.14 |
| | **Market Level Capacity per 100,000 Population** | | | | | |
| | Number of Short-Term General Hospitals | 3.3 | 3.4 | 3.7 | 4.9 | -0.10 |
| | Number of LTCHs | 0.25 | 0.37 | 0.23 | 0.36 | 0.08 |
| | Number of Short-Term General Hospitals with HD | 1.3 | 1.9 | 1.4 | 2.3 | -0.09 |
| | Number of Non-Federal Transplant (that is, Transplant Surgeons) | 0.32 | 0.86 | 0.36 | 0.80 | -0.05 |
| | Number of Non-Federal PCP, Patient Care | 288.9 | 433.4 | 331.9 | 585.3 | -0.08 |
| | Number of Non-Federal PCP, Hospital Resident | 41.5 | 80.9 | 45.0 | 92.3 | -0.04 |
| | **ADI** | 60.6 | 15.6 | 59.9 | 16.8 | 0.04 |
| | **Percent of ACO Beneficiaries** | 31.0% | 14.0% | 28.9% | 13.6% | 0.15 |
| | **Percent of CEC Beneficiaries** | 0.14% | 0.22% | 0.09% | 0.18% | 0.21 |
| | **Kidney Care Choice (KCC) Beneficiaries* (%)** | 0.37% | 0.40% | 0.30% | 0.36% | 0.18 |

**Note:** Pre-ETC = 2017-2019. SD = standard deviation. SMD = standardized mean difference. 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. 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/). *Only for 2022. Shading indicates a SMD > 0.2.

### 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 tested 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 pre-ETC trend for all outcomes. We examined and tested for parallel trends in two 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 (that is, 2017-2018) and the last year of the pre-ETC period (that is, 2019) as a "placebo test." That is, we applied the exact same risk-adjusted DiD specification (see **Exhibit B-19** for the set of covariates**)** 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. 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 (that is, 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-15**.

2) ***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 (that is, 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-19**). 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 shown below in **Exhibit B-16**.

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

Additionally, in AR1, we had plotted annual trends in select outcomes between ETC and comparison groups and had shown the difference between ETC and comparison groups in means of the unadjusted and risk-adjusted outcome values (adjusted for a list of patient-, facility-, and market-level characteristics) across the pre-ETC period (2017-2019). As shown in the first annual report, we examined the slopes of the plotted lines to graphically assess parallel trends and also to

determine whether risk adjustment improved the degree of balance between the two groups in the pre-ETC period. [28]

**Exhibit B-15. 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** | 0.05 | 0.16 | 0.76 | -0.21 | 0.31 |
| | Peritoneal Dialysis | 0.002 | 0.14 | 0.99 | -0.23 | 0.23 |
| | Home HD | 0.05 | 0.06 | 0.45 | -0.06 | 0.15 |
| | **In-Center HD** | -0.05 | 0.16 | 0.76 | -0.31 | 0.22 |
| | In-Center Hemodialysis | -0.03 | 0.17 | 0.87 | -0.30 | 0.25 |
| | In-Center Self-Dialysis | 0.01 | 0.01 | 0.59 | -0.02 | 0.03 |
| | Nocturnal HD | -0.03 | 0.03 | 0.38 | -0.09 | 0.03 |
| | **Home Dialysis Training** | 0.02 | 0.02 | 0.42 | -0.02 | 0.06 |
| Waitlisting (%) | **Overall** | 0.46 | 0.31 | 0.14 | -0.04 | 0.97 |
| | Active Status | 0.11 | 0.25 | 0.66 | -0.30 | 0.52 |
| | Inactive Status | 0.35 | 0.24 | 0.15 | -0.04 | 0.74 |
| Transplant (per 1,000 Patient Months) | **Total[1]** | -0.09 | 0.16 | 0.54 | -0.35 | 0.16 |
| | Deceased Donor[1] | -0.06 | 0.15 | 0.66 | -0.31 | 0.18 |
| | Living Donor[1] | -0.03 | 0.04 | 0.45 | -0.10 | 0.04 |
| | **Living Donor (Dialysis and Pre-Emptive)** | -0.01 | 0.03 | 0.82 | -0.06 | 0.05 |
| Utilization (%) | **Acute Care Hospitalization[2]** | -0.04 | 0.07 | 0.57 | -0.15 | 0.07 |
| | **Readmission** | -0.20 | 0.23 | 0.37 | -0.57 | 0.17 |
| | **Outpatient ED Use[2]** | -0.08 | 0.09 | 0.37 | -0.22 | 0.06 |
| Medicare Payments (PPPM) | **Total Parts A & B** | -$19 | $18 | 0.29 | -$47 | $10 |
| | ***Total Part A[3]*** | -$13 | $11 | 0.21 | -$31 | $4 |
| | Acute Care Hospitalization[3] | -$13 | $9 | 0.14 | -$27 | $1 |
| | Part A LTCH, IRF[3] | $2 | $3 | 0.48 | -$2 | $6 |
| | Other Part A[3] | -$1 | $1 | 0.56 | -$2 | $1 |
| | ***Total Part B*** | -$3 | $12 | 0.79 | -$23 | $17 |
| | Part B Dialysis | $0 | $8 | 0.97 | -$14 | $13 |
| | Other Part B | -$3 | $9 | 0.75 | -$18 | $12 |
| | **Total Part D[3]** | $14 | $11 | 0.21 | -$5 | $33 |
| Quality (%) | **Peritonitis** | -0.03 | 0.17 | 0.85 | -0.31 | 0.25 |
| | **ESRD complications** | 0.004 | 0.02 | 0.83 | -0.03 | 0.04 |
| | **VA complications** | -0.001 | 0.02 | 0.97 | -0.03 | 0.03 |
| | **Vascular Infection** | 0.02 | 0.03 | 0.58 | -0.03 | 0.06 |

**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. * All dialysis modality measures with the exception of home dialysis training are based on primary modality and are mutually exclusive (see **Exhibit B-3** for details).

[28] Upward or downward sloping lines indicated lack of parallel trends as that would imply differences between the ETC and comparison groups became larger or smaller during the pre-ETC period.

**Exhibit B-16. Assessing Parallel Trends: Dynamic Trend Test for Outcome Measures**

| Domain | Measure and Year | Joint Test p-value |
|---|---|---|
| ***Dialysis Modality Measures**** | **Home Dialysis** | 0.57 |
| | Peritoneal Dialysis | 0.44 |
| | Home HD | 0.74 |
| | **In-Center HD** | 0.58 |
| | In-Center Hemodialysis | 0.46 |
| | In-Center Self-Dialysis | 0.28 |
| | Nocturnal HD | 0.59 |
| | **Home Dialysis Training** | 0.62 |
| ***Waitlisting*** | **Overall** | 0.14 |
| | Active Status | 0.33 |
| | Inactive Status | 0.35 |
| ***Transplant (per 1,000 Patient Months)*** | **Total[2]** | 0.49 |
| | Deceased Donor[2] | 0.81 |
| | Living Donor[2] | 0.12 |
| | **Living Donor (among dialysis patients and pre-emptive transplant recipients)** | 0.13 |
| ***Utilization*** | **Acute Care Hospitalization[1]** | 0.72 |
| | **Readmission** | 0.16 |
| | **Outpatient ED use[1]** | 0.64 |
| ***Medicare Payments (PPM)*** | **Total Parts A & B** | 0.42 |
| | ***Total Part A[3]*** | 0.62 |
| | Part A Acute Care Hospitalization[3] | 0.34 |
| | Part A LTCH, IRF[3] | 0.21 |
| | Other Part A[3] | 0.44 |
| | ***Total Part B*** | 0.41 |
| | Part B Dialysis | 0.76 |
| | Other Part B | 0.48 |
| | **Total Part D[3]** | 0.25 |
| ***Quality (%)*** | **Peritonitis** | 0.92 |
| | **ESRD complications** | 0.55 |
| | **VA complications** | 0.54 |
| | **Vascular Infection** | 0.77 |

**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. *All dialysis modality measures with the exception of home dialysis training are based on primary modality and are mutually exclusive (see **Exhibit B-3** for details).

## B.5. DiD Regression Model and Estimated ETC Impacts

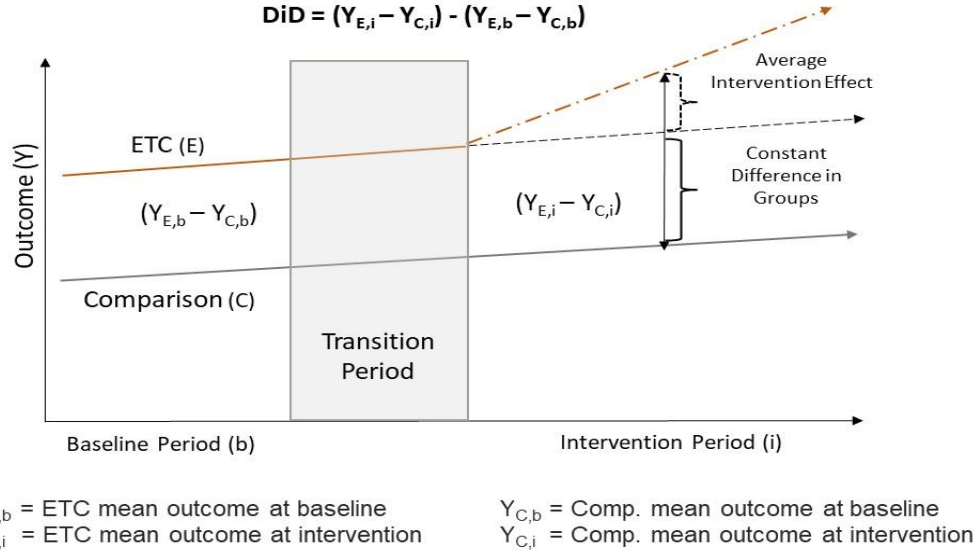
The DiD framework quantifies the impact of the ETC Model by comparing changes in outcomes for the ETC population before and after the start of the ETC Model with changes in outcomes for the comparison population before and after the start of the ETC Model. The DiD framework by design controls for unobserved, time-varying changes that are common to all patients (that is, 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-17**. $Y_{E,i}$ 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-17. Illustration of DiD Model**




We used repeated cross-sectional regression models for estimating the effects of the ETC Model on patient outcomes for 2021 and 2022, the first two years of the model. We also calculated the aggregate (cumulative) estimate (CY 2021-0222) as the weighted average of the yearly DiD estimates, weighted by the number of participant (ETC) intervention bene-months in each year. 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 = $Year_t$ with t = 1,2 for post-ETC years 2021 and 2022, respectively; 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:

$$Y_{it} = a_0 + a_1 Treat_i + \sum_{k=1}^{2} \beta_k Year_k + \sum_{k=1}^{2} \delta_k Treat_i * Year_k + \omega P_{Cov} + \epsilon_{it}$$

Coefficients as described above.

- The coefficient $\alpha_1$ is the average difference between the ETC and comparison group over the pre-ETC period.
- The coefficient $\beta_k$ captures changes in the ETC and comparison groups between the pre-ETC period and $CY_i$.
- The coefficient $\delta_k$ *with* $i = 1,2$ are the DiD effects in 2021 and 2022 respectively. In a linear model, this can be interpreted as the regression adjusted average difference in $CY_t$ *with* $t = 1,2$ for post-ETC years 2021 and 2022, respectively between ETC patients and comparison patients.

Additionally, we adjusted for year and within year quarter effects to account for overall yearly and seasonal variations, respectively.

**Two-part model.** Five of the nine 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 we used 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.[29]

**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, also accounted 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 ($\omega P_{Cov}$) 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.

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

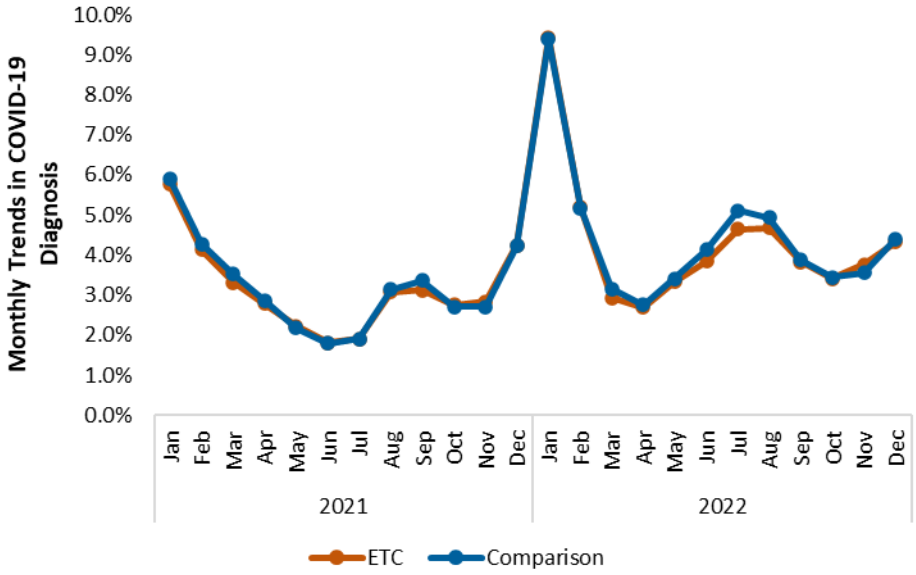
- **Degree of imbalance between ETC and comparison groups**. Covariate adjustments for selected patient and facility characteristics, and market-level characteristics were used to address any observed lack of balance during the pre-ETC period.
- **Differential trends between ETC and comparison groups 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.
- **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 (that is, 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 source of confounding due to other CMS initiatives and APMs.** These initiatives, which may have been initiated before or during the ETC evaluation, can influence provider operations and the process of care, potentially affecting patient outcomes. Patients with ESRD who are enrolled in any of these APMs may have a different health care course compared to those who are not. Particularly significant is the participation of Managing Clinicians in the KCC model (implemented in January 2022), which may vary between the ETC and comparison areas. As mentioned in Appendix A, given the overlapping goals of the ETC and KCC models, it is essential to comprehend and account for the potential effects of the KCC model on the impact estimates of the ETC evaluation. This understanding is critical in ensuring accurate assessments of the ETC program's effectiveness.
- **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 beyond 2020, 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 in the post-ETC period may be biased. For these reasons, we examined both patient COVID-19 diagnoses reported in the claims data and county-level COVID-19 data (for instace, county level COVID-19 incidence rates) for assessment of balance and potential covariate adjustment.[30] As shown in **Exhibit B-18**, we did not find evidence to suggest that COVID-19 had a markedly (observable) different impact on patients in ETC and comparison group HRRs; overall, we

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

observed relatively similar trends in the percentage of patient months with an initial COVID-19 diagnosis in the two groups throughout 2021 – 2022.

**Exhibit B-18. Monthly Trends in COVID-19 Diagnoses in ETC and Comparison Areas during 2021 – 2022**




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 variables (see **Exhibit B-19**). They are: (1) county-month-level rates of incidence of COVID-19 diagnoses;[30] (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. Given that, claims data will not capture all COVID-19 infections (for example, due to home testing) and availability of vaccines may not occur uniformly in both ETC and comparison areas and all these may affect patient outcomes; we had conducted additional analyses to examine the sensitivity of impact estimates to COVID-19 covariate adjustments. As shown in AR1, impact estimates were similar 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-19**. By using multivariate regression, we were able to adjust for observed patients, facility, and market level characteristics influencing the outcomes, which may not be differenced out by the DiD design. We used same set of covariates and ran the same multivariate DiD specification for each of the outcomes.

**Exhibit B-19. Covariate Adjustments Included in the DiD Models**

| Patient-Level | Facility-Level | Market-Level |
|---|---|---|
| ▪ Age categories*<br>▪ Female<br>▪ Race and Ethnicity (Hispanic) categories*<br>▪ BMI at ESRD incidence<br>▪ ESRD vintage categories* (that is, time on dialysis)<br>▪ Indicator for dually eligible (full or partial Medicaid benefits) status (monthly)<br>▪ Indicator Original Reason for Entitlement Code: age, disabled, ESRD, ESRD and Disabled<br>▪ Indicator for primary cause of ESRD: diabetes, glomerulonephritis, hypertension, other<br>▪ Indicators for comorbidities: Cancer (annual), acute myocardial infarction I, diabetes, pneumonia, rheumatoid arthritis<br>▪ 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.<br>▪ Indicators for alignment with: CEC, NGACO, Medicare Shared Savings Program. Kidney Care Choice (KCC)*<br>▪ Pre-ESRD nephrology care<br>▪ 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<br>▪ Rural Urban Indicator: Metro, Urban, Rural<br>▪ Facility chain/ownership indicator categories*<br>▪ Facility patient count (annual) | ▪ Poverty indicator<br>▪ Education attainment[2]<br>▪ CBSA MA penetration (annual)<br>▪ CBSA geographic rate of primary care providers per 10,000 population (annual)<br>▪ ADI<br>▪ Percent of ACO beneficiaries in the market<br>▪ Percent of CEC beneficiaries in the market<br>▪ 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/ Ethnicity categories are mutually exclusive, obtained from self-reported patient race data from EQRS form 2728 supplemented by RTI race from the claims. The mutually exclusive categories are: Hispanic, Non-Hispanic White, Non-Hispanic African American, Non-Hispanic Asian, Non-Hispanic Native Hawaiian/Pacific Islander, Non-Hispanic American Indian/Alaska Native, Non-Hispanic Other/Unknown Race. Time on dialysis categories: <6 months, 6 -12 months, 1-2 years, 2-3 years, 3-6 years, 6-10,10 years and higher. *KCC indicator for patient months aligned with a clinician participating in KCC Model. For pre-ETC years, it meant alignment with a clinician who eventually volunteered for KCC model that was implemented in 2022. 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.

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

The following two exhibits illustrate trends and estimated impacts of the ETC Model for all the outcomes. We examined the unadjusted trends of outcomes along with SMD between ETC and the comparison group for both pre-ETC and post-ETC period in **Exhibit B-20.** In **Exhibit B-21**, we show the yearly and cumulative (CY 2021 and CY 2021) impact estimates along with risk-adjusted pre-ETC and post-ETC means and estimates of the relative change for all the outcomes.

**Exhibit B-20. Unadjusted Means of Outcome Measures Used to Evaluate the ETC Model**

| Outcomes | | ETC | | | | Comparison | | | | SMD (ETC vs. Comparison) Pre-ETC period | SMD (ETC vs. Comparison) Post-ETC period |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Pre-ETC | | Post-ETC | | Pre-ETC | | Post-ETC | | | |
| | | N = 3,116,658 | | N = 1,550,586 | | N = 6,165,640 | | N = 3,034,722 | | | |
| | | Mean | SD | Mean | SD | Mean | SD | Mean | SD | | |
| Dialysis Modality Measures[1] (%) | **Home Dialysis** | 12.0% | 32.5% | 15.2% | 35.9% | 12.7% | 33.3% | 15.9% | 36.6% | -0.02 | -0.02 |
| | Peritoneal Dialysis | 9.9% | 29.8% | 12.1% | 32.6% | 10.7% | 31.0% | 13.0% | 33.7% | -0.03 | -0.03 |
| | Home HD | 2.2% | 14.5% | 3.1% | 17.4% | 2.0% | 14.0% | 2.9% | 16.7% | 0.01 | 0.02 |
| | **In-Center HD** | 87.9% | 32.6% | 84.6% | 36.1% | 87.1% | 33.5% | 83.9% | 36.7% | 0.02 | 0.02 |
| | In-Center hemodialysis | 87.6% | 33.0% | 84.5% | 36.2% | 86.7% | 34.0% | 83.7% | 36.9% | 0.03 | 0.02 |
| | In-Center Self-Dialysis | 0.04% | 1.9% | 0.03% | 1.6% | 0.09% | 2.9% | 0.04% | 1.9% | -0.02 | -0.01 |
| | Nocturnal HD | 0.28% | 5.3% | 0.14% | 3.7% | 0.34% | 5.8% | 0.17% | 4.1% | -0.01 | -0.01 |
| | **Home Dialysis Training** | 0.75% | 8.6% | 0.92% | 9.6% | 0.77% | 8.8% | 0.88% | 9.4% | -0.003 | 0.004 |
| Waitlisting (%) | **Overall** | 18.8% | 39.0% | 18.5% | 38.8% | 21.2% | 40.9% | 20.0% | 40.0% | -0.06 | -0.04 |
| | Active Status | 11.9% | 32.3% | 10.6% | 30.7% | 13.5% | 34.2% | 11.9% | 32.4% | -0.05 | -0.04 |
| | Inactive Status | 6.9% | 25.4% | 7.9% | 27.0% | 7.7% | 26.6% | 8.1% | 27.3% | -0.03 | -0.01 |
| Transplant (per 1000 Patient Months) | **Total[2]** | 3.7 | 61.1 | 5.0 | 70.7 | 3.9 | 62.4 | 4.9 | 69.6 | -0.003 | 0.002 |
| | Deceased Donor [2] | 3.2 | 56.3 | 4.4 | 66.5 | 3.3 | 57.1 | 4.2 | 64.9 | -0.002 | 0.003 |
| | Living Donor[2] | 0.56 | 23.7 | 0.58 | 24.2 | 0.64 | 25.4 | 0.64 | 25.2 | -0.003 | -0.002 |
| | **Living Donor (Dialysis and Pre-emptive)[3]** | 0.56 | 23.7 | 0.58 | 24.2 | 0.64 | 25.4 | 0.64 | 25.3 | -0.003 | -0.002 |
| Utilization (%) | **Acute Care Hospitalization** | 9.7% | 29.6% | 9.3% | 29.1% | 9.8% | 29.8% | 9.4% | 29.2% | -0.004 | -0.003 |
| | **Readmission** | 29.9% | 44.8% | 29.3% | 44.5% | 29.9% | 44.8% | 29.6% | 44.6% | 0.001 | -0.01 |
| | **Outpatient ED Use** | 11.4% | 31.8% | 9.8% | 29.7% | 11.1% | 31.4% | 9.6% | 29.5% | 0.01 | 0.01 |

| Outcomes | | ETC | | | | Comparison | | | | SMD (ETC vs. Comparison) Pre-ETC period | SMD (ETC vs. Comparison) Post-ETC period |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Pre-ETC | | Post-ETC | | Pre-ETC | | Post-ETC | | | |
| | | N = 3,116,658 | | N = 1,550,586 | | N = 6,165,640 | | N = 3,034,722 | | | |
| | | Mean | SD | Mean | SD | Mean | SD | Mean | SD | | |
| Medicare Payments (PPPM) | **Total Parts A & B** | $5,667 | $6,336 | $6,061 | $7,005 | $5,723 | $6,469 | $6,110 | $7,133 | -0.01 | -0.01 |
| | ***Total Part A*** | $1,579 | $6,089 | $1,753 | $6,841 | $1,649 | $6,293 | $1,823 | $7,033 | -0.01 | -0.01 |
| | Part A Acute Care Hospitalization | $1,359 | $5,531 | $1,500 | $6,355 | $1,399 | $5,659 | $1,536 | $6,484 | -0.01 | -0.01 |
| | Part A LTCH, IRF | $100 | $1,785 | $121 | $2,050 | $119 | $1,945 | $141 | $2,226 | -0.01 | -0.01 |
| | Other Part A | $120 | $626 | $143 | $546 | $133 | $657 | $159 | $574 | -0.02 | -0.03 |
| | ***Total Part B*** | $4,136 | $2,214 | $4,363 | $2,366 | $4,136 | $2,231 | $4,354 | $2,385 | 0.000 | 0.004 |
| | Part B Dialysis | $2,899 | $782 | $2,990 | $682 | $2,882 | $786 | $2,972 | $685 | 0.02 | 0.03 |
| | Other Part B | $1,237 | $2,157 | $1,373 | $2,360 | $1,253 | $2,179 | $1,382 | $2,375 | -0.01 | -0.004 |
| | **Total Part D** | $867 | $1,532 | $797 | $1,624 | $901 | $1,550 | $830 | $1,649 | -0.02 | -0.02 |
| Quality | **Peritonitis[4]** | 4.4% | 20.4% | 4.4% | 20.5% | 4.2% | 20.0% | 4.4% | 20.5% | 0.01 | 0.002 |
| | **Hospitalization with ESRD complications** | 0.84% | 9.5% | 0.81% | 9.3% | 0.80% | 9.3% | 0.78% | 9.2% | 0.005 | 0.003 |
| | **Hospitalization with VA complications** | 0.77% | 9.1% | 0.82% | 9.4% | 0.83% | 9.5% | 0.87% | 9.7% | -0.01 | -0.005 |
| | **Vascular Infection[5]** | 1.0% | 9.9% | 0.90% | 9.4% | 1.0% | 10.1% | 0.92% | 9.6% | -0.005 | -0.003 |

**Notes:** [1]Dialysis modality indicators except for home dialysis training are mutually exclusive (primary modality in a patient-month). Home dialysis: peritoneal dialysis or home HD. In- center HD includes in-center hemodialysis, in-center self-dialysis and nocturnal. Waitlisting and transplant measures are restricted to patients ages < 75 years. [2]Among dialysis patients. [3]Among dialysis patients and pre-emptive transplant recipients. [4]Among PD patients. [5]Among HD patients.

## Exhibit B-21. Estimated Impacts of the ETC Model for CY 2021 – 2022

| Outcomes | | Calendar Year | ETC | | Comparison | | Model Estimates | | | % Relative Change |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | Pre-ETC Mean | CY Mean | Pre-ETC Mean | CY Mean | DiD | Lower 90% CI | Upper 90% CI | |
| **Dialysis Modality Measures[1] (%)** | **Home Dialysis** | CY 2021-22 | 11.8% | 14.9% | 12.8% | 16.0% | -0.07 | -0.46 | 0.32 | -0.59% |
| | | CY 2021 | 11.8% | 14.7% | 12.8% | 15.8% | -0.10 | -0.47 | 0.27 | -0.88% |
| | | CY 2022 | 11.8% | 15.1% | 12.8% | 16.2% | -0.03 | -0.48 | 0.42 | -0.26% |
| | Peritoneal Dialysis | CY 2021-22 | 9.8% | 11.9% | 10.8% | 13.0% | -0.13 | -0.48 | 0.21 | -1.4% |
| | | CY 2021 | 9.8% | 11.8% | 10.8% | 12.9% | -0.14 | -0.47 | 0.19 | -1.4% |
| | | CY 2022 | 9.8% | 12.0% | 10.8% | 13.1% | -0.13 | -0.54 | 0.28 | -1.3% |
| | Home HD | CY 2021-22 | 2.1% | 3.0% | 2.1% | 3.0% | 0.06 | -0.14 | 0.27 | 3.1% |
| | | CY 2021 | 2.1% | 2.9% | 2.1% | 2.9% | 0.04 | -0.16 | 0.23 | 1.7% |
| | | CY 2022 | 2.1% | 3.1% | 2.1% | 3.1% | 0.10 | -0.14 | 0.34 | 4.8% |
| | **In-Center HD** | CY 2021-22 | 88.1% | 84.9% | 87.1% | 83.9% | 0.07 | -0.32 | 0.46 | 0.08% |
| | | CY 2021 | 88.1% | 85.1% | 87.1% | 84.1% | 0.10 | -0.27 | 0.48 | 0.12% |
| | | CY 2022 | 88.1% | 84.7% | 87.1% | 83.7% | 0.02 | -0.43 | 0.48 | 0.03% |
| | In-Center Hemodialysis | CY 2021-22 | 87.8% | 84.8% | 86.7% | 83.6% | 0.03 | -0.39 | 0.44 | 0.03% |
| | | CY 2021 | 87.8% | 85.0% | 86.7% | 83.8% | 0.09 | -0.30 | 0.49 | 0.11% |
| | | CY 2022 | 87.8% | 84.5% | 86.7% | 83.4% | -0.05 | -0.53 | 0.43 | -0.06% |
| | In-Center Self-Dialysis | CY 2021-22 | 0.03% | 0.01% | 0.09% | 0.04% | 0.03 | -0.03 | 0.09 | 111.7% |
| | | CY 2021 | 0.03% | -0.005% | 0.09% | 0.04% | 0.02 | -0.04 | 0.08 | 73.9% |
| | | CY 2022 | 0.03% | 0.03% | 0.09% | 0.05% | 0.04 | -0.02 | 0.11 | 155.9% |
| | Nocturnal HD | CY 2021-22 | 0.29% | 0.16% | 0.33% | 0.19% | 0.01 | -0.07 | 0.08 | 2.6% |
| | | CY 2021 | 0.29% | 0.16% | 0.33% | 0.21% | -0.01 | -0.08 | 0.06 | -4.4% |
| | | CY 2022 | 0.29% | 0.16% | 0.33% | 0.17% | 0.03 | -0.05 | 0.11 | 10.8% |
| | **Home Dialysis Training** | CY 2021-22 | 0.70% | 0.84% | 0.73% | 0.81% | **0.05**** | 0.01 | 0.10 | **7.7%** |
| | | CY 2021 | 0.70% | 0.84% | 0.73% | 0.80% | **0.07**** | 0.02 | 0.11 | **9.5%** |
| | | CY 2022 | 0.70% | 0.84% | 0.73% | 0.83% | 0.04 | -0.01 | 0.09 | 5.6% |

| Outcomes | | Calendar Year | ETC | | Comparison | | Model Estimates | | | % Relative Change |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | Pre-ETC Mean | CY Mean | Pre-ETC Mean | CY Mean | DiD | Lower 90% CI | Upper 90% CI | |
| **Waitlisting (%)** | **Overall**[2] | CY 2021-22 | 19.4% | 18.9% | 21.1% | 19.9% | 0.80 | -0.08 | 1.7 | 4.1% |
| | | CY 2021 | 19.4% | 18.9% | 21.1% | 19.8% | 0.78 | -0.04 | 1.6 | 4.0% |
| | | CY 2022 | 19.4% | 19.0% | 21.1% | 19.9% | 0.83 | -0.17 | 1.8 | 4.3% |
| | Active Status[2] | CY 2021-22 | 12.2% | 11.1% | 13.4% | 11.9% | 0.42 | -0.36 | 1.2 | 3.5% |
| | | CY 2021 | 12.2% | 11.4% | 13.4% | 12.2% | 0.38 | -0.31 | 1.1 | 3.1% |
| | | CY 2022 | 12.2% | 10.8% | 13.4% | 11.6% | 0.47 | -0.49 | 1.4 | 3.9% |
| | Inactive Status[2] | CY 2021-22 | 7.2% | 7.8% | 7.7% | 7.9% | 0.38 | -0.22 | 0.98 | 5.3% |
| | | CY 2021 | 7.2% | 7.5% | 7.7% | 7.6% | 0.40 | -0.14 | 0.93 | 5.5% |
| | | CY 2022 | 7.2% | 8.2% | 7.7% | 8.3% | 0.36 | -0.38 | 1.1 | 4.9% |
| **Transplant (per 1,000 Patient Months)** | **Total** [2 3] | CY 2021-22 | 3.9 | 5.4 | 3.8 | 4.9 | **0.38*** | 0.06 | 0.69 | **9.7%** |
| | | CY 2021 | 3.9 | 5.1 | 3.8 | 4.7 | **0.40*** | 0.05 | 0.74 | **10.3%** |
| | | CY 2022 | 3.9 | 5.7 | 3.8 | 5.3 | 0.35 | -0.005 | 0.70 | 9.1% |
| | Deceased Donor [2 3] | CY 2021-22 | 3.3 | 4.8 | 3.2 | 4.3 | **0.36*** | 0.05 | 0.67 | **11.1%** |
| | | CY 2021 | 3.3 | 4.5 | 3.2 | 4.1 | **0.39*** | 0.06 | 0.73 | **12.1%** |
| | | CY 2022 | 3.3 | 5.1 | 3.2 | 4.7 | 0.32 | -0.03 | 0.68 | 9.9% |
| | Living Donor [2 3] | CY 2021-22 | 0.60 | 0.59 | 0.64 | 0.61 | 0.01 | -0.04 | 0.07 | 2.3% |
| | | CY 2021 | 0.60 | 0.58 | 0.64 | 0.62 | 0.002 | -0.07 | 0.07 | 0.35% |
| | | CY 2022 | 0.60 | 0.60 | 0.64 | 0.61 | 0.03 | -0.06 | 0.11 | 4.5% |
| | **Living Donor (among Both Dialysis Patients and Pre-emptive Transplant Recipients)** [2 4] | CY 2021-22 | 0.60 | 0.59 | 0.64 | 0.61 | 0.01 | -0.05 | 0.07 | 2.2% |
| | | CY 2021 | 0.60 | 0.58 | 0.64 | 0.62 | 0.003 | -0.07 | 0.07 | 0.50% |
| | | CY 2022 | 0.60 | 0.60 | 0.64 | 0.61 | 0.03 | -0.06 | 0.11 | 4.3% |
| **Utilization (%)** | **Acute Care Hospitalization** | CY 2021-22 | 10.0% | 9.2% | 9.9% | 9.0% | 0.05 | -0.11 | 0.21 | 0.52% |
| | | CY 2021 | 10.0% | 9.2% | 9.9% | 9.0% | 0.08 | -0.09 | 0.24 | 0.76% |
| | | CY 2022 | 10.0% | 9.2% | 9.9% | 9.1% | 0.02 | -0.16 | 0.21 | 0.23% |
| | **Readmission** | CY 2021-22 | 30.1% | 29.1% | 30.0% | 29.2% | -0.22 | -0.70 | 0.27 | -0.72% |
| | | CY 2021 | 30.1% | 29.1% | 30.0% | 29.4% | -0.47 | -0.98 | 0.03 | -1.6% |
| | | CY 2022 | 30.1% | 29.1% | 30.0% | 28.9% | 0.08 | -0.55 | 0.71 | 0.27% |
| | **Outpatient ED Use** | CY 2021-22 | 11.3% | 9.5% | 11.2% | 9.5% | **-0.17*** | -0.33 | -0.01 | **-1.5%** |
| | | CY 2021 | 11.3% | 9.4% | 11.2% | 9.4% | -0.14 | -0.31 | 0.04 | -1.2% |
| | | CY 2022 | 11.3% | 9.6% | 11.2% | 9.6% | **-0.20*** | -0.39 | -0.02 | **-1.8%** |

| Outcomes | | Calendar Year | ETC | | Comparison | | Model Estimates | | | % Relative Change |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | Pre-ETC Mean | CY Mean | Pre-ETC Mean | CY Mean | DiD | Lower 90% CI | Upper 90% CI | |
| **Medicare Payments (PPPM)** | **Total Parts A & B** | CY 2021-22 | $5,704 | $6,015 | $5,760 | $6,055 | $16 | -$26 | $57 | 0.28% |
| | | CY 2021 | $5,704 | $5,986 | $5,760 | $6,052 | -$10 | -$50 | $30 | -0.18% |
| | | CY 2022 | $5,704 | $6,048 | $5,760 | $6,058 | $46 | -$4 | $97 | 0.81% |
| | ***Total Part A*[5] | CY 2021-22 | $1,647 | $1,705 | $1,681 | $1,730 | $9 | -$35 | $53 | 0.56% |
| | | CY 2021 | $1,647 | $1,702 | $1,681 | $1,739 | -$4 | -$49 | $41 | -0.23% |
| | | CY 2022 | $1,647 | $1,710 | $1,681 | $1,719 | $24 | -$23 | $72 | 1.5% |
| | Part A Hospital[5] | CY 2021-22 | $1,413 | $1,458 | $1,421 | $1,453 | $13 | -$3 | $29 | 0.92% |
| | | CY 2021 | $1,413 | $1,463 | $1,421 | $1,463 | $8 | -$11 | $27 | 0.57% |
| | | CY 2022 | $1,413 | $1,452 | $1,421 | $1,440 | $19 | -$0.12 | $38 | 1.3% |
| | Part A LTCH, IRF[5] | CY 2021-22 | $104 | $121 | $120 | $135 | $2 | -$2 | $6 | 1.9% |
| | | CY 2021 | $104 | $110 | $120 | $133 | **-$7**** | -$12 | -$2 | **-6.3%** |
| | | CY 2022 | $104 | $134 | $120 | $139 | **$12**** | $6 | $18 | **11.5%** |
| | Other Part A[5] | CY 2021-22 | $128 | $142 | $135 | $151 | -$2 | -$5 | $2 | -1.3% |
| | | CY 2021 | $128 | $146 | $135 | $156 | -$2 | -$5 | $1 | -1.6% |
| | | CY 2022 | $128 | $137 | $135 | $145 | -$1 | -$5 | $2 | -0.93% |
| | ***Total Part B*** | CY 2021-22 | $4,117 | $4,344 | $4,153 | $4,370 | $10 | -$11 | $31 | 0.24% |
| | | CY 2021 | $4,117 | $4,319 | $4,153 | $4,360 | -$5 | -$28 | $18 | -0.11% |
| | | CY 2022 | $4,117 | $4,372 | $4,153 | $4,381 | $27 | $2 | $51 | 0.65% |
| | Part B Dialysis | CY 2021-22 | $2,879 | $2,985 | $2,886 | $2,990 | $2 | -$9 | $13 | 0.06% |
| | | CY 2021 | $2,879 | $2,971 | $2,886 | $2,975 | $2 | -$9 | $14 | 0.08% |
| | | CY 2022 | $2,879 | $3,002 | $2,886 | $3,008 | $1 | -$11 | $13 | 0.03% |
| | Other Part B | CY 2021-22 | $1,238 | $1,359 | $1,267 | $1,379 | $8 | -$10 | $26 | 0.66% |
| | | CY 2021 | $1,238 | $1,349 | $1,267 | $1,385 | -$7 | -$27 | $14 | -0.56% |
| | | CY 2022 | $1,238 | $1,370 | $1,267 | $1,373 | $26 | $5 | $47 | 2.1% |
| | **Total Part D** | CY 2021-22 | $873 | $806 | $899 | $831 | $0.2 | -$19 | $19 | 0.02% |
| | | CY 2021 | $873 | $784 | $899 | $802 | $8 | -$10 | $26 | 0.89% |
| | | CY 2022 | $873 | $832 | $899 | $866 | -$9 | -$32 | $14 | -1.0% |

| Outcomes | | Calendar Year | ETC | | Comparison | | Model Estimates | | | % Relative Change |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | Pre-ETC Mean | CY Mean | Pre-ETC Mean | CY Mean | DiD | Lower 90% CI | Upper 90% CI | |
| Quality (%) | Peritonitis[6] | CY 2021-22 | 4.3% | 4.4% | 4.2% | 4.4% | -0.08 | -0.35 | 0.20 | -1.8% |
| | | CY 2021 | 4.3% | 4.3% | 4.2% | 4.4% | -0.16 | -0.47 | 0.14 | -3.8% |
| | | CY 2022 | 4.3% | 4.5% | 4.2% | 4.4% | 0.02 | -0.30 | 0.34 | 0.49% |
| | Hospitalization with ESRD complications | CY 2021-22 | 0.85% | 0.81% | 0.79% | 0.77% | -0.02 | -0.06 | 0.02 | -2.5% |
| | | CY 2021 | 0.85% | 0.80% | 0.79% | 0.76% | -0.01 | -0.05 | 0.03 | -1.7% |
| | | CY 2022 | 0.85% | 0.82% | 0.79% | 0.79% | -0.03 | -0.07 | 0.02 | -3.5% |
| | Hospitalization with VA complications | CY 2021-22 | 0.79% | 0.84% | 0.81% | 0.86% | 0.01 | -0.02 | 0.04 | 1.0% |
| | | CY 2021 | 0.79% | 0.83% | 0.81% | 0.84% | 0.01 | -0.02 | 0.05 | 1.9% |
| | | CY 2022 | 0.79% | 0.85% | 0.81% | 0.88% | -0.001 | -0.04 | 0.04 | -0.07% |
| | Vascular Infection[7] | CY 2021-22 | 0.97% | 0.89% | 1.0% | 0.92% | 0.03 | -0.03 | 0.08 | 2.6% |
| | | CY 2021 | 0.97% | 0.87% | 1.0% | 0.92% | 0.005 | -0.06 | 0.06 | 0.47% |
| | | CY 2022 | 0.97% | 0.91% | 1.0% | 0.92% | 0.05 | -0.01 | 0.11 | 5.2% |

**Notes:** A summary of the results of the Pre-ETC period includes CY 2017 – CY 2019. Pre-ETC and CY 2021-2022 means were adjusted for patient, facility, and market characteristics. 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. Cumulative (CY 2021-22) DID estimate is a weighted average of the yearly DiD estimates (see **Appendix B**, Section B.5). % Relative change based on DiD estimates and Pre-ETC Mean (before rounding). [1]Dialysis modality indicators except for home dialysis training are mutually exclusive (primary modality in a patient-month). Home dialysis: peritoneal dialysis or home HD. In- center HD includes in-center hemodialysis, in-center self-dialysis and nocturnal. [2]Transplant and waitlisting 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]Among PD patients. [7]Among HD patients.

## B.6. Health Equity and Other Subgroup Analyses

The ETC Model was amended in CY 2022 to include two provisions that were intended to promote greater equity in home dialysis and transplantation among beneficiaries with ESRD.[31] First, starting with MY3, which began on January 1, 2022, the PPA achievement benchmarks were stratified by whether the percentage of attributed beneficiary years during the MY for FFS beneficiaries who were dually eligible for Medicare and Medicaid or who were eligible for the Part D LIS was less than 50 percent or 50 percent or more.[10]

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 achieved sufficient improvement in home dialysis and transplant rates among attributed beneficiaries who were dually eligible for Medicare and Medicaid or Part D LIS recipients. In the absence of the Health Equity Incentive, ETC participants can earn maximum home dialysis and transplant improvement scores of 1.5 points. With the Health Equity Incentive, ETC participants have the opportunity to earn a Health Equity Bonus of 0.5 points to be added to their improvement score, thereby increasing the maximum improvement score to 2.0. With the potential for ETC participants to earn the Health Equity Bonus, the MPS was calculated as follows starting in CY 2022:

*MPS = 2 * (Higher of the home dialysis achievement score[32] or (home dialysis improvement score + Health Equity Bonus)) + (Higher of the transplant achievement score[8] or (transplant improvement score + Health Equity Bonus)).*

For both CY 2021 and CY 2022, the MPS for ETC participants ranged from 0 to 6 points. However, based on the above formula, there was potential for ETC participants to earn up to 2 points towards their MPS for CY 2022 if they earned the Health Equity Bonus.

To assess whether the ETC Model had implications for health equity among patients with ESRD, we examined whether the impacts of the Model during CY 2021-CY 2022 differed for historically underserved populations. This included dually eligible beneficiaries, beneficiaries enrolled in Part D plans who are recipients of the Part D LIS, and racial and ethnic minority groups. We both estimated impacts for these beneficiary subgroups and assessed whether they differed from those observed for corresponding reference populations.

We also considered the possibility that early effects of the model on home dialysis use might be more pronounced among specific subgroups of beneficiaries. Changes in dialysis modality use were likely to be more evident among beneficiaries initiating renal replacement therapy (RRT) rather than those with an established history of in-center HD. Additionally, we hypothesized that younger patients might be more inclined to choose home dialysis due to its advantages in flexibility, independence, and employment opportunities.

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[31] 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.

[32] Achievement scores range from 0 to 2.0 points. The Health Equity Bonus does not apply to the achievement scores.

Furthermore, we explored facility characteristics to identify facilities more likely to expand home dialysis. We theorized that facilities with higher home dialysis patient volume and experience would possess a robust infrastructure, making them better equipped to respond to ETC Model incentives and expand home dialysis services. With these hypotheses in mind, we examined the impacts among beneficiary subgroups categorized based on the duration of ESRD, beneficiary age, and whether the beneficiary received treatment at an ESRD facility with an established home dialysis program.

**In the context of health equity, we examined ETC Model impacts among patient subgroups on select outcomes:**

- Home dialysis use
- Waitlisting
- Overall transplantation among dialysis patients
- Utilization and quality of care: acute care hospitalizations; hospital readmissions; peritonitis among PD patients
- Total Medicare Parts A & B payments PPPM

**based on:**

- Dual eligibility (Dual enrollment in Medicare and Medicaid for beneficiaries with full Medicaid benefits)
- Receipt of Part D LIS (among Part D enrollees)
- Race and ethnicity[33]: Hispanic, Non-Hispanic Black, Non-Hispanic White, Non-Hispanic Other Race

[33] Mutually exclusive categories based primarily on patient-reported race and ethnicity from the CMS ESRD Medical Evidence Form. Other includes Non-Hispanic Asian, Non-Hispanic Native Hawaiian/Pacific Islander, Non-Hispanic American Indian/Alaska Native, Non-Hispanic Other/Unknown Race.

**In the context of health equity, we examined ETC Model impacts among patient subgroups on select outcomes:**

- Home dialysis use
- Waitlisting
- Overall transplantation among dialysis patients
- Utilization and quality of care: acute care hospitalizations; hospital readmissions; peritonitis among PD patients
- Total Medicare Parts A & B payments PPPM

**based on:**

- Dual eligibility (Dual enrollment in Medicare and Medicaid for beneficiaries with full Medicaid benefits)
- Receipt of Part D LIS (among Part D enrollees)
- Race and ethnicity:[34] Hispanic, Non-Hispanic Black, Non-Hispanic White, Non-Hispanic Other Race

**To assess early impacts of the model, we examined ETC Model impacts among patient subgroups on select outcomes:**

- Home dialysis use
- Waitlisting
- Overall transplantation among dialysis patients

**based on:**

- Time on dialysis (subgroups defined as 0-90 days, 90-1 year, 1-5 years, >5 years)
- Age (subgroups defined as 18-44, 45-64, >65 years)
- Facility with an established home dialysis program35 (subgroups defined as facilities who had at least 20 home dialysis patients for each of the pre-ETC years vs. not)

To answer both the research questions, we used a difference-in-difference-in-differences (DDD) model by assessing whether the impact of the ETC Model differs (is heterogeneous) among subgroups of interest. A triple difference (DDD) model allows us to estimate the impact of the ETC Model on a subgroup of interest and formally test whether the impact differs from that of a reference subgroup using a common set of risk adjusters.

Mathematically, we implemented a DDD model by specifying a three-way interaction between indicators of treatment, post-intervention, and subgroup membership. We used the estimated

[34] Mutually exclusive categories based primarily on patient-reported race and ethnicity from the CMS ESRD Medical Evidence Form. Other includes Non-Hispanic Asian, Non-Hispanic Native Hawaiian/Pacific Islander, Non-Hispanic American Indian/Alaska Native, Non-Hispanic Other/Unknown Race.

[35] We only examined home dialysis use for this subgroup analyses.

coefficient for this interaction term to test whether there is a differential impact of the model for a subgroup of interest relative to a reference subgroup. The associated DDD model also includes the two-way interactions among pairs of subgroup, intervention, and post-intervention indicators as well as the main effect of subgroup membership.

DDD uses the entire sample (unlike stratified analyses) and has all the advantages of a DiD model, accounting for both time-invariant and time-varying confounders. It estimates a specification similar to the overall DiD analyses with inclusion of additional interaction terms for subgroups of interest to estimate the marginal effect of all categories within an interest group. It is comparable to performing DiD on two subgroups and then comparing the resulting estimates in a single regression[36], subject to the constraint that the coefficients on risk-adjustment variables were the same for both subpopulations.

$$Outcome = \beta_0 + \beta_1 treat + \beta_2 post + \beta_3 Subgroup_i + \beta_4 (treat * Subgroupi) + \beta_5 (post * Subgroup_i) + \beta_6 (treat * post) + \beta_7 (treat * post * Subgroup_i) + covariates + error$$

- $\beta_6$: DiD for the reference subgroup
- $\beta_7$: DDD estimate; difference between the subgroup of interest and the reference subgroup
- $\beta_6 + \beta_7$: Treatment effect (DiD) for the subgroup of interest

We conducted descriptive analyses of trends in outcome measures by subgroups (that is, by dual eligible/Part D LIS status, race/ethnicity, time on dialysis, age, etc.) during both the ETC and pre-ETC periods and assessed balance between the groups on patient and facility characteristics. We also calculated the pre-ETC gap in ETC areas corresponding to the difference in pre-ETC means between the patient subgroup and the reference subgroup while adjusting for patient, facility, and market characteristics (see **Exhibit B-19** for the entire list of covariates). Like DiD analyses, we calculated both yearly (CY 2021 and CY 2022) and cumulative DiD and DDD estimates, with cumulative being the weighted average of the yearly estimates, weighted by the number of participant (ETC) intervention bene-months in each year. DDD modeling was performed at the patient month-level. As explained in **Section B.4.2**, we also examined parallel trends assumptions for each subgroup using falsification (placebo) models and dynamic trend tests (joint-F) as shown in **Exhibits B-31 – 33.**

There could be tradeoffs in controlling for factors that represent potential confounders and are also potential sources of disparities in ESRD patient care. For example, adjusting for dual eligibility when measuring racial and ethnic disparities. Therefore, we tested three approaches for risk adjustment:

- Fully adjusted model: As specified for overall impact analyses (**Exhibit B-19**)
- Parsimonious model: Age, sex, primary cause of ESRD, comorbidities and BMI at onset of ESRD, and duration of ESRD
- Unadjusted model

Findings were generally not sensitive to which risk adjustment approach was used.

[36] To note, that it does not equate to running two separate DiD analyses as the DDD model (the way specified here is not a fully interacted model) did not include interaction of all covariates with the subgroup of interest

All the DDD results included in the main report and appendix were adjusted for a full set of covariates as specified in **Exhibit B-19**.

We compared the overlap among patient subgroups used in the health equity analyses. There was a high level of overlap between dual eligibility and Part D LIS status (see **Exhibit B-22**). Racial and ethnic minorities were more likely to be dually eligible and recipients of the Part D LIS (see **Exhibit B-23** and **Exhibit B-24**).

**Exhibit B-22. Distribution of Patient Months by Dual Eligibility and Part D LIS, for ETC and Comparison Areas**

| Part D LIS Recipient | ETC | | Comparison | |
|---|---|---|---|---|
| | Dually Eligible[1] | Non-Dually Eligible | Dually Eligible[1] | Non-Dually Eligible |
| Yes | 99.7% | 42.4% | 99.7% | 40.9% |
| No | 0.25% | 57.6% | 0.29% | 59.1% |

**Note:** [1]Includes dually eligible beneficiaries with full Medicaid benefits.

**Exhibit B-23. Distribution of Patient Months by Dual Eligibility and Race/Ethnicity, for ETC and Comparison Areas**

| Race/Ethnicity | ETC | | Comparison | |
|---|---|---|---|---|
| | Dually Eligible[1] | Non-Dually Eligible | Dually Eligible[1] | Non-Dually Eligible |
| Hispanic | 15.4% | 8.9% | 25.3% | 12.8% |
| White[2] | 30.8% | 50.4% | 28.6% | 50.7% |
| Black/African American[2] | 43.3% | 34.8% | 35.4% | 30.4% |
| Asian[2] | 4.6% | 2.8% | 7.2% | 3.9% |
| American Indian/Alaska Native[2] | 4.1% | 2.0% | 1.2% | 0.92% |
| Native Hawaiian/Pacific Islander[2] | 1.2% | 0.83% | 1.6% | 0.95% |
| Other[2] | 0.54% | 0.32% | 0.57% | 0.37% |

**Notes:** [1]Includes dually eligible beneficiaries with full Medicaid benefits. [2]Among Non-Hispanic population.

**Exhibit B-24. Distribution of Patient Months by Part D LIS and Race/Ethnicity, for ETC and Comparison Areas**

| Race/Ethnicity | ETC | | Comparison | |
|---|---|---|---|---|
| | Part D LIS Recipient: Yes | Part D LIS Recipient: No | Part D LIS Recipient: Yes | Part D LIS Recipient: No |
| Hispanic | 15.0% | 5.5% | 23.8% | 8.1% |
| White[1] | 30.8% | 65.6% | 29.7% | 64.8% |
| Black/African American[1] | 45.4% | 25.0% | 37.8% | 21.8% |
| Asian[1] | 3.8% | 2.5% | 5.6% | 3.8% |
| American Indian/Alaska Native[1] | 3.5% | 0.70% | 1.2% | 0.42% |
| Native Hawaiian/Pacific Islander[1] | 1.1% | 0.49% | 1.4% | 0.66% |
| Other[1] | 0.44% | 0.25% | 0.51% | 0.32% |

**Note:** [1]Among Non-Hispanic population

The health equity DDD model impact estimate results for select outcomes are shown in **Exhibits B-25 – B-28** and subgroup DDD model impact estimates for select outcomes are shown in **Exhibits B-29** and **B-30**.

### Exhibit B-25. Health Equity DDD Model Impact Estimates for Acute Care Hospitalization, CY 2021 – CY 2022

| Patient Subgroup | | Cumulative DiD[1] | % Relative Change | DDD[1] (vs. Ref) | Pre-ETC Gap in ETC areas (vs. Ref) | % Change in Pre-ETC Gap |
|---|---|---|---|---|---|---|
| Dually Eligible[2] | Yes | 0.03 | 0.30% | -0.004 | 0.92% | -0.4% |
| | No (Ref) | 0.04 | 0.37% | - | - | - |
| Part D LIS Recipient | Yes | 0.13 | 1.3% | 0.26** | 0.36% | 72.3% |
| | No (Ref) | -0.13 | -1.3% | - | - | - |
| Race and Ethnicity | Hispanic | 0.14 | 1.5% | 0.14 | -1.2% | -11.7% |
| | Black[3] | 0.04 | 0.37% | 0.03 | -0.70% | -4.3% |
| | Other race[3] | 0.03 | 0.34% | 0.03 | -1.4% | -1.8% |
| | White (Ref)[3] | 0.01 | 0.05% | - | - | - |

**Notes:** Ref corresponds to reference subgroup. Results are based on DDD models of cumulative impacts in CY 2021 and CY 2022, adjusted for the full set of patient, facility, and market characteristics (for the list of covariates see **Exhibit B-19**). DDD estimates correspond to the relative impact of the ETC Model for the patient subgroup relative to the reference subgroup. The pre-ETC period includes CY 2017-CY 2019. The pre-ETC gap in ETC areas corresponds to the difference in pre-ETC means between the patient subgroup and the reference subgroup while adjusting for patient, facility, and market characteristics. Analysis of Part D LIS status is limited to patients enrolled in Part D. [1]Corresponds to percentage point change. [2]Includes dually eligible beneficiaries with full Medicaid benefits. [3]Indicates race among Non-Hispanic patients. **Indicates statistical significance of DiD or DDD estimate at p-value <0.05.

### Exhibit B-26. Health Equity DDD Model Impact Estimates for Hospital Readmission, CY 2021 – CY 2022

| Patient Subgroup | | Cumulative DiD[1] | % Relative Change | DDD[1] (vs. Ref) | Pre-ETC Gap in ETC areas (vs. Ref) | % Change in Pre-ETC Gap |
|---|---|---|---|---|---|---|
| Dually Eligible[2] | Yes | -0.08 | -0.25% | 0.24 | 2.6% | 9.3% |
| | No (Ref) | -0.32 | -1.1% | - | - | - |
| Part D LIS Recipient | Yes | -0.10 | -0.33% | 0.33 | 1.8% | 18.2% |
| | No (Ref) | -0.44 | -1.5% | - | - | - |
| Race and Ethnicity | Hispanic | -0.16 | -0.57% | 0.17 | -3.6% | -4.8% |
| | Black[3] | -0.58 | -1.9% | -0.25 | -0.60% | 41.3% |
| | Other race[3] | 1.7** | 6.3% | 2.0** | -4.1% | -49.3% |
| | White (Ref)[3] | -0.33 | -1.1% | - | - | - |

**Notes:** Ref corresponds to reference subgroup. Results are based on DDD models of cumulative impacts in CY 2021 and CY 2022, with adjustment for patient, facility, and market characteristics. DDD estimates correspond to the relative impact of the ETC Model for the patient subgroup relative to the reference subgroup. The pre-ETC period includes CY 2017-CY 2019. The pre-ETC gap in ETC areas corresponds to the difference in pre-ETC means between the patient subgroup and the reference subgroup while adjusting for patient, facility, and market characteristics. Analysis of Part D LIS status is limited to patients enrolled in Part D. [1]Corresponds to percentage point change. [2]Includes dually eligible beneficiaries with full Medicaid benefits. [3]Indicates race among Non-Hispanic patients. *Indicates statistical significance of DiD or DDD estimate at p-value <0.1. **Indicates statistical significance of DiD or DDD estimate at p-value <0.05.

## Exhibit B-27. Health Equity DDD Model Impact Estimates for Peritonitis among PD Patients, CY 2021 – CY 2022

| Patient Subgroup | | Cumulative DiD[1] | % Relative Change | DDD[1] (vs. Ref) | Pre-ETC Gap in ETC areas (vs. Ref) | % Change in Pre-ETC Gap |
|---|---|---|---|---|---|---|
| Dually Eligible[2] | Yes | 0.02 | 0.4% | 0.12 | 0.49% | 24.7% |
| | No (Ref) | -0.10 | -2.5% | - | - | - |
| Part D LIS Recipient | Yes | -0.07 | -1.6% | 0.02 | 0.60% | 2.6% |
| | No (Ref) | -0.09 | -2.2% | - | - | - |
| Race and Ethnicity | Hispanic | 0.12 | 3.2% | 0.12 | -0.61% | -20.4% |
| | Black[3] | -0.46 | -9.2% | -0.45 | 0.73% | -61.8% |
| | Other race[3] | 0.22 | 6.2% | 0.23 | -0.70% | -33.2% |
| | White (Ref)[3] | -0.01 | -0.18% | - | - | - |

**Notes:** Ref corresponds to reference subgroup. Results are based on DDD models of cumulative impacts in CY 2021 and CY 2022, with adjustment for patient, facility, and market characteristics. DDD estimates correspond to the relative impact of the ETC Model for the patient subgroup relative to the reference subgroup. The pre-ETC period includes CY 2017-CY 2019. The pre-ETC gap in ETC areas corresponds to the difference in pre-ETC means between the patient subgroup and the reference subgroup while adjusting for patient, facility, and market characteristics. Analyses of Part D LIS recipients are limited to patients enrolled in Part D. [1]Corresponds to percentage point change. [2]Includes dually eligible beneficiaries with full Medicaid benefits. [3]Indicates race among Non-Hispanic patients. No DiD or DDD estimates are statistically significant at p-value <0.1.

## Exhibit B-28. Health Equity DDD Model Impact Estimates for Total Medicare Parts A & B Payments PPPM, CY 2021 – CY 2022

| Patient Subgroup | | Cumulative DiD | % Relative Change | DDD (vs. Ref) | Pre-ETC Gap in ETC areas (vs. Ref) | % Change in Pre-ETC Gap |
|---|---|---|---|---|---|---|
| Dually Eligible[1] | Yes | $4 | 0.08% | -$9 | $137 | -6.9% |
| | No (Ref) | $14 | 0.25% | - | - | - |
| Part D LIS Recipient | Yes | $18 | 0.31% | $21 | -$91 | -22.6% |
| | No (Ref) | -$3 | -0.05% | - | - | - |
| Race and Ethnicity | Hispanic | $30 | 0.56% | $30 | -$439 | -6.9% |
| | Black[2] | $13 | 0.23% | $13 | -$102 | -13.1% |
| | Other race[2] | $103** | 1.9% | $103** | -$516 | -19.9% |
| | White (Ref)[2] | -$0.3 | -0.005% | - | - | - |

**Notes:** Ref corresponds to reference subgroup. Results are based on DDD models of cumulative impacts in CY 2021 and CY 2022, with adjustment for patient, facility, and market characteristics. DDD estimates correspond to the relative impact of the ETC Model for the patient subgroup relative to the reference subgroup. The pre-ETC period includes CY 2017-CY 2019. The pre-ETC gap in ETC areas corresponds to the difference in pre-ETC means between the patient subgroup and the reference subgroup while adjusting for patient, facility, and market characteristics. Analysis of Part D LIS status is limited to patients enrolled in Part D. [1]Includes dually eligible beneficiaries with full Medicaid benefits. [2]Indicates race among Non-Hispanic patients. **Indicates statistical significance of DiD or DDD estimate at p-value <0.05.

### Exhibit B-29. Duration of ESRD DDD Model Impact Estimates for Home Dialysis Use, CY 2021 – CY 2022

| Patient Subgroup: Duration of ESRD | Number of Patients | Cumulative DiD | % Relative Change | DDD (vs. Ref) | Pre-ETC Gap (vs. Ref) | % Change in Pre-ETC Gap |
|---|---|---|---|---|---|---|
| 90 days – 1 year | 268,866 | 0.69 | 4.3% | 0.24 | 2.7% | 8.9% |
| 1 year – 5 years | 413,292 | -0.24 | -1.8% | -0.69 | 0.16% | -427.1% |
| Over 5 years | 242,061 | -0.15 | -1.7% | -0.60 | -4.7% | 12.7% |
| 0-90 days (Ref) | 216,185 | 0.45 | 3.4% | - | - | - |

**Notes:** Ref corresponds to reference subgroup. Results are based on DDD models of cumulative impacts in CY 2021 and CY 2022, with adjustment for patient, facility, and market characteristics. DDD estimates correspond to the relative impact of the ETC Model for the patient subgroup relative to the reference subgroup. The pre-ETC period includes CY 2017-CY 2019. The pre-ETC gap in ETC areas corresponds to the difference in pre-ETC means between the patient subgroup and the reference subgroup while adjusting for patient, facility, and market characteristics. No DiD or DDD estimates are statistically significant at p-value <0.1. DiD and DDD values represent percentage point changes.

### Exhibit B-30. Facility Characteristics DDD Model Impact Estimates for Home Dialysis Use, CY 2021 – CY 2022

| Facility Subgroup: Size of home dialysis program | Number of Facilities | Cumulative DiD | % Relative Change | DDD (vs. Ref) | Pre-ETC Gap (vs. Ref) | % Change in Pre-ETC Gap |
|---|---|---|---|---|---|---|
| Large | 818 | 0.05 | 0.14% | 0.17 | 31.5% | 0.54% |
| Small or none (Ref) | 7,375 | -0.12 | -0.31% | - | - | - |

**Notes:** Ref corresponds to reference subgroup. Results are based on DDD models of cumulative impacts in CY 2021 and CY 2022, with adjustment for patient, facility, and market characteristics. DDD estimates correspond to the relative impact of the ETC Model for the patient subgroup relative to the reference subgroup. The pre-ETC period includes CY 2017-CY 2019. The pre-ETC gap in ETC areas corresponds to the difference in pre-ETC means between the patient subgroup and the reference subgroup while adjusting for patient, facility, and market characteristics. No DiD or DDD estimates are statistically significant at p-value <0.1. DiD and DDD values represent percentage point changes

### Exhibit B-31. Health Equity DDD Falsification and Dynamic Trend Test Results

| Patient Subgroups | Outcomes | Falsification Parallel Trend Test | | Dynamic Trend Test |
|---|---|---|---|---|
| | | DDD Estimate [a] | p-value | Joint F-test p-value |
| Dually Eligible: Yes vs. No | Home Dialysis | -0.01 | 0.95 | 0.43 |
| | Overall Waitlisting | -0.36 | 0.28 | 0.40 |
| | Total Transplant[1] | 0.28 | 0.17 | 0.39 |
| | Living Donor Transplant[2] | 0.11 | 0.11 | 0.24 |
| | Acute Care Hospitalization | -0.05 | 0.66 | 0.91 |
| | Total Parts A & B Medicare Payments (PPPM) | $6 | 0.82 | 0.84 |
| | Readmission | -0.30 | 0.61 | 0.88 |
| | Peritonitis | 0.22 | 0.49 | 0.66 |

| Patient Subgroups | Outcomes | Falsification Parallel Trend Test | | Dynamic Trend Test |
|---|---|---|---|---|
| | | DDD Estimate [a] | p-value | Joint F-test p-value |
| **Part D LIS Recipient: Yes vs. No** | Home Dialysis | 0.42 | 0.11 | 0.10* |
| | Overall Waitlisting | -0.22 | 0.56 | 0.85 |
| | Total Transplant[1] | 0.39 | 0.20 | 0.43 |
| | Living Donor Transplant[2] | 0.09 | 0.49 | 0.71 |
| | Acute Care Hospitalization | -0.04 | 0.72 | 0.63 |
| | Total Parts A & B Medicare Payments (PPPM) | $12 | 0.69 | 0.09* |
| | Readmission | 0.22 | 0.69 | 0.81 |
| | Peritonitis | 0.02 | 0.94 | 0.88 |
| **Race / Ethnicity: Non-Hispanic Black vs. Non-Hispanic White** | Home Dialysis | 0.49 | 0.07* | 0.16 |
| | Overall Waitlisting | -0.04 | 0.92 | 0.98 |
| | Total Transplant[1] | 0.29 | 0.25 | 0.23 |
| | Living Donor Transplant[2] | -0.02 | 0.79 | 0.93 |
| | Acute Care Hospitalization | -0.18 | 0.17 | 0.37 |
| | Total Parts A & B Medicare Payments (PPPM) | -$20 | 0.52 | 0.82 |
| | Readmission | -0.11 | 0.87 | 0.52 |
| | Peritonitis | 0.47 | 0.19 | 0.42 |
| **Race / Ethnicity: Hispanic vs. Non-Hispanic White** | Home Dialysis | 0.12 | 0.75 | 0.87 |
| | Overall Waitlisting | 1.0 | 0.07* | 0.09* |
| | Total Transplant[1] | 0.43 | 0.23 | 0.06* |
| | Living Donor Transplant[1] | 0.07 | 0.59 | 0.86 |
| | Acute Care Hospitalization | -0.20 | 0.31 | 0.28 |
| | Total Parts A & B Medicare Payments (PPPM) | -$40 | 0.33 | 0.05* |
| | Readmission | -0.17 | 0.80 | 0.84 |
| | Peritonitis | -0.05 | 0.88 | 0.62 |
| **Race / Ethnicity: Non-Hispanic Other Race vs. Non-Hispanic White** | Home Dialysis | -0.36 | 0.34 | 0.51 |
| | Overall Waitlisting | -0.43 | 0.53 | 0.80 |
| | Total Transplant[1] | -0.07 | 0.86 | 0.25 |
| | Living Donor Transplant[1] | -0.07 | 0.61 | 0.65 |
| | Acute Care Hospitalization | -0.12 | 0.55 | 0.69 |
| | Total Parts A & B Medicare Payments (PPPM) | $4 | 0.95 | 0.37 |
| | Readmission | 1.5 | 0.22 | 0.39 |
| | Peritonitis | 0.58 | 0.24 | 0.50 |

**Notes:** 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. Home dialysis (peritoneal dialysis or home HD) based on primary modality. *Indicates statistical significance of DiD or DDD estimate at p-value <0.1.

**Exhibit B-32. Duration of ESRD DDD Falsification and Dynamic Trend Test Results**

| Duration of ESRD | Outcomes | Falsification Parallel Trend Test | | Dynamic Trend Test |
|---|---|---|---|---|
| | | DDD Estimate for 2019 | p-value | Joint F-test p-value |
| 90 days - 1 year vs. 0-90 days | Home Dialysis | 0.37 | 0.44 | 0.68 |
| | Overall Waitlisting | -0.47 | 0.29 | 0.58 |
| | Total Transplant[1] | 0.29 | 0.53 | 0.74 |
| 1-5 years vs. 0-90 days | Home Dialysis | 0.13 | 0.78 | 0.96 |
| | Overall Waitlisting | 0.46 | 0.38 | 0.61 |
| | Total Transplant[1] | -0.05 | 0.92 | 0.96 |
| Over 5 years vs. 0-90 days | Home Dialysis | 0.41 | 0.34 | 0.64 |
| | Overall Waitlisting | 0.58 | 0.35 | 0.55 |
| | Total Transplant[1] | 0.17 | 0.73 | 0.84 |

**Notes**: 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. Home dialysis (peritoneal dialysis or home HD) based on primary modality.

**Exhibit B-33. Facility Characteristics DDD Falsification and Dynamic Trend Test Results**

| Facility Subgroups | Outcomes | Falsification Parallel Trend Test | | Dynamic Trend Test |
|---|---|---|---|---|
| | | DDD Estimate[a] | p-value | Joint F-test p-value |
| Large vs. Small Home Dialysis Program | Home Dialysis | 0.15 | 0.84 | 0.87 |

**Notes**: [a] Represents the estimated effect of the ETC Model in 2019 (before the model was implemented) Home dialysis (peritoneal dialysis or home HD) based on primary modality.

## B.7 Analyses of TDAPA and TPNIES claims

In the context of the ETC model, we analyzed Transitional Drug Add-on Payment Adjustment (TDAPA) and Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) claim frequency and payments for the possibility of differences between the ETC and comparison groups. Medicare payments to ESRD facilities are determined under a prospective payment system (PPS). The payment covers a bundled set of services based on historical use patterns. TDAPA and TPNIES provide extra payments to ESRD facilities for newly developed drugs, supplies and equipment that are covered under Part B but not included in the PPS service bundle. The payments are provided for a transitional two-year period until alternate payment mechanisms are activated.

Definitions below are from CMS' ESRD Prospective Payment System (PPS).[37]

**Transitional Drug Add-on Payment Adjustment (TDAPA).** As established in 42 CFR § 413.234 a new injectable or intravenous drug or biological used for the treatment of ESRD for which there is no current functional category and therefore is not considered accounted for in the ESRD PPS base rate is paid using a Transitional Drug Add-on Payment Adjustment (TDAPA). CMS bases the TDAPA on payment methodologies under section 1847A and would continue for a period of two years.

[37] From CMS End Stage Renal Disease (ESRD) Prospective Payment System (PPS) https://www.cms.gov/medicare/medicare-fee-for-service-payment/esrdpayment

**Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES).** As established in 42 CFR § 413.236 certain new and innovative renal dialysis equipment or supplies furnished by ESRD facilities are paid using a Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES). The TPNIES will be based on 65 percent of the price established by the Medicare Administrative Contractors, using the information from the invoice and other relevant sources of information. CMS will pay the TPNIES for two calendar years.

### Identification of TDAPA/ TPNIES claims:

TDAPA and TPNIES claim items are identified in the outpatient revenue center files by the presence of HCPCS modifier code AX (item furnished in conjunction with dialysis services). The Appendix table lists all HCPCS-coded items with the AX modifier code for the years CY 2017 – CY 2019 (pre-ETC) and CY 2021 – CY 2022 (post-ETC). The item numbers 1, 2 and 4 indicate TDAPA drugs (cinacalcet, etelcalcitide, difelikefalin [Korsuva]) and item number 6 identifies dialysis equipment (Tablo hemodialysis system) covered by TPNIES. The remaining items are not covered by transitional pricing.[38]

### Assessment of TDAPA /TPNIES claims for ETC and the comparison group:

**Exhibit B-34** compares the use of each item for ETC and the comparison group in the pre-ETC (CY 2017 – CY 2019) and post-ETC (CY 2021 – CY 2022) time periods. Cinacalcet and etelcalcitide are calcimimetic agents for which claims were relatively frequent in CY 2018 – CY 2021. Difelikefalin (Korsuva), a new anti-pruritis drug and the Tablo System, a home hemodialysis technology, were introduced in CY 2022. We found similar usage of each item in both groups. We used standardized mean difference (SMD) to assess balance (see Section B.4.1) and using a threshold of 0.2 to indicate lack of balance, we noted that the SMDs were small for all items, indicating a high degree of balance for these items.

**Exhibit B-34. TDAPA and TPNIES Claims for ETC and Comparison Groups (shown as % of overall beneficiary months)**

| Years | Program | Item | ETC | | | Comparison | | | SMD |
|---|---|---|---|---|---|---|---|---|---|
| | | | N | Mean | SD | N | Mean | SD | |
| Pre-ETC (2017-2019) | TDAPA | Cinacalcet | 3,116,806 | 15.43% | 36.12% | 6,165,899 | 14.44% | 35.15% | 0.020 |
| | | Etelcalcitide | 3,116,806 | 4.03% | 19.67% | 6,165,899 | 4.21% | 20.08% | -0.006 |
| | | Korsuva | 3,116,806 | 0 | 0 | 6,165,899 | 0 | 0 | - |
| | TPNIES | Tablo System | 3,116,806 | 0 | 0 | 6,165,899 | 0 | 0 | - |
| ETC (2021-2022) | TDAPA | Cinacalcet | 1,557,315 | 0.34% | 5.83% | 3,048,259 | 0.68% | 8.23% | -0.034 |
| | | Etelcalcitide | 1,557,315 | 1.62% | 12.64% | 3,048,259 | 1.54% | 12.31% | 0.005 |
| | | Korsuva | 1,557,315 | 0.05% | 2.24% | 3,048,259 | 0.05% | 2.23% | 0.000 |
| | TPNIES | Tablo System | 1,557,315 | 0.01% | 0.74% | 3,048,259 | 0.02% | 1.23% | -0.007 |

**Note:** SMD=Standardized Mean Difference

[38] AX modifier is not specific for TDAPA and TPNIES items.

### 5.7.1. Conclusion

The frequency of claims for TDAPA and TPNIES items were balanced for facilities located in the ETC and comparison areas in both the pre-ETC and post-ETC periods. Claims for calcimimetic agents (cinacalcet and etelcalcitide) were relatively frequent in the pre-ETC period (CY 2017-CY 2019) compared to the post-ETC period but showed similar trends in both groups. There was no evidence of group differences in facility billing for items covered by TDAPA or TPNIES that would have potential implications for the ETC Model evaluation.

## Appendix C: 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, that is, 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 computed under the assumption of simple random sampling.[39]

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 1.9 percentage points difference for home dialysis and a 2.0 percentage points difference for the transplant waitlisting measure.

We also conducted power analyses separately for each of the subgroups (dual and non-dual), Part D LIS eligible (yes and no) and race ethnicity subgroups (Hispanic, non-Hispanic White and non-Hispanic Black groups) for the same two main outcomes: home dialysis and overall transplant waitlisting. Using a two-tailed test at 0.1 level of significance, the evaluation has 80 percent power to detect a minimum effect size ranging between 1.5 to 2.4 percentage points for home dialysis with the exception of the Hispanic subgroup where the minimum detectable effect size was 3.4 percentage points. For the transplant waitlisting measure using exact same criteria as above, the minimum effect size for each of the subgroups ranged between 1.9 to 2.6 percentage points, again with the exception of the Hispanic subgroup where the minimum detectable effect size was 3.9 percentage points.

[39] 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.

# Appendix D: Mortality

This appendix defines the methodology used to conduct mortality analyses. We used the same beneficiary month file (see **Section B.1** and **B.2**) and reconstructed it to have a single row per patient by ETC status. Date of death was extracted from a combination of sources (1) the Master Beneficiary Summary Files which include validated dates of death for each beneficiary if death occurred and (2) Death Notification form CMS-2746 from EQRS supplemented by Patient Events, CMS-2728, Current Patient Form and Remis Patient Form from EQRS (**Exhibit B-3**).

For this mortality analysis, beneficiary time-at-risk was defined as the duration of time over which the death of a beneficiary would be attributed to an ETC or comparison group facility, thus counting as an observed event. Patient time at risk was defined as the duration of time over which death would be attributed to the ETC or the comparison group. This analysis does not incorporate the monthly ETC eligibility criteria. If a beneficiary became ineligible during the follow-up period, that beneficiary was retained for this analysis.

This is an intent-to-treat analyses where patients were followed from entry in model until death or censoring event (regardless of ETC attribution/ eligibility). Intent-to-treat analysis eliminates potential bias if attribution/eligibility criteria affect ETC and comparison groups differently and is consistent with randomized clinical trial (RCT) practices. It helps to address important issues such as interruptions in follow-up period, concentration of deaths in bene-months where eligibility / attribution criteria are not valid, often due to discontinuation of dialysis, hospice status, nursing home status or prolonged hospitalization.

Start date is the first ETC date in which the patient was either in the ETC or comparison group. We conducted two mortality analyses. We followed the patient for the outcome of death:

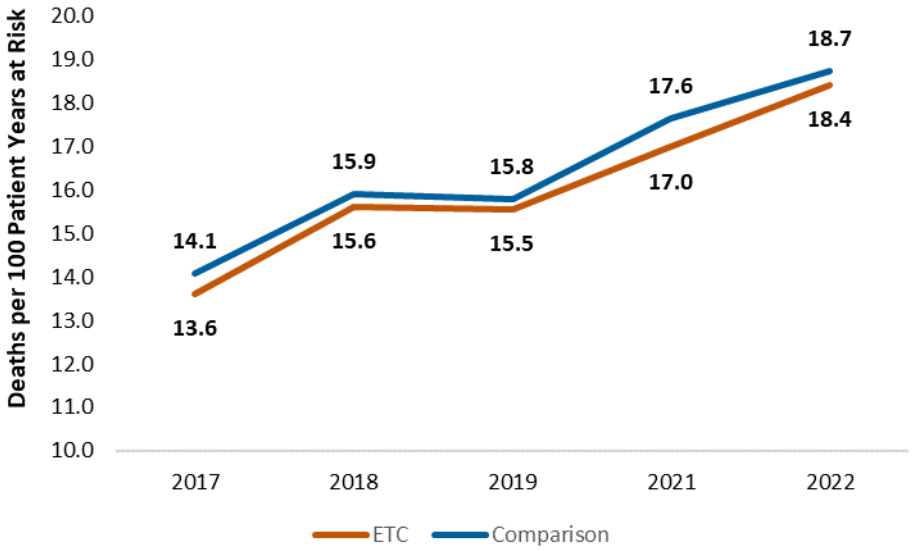
1) until censored at transplant or end of the study period.
2) until censored at the end of study period.

Transplantation is associated with survival advantage. Transplant expansion could have a favorable effect on survival (to the extent that the ETC Model results in expanded transplantation) and hence the rationale for conducting two types of mortality analyses.

## D.1. Unadjusted Rates and Survival Models

We described unadjusted mortality rates defined as death per 100 patient years at risk in **Exhibit D-1**. Unadjusted death rates increased from 13.6 to 18.4 per 100 patient years at risk for the ETC group and from 14.07 to 18.74 for the comparison group between 2017 and 2022. Death rates for the ETC group remained lower than the comparison group throughout this period.

**Exhibit D-1. Unadjusted Mortality Rates by ETC Status, 2017-2022**




We used Cox proportional hazards model to evaluate the impact of the ETC Model accounting for patients and provider characteristics.[40] We used the same set of covariates as used for the DiD model (see **Exhibit B-19**) and conducted separate baseline and intervention period analyses. We compared survival in the ETC group relative to the comparison group. A hazard ratio less than one implies a survival advantage for the ETC patients. When the hazard ratio is less than one (or greater than one), it means that ETC group (treatment) has a lower (or higher) risk of death relative to the comparison group. If the 90 percent confidence interval of hazard ratio doesn't include a value of one that means it is statistically significant at 0.1 level of significance. We also performed model diagnostics to confirm the underlying proportional hazards assumption of the Cox model.

We also checked average Standardized Mortality Ratios (SMR) at the facility level and noted SMRs were lower for the ETC group than the comparison group over CY 2017-CY 2021.[41] SMR was consistently lower for the ETC group relative to the comparison group, implying a survival advantage in ETC HRRs (see **Exhibit D-2**).

**Exhibit D-2. Average Facility SMR by ETC Status, 2017-2021**

| Group | 2017 | 2018 | 2019 | 2020 | 2021 |
|---|---|---|---|---|---|
| ETC | 0.98 | 0.97 | 0.97 | 1.02 | 0.93 |
| Comparison | 1.02 | 1.01 | 1.01 | 1.06 | 0.99 |

[40] Cox (1972). Regression models and life tables (with discussion). J R Statist Soc B 34: 187–220.
[41] Obtained SMR from publicly available Dialysis Facility Report.

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

## E.1. Data Sources

We used the ICH CAHPS survey data for 2017-2019 (pre-ETC) and CY 2021-2022 (post-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).[42] 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.[43] 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.[44] 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.[20] Given the ECE and the COVID-19 PHE's potential effect on response rates for the fall wave, we excluded all 2020 ICH CAHPS data from our analyses.

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

We analyzed six In-Center HD Patient Experience of Care measures that are publicly reported and 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 E-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 E-2**).[45] The six measures are adjusted for survey mode and several patient-mix factors by the ICH CAHPS Data Center contractor, including overall health; overall mental health; heart disease; difficulty hearing; visually impaired; difficulty concentrating, remembering, or making decisions; difficult

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

[43] 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.

[44] 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.

[45] 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.

dressing/bathing; age; sex; education; language other than English spoken at home; whether or not someone helped complete the survey; and number of years on dialysis.[20]

**Exhibit E-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**<br><br>**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**<br><br>**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**<br><br>**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.

**Exhibit E-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**<br>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? | |

| Composite Measure | ICH CAHPS Questions | Interpretation of Measure |
|---|---|---|
| **Quality of Dialysis Center Care and Operations**<br>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**<br>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? | |

## E.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 (that is, the ETC group) and comparison HRRs (that is, 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.[46] 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 facilities having ICH CAHPS in the pre-ETC period (CY 2017-CY 2019) with similar declining shares between the ETC and the comparison group (see **Exhibit E-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 (see **Exhibit E-4**). The proportion of ESRD facilities with ICH CAHPS data increased in the second CY of the ETC model (53 to 54 percent in spring 2022 and 42 to 43 percent in fall 2022) but did not reach pre-ETC levels. 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 (for example, 63 percent versus 66 percent for the spring 2017 wave).

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

The ICH CAHPS response rates of surveyed patients also decreased in the sample, dropping from 33 percent in spring 2017 to 29 percent in spring 2019, to a low of 20 percent in fall 2021. The response rate increased for both the spring and fall waves in 2022 but continued to be lower than pre-ETC period (26 and 24 percent, respectively; see **Exhibit E-4**). These declines also reflect differences between the earliest and latest waves in terms of the number of facilities (4,312 vs. 3,089) and of completed surveys (98,202 vs. 52,598; see **Exhibit E-3** and **Exhibit E-4**).

**Exhibit E-3. Characteristics of ESRD Facilities Used in the ICH CAHPS Analyses, Pre-ETC**

| Characteristic | Pre-ETC | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Spring 2017 | | Fall 2017 | | Spring 2018 | | Fall 2018 | | Spring 2019 | | Fall 2019 | |
| | ETC | Non-ETC | ETC | Non-ETC | ETC | Non-ETC | ETC | Non-ETC | ETC | Non-ETC | ETC | Non-ETC |
| ESRD Facilities* | 2,174 | 4,412 | 2,174 | 4,412 | 2,266 | 4,647 | 2,266 | 4,647 | 2,334 | 4,786 | 2,334 | 4,786 |
| ESRD Facilities with ICH CAHPS Data | 1,379 | 2,933 | 1,346 | 2,817 | 1,268 | 2,699 | 1,337 | 2,823 | 1,325 | 2,772 | 1,314 | 2,751 |
| Percent with ICH CAHPS Data | 63% | 66% | 62% | 64% | 56% | 58% | 59% | 61% | 57% | 58% | 56% | 57% |
| Number of ICH CAHPS Sampled Patients across Facilities | 92,461 | 203,849 | 91,624 | 199,066 | 84,096 | 183,433 | 88,778 | 192,661 | 89,645 | 195,137 | 88,366 | 193,242 |
| ICH CAHPS Survey Responses across Facilities | 30,763 | 67,439 | 28,422 | 62,237 | 25,901 | 56,550 | 27,391 | 59,371 | 26,012 | 56,143 | 25,080 | 53,689 |
| 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% |

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

**Exhibit E-4. Characteristics of ESRD Facilities Used in the ICH CAHPS Analyses, Post-ETC**

| Characteristic | Post-ETC | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Spring 2021 | | Fall 2021 | | Spring 2022 | | Fall 2022 | |
| | ETC | Non-ETC | ETC | Non-ETC | ETC | Non-ETC | ETC | Non-ETC |
| ESRD Facilities* | 2,387 | 4,909 | 2,387 | 4,909 | 2,356 | 4,863 | 2,356 | 4,863 |
| ESRD Facilities with ICH CAHPS Data | 1,089 | 2,314 | 675 | 1,498 | 1,272 | 2,568 | 980 | 2,109 |
| Percent with ICH CAHPS Data | 46% | 47% | 28% | 31% | 54% | 53% | 42% | 43% |
| Number of ICH CAHPS Sampled Patients across Facilities | 74,744 | 164,714 | 53,993 | 122,767 | 87,296 | 181,829 | 68,099 | 150,309 |
| ICH CAHPS Survey Responses across Facilities | 19,042 | 41,852 | 10,703 | 24,046 | 22,554 | 46,875 | 16,493 | 36,105 |
| Response Rate | 25.5% | 25.4% | 19.8% | 19.6% | 25.8% | 25.8% | 24.2% | 24.0% |

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

## E.4. Analytic Methods

### *E.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 four survey waves (spring 2021-fall 2022) 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 E-5**) as well as across other key patient and facility characteristics (see **Exhibit E-6**). The exceptions included higher rates of CEC participation among facilities in the ETC group (for example, 79 percent for ETC and 67 percent for comparison group in 2022), and a lower percent of patients who are Hispanic among ETC facilities (for example, 11 percent and 18 percent, respectively, in 2022; see **Exhibit E-5**).

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 37,179 facility-survey wave observations for 5,599 unique ESRD facilities.

## Exhibit E-5. Annual Means (and Standard Errors) for Covariates Used in the ICH CAHPS Analyses

| Characteristic | Pre-ETC | | | CY 2021 | | | CY 2022 | | |
|---|---|---|---|---|---|---|---|---|---|
| | ETC | Comparison | SMD | ETC | Comparison | SMD | ETC | Comparison | SMD |
| **Number of Facilities** | 4,421 | 9,273 | N/A | 1,129 | 2,401 | N/A | 1,341 | 2,750 | N/A |
| **Number of Surveys per Wave** | | | | | | | | | |
| Spring | 3,951 | 8,392 | N/A | 1,084 | 2,310 | N/A | 1,268 | 2,565 | N/A |
| Fall | 3,976 | 8,381 | N/A | 674 | 1,495 | N/A | 976 | 2,107 | N/A |
| **Census Region (% in Each Region)** | | | | | | | | | |
| Northeast | 15.3 (36.0) | 14.3 (35.0) | .03 | 17.4 (38.0) | 16.0 (36.7) | .04 | 16.4 (37) | 14.9 (35.6) | .04 |
| South | 49.3 (50) | 44.7 (49.7) | .09 | 5.8 (49.8) | 40.2 (49.0) | .11 | 47.1 (49.9) | 42.7 (49.5) | .09 |
| Midwest | 17.0 (37.6) | 18.0 (38.4) | -.03 | 16.4 (37.0) | 17.3 (37.9) | -.03 | 16.8 (37.4) | 17.2 (37.8) | -.01 |
| West | 18.4 (38.7) | 23.0 (42.1) | -.12 | 20.4 (40.3) | 26.4 (44.1) | -.14 | 19.7 (39.8) | 25.1 (43.4) | -.13 |
| **Number of Patients at ESRD Facility** | 534,970 | 1,167,388 | N/A | 128,737 | 287,481 | N/A | 155,395 | 332,138 | N/A |
| **Hospital-Owned (%)** | 2.4 (15.4) | 2.2 (14.8) | .01 | 2.6 (15.8) | 2.8 (16.5) | -.01 | 2.3 (15) | 2.5 (15.5) | -.01 |
| **Facility Chain/Ownership (%)** | | | | | | | | | |
| DaVita | 38.2 (48.6) | 41.4 (49.3) | -.06 | 35.1 (47.7) | 38.4 (48.7) | -.07 | 36.0 (48.0) | 38.6 (48.7) | -.05 |
| Fresenius | 41.9 (49.3) | 37.5 (48.4) | .09 | 45.3 (49.8) | 8.1 (48.6) | .15 | 44.9 (49.8) | 39.4 (48.9) | .11 |
| Independent/Non-Chain For-Profit | 1.8 (13.2) | 2.6 (15.9) | -.06 | 1.6 (12.5) | 3.3 (17.8) | -.11 | 1.2 (10.9) | 2.8 (16.6) | -.12 |
| Other For-Profit | 10.7 (30.9) | 8.6 (28.1) | .07 | 9.8 (29.8) | 8.9 (28.4) | .03 | 10.7 (30.9) | 8.9 (28.5) | .06 |
| Non-Profit | 7.4 (26.2) | 9.9 (29.9) | -.09 | 8.1 (27.4) | 11.3 (31.7) | -.11 | 7.2 (25.9) | 10.2 (30.3) | -.11 |
| **Facility RUCC (%)** | | | | | | | | | |
| Metro | 84.1 (36.5) | 86.3 (34.3) | -.06 | 86.2 (34.5) | 89.3 (30.9) | -.09 | 85.3 (35.4) | 88.3 (32.2) | -.09 |
| Urban | 15.5 (36.2) | 13.4 (34.0) | .06 | 13.6 (34.2) | 10.5 (30.6) | .10 | 14.5 (35.2) | 11.3 (31.7) | .09 |
| Rural | 0.4 (6.0) | 0.3 (5.5) | .01 | 0.3 (5.2) | 0.2 (4.6) | .01 | 0.2 (4.7) | 0.4 (6.0) | -.03 |

| Characteristic | Pre-ETC | | | CY 2021 | | | CY 2022 | | |
|---|---|---|---|---|---|---|---|---|---|
| | ETC | Comparison | SMD | ETC | Comparison | SMD | ETC | Comparison | SMD |
| **Medicare Shared Savings Program** | 99.7 (5.4) | 99.5 (7.3) | .04 | 99.6 (5.9) | 99.5 (7.3) | .03 | 99.7 (5.5) | 99.4 (7.6) | .04 |
| **APMs (%)** | | | | | | | | | |
| CEC | 77.3 (41.9) | 67.0 (47.0) | .23 | 79.9 (40.1) | 68.3 (46.5) | .27* | 78.7 (41.0) | 67.3 (46.9) | .26 |
| NGACO | 56.6 (49.6) | 57.1 (49.5) | -.01 | 58.0 (49.4) | 60.6 (48.9) | -.05 | 57.4 (49.5) | 58.2 (49.3) | -.02 |
| **COVID-19 Incidence Rate** | 0 (0) | 0 (0) | | 102.0 (73.4) | 87.3 (119.1) | .15 | | | |
| **ADI** | 59.8 (20.3) | 56.2 (23.1) | .16 | 58.0 (20.9) | 53.7 (23.7) | .19 | 58.5 (20.6) | 54.5 (23.2) | .18 |
| **Dually Eligible for Medicare and Medicaid %** | 46.5 (15.6) | 48.5 (17.1) | -.12 | 46.0 (15.5) | 49.1 (17.7) | -.18 | 46.0 (15.6) | 48.4 (17.6) | -.14 |
| **Patient Race (%)** | | | | | | | | | |
| Black or African American | 39.0 (30.2) | 33.6 (28.8) | .18 | 38.1 (29.9) | 32.6 (28.2) | .19 | 38.0 (30.1) | 32.3 (28) | .20 |
| Non-Hispanic White | 43.8 (27.3) | 42.0 (28.1) | .06 | 43.6 (27.0) | 40.5 (27.3) | .11 | 44.1 (27.4) | 41.9 (27.6) | .08 |
| Asian | 3.2 (5.7) | 4.6 (9.2) | -.18 | 3.4 (5.9) | 5.4 (10.4) | -.24* | 3.3 (5.7) | 5.1 (10.0) | -.22 |
| Native Hawaiian/ Pacific Islander | 0.9 (2.6) | 1.2 (4.0) | -.08 | 1.0 (2.6) | 1.4 (4.4) | -.11 | 1.0 (2.8) | 1.3 (4.2) | -.09 |
| American Indian/Alaska Native | 2.1 (10.1) | 0.7 (4.4) | .17 | 2.2 (9.9) | 0.8 (4.5) | .19 | 2.0 (9.8) | 0.7 (4.1) | .18 |
| Other/Unknown Race | 0.4 (0.8) | 0.4 (0.9) | -.04 | 0.4 (0.8) | 0.5 (1.1) | -.08 | 0.4 (0.8) | 0.4 (1) | -.06 |
| **Patient Hispanic Ethnicity (%)** | 10.7 (16.3) | 17.5 (22.7) | -.35 | 11.3 (16.9) | 18.9 (23.1) | -.38* | 11.2 (16.9) | 18.2 (22.6) | -.35 |

**Notes:** APM = Alternative Payment Model. Pre-ETC includes spring 2017-fall 2019 survey waves. CY 2021 and CY 2022 includes spring and-fall survey waves for the respective year. 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 E-6. Annual Means (and Standard Errors) for Selected Characteristics of ESRD Facilities Used in ICH CAHPS Analyses

| Characteristic | Pre-ETC | | | CY 2021 | | | CY 2022 | | |
|---|---|---|---|---|---|---|---|---|---|
| | ETC | Comparison Group | SMD | ETC | Comparison Group | SMD | ETC | Comparison Group | SMD |
| **Number of Facilities** | 4,421 | 9,273 | N/A | 1,129 | 2,401 | N/A | 1,341 | 2,750 | N/A |
| **Offer Home Dialysis (%)** | 42.0 (49.4) | 45.1 (49.8) | -.06 | 44.8 (49.8) | 47.0 (49.9) | -.04 | 44.3 (49.7) | 46.7 (49.9) | -.05 |
| **Average Age of Patients (Years)** | 62.4 (3.7) | 62.6 (3.7) | -.06 | 62.5 (3.7) | 62.7 (3.7) | -.04 | 62.5 (3.7) | 62.7 (3.7) | -.08 |
| **LIS patients (%)** | 53.5 (15.6) | 55.2 (16.6) | -.11 | 52.8 (15.6) | 55.4 (17.0) | -.16 | 52.7 (15.7) | 54.8 (16.9) | -.12 |
| **MD** | | | | | | | | | |
| Facilities (%) | 8.1 | 0.0 | N/A | 9.1 | 0.0 | N/A | 8.4 | 0.0 | N/A |
| Patients (%)* | 4.3 | 0.0 | N/A | 5.5 | 0.0 | N/A | 4.6 | 0.0 | N/A |

**Notes:** Pre-ETC includes spring 2017-fall 2019 survey waves. CY 2021 and CY 2022 includes spring and fall survey waves for the respective year. Patient characteristics reflect overall patient population derived from the Medicare administrative data. * Reflects the percent of ICH CAHPS surveys used in the analyses that are from ESRD facilities in Maryland.

### E.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 (that is, 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 including KCC for 2022
- 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
- ESRD facility's county level yearly average for MA penetration

### E.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 (that is, 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 E-7**), suggesting the parallel trends assumption was upheld.

**Exhibit E-7. 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 | 0.24 | 0.21 | 0.03 | -22 | 0.28 | 0.86 |
| | Rating of Dialysis Center Staff | 0.39 | -0.11 | -0.63 | -0.28 | -0.36 | 0.61 |
| | Rating of Dialysis Center | 0.33 | -0.04 | -0.23 | -0.32 | 0.15 | 0.74 |
| | Nephrologists' Communication and Caring | 0.22 | 0.11 | 0.12 | -0.09 | 0.10 | 0.94 |
| | Quality of Dialysis Center Care and Operations | 0.01 | -0.19 | -0.51 | -0.38 | -0.004 | 0.52 |
| | Providing Information to Patients | 0.10 | 0.41 | -0.01 | 0.18 | -0.19 | 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 the spring 2019 survey wave as the reference.

### *E.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 ETC Model, cumulatively nor for each of the first two years of the model. **Exhibit E-8** complements the DiD findings presented in the main report with additional information on the cumulative 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 (3,451) that had ICH CAHPS data in both the pre-ETC and post-ETC periods (see **Exhibit E-9**).

## Exhibit E-8. Impact of the ETC Model on ICH Patient Experience of Care Measures, Post-ETC

| Measures | | Performance Year | ETC | | Comparison Group | | Model Estimates | | | | % Relative Change |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Pre-ETC Mean | CY Mean | Pre-ETC Mean | CY Mean | DiD | p- value | Lower 90% CI | Upper 90% CI | |
| Patient Experience of Care | Rating of Kidney Doctors | CY 2021-22 | 59.5% | 59.3% | 60.7% | 60.5% | 0.10 | 0.82 | -0.61 | 0.81 | 0.16% |
| | | CY 2021 | 59.5% | 60.1% | 60.7% | 61.3% | 0.03 | 0.95 | -0.81 | 0.87 | 0.05% |
| | | CY 2022 | 59.5% | 58.7% | 60.7% | 59.8% | 0.15 | 0.76 | -0.67 | 0.96 | 0.25% |
| | Rating of Dialysis Center Staff | CY 2021-22 | 62.7% | 63.8% | 63.1% | 64.2% | 0.06 | 0.89 | -0.65 | 0.77 | 0.09% |
| | | CY 2021 | 62.7% | 63.8% | 63.1% | 64.9% | -0.65 | 0.19 | -1.46 | 0.16 | -1.0% |
| | | CY 2022 | 62.7% | 63.8% | 63.1% | 63.7% | 0.61 | 0.22 | -0.21 | 1.44 | 0.98% |
| | Rating of Dialysis Center | CY 2021-22 | 67.8% | 68.4% | 68.3% | 68.6% | 0.18 | 0.69 | -0.56 | 0.92 | 0.26% |
| | | CY 2021 | 67.8% | 68.3% | 68.3% | 69% | -0.29 | 0.55 | -1.1 | 0.52 | -0.43% |
| | | CY 2022 | 67.8% | 68.4% | 68.3% | 68.3% | 0.55 | 0.29 | -0.31 | 1.4 | 0.81% |
| | Nephrologists' Communication and Caring | CY 2021-22 | 67.3% | 67.0% | 67.8% | 67.1% | 0.46 | 0.15 | -0.07 | 0.99 | 0.68% |
| | | CY 2021 | 67.3% | 67.2% | 67.8% | 67.6% | 0.20 | 0.59 | -0.41 | 0.81 | 0.30% |
| | | CY 2022 | 67.3% | 66.8% | 67.8% | 66.7% | 0.66 | 0.08 | 0.03 | 1.3 | 0.98% |
| | Quality of Dialysis Center Care and Operations | CY 2021-22 | 62.6% | 63.3% | 63.1% | 63.6% | 0.24 | 0.44 | -0.26 | 0.74 | 0.38% |
| | | CY 2021 | 62.6% | 63.2% | 63.1% | 63.8% | -0.18 | 0.60 | -0.74 | 0.38 | -0.28% |
| | | CY 2022 | 62.6% | 63.5% | 63.1% | 63.4% | 0.56 | 0.11 | -0.02 | 1.1 | 0.89% |
| | Providing Information to Patients | CY 2021-22 | 80.2% | 79.5% | 80.5% | 79.5% | 0.26 | 0.23 | -0.09 | 0.61 | 0.32% |
| | | CY 2021 | 80.2% | 79.9% | 80.5% | 80.2% | -0.01 | 0.96 | -0.36 | 0.33 | -0.01% |
| | | CY 2022 | 80.2% | 79.1% | 80.5% | 78.9% | 0.47 | 0.11 | -0.01 | 0.94 | 0.58% |

**Notes:** Sample size = 37,179 facility-survey wave observations. Pre-ETC includes spring 2017-fall 2019 survey waves. CYCY includes spring 2021-fall 2022 survey waves. Values reflected weighted adjusted measure values.

**Exhibit E-9. Sensitivity Analysis: Impact of the ETC Model on ICH Patient Experience of Care Measures for Post-ETC Among Subset of Facilities with ICH CAHPS Data in Both Pre-ETC and Post-ETC Periods**

| Measures | | Performance Year | ETC | | Comparison Group | | Model Estimates | | | | % Relative Change |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Pre-ETC Mean | CY Mean | Pre-ETC Mean | CY Mean | DiD | p-value | Lower 90% CI | Upper 90% CI | |
| **Patient Experience of Care** | Rating of Kidney Doctors | CY 2021-22 | 59.2% | 59.4% | 60.6% | 60.6% | 0.18 | 0.68 | -0.54 | 0.89 | 0.30% |
| | | CY 2021 | 59.2% | 60.0% | 60.6% | 61.3% | 0.06 | 0.90 | -0.75 | 0.88 | 0.11% |
| | | CY 2022 | 59.2% | 58.9% | 60.6% | 60.0% | 0.27 | 0.60 | -0.59 | 1.13 | 0.46% |
| | Rating of Dialysis Center Staff | CY 2021-22 | 62.5% | 63.1% | 63.0% | 63.7% | -0.10 | 0.82 | -0.80 | 0.60 | -0.16% |
| | | CY 2021 | 62.5% | 63.2% | 63.0% | 64.4% | -0.71 | 0.13 | -1.48 | 0.07 | -1.1% |
| | | CY 2022 | 62.5% | 63.0% | 63.0% | 63.1% | 0.41 | 0.43 | -0.44 | 1.25 | 0.65% |
| | Rating of Dialysis Center | CY 2021-22 | 67.5% | 67.8% | 68.0% | 68.2% | 0.10 | 0.82 | -0.63 | 0.83 | 0.15% |
| | | CY 2021 | 67.5% | 67.7% | 68.0% | 68.6% | -0.35 | 0.45 | -1.10 | 0.41 | -0.51% |
| | | CY 2022 | 67.5% | 67.8% | 68.0% | 67.8% | 0.47 | 0.39 | -0.42 | 1.36 | 0.70% |
| | Nephrologists' Communication and Caring | CY 2021-22 | 67.1% | 67.0% | 67.8% | 67.2% | 0.48 | 0.15 | -0.07 | 1.02 | 0.71% |
| | | CY 2021 | 67.1% | 67.2% | 67.8% | 67.6% | 0.32 | 0.37 | -0.27 | 0.92 | 0.48% |
| | | CY 2022 | 67.1% | 66.7% | 67.8% | 66.8% | 0.61 | 0.13 | -0.06 | 1.27 | 0.90% |
| | Quality of Dialysis Center Care and Operations | CY 2021-22 | 62.4% | 62.8% | 62.9% | 63.2% | 0.12 | 0.67 | -0.37 | 0.62 | 0.20% |
| | | CY 2021 | 62.4% | 62.8% | 62.9% | 63.5% | -0.26 | 0.45 | -0.83 | 0.31 | -0.42% |
| | | CY 2022 | 62.4% | 62.9% | 62.9% | 62.9% | 0.45 | 0.20 | -0.13 | 1.03 | 0.72% |
| | Providing Information to Patients | CY 2021-22 | 80.1% | 79.3% | 80.5% | 79.3% | 0.42 | 0.05 | 0.06 | 0.78 | 0.52% |
| | | CY 2021 | 80.1% | 79.8% | 80.5% | 80.0% | 0.17 | 0.44 | -0.19 | 0.53 | 0.21% |
| | | CY 2022 | 80.1% | 78.9% | 80.5% | 78.6% | 0.63 | 0.03 | 0.15 | 1.11 | 0.78% |

**Notes:** Sample size = 30,237 facility-survey wave observations among 3,451 unique ESRD facilities that have ICH CAHPS data in both the pre-ETC and post-ETC periods. Pre-ETC includes spring 2017-fall 2019 survey waves. Post-ETC includes spring 2021-fall 2022 survey waves. Values reflected weighted adjusted measure values.

# Appendix F: Methods for ETC ESRD Facility Interviews

## F.1. Sample Selection

We drew an initial sample of 80 ESRD facility interviews from a pool of facilities attributed to the ETC Model. To ensure a range of views, we diversified the sample based on the following criteria:

1. Census-defined geographic region: Midwest, Northeast, South and West
2. In-center HD only or both home and in-center dialysis
3. High and low percent of dually eligible beneficiaries served, based on top and bottom tertiles of ETC Model participants
4. Higher and lower levels of performance on measures tied to payment through the ETC Model, where facilities with higher performance were ranked in the top half for both dialysis and transplant and facilities with lower performance were ranked in the bottom half for both home dialysis and transplant; for transplant performance, we excluded patients age 75 or older
5. LDO (DaVita and Fresenius) versus non-LDO (all other facilities)

We restricted the sample to facilities who served a minimum threshold of 11 beneficiary years (132 beneficiary months) to ensure a minimum sample size of patients in each facility. After drawing the sample of 80, we found that five facilities were closed. The distribution without these five facilities did not show obvious influence on the balance of diversity in the sample.

## F.2. Recruitment

We recruited participants via phone and email. If after several attempts at outreach a potential interview participant declined to participate or did not respond, we replaced them with another potential participant with similar sampling characteristics as described above. In total, we contacted 33 facilities to yield the sample of 20 participants (approximate 60% participation rate).

## F.3. Data Collection

Between March and May of 2023, one interviewer conducted each of the 20 interviews with staff from ESRD facilities. Interviews were conducted with small groups (n=7) and one-on-one (n =13). Interviews were conducted via phone or video conferencing. They typically lasted up to one hour. The interviewer used a semi-structured interview guide on model implementation and perceptions of patient experience. A semi-structured interview format enabled us to systematically collect data to compare across interview participants while also allowing flexibility to explore emergent topics. Specific topics included:

- Background information about the job role of each interview participant and the type of dialysis provided by the facility
- Staffing and operational changes made in response to the ETC Model
- Ways in which patient engagement strategies regarding treatment options have changed since the introduction of the ETC Model
- Extent to which participants have adequate resources to encourage and educate beneficiaries regarding treatment choices

- The impact of patient modality choices on patients' and care partners' quality of life
- Changes made under the model to increase health equity
- Perceived unintended consequences of the model on how care is provided, quality of care or patient experience
- How concurrent and past participation in other CMS models and programs impacts ETC implementation
- Use of ETC Reports from CMS to inform care provided under the ETC Model

Interview participants were also encouraged to provide additional information relevant to the topic areas that they thought was informative. Interviews were conducted with Microsoft Teams conferencing software through video or audio only. All interviews were recorded with participant consent and professionally transcribed. Data collection continued until we reached saturation, the point at which we were no longer learning new substantive information via further interviews.

## F.4. Sample Description

The distribution of facility participants in the four regions was as follows: South (6), Northeast (5), West (5), and Midwest (4) in eighteen states (IA, IL, MN, OH, CT, NJ, NY, PA, FL, LA, MD, MS, NC, SC, AZ, CA, NM, OR). Type of hemodialysis offered was as follows: in-center only (10 facilities); home dialysis only (one facility); both home and in-center dialysis (nine facilities). There were 15 LDOs and five non-LDOs in the sample. Twelve facilities served a high percentage of dually eligible beneficiaries and eight facilities served a low percentage of dually eligible beneficiaries. With regard to ETC Model performance, 10 facilities were high performers and 10 facilities were low performers. Three facilities participated in the CEC Model and four facilities participated in the KCC Model. Most facility interview participants were administrators, clinical managers, social workers, and nurses. In two cases, medical directors attended and in one case a dietician was present.

## F.5. Analysis

We used a grounded theory approach, a systematic data coding and analytic process that uses the constant comparative method to iteratively categorize data into themes. The interviewer coded all transcripts in ATLAS.ti software (version 23). They used inductive codes based on emergent findings, as well as deductive codes based on the research questions. Higher level codes represented themes from the interviews. Additionally, they analyzed the data to see if responses differed between LDO and non-LDO facilities. To increase rigor and aid in data interpretation, themes were discussed across the Lewin Team.

# Appendix G: Methods for ETC Managing Clinician Interviews

## G.1. Sample Selection

An initial sample of 50 Managing Clinicians was selected. The sample was restricted to those who provided service to at least five patients monthly on average during the 2021 calendar year and were in one of four Census-defined geographic regions (Midwest, Northeast, South, West). An effort was also made to balance clinicians between lower performance levels (bottom half for both transplantation and dialysis measures) and higher performance levels (top half for both transplantation and dialysis measures).

In order to recruit more participants after a low response rate from the first sample, a list of 30 additional clinicians was drawn from 4innovation. 4innovation (4i) is a web platform maintained by CMMI and is used by entities in some CMMI Models to manage their programs. The list was filtered to participants in the ETC Model and was further refined to physicians that were listed as both a participant and their practice contact for the ETC Model. This process resulted in a total of 23 clinicians in the sample.

## G.2. Recruitment

Initial outreach to clinicians in the first sample included phone, fax, and email outreach by project staff in various roles, including a University of Michigan nephrologist with an active practice. Though engagement was better when email came from the nephrologist, this sample yielded just three complete interviews. For the second sample, the nephrologist made all initial outreach attempts via email, resulting in nine more interviews for a total of 13 Managing Clinicians. The overall response rate (18%) remained low despite multiple recruiting attempts.

## G.3. Data Collection

Between April and July of 2023, two interviewers conducted the 13 interviews. All interviews with the sample of Managing Clinicians participating in the ETC Model were conducted one-on-one. A semi-structured interview protocol was designed to query Managing Clinicians on a number of topics. These included:

- Background information about the interview participant and their practice (for instance, if they are a solo practitioner or in a group, how they divide responsibilities if they are in a group)
- Exposure to home dialysis during nephrology training
- Staffing and operational changes made in response to the ETC Model
- Ways in which patient engagement strategies regarding treatment options have changed since the introduction of the ETC Model
- Barriers to treatment options among patients
- The impact of modality choices on patients' quality of life
- Changes made under the model to increase health equity
- Impact of Medicare program waivers that expand the use of Kidney Disease Patient Education Services

- Perceived unintended consequences of the model on how care is provided, quality of care or patient experience

Interview participants were also encouraged to provide additional information relevant to the topic areas that they thought was informative. All but two interviews were carried out via Microsoft Teams video-conferencing software. The other two interviews were conducted via phone to accommodate provider preferences. Though interviews were anticipated to last around 20 minutes, the majority ran over with some lasting over 60 minutes. Interviews were recorded with participant verbal consent and professionally transcribed. Due to challenges recruiting Managing Clinicians, we did not reach saturation in the Managing Clinician sample.

## G.4. Sample Description

We interviewed Managing Clinicians represented in the four Census regions, including South (6), Northeast (4), West (2), Midwest (1), and practicing in nine states (CA, FL, IL, MS, NC, NY, OR, TX, VT). Though we hoped to have more balance, there were three clinicians with lower performance in the sample and ten clinicians with higher performance. Five Managing Clinicians participated in the CEC and KCC Models, and one other Managing Clinician participated in the KCC Model. Interview participants were all nephrologists; six who worked in a private practice and seven from large hospital systems. Participants ranged from solo clinicians affiliated with multiple ESRD facilities to clinicians working in groups of one hundred or more nephrologists, with most participants working in groups of ten to twenty other nephrologists in either private practice or within a hospital system.

## G.5. Analysis

Two researchers (one of whom had conducted interviews with Managing Clinicians) read all 13 transcripts and independently developed a list of emergent themes using the interview questions as an organizing structure. Additionally, they analyzed the data to see if responses differed between providers from different types of practices (for example, private practice physicians and those associated with large health systems). The two researchers compared identification of themes and had a high level of agreement. Where they did not agree, they used a consensus process to resolve any discrepancies. Additionally, the researchers identified and discussed anecdotes that may have only arisen once or twice but point to a potentially relevant insight.