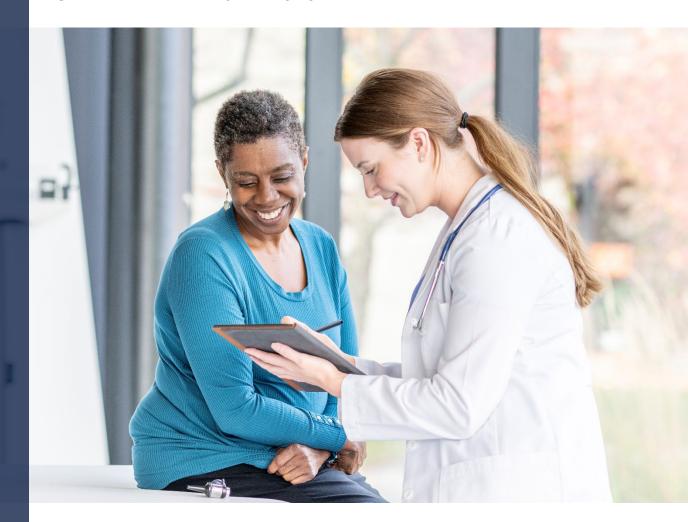


End-Stage Renal Disease Treatment Choices (ETC) Model

Third Annual Evaluation Report Appendices, Calendar Years 2021–2023



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Table of Contents

Appendix A: ETC Evaluation Logic Model	A-1
Appendix B: Difference-in-Differences Approach	B-1
B.1. Data Sources and Outcome Measures	B-2
B.2. Beneficiary Attribution and Eligibility	B-9
B.3. Pre-ETC Period Determination.	B-11
B.4. Comparison Group Assessment	B-13
B.5. DiD Regression Model and Estimated ETC Impacts.	B-30
B.6. Net Impact on Medicare Payments	B-47
B.7. Analyses of TDAPA and TPNIES claims	B-50
B.8. Analyses of Patient Subpopulations of Interest	B-51
B.9. Performance of ETC Participants by Patient Subpopulations of Interest	B-66
Appendix C: Power Calculation Methodology	C-1
Appendix D: Mortality	D-1
D.1. Unadjusted Rates and Survival Models	D-1
Appendix E: In-Center Hemodialysis (ICH) Consumer Assessment of Healthcare Providers (CAHPS) Survey Analysis Supplement	E-1
E.1. Data Sources	E-1
E.2. Description of the In-Center Hemodialysis Consumer Assessment of Healthcare Providers Survey Measures	E-1
E.3. Study Populations	E-4
E.4. Analytic Methods	E-8
Appendix F: Home Dialysis Patient Experience Survey	F-1
F.1. The Home-DCE Survey Instrument	F-1
F.2. Sample Design	F-1
F.3. Fielding	F-2
F.4. Data Sources	F-2
F.5. Study Sample	F-3
F.6. Description of Home Dialysis Patient Experience Survey Measures	F-3
F 7 Analytic Methods	F-4



Appendix G: Patient Quality of Life Survey	G-1
G.1. The PROMIS-29 Survey Instrument	G-1
G.2. Sample Design	G-1
G.3. Fielding	G-2
G.4. Data Sources	G-2
G.5. Study Sample	G-2
G.6. Description and Scoring of PROMIS-29 Survey Measures	G-3
G.7. Analytic Methods	G-4
Appendix H: Case Studies of Patient Access to Care	H-1
H.1. Case Study Area Selection	H-1
H.2. Sample Selection	H-3
H.3. Recruitment	H-3
H.4. Data Collection	H-3
H.5. Sample Description	H-4
H 6 Analysis	H_5



Table of Exhibits

Exhibit A-1. ETC Evaluation Logic Model	A-1
Exhibit B-1. DiD Implementation Steps	B-1
Exhibit B-2. Data Sources Used for the ETC Model Evaluation	B-2
Exhibit B-3. Outcome Measures Used to Evaluate the ETC Model	B-4
Exhibit B-4. Monthly Eligibility Criteria	B-10
Exhibit B-5. Attribution Definition (ESRD)	B-10
Exhibit B-6. Attribution Definition (CKD)	B-11
Exhibit B-7. ETC Timeline	B-11
Exhibit B-8. Flow Chart of ETC Cohort Construction	B-12
Exhibit B-9. Characteristics of ETC and Comparison Areas, Pre-ETC and Post-ETC	B-12
Exhibit B-10. Characteristics of ETC and Comparison Areas by year	B-13
Exhibit B-11. Means and SMDs for Patient Characteristics at Patient Month-Level	B-15
Exhibit B-12. Means and SMDs for Facility Characteristics at Facility-Level	B-20
Exhibit B-13. Means and SMDs for Managing Clinician Characteristics at Clinician-Leve	e1B-22
Exhibit B-14. Means and SMDs for Market Characteristics at HRR Level	B-23
Exhibit B-15. Patient Characteristics by Enrollment Status, 2021-2023	B-24
Exhibit B-16. Assessing Parallel Trends: Falsification Test Results	B-25
Exhibit B-17. Assessing Parallel Trends: Dynamic Trend Test for Outcome Measures	B-27
Exhibit B-18. Unadjusted Trends of Select Measures That Failed Parallel Trends Assumption	B-29
Exhibit B-19. Illustration of DiD Model	B-30
Exhibit B-20. Covariate Adjustments Included in the DiD Models	B-34
Exhibit B-21. Unadjusted Means of Outcome Measures Used to Evaluate the ETC Model	B-37
Exhibit B-22. Estimated Impacts of the ETC Model for CY 2021 - 2023	B-40
Exhibit B-23. Overview of ETC Model Payment Adjustments	B-47
Exhibit B-24. Measurement Years (MYs) and Range of Potential PPAs, by PPA Period	B-47
Exhibit B-25. Analysis of HDPA Amounts for ETC Participants, CYs 2021-2023	B-48
Exhibit B-26. Analysis of PPA Amounts for ETC Participants, CYs 2022-2023	B-48
Exhibit B-27. Calculation of Net Impact of ETC Model on Total Medicare Payments	B-49
Exhibit B-28. TDAPA and TPNIES Claims for ETC and Comparison Groups (shown as % of overall beneficiary months)	B-51



Exhibit B-29.	Distribution of Patient Months by Dual Eligibility and Part D LIS, for ETC and Comparison Areas	B-55
Exhibit B-30.	Distribution of Patient Months by Dual Eligibility and Rural/Urban, for ETC and Comparison Areas	B-55
Exhibit B-31.	Distribution of Patient Months by Part D LIS and Rural/Urban, for ETC and Comparison Areas	B-55
Exhibit B-32.	Adjusted Trends in Home Dialysis Use by Patient Dual Eligibility, for ETC and Comparison Areas, CY 2017-CY 2023	B-56
Exhibit B-33.	Adjusted Trends in Waitlisting by Patient Dual Eligibility, for ETC and Comparison Areas, CY 2017-CY 2023	B-56
Exhibit B-34.	Adjusted Trends in Transplant Rates by Patient Dual Eligibility, for ETC and Comparison Areas, CY 2017-CY 2023	B-57
Exhibit B-35.	Patient Subgroup DDD Model Impact Estimates for Home Dialysis Gains, CY 2021–CY 2023	B-57
Exhibit B-36.	Patient Subgroup DDD Model Impact Estimates for Home Dialysis Losses, CY 2021–CY 2023	B-58
Exhibit B-37.	Patient Subgroup DDD Model Impact Estimates for Living Donor Transplantation, CY 2021–CY 2023	B-58
Exhibit B-38.	Subgroup DDD Model Impact Estimates for Acute Care Hospitalization, CY 2021–CY 2023	B-59
Exhibit B-39.	Patient Subgroup DDD Model Impact Estimates for Hospital Readmission, CY 2021–CY 2023	B-59
Exhibit B-40.	Patient Subgroup DDD Model Impact Estimates for Outpatient ED Use, CY 2021–CY 2023	B-60
Exhibit B-41.	Patient Subgroup DDD Model Impact Estimates for Hospitalizations with ESRD Complications, CY 2021–CY 2023	B-60
Exhibit B-42.	Patient Subgroup DDD Model Impact Estimates for Hospitalizations with VA Complications, CY 2021–CY 2023	B - 61
Exhibit B-43.	Patient Subgroup DDD Model Impact Estimates for Peritonitis among PD Patients, CY 2021–CY 2023	B-61
Exhibit B-44.	Patient Subgroup DDD Model Impact Estimates for Vascular Infection, CY 2021–CY 2023	B-62
Exhibit B-45.	Patient Subgroup DDD Model Impact Estimates for Kt/V, CY 2021–CY 2023.	B-62
Exhibit B-46.	Patient Subgroup DDD Model Impact Estimates for Total Medicare Parts A & B Payments PPPM, CY 2021–CY 2023	B-63
Exhibit B-47.	Age DDD Model Impact Estimates for Home Dialysis Use, CY 2021–	D (2



Exhibit B-48	3. Facility Characteristics DDD Model Impact Estimates for Home Dialysis Use, CY 2021–CY 2023	B-63
Exhibit B-49	Patient Subgroup DDD Falsification and Dynamic Trend Test Results	B-64
Exhibit B-50). Patient age DDD Falsification and Dynamic Trend Test Results	B-65
Exhibit B-51	. Facility Characteristics DDD Falsification and Dynamic Trend Test Results	B-65
Exhibit B-52	2. MPS Distribution for ETC Facilities, MY1-MY4	B-66
Exhibit B-53	3. MPS Distribution for ETC Managing Clinicians, MY1-MY4	B-67
Exhibit B-54	l. Subpopulations of Interest by Facility MPS Group, MY1-MY4	B-67
Exhibit B-55	5. Subpopulations of Interest by Managing Clinician MPS Group, MY1-MY4	B-68
Exhibit D-1.	Unadjusted Mortality Rates by ETC Status, 2017-2023	. D-2
Exhibit D-2.	Average Facility SMR by ETC Status, 2017-2022	. D-2
Exhibit E-1.	In-Center HD Patient Experience of Care Global Rating Measures and their Corresponding ICH CAHPS Questions	E-2
Exhibit E-2.	In-Center HD Patient Experience of Care Composite Measures and their Corresponding ICH CAHPS Questions	E-2
Exhibit E-3.	Characteristics of ESRD Facilities Used in the ICH CAHPS Analyses, Pre-ETC	E-6
Exhibit E-4.	Characteristics of ESRD Facilities Used in the ICH CAHPS Analyses, Post-ETC	E-7
Exhibit E-5.	Annual Means (and Standard Deviations) for Covariates Used in the ICH CAHPS Analyses	E-9
Exhibit E-6.	Annual Means (and Standard Errors) for Selected Characteristics of ESRD Facilities Used in ICH CAHPS Analyses	E-11
Exhibit E-7.	Assessing Parallel Trends: DiD Estimates for ICH Patient Experience of Care Measures	E-13
Exhibit E-8.	Impact of the ETC Model on ICH Patient Experience of Care Measures Post-ETC	E-14
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	E-15
Exhibit F-1.	Exclusion Criteria Applied to the Home Dialysis Patient Population	F-2
Exhibit F-2.	Distribution of the ETC Home-DCE Patient Sample	F-2
Exhibit F-3.	Timeline for Fielding the Home-DCE Survey	F-2
Exhibit F-4.	Home-DCE Measures and their Corresponding Survey Questions	F-3
Exhibit F-5.	Characteristics of Eligible Patients and Survey Respondents, by ETC Treatment	F 5



Exhibit F-6. Means (and Standard Deviations) for Covariates Used in the Home-DCE Analysis	F-6
Exhibit F-7. Sensitivity Analysis: Impact of the ETC Model on the Home-DCE Measures	
Exhibit G-1 Exclusion Criteria Applied to the Patient QoL Analysis Sample	
Exhibit G-2. Patient QoL Survey Sample for the ETC Model	G-2
Exhibit G-3. Timeline for Fielding the QoL Survey	G-2
Exhibit G-4. Patient QoL Survey Response Rate	G-3
Exhibit G-5. Characteristics of Eligible Patients and Survey Respondents, by ETC Treatment and Comparison	G-5
Exhibit G-6. Means (and Standard Deviations) for Covariates Used in the Patient QoL Analysis	G-6
Exhibit G-7. Impact of the ETC Model on Patient QoL: Home Dialysis Patients	G-8
Exhibit G-8. Impact of the ETC Model on Patient QoL: In-center Hemodialysis Patients	G-8
Exhibit G-9. Impact of the ETC Model on Patient QoL: Transplant Recipients	G-9
Exhibit H-1. Provider Case Study Area Characteristics: Patient, Facility, and Market Characteristics and Patient Outcomes	H-2
Exhibit H-2. Patient Sample Characteristics	H-4



Appendix A: ETC Evaluation Logic Model

Exhibit A-1. ETC Evaluation Logic Model

Program Design

Resources, requirements, incentives, and levers CMS designed for the models.

New Investments and Behaviors

Organizational activities that participants undertake to activate the models.

Drivers of Change

Activities participants undertake to meet the goals of the models.

Outputs

Measurable quantities that capture clinician and ESRD facility activities.

Outcomes

Intended short-, medium-, and long-term outcomes.

KCC Specific

- Voluntary participation of nephrologists, dialysis facilities, and transplant programs
- Preferred providers
- CKD, ESRD, and transplant patients attributed based on plurality of care
- Progressive CKCC risk sharing for total cost of care
- MIPS APM and Advanced APM status
- Mandatory Learning System
- Benefit Enhancements (for example, home health, telehealth)

Shared ETC and KCC

- Financial incentives to promote home dialysis, transplants and improve quality and sustain improvement
- KDE benefit enhancements

KCC Specific

- Creation of KCEs
- Contracts with preferred providers
- Partnerships with community health centers to facilitate CKD Stage 2 and 3 patient referrals to nephrologists and Stage 4 and 5 to transplant centers

Shared ETC and KCC

- Capital and IT investments: telehealth, remote monitoring services
- Hiring new staff to coordinate care
- Increased outreach to patients
- Innovations in business and clinical practices
- Development of quality tools to enforce best practices
- Enhanced staff training and quality improvement

KCC Specific

- Enhanced person-centered care and shared decisionmaking
- Increased nephrologist involvement across CKD, ESRD, and transplant stages
- Depression screening and management
- Rescheduling missed dialysis

Shared ETC and KCC

- Beneficiary education and care coordination
- Coordinated primary care to remain active on transplant waitlist
- Improved patient access to care
- Medication management
- ols Lifestyle and nutritional interventions

KCC Specific

- Uptake of Medicare Kidney Disease Patient Education Services
- Increased testing: basic/comprehensive metabolic panel or creatinine for eGFR
- Care management for chronic conditions

Shared ETC and KCC

- Improved rates of waitlisting, preemptive waitlisting, time from waitlisting to transplantation, time on waitlist spent in inactive or active status
- Increased live and deceased donor kidney transplant rates

KCC Specific

- Optimal ESRD Starts
- Control of HbA1c for diabetes and control of BP for hypertension for CKD patients
- Increased use of home health
- Improved patient activation
- Delay in disease progression
- · Lower total per capita costs

Shared ETC and KCC

- Increased home/peritoneal dialysis
- Reduced hospitalizations/readmissions
- Increased transplant rates
- Immunosuppression adherence
- Improved physical/mental health
- Improved quality of life
- Reduce treatment variation across patient subgroups
- Reduced mortality rates

Unintended Consequences

Increased Part D costs

EXTERNAL INFLUENCES, ENVIRONMENTAL, RELATED PROGRAMS



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 additional support to ETC participants treating patients who are dually eligible for Medicare and Medicaid or recipients of the Part D Low Income Subsidy (LIS) 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

Pool all eligible beneficiary months each year (2017-2023) for 95 ETC HRRs and 211 comparison HRRs

Apply eligibility and attribution rules
Define participant status of beneficiary months

Determination of pre-ETC period

Leveraging the key design features of the model, establish all HRRs not selected for ETC Model as comparison group

Check balance on observed beneficiary, facility, and market level characteristics

Check parallel trends assumption for outcomes

Use covariate adjustment to account for residual imbalances between ETC and comparison group HRRs

Estimate the impact of the ETC Model on dialysis modality, transplant, and waitlisting, utilization, and Medicare payment measures using DiD regression models



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 2023	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, other patient demographics, 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
End Stage Renal Disease Quality Reporting System (EQRS)	January 2017 – December 2023	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 subgroup analyses
Kidney and Transplant Waitlisting Data from Scientific Registry of Transplant Recipients (SRTR)	January 2017 – December 2023	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).
Area Health Resource File (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 – 2023	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
In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey	Spring 2017 – Fall 2023	Patient experience with in-center HD care	Used to assess patient experience among in-center dialysis patients



Data Source Name	Date Range*	Data Contents	Use
Medicare Data on Provider Practice and Specialty (MD-PPAS) National Plan and Provider Enumeration System (NPPES)	2017 – 2023	Information on the provider's name, gender, age, ZIP code, specialty (taxonomy) and practice address.	Used to identify Managing Clinician characteristics for assessing balance
The ZIP Code File-SAS	N/A	ZIP codes and Core-Based Statistical Areas (CBSAs)	Used to link ZIP codes to counties, CBSA
Files from KCC Implementation contractor	2023	PY 2022&2023 Q2 list contains unduplicated NPI participating in KCC model	Used to indicate whether the Managing Clinician a KCC participant or not

Note: AHRF = Area Health Resource File; CBSA = Core-Based Statistical Area; CEC = Comprehensive End-Stage Renal Disease Care; ETC = ESRD Treatment Choices; EQRS = End Stage Renal Disease Quality Reporting System; FFS = Free-For-Service; HD = Hemodialysis; ICH CAHPS = In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems; KCC = Kidney Care Choices Model; NGACO = Next Generation ACO; NPI = National Provider Identifier; SRTR = Scientific Registry of Transplant Recipients. *As discussed in detail below, we drop 2020 data from our analyses.

The dialysis modality, transplant, waitlisting, utilization, and Medicare payment outcome 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, see **Exhibit F-4** for Home-DCE measures, and **Appendix G, Section G.1.**).



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. 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 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.
	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.



0	utcomes	Description of Outcomes		
	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.		
Dialysis Modality Measures (%)	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.		
(cont.)	Home Dialysis Gains	Monthly flag set to 1 if beneficiary started home dialysis this month (i.e., first month with home dialysis as primary modality) as a new ESRD patient, due to a modality switch from ICHD, or a return to dialysis after a failed transplant, and 0 otherwise. Data obtained from EQRS.		
	Home Dialysis Gain from New ESRD Patient	Monthly flag set to 1 for home dialysis gain with no prior evidence of dialysis (i.e., no previous dialysis claim and no prior treatment types = 'DIALYSIS'), and 0 otherwise. Data obtained from EQRS.		
	Home Dialysis Gain Switched from ICHD	Monthly flag set to 1 for a home dialysis gain proceeding a month where the primary dialysis modality was ICHD and preceding a month where the primary dialysis modality was home dialysis, and 0 otherwise. Data obtained from EQRS.		
	Home Dialysis Gain from Failed Transplantation	Monthly flag set to 1 for a home dialysis gain within a month of having a reason for patient admission as 'Dialysis after Transplant Failed', and 0 otherwise. Data obtained from EQRS.		
	Home Dialysis Losses	Monthly flag set to 1 if beneficiary stopped home dialysis this month (i.e., last month with home dialysis as primary modality) due to death, modality switch to ICHD, transplantation, recovery, or loss to follow up, and 0 otherwise.		
	Home Dialysis Loss to Death	Monthly flag set to 1 for a home dialysis loss within a month of having a reason for patient discharge as 'Death', and 0 otherwise. Data obtained from EQRS.		
	Home Dialysis Loss to Transplantation	Monthly flag set to 1 for a home dialysis loss within a month of evidence of having a transplant (living or deceased), and 0 otherwise. Data obtained from EQRS.		



0	utcomes	Description of Outcomes
Dialysis	Home Dialysis Loss Switched to ICHD	Monthly flag set to 1 for a home dialysis loss preceding two consecutive months where the primary dialysis modality was ICHD, and 0 otherwise. Data obtained from EQRS.
Modality Measures (%)	Home Dialysis Loss to Follow-up	Monthly flag set to 1 for a home dialysis loss within a month of having a reason for patient discharge as 'Loss to Follow Up', and 0 otherwise. Data obtained from EQRS.
(cont.)	Home Dialysis loss to recovery	Monthly flag set to 1 for a home dialysis loss within a month of having a reason for patient discharge as 'Recover Function', and 0 otherwise. Data obtained from EQRS.
	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.
Waitlisting (%)	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.
	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.
Transplant (per 1,000	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.
Beneficiary Months)	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 an 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.



	Outcomes	Description of Outcomes
Utilization	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.
(%) (cont.)	Total ED Use	Monthly beneficiary count of total emergency department visits (i.e., inpatient and outpatient). The outpatient ED visit is based on Part B institutional claims that have a claim line with a revenue center code starting with 045. The inpatient ED visits is based on Part A claims that have a claim line with a revenue center code starting with 045. All ED visits are counted in the month of the claim from date on the claim.
	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.
Medicare	Other Part A	Monthly beneficiary sum of Part A Actual (that is, CMS payments only) home health standardized amounts, winsorized at the 99th percentile.
Payments (PPPM)	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.
	Part B In-center Dialysis	Monthly beneficiary sum of Part B institutional Actual (i.e., CMS payments only) outpatient dialysis facility in-center dialysis standardized amounts, winsorized at the 99 th percentile.
	Part B Home Dialysis	Monthly beneficiary sum of Part B institutional Actual (i.e., CMS payments only) outpatient dialysis facility home dialysis standardized amounts, winsorized at the 99 th percentile.
	Part B Home HD	Monthly beneficiary sum of Part B institutional Actual (i.e., CMS payments only) outpatient dialysis facility home hemodialysis standardized amounts, winsorized at the 99 th percentile.
	Part B Home Peritoneal Dialysis	Monthly beneficiary sum of Part B institutional Actual (i.e., CMS payments only) outpatient dialysis facility home Peritoneal Dialysis standardized amounts, winsorized at the 99 th 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.



0	utcomes	Description of Outcomes
PPPM (cont.)	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. Restricted to patients enrolled in a Part D plan.
	Peritonitis	Monthly flag set to 1 if beneficiary is diagnosed with 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, I322, J810, J811 and I50x
Quality	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, T82399A, 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.
	Kt/V Dialysis Adequacy	Monthly indicator set to 1 if Kt/V labs obtained from EQRS are above specified targets for eligible bene-months (Kt/V greater than or equal to 1.2 or having at least 4 treatment sessions per week for HD patients; and Kt/V greater than or equal to 1.7 for PD patients). Monthly indicator set to 0 if Kt/V labs are missing, below the targets, or out of range (>5.0 for HD and >8.5 for PD). Bene-months are excluded from analysis for this outcome if meeting any of the following criteria: bene-months with more than one treatment modality; bene-months where the patient is on ESRD treatment for fewer than 91 days; bene-months where the patient has at least one day of hospitalization; bene-months where HD patients having less than or equal to 2 sessions per week.
	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: CAPD = Continuous Ambulatory Peritoneal Dialysis; CCPD = Continuous Cycling Peritoneal Dialysis; CCN = CMS Certification Number; CY = Calendar Year; ED = Emergency Department; ESRD = End Stage Renal Disease; EQRS = End Stage Renal Disease Quality Reporting System; HD = Hemodialysis; ICD = International Classification of Diseases; ICHD = In-Center Hemodialysis; IRF = Inpatient Rehabilitation Facility; LTCH = Long-Term Care Hospital; MBSF = Master Beneficiary Summary File; PD = Peritoneal Dialysis; PPPM = Per-Patient Per-Month; SRTR = Scientific Registry of Transplant Recipients; VA = Vascular Access. We also examine facility survey-wave level measures of patient experience among in-center dialysis patients (see

Appendix E: In-Center Hemodialysis Consumer Assessment of Healthcare Providers Survey Analysis Supplement). 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. 1Among dialysis patients.



B.2. Beneficiary Attribution and Eligibility

We applied a series of inclusion/exclusion criteria, (see <u>Exhibit B-4</u>), 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 <u>Exhibit B-5</u> and <u>Exhibit B-6</u>). We applied these criteria to all beneficiary months before death from January 2017-December 2023 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 were 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.

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
 - o 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.²
- 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.: ESRD 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 a 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.

There was an announced change in the ESRD eligibility criteria in the ESRD PPS CY 2025 Final Rule but did not apply to PY2023. In future Annual Reports, ESRD eligibility criteria will be changed https://www.cms.gov/newsroom/fact-sheets/calendar-year-2025-end-stage-renal-disease-esrd-prospective-payment-system-pps-final-rule-cms-1805-f



B-10

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 were 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.³ 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**).

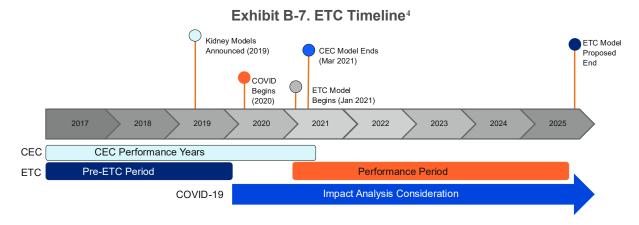


Exhibit B-8 below shows how we derived our final sample. **Exhibit B-9** and **Exhibit B-10** report the size of the final sample by pre-ETC and post-ETC periods as well as by individual years for the ETC and comparison groups, respectively.

⁴ The CY 2026 ESRD Prospective Payment System Proposed Rule contains the proposed end of the ETC Model.



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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

Pool of beneficiary months (2017-2023) N = 55,594,967

Attributed to either dialysis facility or managing clinician and eligible beneficiary months

N = 19,306,658 (34.7%)

ETC treatment status based on location of attributed facility

Missing attributed facilities: 2.7%

Unable to map zip code to HRR: 0.3%

Excluded all beneficiary months in 2020.

Final N for eligible beneficiary months (for 2017-2019, 2021-2023) N = 15,722,153

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

	ET	гс	Comparison					
Characteristic	Pre-ETC (2017-2019)	Post-ETC (2021-2023)	Pre-ETC (2017-2019)	Post-ETC (2021-2023)				
Number of HRRs	95	95	211	211				
Number of ESRD Facilities	2,512	2,591	5,227	5,402				
Number of Managing Clinicians	6,650	6,379	9,539	9,678				
Number of Unique Beneficiaries	171,190	141,890	336,262	275,129				
Number of Patient Months	3,116,487	2,172,797	6,165,610	4,267,259				

Note: ESRD = End-Stage Renal Disease; ETC = ESRD Treatment Choices; HRR = Hospital Referral Region. 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.



Number of Number of Unique Number of **Number of** Group Year Managing **ESRD Facilities Beneficiaries Patient Months** Clinicians 2017 4,753 115,971 1,031,382 2,284 2018 2,382 4,866 116,574 1,038,308 2019 1,046,797 2,450 4,956 117,566 **ETC** 2021 2,515 4,739 99.368 833.414 2022 4,716 711,585 2,502 85,910 627.798 2023 2.445 4,611 76,715 2017 4,727 7,602 229,963 2,053,806 2018 4,979 7,751 229,905 2,058,184 2019 5,102 7,895 229,717 2,053,620 Comparison 2021 5,244 7,753 193,453 1,631,778 2022 5,239 7,901 167,110 1,393,602 150.098 2023 5.132 7.855 1,241,879

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

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. 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.

⁵ As noted in the Final Rule, CMS also included all HRRs that had at least 20% of ZIP Codes in Maryland. (Ibid.).



B-13

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:

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

We compared SMDs against a standard threshold value of 0.2 to understand the extent of any differences between the ETC and comparison regions. We assessed balance on the following list of factors:

- Patient characteristics:
 - Age, sex, and other demographics, duration of ESRD, indicators of socioeconomic 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), poverty rate, educational attainment, MA penetration, numbers of hospitals and physicians per 100,000 population

As shown in <u>AR1</u>, 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 **Exhibit B-11** – **Exhibit B-14**. Of the 155 characteristics assessed, only five had a SMD greater than 0.2.



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

				E	тс		Comparison				SMD (ETC vs.	SMD (ETC vs.
Chamantaniatia			Pre	-ETC	Post	-ETC	Pre-	ETC	Post	-ETC	Comparison)	Comparison)
Characteristic			N = 3,1	16,487	N = 2,1	72,797	N = 6,1	65,610	N = 4,2	67,259	Pre-ETC	Post-ETC
			Mean	SD	Mean	SD	Mean	SD	Mean	SD	period	period
	Age, Continu	ous (Years)	61.7	14.2	63.4	14.5	62.0	14.2	63.6	14.5	-0.02	-0.01
	Age, Continu	ous (Median, years)	63.0	-	65.0	-	63.0	-	65.0	-	-	-
		18 - <25 Years	0.68%	8.2%	0.60%	7.7%	0.64%	8.0%	0.56%	7.5%	0.005	0.005
		25 - <35 Years	4.0%	19.5%	3.8%	19.0%	3.8%	19.1%	3.6%	18.7%	0.01	0.01
		35 - <45 Years	9.0%	28.6%	8.4%	27.7%	8.8%	28.3%	8.2%	27.4%	0.01	0.01
	Age, Categorical	45 - <55 Years	18.1%	38.5%	15.1%	35.8%	17.7%	38.2%	15.1%	35.8%	0.01	0.000
	categorical	55 - <65 Years	25.6%	43.6%	22.8%	42.0%	25.9%	43.8%	22.7%	41.9%	-0.01	0.00
		65 - <75 Years	25.7%	43.7%	28.1%	45.0%	25.7%	43.7%	28.4%	45.1%	-0.001	-0.01
		75 Years & Over	17.0%	37.6%	21.2%	40.8%	17.4%	37.9%	21.4%	41.0%	-0.01	-0.01
	Female		43.2%	49.5%	42.3%	49.4%	42.9%	49.5%	41.9%	49.3%	0.01	0.01
	RMI	<18.5	2.7%	16.2%	2.7%	16.2%	2.7%	16.1%	2.7%	16.1%	0.001	0.003
		18.5- <25	22.9%	42.0%	23.1%	42.2%	23.8%	42.6%	24.1%	42.7%	-0.021	-0.022
		25- <30	27.1%	44.5%	27.4%	44.6%	27.2%	44.5%	27.6%	44.7%	-0.003	-0.004
Patient		30- <35	20.1%	40.1%	20.3%	40.2%	19.7%	39.8%	19.9%	39.9%	0.009	0.009
Characteristics	Categorical	35- <40	12.2%	32.7%	12.3%	32.9%	12.1%	32.7%	12.1%	32.6%	0.002	0.01
		40 or greater	13.0%	33.6%	12.5%	33.1%	12.4%	32.9%	12.0%	32.5%	0.019	0.02
		Missing	2.0%	14.1%	1.6%	12.6%	2.1%	14.2%	1.6%	12.6%	-0.002	0.000
	ESRD Vintage	, Continuous (Years)	5.2	5.1	5.4	5.5	5.2	5.1	5.3	5.4	0.01	0.01
		<6 Months	8.4%	27.8%	9.5%	29.3%	8.6%	28.0%	9.7%	29.6%	-0.005	-0.01
		6 Months - <1 Year	7.3%	26.0%	7.6%	26.5%	7.3%	26.1%	7.7%	26.6%	-0.002	-0.003
	ESRD	1 - <2 Years	13.4%	34.1%	13.2%	33.9%	13.5%	34.1%	13.4%	34.0%	-0.001	-0.004
	Vintage,	2 - <3 Years	12.6%	33.2%	12.3%	32.9%	12.6%	33.2%	12.3%	32.8%	0.001	0.000
	Categorical	4 - <7 Years	27.9%	44.9%	27.2%	44.5%	28.0%	44.9%	27.2%	44.5%	-0.002	0.001
		7 - <10 Years	16.4%	37.0%	15.6%	36.3%	16.5%	37.1%	15.7%	36.3%	-0.004	-0.001
		10 Years and Over	14.0%	34.7%	14.6%	35.3%	13.5%	34.2%	14.2%	34.9%	0.01	0.01
	Dual Medicar (Full or Partia	re/Medicaid Enrollment al Benefits)	47.2%	49.9%	44.5%	49.7%	48.6%	50.0%	46.9%	49.9%	-0.03	-0.05
	Dual Medicare/Medicaid Enrollment (Full Benefits)		33.3%	47.1%	34.7%	47.6%	36.5%	48.1%	38.9%	48.8%	-0.07	-0.09



				E	TC			Comp	arison		SMD (ETC vs.	SMD (ETC vs.
			Pre	-ETC	Post	-ETC	Pre-	ETC	Post	-ETC	Comparison)	Comparison)
Characteristic			N = 3,1	16,487	N = 2,1	72,797	N = 6,1	65,610	N = 4,2	67 , 259	Pre-ETC	Post-ETC
			Mean	SD	Mean	SD	Mean	SD	Mean	SD	period	period
	Part D Benefi	t Enrollment	81.6%	38.7%	78.5%	41.1%	81.9%	38.5%	79.1%	40.6%	-0.01	-0.02
	Part D LIS (W Benefits)	here Enrolled in Part D	67.8%	46.7%	61.2%	48.7%	69.2%	46.2%	63.0%	48.3%	-0.03	-0.04
	Medicare Sha	red Savings Program	22.3%	41.6%	19.3%	39.4%	22.3%	41.6%	23.6%	42.4%	-0.001	-0.10
		CEC	20.3%	40.2%	2.4%	15.4%	12.4%	32.9%	1.1%	10.5%	0.22	0.10
Patient	Alternative	KCC Provider*	49.1%	50.0%	52.4%	49.9%	39.8%	48.9%	42.3%	49.4%	0.19	0.20
Characteristics	Payment	KCC Model 2022	0.0%	0.0%	10.7%	31.0%	0.0%	0.0%	8.0%	27.2%	N/A	0.09
(cont.)	Models	KCC Model 2023	0.0%	0.0%	14.8%	35.5%	0.0%	0.0%	12.0%	32.5%	N/A	0.08
		NGACO	2.9%	16.9%	0.8%	9.1%	3.5%	18.4%	0.8%	8.9%	-0.03	0.004
		ESRD and Disability	19.1%	39.3%	10.3%	30.4%	18.6%	38.9%	9.8%	29.8%	0.01	0.01
	Original Medicare	ESRD	31.7%	46.5%	34.7%	47.6%	32.1%	46.7%	35.1%	47.7%	-0.01	-0.01
	Entitlement	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%	33.8%	47.3%	28.5%	45.2%	34.4%	47.5%	-0.01	-0.01
	Acute Myocardial Infarction		3.5%	18.5%	4.8%	21.4%	3.8%	19.0%	5.2%	22.2%	-0.01	-0.02
	Alzheimer's Disease		0.04%	2.0%	0.04%	1.9%	0.04%	2.1%	0.04%	1.9%	-0.002	0.000
	Asthma		10.4%	30.5%	10.1%	30.1%	10.4%	30.5%	10.1%	30.1%	0.000	0.000
	Atrial Fibrillat	tion and Flutter	20.1%	40.1%	23.4%	42.4%	20.5%	40.4%	23.9%	42.7%	-0.01	-0.01
	Benign Prosta	atic Hyperplasia	9.1%	28.8%	12.0%	32.6%	9.1%	28.8%	12.2%	32.7%	0.001	-0.005
	Cancer, Any		10.2%	30.2%	11.8%	32.2%	10.0%	30.0%	11.5%	31.9%	0.01	0.01
	Cancer, Breas	it	2.1%	14.3%	2.4%	15.4%	2.0%	14.1%	2.4%	15.2%	0.004	0.004
	Cancer, Color	ectal	1.7%	12.7%	1.8%	13.3%	1.7%	12.7%	1.8%	13.4%	0.000	-0.002
Comorbidities	Cancer, Endo	metrial	0.49%	7.0%	0.54%	7.3%	0.48%	6.9%	0.56%	7.5%	0.001	-0.004
	Cancer, Lung		0.72%	8.5%	0.92%	9.5%	0.75%	8.6%	0.90%	9.4%	-0.003	0.002
	Cancer, Prost	ate	3.0%	17.1%	3.8%	19.0%	3.0%	17.2%	3.5%	18.5%	-0.002	0.01
	Cancer, Urolo	gic	3.2%	17.7%	3.7%	18.8%	3.0%	17.0%	3.5%	18.4%	0.02	0.01
	Cataract		17.2%	37.7%	18.6%	38.9%	17.2%	37.8%	18.4%	38.8%	-0.001	0.003
	Disease	ructive Pulmonary	21.7%	41.2%	19.0%	39.2%	21.9%	41.4%	19.3%	39.4%	-0.004	-0.01
		Sipolar, or Other Sood Disorders	21.8%	41.3%	23.7%	42.5%	21.4%	41.0%	23.1%	42.1%	0.01	0.02
	Diabetes		65.2%	47.6%	65.6%	47.5%	66.7%	47.1%	67.2%	47.0%	-0.03	-0.03



			Е	TC			Comp	arison		SMD (ETC vs.	SMD (ETC vs.
Chavastavistis		Pre	-ETC	Post	-ETC	Pre-	ETC	Post	-ETC	Comparison)	Comparison)
Characteristic	Cital acteristic		16,487	7 N = 2,172,797		N = 6,165,610		N = 4,267,259		Pre-ETC	Post-ETC
		Mean	SD	Mean	SD	Mean	SD	Mean	SD	period	period
	Glaucoma	13.2%	33.9%	14.3%	35.0%	13.3%	33.9%	14.1%	34.8%	-0.001	0.006
	Congestive Heart Failure	45.1%	49.8%	48.6%	50.0%	46.1%	49.8%	49.6%	50.0%	-0.02	-0.02
	Hip/Pelvic Fracture	0.87%	9.3%	1.1%	10.5%	0.94%	9.7%	1.1%	10.7%	-0.01	-0.003
	Hyperlipidemia	69.7%	46.0%	74.0%	43.9%	69.6%	46.0%	74.0%	43.8%	0.003	-0.002
	Hypertension	92.7%	25.9%	93.3%	25.0%	92.8%	25.8%	93.2%	25.2%	-0.002	0.005
	Hypothyroidism	18.9%	39.2%	20.4%	40.3%	19.7%	39.8%	20.9%	40.7%	-0.02	-0.01
Comorbidities	Ischemic Heart Disease	42.1%	49.4%	44.3%	49.7%	44.0%	49.6%	45.8%	49.8%	-0.04	-0.03
(cont.)	Non-Alzheimer's Dementia	1.5%	12.1%	2.0%	13.8%	1.5%	12.3%	1.9%	13.8%	-0.005	0.002
(contr)	Osteoporosis with or without Pathological Fracture	4.4%	20.4%	5.5%	22.8%	4.7%	21.2%	5.8%	23.4%	-0.02	-0.01
	Pneumonia	12.6%	33.2%	14.5%	35.3%	12.8%	33.4%	14.6%	35.3%	-0.01	-0.001
	Parkinson's Disease and Secondary Parkinsonism	0.53%	7.3%	0.61%	7.8%	0.61%	7.8%	0.65%	8.1%	-0.01	-0.005
	Rheumatoid Arthritis/Osteoarthritis	28.9%	45.3%	30.8%	46.2%	28.9%	45.3%	30.6%	46.1%	0.000	0.004
	Stroke/Transient Ischemic Attack	8.3%	27.6%	9.3%	29.0%	8.4%	27.7%	9.2%	28.9%	-0.003	0.003



				Е	TC		Comparison				SMD (ETC vs.	SMD (ETC vs.
Characteristic			Pre	-ETC	Post	-ETC	Pre-	ETC	Post	-ETC	Comparison)	Comparison)
Characteristic			N = 3,1	.16,487	N = 2,1	72,797	N = 6,1	65,610	N = 4,2	67,259	Pre-ETC	Post-ETC
			Mean	SD	Mean	SD	Mean	SD	Mean	SD	period	period
		Diabetes	42.9%	49.5%	41.8%	49.3%	44.6%	49.7%	43.1%	49.5%	-0.03	-0.03
		Glomerulonephritis	11.5%	31.9%	11.0%	31.3%	11.0%	31.3%	10.3%	30.4%	0.01	0.02
		Hypertension	31.4%	46.4%	31.0%	46.2%	30.1%	45.8%	30.0%	45.8%	0.03	0.02
		Other	14.1%	34.8%	16.2%	36.8%	14.3%	35.0%	16.6%	37.2%	-0.01	-0.01
		Diabetes	51.3%	50.0%	52.4%	49.9%	52.4%	49.9%	53.6%	49.9%	-0.02	-0.03
		Congestive Heart Failure	21.5%	41.1%	20.5%	40.4%	21.7%	41.2%	20.6%	40.5%	-0.004	-0.003
		Atherosclerotic Heart Disease	10.2%	30.2%	9.1%	28.8%	9.9%	29.9%	9.0%	28.6%	0.01	0.01
Health		Other Cardiac Disease	13.0%	33.6%	14.5%	35.3%	13.0%	33.6%	14.7%	35.4%	0.000	-0.004
Conditions at Start of	Primary Cause of	Cerebrovascular Disease, CVA, TIA	5.8%	23.3%	5.8%	23.4%	5.8%	23.4%	5.7%	23.2%	-0.002	0.005
Dialysis (Data Source: EQRS	ESRD, Categorical	Peripheral Vascular Disease	7.3%	26.1%	6.6%	24.8%	6.9%	25.3%	6.0%	23.7%	0.02	0.02
2728 form)		Chronic Obstructive Pulmonary Disease	5.4%	22.5%	5.0%	21.8%	5.3%	22.4%	5.0%	21.8%	0.002	0.000
		Tobacco Use (Current Smoker)	6.5%	24.6%	5.9%	23.6%	6.2%	24.1%	5.7%	23.2%	0.01	0.01
		Malignant Neoplasm, Cancer	4.5%	20.8%	5.4%	22.6%	4.6%	20.9%	5.4%	22.6%	-0.001	-0.002
		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%	10.8%	1.1%	10.5%	1.0%	10.1%	0.01	0.01
		Inability to Ambulate	2.4%	15.4%	2.5%	15.7%	2.6%	15.8%	2.7%	16.3%	-0.01	-0.01
		Inability to Transfer	1.0%	9.8%	1.0%	10.1%	1.0%	10.1%	1.2%	10.7%	-0.01	-0.01



				E	тс			Comp	arison		SMD (ETC vs.	SMD (ETC vs.
Characteristic			Pre	-ETC	Post-	-ETC	Pre-	ETC	Post-	-ETC	Comparison)	Comparison)
Characteristic			N = 3,1	N = 3,116,487		N = 2,172,797		65,610	N = 4,267,259		Pre-ETC	Post-ETC
			Mean	SD	Mean	SD	Mean	SD	Mean	SD	period	period
		Not under Care of Nephrologist prior to ESRD	20.8%	40.6%	17.0%	37.5%	21.3%	40.9%	18.0%	38.4%	-0.01	-0.03
		Unknown If under Care of Nephrologist	18.5%	38.8%	16.9%	37.5%	19.6%	39.7%	17.5%	38.0%	-0.03	-0.02
	Patient Months under	< 6 Months under Care	12.4%	32.9%	14.3%	35.1%	12.5%	33.1%	14.5%	35.2%	-0.004	-0.003
Health Conditions at	Care of Nephrologist	6 - <12 Months under Care	19.1%	39.3%	19.5%	39.6%	18.3%	38.6%	18.9%	39.1%	0.02	0.02
Start of Dialysis (Data	Prior to ESRD Therapy,	12 Months or Longer under Care	29.2%	45.5%	32.3%	46.8%	28.3%	45.1%	31.2%	46.3%	0.02	0.02
Source: EQRS 2728 form) (cont.)	Categorical	Prior Employment Status (Employed Full or Part-Time)	24.8%	43.2%	25.8%	43.8%	24.6%	43.1%	25.4%	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	0.02
	Beneficiary	Metro	81.8%	38.6%	82.3%	38.2%	84.3%	36.4%	84.4%	36.2%	-0.07	-0.06
	RUCC	Urban	16.7%	37.3%	16.2%	36.9%	14.1%	34.8%	13.9%	34.6%	0.07	0.07
		Rural	1.5%	12.1%	1.5%	12.2%	1.6%	12.7%	1.7%	12.8%	-0.01	-0.01

Note: BMI = Body Mass Index; CEC = Comprehensive End-Stage Renal Disease Care; CVA = Cerebrovascular Accident; EQRS = End Stage Renal Disease Quality Reporting System; ESRD = End Stage Renal Disease; ETC = ESRD Treatment Choices; KCC = Kidney Care Choices Model; LIS = Low Income Subsidy; NGACO = Next Generation ACO; RUCC = Rural-Urban Continuum Code; SD = standard deviation. SMD = standardized mean difference. TIA = Transient Ischemic Attack. Pre-ETC = 2017-2019 Post-ETC period = 2021-2023. A patient may contribute up to 12 observations per year to this patient-month summary.

*Percent of patient months aligned with a clinician who later volunteered for KCC anytime between 2022 and 2023. Missingness for KCC participation variables was 2.9% for provider effect and 0.45% for both 2022 and 2023 effects. Shading indicates a SMD > 0.2.



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

				E1	ГС			Comp	arison		SMD (ETC vs.	SMD (ETC vs.
Chavastavistis			Pre-	ETC	Post-	-ETC	Pre-	ETC	Post	-ETC	Comparaison)	Comparaison)
Characteristic			N = 2	,512	N = 2	,591	N = 5,227		N = 5,402		Pre-ETC	Post-ETC
			Mean	SD	Mean	SD	Mean	SD	Mean	SD	period	period
	Number of HD S	tations	17.4	8.1	17.3	8.2	17.5	8.6	17.5	8.6	-0.01	-0.02
	For-Profit		89.7%	30.4%	91.1%	28.6%	87.5%	33.1%	88.8%	31.5%	0.07	0.07
		DaVita	37.7%	48.5%	37.3%	48.4%	39.5%	48.9%	39.4%	48.9%	-0.04	-0.04
		Fresenius Medical Care	39.1%	48.8%	38.8%	48.7%	34.9%	47.7%	34.6%	47.6%	0.09	0.09
	Facility Ownership	Independent/ Non-Chain For-Profit	3.5%	18.4%	4.4%	20.5%	5.1%	22.0%	5.6%	23.1%	-0.08	-0.06
		Other For-Profit	9.9%	29.9%	10.8%	31.0%	8.4%	27.7%	8.9%	28.5%	0.05	0.06
		Non-Profit	9.7%	29.6%	8.8%	28.4%	12.2%	32.8%	11.5%	31.9%	-0.08	-0.09
		<=50	36.7%	48.2%	50.3%	50.0%	39.3%	48.9%	53.1%	49.9%	-0.05	-0.06
Facility Characteristics	Facility Patient Volume	>50 and <=75	21.2%	40.9%	25.4%	43.6%	21.8%	41.3%	26.3%	44.1%	-0.01	-0.02
from AFS	(Patients)*	>75 and <=100	18.0%	38.5%	13.5%	34.2%	17.1%	37.7%	12.0%	32.5%	0.02	0.05
		>100	24.0%	42.7%	10.8%	31.1%	21.8%	41.3%	8.6%	28.1%	0.05	0.07
	Provides In-Cent	er HD Service	94.8%	22.2%	94.1%	23.5%	92.9%	25.7%	92.8%	25.9%	0.08	0.05
	Provides Periton	eal Dialysis Service	50.5%	50.0%	50.3%	50.0%	54.1%	49.8%	54.0%	49.8%	-0.07	-0.07
	Provides Home I	ID Training Service	28.9%	45.3%	28.7%	45.3%	30.5%	46.1%	30.3%	46.0%	-0.04	-0.04
	Facility has Shift	after 5 p.m.	15.9%	36.6%	15.0%	35.7%	16.4%	37.0%	15.5%	36.2%	-0.01	-0.01
	Total In-Center D	Dialysis Patients	57.4	42.7	53.6	37.8	59.0	44.7	54.7	38.9	-0.04	-0.03
	Total Home Dial	ysis Patients	7.6	15.2	9.7	18.8	8.1	16.5	10.0	20.9	-0.03	-0.02
	Total Patients Re Survey Period	eceiving Care at End of	65.0	47.5	63.3	42.8	67.1	48.6	64.7	43.9	-0.05	-0.03



					ETC				arison		SMD (ETC vs.	SMD (ETC vs.
Characteristic	Characteristic			ETC	Post-	-ETC	Pre-	ETC	Post	-ETC	Comparaison)	Comparaison)
Characteristic			N = 2	,512	N = 2,591		N = 5,227		N = 5,402		Pre-ETC	Post-ETC
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	period	period		
		Northeast	14.7%	35.4%	15.0%	35.7%	13.3%	34.0%	13.5%	34.2%	0.04	0.04
	Facility Region	Midwest	20.3%	40.2%	19.5%	39.7%	21.2%	40.9%	20.4%	40.3%	-0.02	-0.02
Facility	racility Region	South	47.3%	49.9%	47.6%	50.0%	45.2%	49.8%	44.9%	49.7%	0.04	0.05
Location		West	17.8%	38.3%	17.9%	38.4%	20.3%	40.3%	21.2%	40.9%	-0.06	-0.08
Characteristics		Metro	83.0%	37.5%	83.3%	37.3%	83.4%	37.2%	84.3%	36.4%	-0.01	-0.03
	Facility RUCC	Urban	16.3%	37.0%	16.0%	36.7%	15.9%	36.6%	15.0%	35.7%	0.01	0.03
		Rural	0.64%	8.0%	0.69%	8.3%	0.69%	8.3%	0.65%	8.0%	-0.01	0.005

Note: AFS = Annual Facility Survey; ETC = ESRD Treatment Choices; HD = Hemodialysis; RUCC= Rural-Urban Continuum Code; SD = standard deviation; SMDs = Standardized Mean Difference. Pre-ETC period = 2017-2019. Post-ETC period = 2021-2023.

*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

			E1	ГС			Comp	arison		SMD (ETC vs.	SMD (ETC vs.
Observation to the		Pre-	ETC	Post	-ETC	Pre-	ETC	Post	-ETC	Comparison)	Comparison)
Characteristic		N = 6	,650	N = 6	,379	N = 9	,539	N = 9	,678	Pre-ETC	Post-ETC
		Mean	SD	Mean	SD	Mean	SD	Mean	SD	period	period
Demographics	Mean Age	48.7	10.9	49.3	10.8	49.7	11.5	50.3	11.5	-0.09	-0.08
Demographics	Male	64.7%	47.8%	60.3%	48.9%	65.8%	47.4%	62.3%	48.4%	-0.02	-0.04
	Nephrology	75.3%	43.1%	71.8%	45.0%	74.3%	43.7%	71.1%	45.3%	0.02	0.02
	Nurse Practitioner	11.9%	32.4%	14.9%	35.7%	10.6%	30.8%	13.3%	33.9%	0.04	0.05
	Internal Medicine	8.0%	27.2%	7.2%	25.9%	9.3%	29.1%	9.0%	28.7%	-0.05	-0.07
Specialty	Physician Assistant	2.1%	14.4%	2.5%	15.7%	2.2%	14.8%	2.5%	15.6%	-0.01	0.002
	Certified Clinical Nurse Specialist	0.11%	3.3%	0.04%	2.0%	0.23%	4.7%	0.20%	4.4%	-0.03	-0.05
	Other	2.5%	15.7%	3.5%	18.3%	3.3%	17.8%	3.9%	19.3%	-0.04	-0.02
	Number of Dialysis Patients per Month	28.6	24.7	18.9	16.4	28.3	24.5	18.7	16.0	0.01	0.01
	Average Age	61.4	6.9	63.2	7.4	61.8	7.2	63.5	7.5	-0.06	-0.04
Average Patient	Age >75	18.1%	14.6%	22.6%	18.1%	19.1%	15.5%	23.1%	18.6%	-0.06	-0.03
Volume and Characteristics	Male	56.8%	17.7%	57.6%	20.0%	57.1%	18.2%	58.0%	20.5%	-0.01	-0.02
Cital acteristics	Dually Eligible for Medicare and Medicaid	47.2%	22.2%	44.7%	24.1%	48.3%	23.8%	46.2%	26.4%	-0.04	-0.06
	Cause of ESRD – Diabetes	42.2%	18.9%	40.9%	21.1%	43.0%	19.6%	41.5%	21.6%	-0.04	-0.03
Average Number	In-Center HD	25.4	22.6	16.1	14.5	25.0	22.4	15.8	14.3	0.02	0.02
of Patients Treated	Peritoneal Dialysis	2.6	4.4	2.2	3.4	2.8	4.1	2.3	3.3	-0.04	-0.03
per Month by	Home HD	0.54	1.5	0.57	1.4	0.51	1.2	0.51	1.2	0.03	0.04
Dialysis Modality	Other	0.01	0.12	0.01	0.14	0.01	0.14	0.01	0.12	-0.01	0.003
Percent of Patients	In-Center HD	88.5%	19.3%	85.6%	21.3%	87.2%	20.0%	84.3%	22.0%	0.07	0.06
Treated per Month	Peritoneal Dialysis	9.6%	17.1%	11.4%	18.4%	10.8%	18.0%	12.7%	19.2%	-0.07	-0.07
by Dialysis	Home HD	1.9%	6.6%	2.9%	8.4%	2.0%	6.9%	2.9%	8.6%	-0.009	-0.003
Modality	Other	0.05%	1.2%	0.08%	1.2%	0.06%	1.1%	0.08%	1.3%	-0.004	-0.01

Note: ETC = ESRD Treatment Choices; ESRD = End Stage Renal Disease; HD = Hemodialysis; RUCC= Rural-Urban Continuum Code; SD = standard deviation; SMDs = Standardized Mean Difference Pre-ETC period = 2017-2019. Post-ETC period = 2021-2023. Results displayed are based on yearly averages and cover years 2017-2019 for Pre-ETC and years 2021-2023 for Post-ETC. Shading indicates a SMD > 0.2.



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

Chamada viakia				TC -ETC		arison -ETC	SMD (ETC vs. Comparison)
Characteristic			N =	= 95	N =	211	Pre-ETC
			Mean	SD	Mean	SD	period
	Persons > 25 Ye	ears Old with Less than High School Diploma	9.0%	3.0%	9.0%	4.0%	0.000
	MA Penetratio	n	31.1	12.9	33.7	11.6	-0.21
	Poverty		13.0%	4.0%	13.0%	4.0%	0.000
	Median Age, 20	010	38.8	3.3	38.4	3.1	0.14
		Number of Short-Term General Hospitals	2.4	1.5	2.5	1.8	-0.06
		Number of LTCHs	0.11	0.23	0.12	0.35	-0.03
Market	Market Level Capacity per	Number of Short-Term General Hospitals with HD	0.38	0.34	0.41	0.45	-0.08
Characteristics	100,000 Population	Number of Non-Federal Transplant (that is, Transplant Surgeons)	0.03	0.06	0.04	0.11	-0.11
		Number of Non-Federal PCP, Patient Care	67.3	18.3	66.7	19.1	0.03
		Number of Non-Federal PCP, Hospital Resident	6.1	4.8	6.3	5.6	-0.03
	Key Demograp	hics of Interest ¹	60.6	16.6	60.0	17.6	0.03
	Percent of ACC	Beneficiaries	31.0%	14.0%	28.9%	13.6%	0.15
	Percent of CEC	Beneficiaries	0.14%	0.22%	0.09%	0.18%	0.25
	Kidney Care Ch	oice (KCC) Beneficiaries* (%)	0.31%	0.25%	0.25%	0.24%	0.24

Note: ACO = Accountable Care Organization; CEC = Comprehensive End-Stage Renal Disease Care; ETC = ESRD Treatment Choices; HD = Hemodialysis; HRR = Hospital Referral Region; KCC = Kidney Care Choices Model; LTCH = Long-Term Care Hospitals; MA = Medicare Advantage; PCP = Primary Care Physician; SD = standard deviation. SMD = standardized mean difference. Pre-ETC = 2017-2019. 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. ¹Key demographics of interest based on the University of Wisconsin's publicly available values (https://www.neighborhoodatlas.medicine.wisc.edu/).



^{*} Only for 2022-2023. Shading indicates a SMD > 0.2.

B.4.1.1. Medicare Advantage

The ETC Model began in 2021, coinciding with the implementation of the 21st Century Cures Act, which changed the rules governing the enrollment of patients with ESRD in Medicare managed care plans (Medicare Advantage, MA). Prior to 2021, MA was only available to beneficiaries who were Medicare-eligible based on age or disability and had enrolled in an MA plan before developing ESRD. As a result, most patients with ESRD were covered by the traditional Medicare Fee-for-Service (FFS) program. Starting in 2021, all new and existing ESRD beneficiaries had the option to select MA coverage. We used Medicare Beneficiary Summary Files (MBSF) to classify ESRD dialysis patients by Medicare coverage type—either FFS or MA. The yearly distribution between FFS and MA was determined from cumulative beneficiary-month counts. **Exhibit B-15** shows patient characteristics by enrollment status (FFS vs. MA) during the post-ETC (2021-2023) period. Patient characteristics, including age, sex, dual eligibility (Medicare + Medicaid), and reason for Medicare eligibility, were all obtained from the MBSF files.

Characteristic			r Service L-2023	Medi Advar 2021-	ntage	Standardized Mean Difference
		Mean	Std. Dev.	Mean	Std Dev.	(SMD)
Age		62.6	15.0	66.4	12.8	-0.27
Sex	Male	59.5%	49.1%	56.1%	49.6%	0.07
Sex	Female	40.5%	49.1%	43.9%	49.6%	-0.07
Dual eligibility (any	status)	40.2%	49.0%	50.5%	50.0%	-0.21
Reason for	Aged with ESRD	45.8%	49.8%	59.0%	49.2%	-0.27
Medicare	Disable design FCDD		45.1%	31.4%	46.4%	-0.07
Entitlement	ESRD only	25.9%	43.8%	9.6%	29.5%	0.44

Exhibit B-15. Patient Characteristics by Enrollment Status, 2021-2023

Note: ESRD = End Stage Renal Disease; SMD = Standardized Mean Difference. 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 changes in outcomes from the pre-ETC period to CY would have been similar in the ETC and comparison group HRRs in the absence of 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-20** 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-16**.



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-20). 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-17.

Results of the parallel trends tests. All outcomes with the exception of three modality transition specific outcomes - any loss, new patient gain and established patient gain, **passed statistical parallel trend tests.** Those that satisfied parallel trends assumption (passed the test) implied that there was no meaningful difference in trends between the ETC and comparison group during the pre-ETC period. The measures that did not pass the statistical testing of the parallel trends test imply that the treatment and comparison groups were on differential trends before the implementation of the model. For these outcomes, we followed a two-pronged approach to assess the validity of the impact estimates.

- We visually inspected unadjusted trend graphs to compare the trends between the ETC and the comparison group visually (see **Exhibit B-18**)
- We considered the significance as well as the magnitude of the difference in pre-ETC trends (that is, the size of the coefficient that captured the differential trends prior to model intervention).

Exhibit B-16. Assessing Parallel Trends: Falsification Test Results

Outcomes		Adjusted model					
		Estimate	Standard Error	p-value	90% CI Lower	90% CI Upper	
Dialysis Modality Measures (%)	Home Dialysis	0.07	0.16	0.68	-0.20	0.33	
	Peritoneal Dialysis	0.02	0.14	0.9	-0.22	0.25	
	Home HD	0.05	0.06	0.43	-0.05	0.16	
	In-center HD	-0.06	0.16	0.69	-0.33	0.20	
	In-center Hemodialysis	-0.04	0.17	0.79	-0.32	0.23	
	In-center Self-Dialysis	0.01	0.01	0.64	-0.02	0.03	
	Nocturnal HD	-0.03	0.03	0.42	-0.08	0.03	
	Home Dialysis Training	0.02	0.02	0.49	-0.02	0.06	



Outcomes		Adjusted model					
		Estimate	Standard Error	p-value	90% CI Lower	90% CI Upper	
Modality Transition	Home dialysis gains	0.05	0.07	0.47	-0.06	0.17	
	Gain from New ESRD patient	-0.09	0.04	0.01	-0.16	-0.03	
	Gain from return to dialysis after failed transplantation	0.001	0.01	0.90	-0.02	0.02	
	Gain from In-center Hemodialysis switch	0.14	0.06	0.02	0.04	0.24	
	Home dialysis losses	-0.12	0.07	0.09	-0.24	-0.005	
	Loss to In-center Hemodialysis switch	-0.08	0.06	0.23	-0.18	0.03	
	Loss to transplantation	-0.04	0.04	0.33	-0.11	0.03	
	Loss to death or withdrawal	-0.03	0.03	0.34	-0.09	0.02	
	Loss to other types (Recovery and Loss to follow-up)	0.004	0.005	0.37	-0.004	0.01	
Waitlisting (%)	Overall ²	0.46	0.31	0.14	-0.05	0.97	
	Active Status ²	0.12	0.25	0.64	-0.30	0.53	
	Inactive Status ²	0.35	0.24	0.15	-0.05	0.74	
Transplant (per 1,000 Patient Months)	Total ^{2, 3}	-0.05	0.15	0.73	-0.30	0.20	
	Deceased Donor 2, 3	-0.03	0.14	0.82	-0.27	0.20	
	Living Donor ^{2, 3}	-0.02	0.04	0.62	-0.09	0.05	
	Living Donor (among Both Dialysis Patients and Pre-emptive Transplant Recipients) 2,4	0.01	0.03	0.79	-0.04	0.06	
Utilization (%)	Acute Care Hospitalization	-0.02	0.06	0.75	-0.13	0.09	
	Readmission	-0.27	0.26	0.31	-0.70	0.16	
	Outpatient ED Use	-0.08	0.09	0.37	-0.22	0.07	
	Emergency Department Visits	-0.002	0.002	0.23	-0.005	0.001	
Medicare Payments (PPPM)	Total Parts A & B	-\$14	16.96	0.4	-\$42	\$14	
	Total Part A ⁵	-\$11	12.51	0.37	-\$32	\$9	
	Part A Hospital⁵	-\$11	10.59	0.31	-\$28	\$7	
	Part A LTCH, IRF ⁵	\$1	3.91	0.84	-\$6	\$7	
	Other Part A ⁵	-\$1	2.2	0.51	-\$5	\$2	
	Total Part B	-\$3	12.26	0.83	-\$23	\$18	
	Part B Dialysis	-\$1	8.03	0.94	-\$14	\$13	
	In Center Dialysis	-\$5	9.3	0.6	-\$20	\$10	
	Home Dialysis	-\$5	9.26	0.61	-\$20	\$10	
	Home Hemodialysis	\$3	2.62	0.25	-\$1	\$7	
	Peritoneal Dialysis	\$1	4.02	0.86	-\$6	\$7	
	Other Part B	-\$2	9.13	0.82	-\$17	\$13	
	Total Part D	\$14	11.45	0.22	-\$5	\$33	



		Adjusted model								
Outcomes		Estimate	Standard Error	p-value	90% CI Lower	90% CI Upper				
	Peritonitis ⁶	-0.05	0.17	0.78	-0.33	0.23				
	ESRD complications	0.01	0.02	0.75	-0.03	0.04				
Quality (%)	VA complications	0.001	0.02	0.95	-0.03	0.03				
	Vascular Infection ⁷	0.02	0.03	0.56	-0.03	0.06				
	Kt/V	0.11	0.15	0.49	-0.15	0.36				

Notes: CI = Confidence Interval; ED = Emergency Department; ESRD = End Stage Renal Disease; HD = Hemodialysis; LTCH = Long-Term Care Hospital; PPPM = Per-Patient Per-Month; VA = Vascular Access. 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)

- 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 (see **Exhibit B-3** for details). Shading means p-value < 0.1.

Exhibit B-17. Assessing Parallel Trends: Dynamic Trend Test for Outcome Measures

Domain	Measure and Year	Joint Test p-value
	Home Dialysis	0.51
	Peritoneal Dialysis	0.39
	Home HD	0.72
Dialysis Modality	In-Center HD	0.51
Measures ¹	In-Center Hemodialysis	0.40
	In-Center Self-Dialysis	0.28
	Nocturnal HD	0.62
	Home Dialysis Training	0.57
	Home dialysis gains	0.62
	Gain from New ESRD patient	0.05
	Gain from return to dialysis after failed transplantation	0.64
Bandalta.	Gain from In-center Hemodialysis switch	0.06
Modality Transition	Home dialysis losses	0.08
Transition	Loss to In-center Hemodialysis switch	0.31
	Loss to transplantation	0.54
	Loss to death or withdrawal	0.25
	Loss to other types (Recovery and Loss to follow-up)	<0.01
	Overall ²	0.14
Waitlisting	Active Status ²	0.33
	Inactive Status ²	0.36



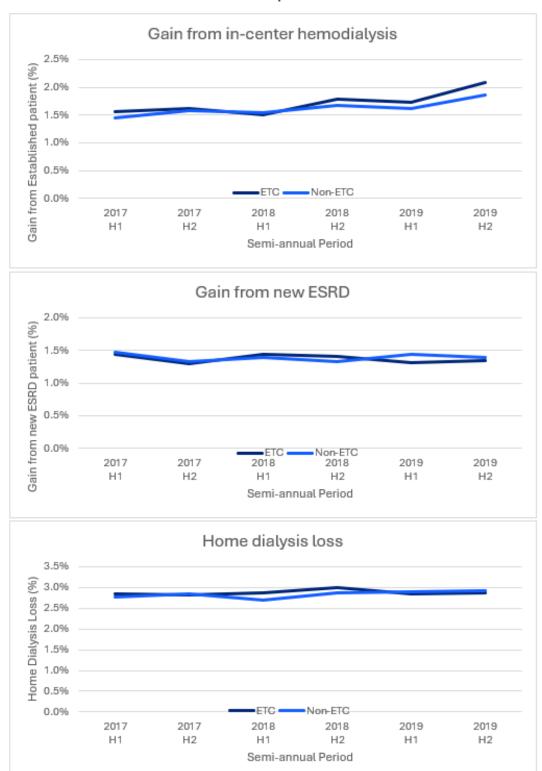
Domain	Measure and Year	Joint Test p-value		
	Total ²³	0.54		
Transplant (per 1,000 Patient	Deceased Donor ²³	0.89		
Months)	Living Donor ²³	0.12		
Wienis,	Living Donor (Dialysis and Pre-Emptive) ²⁴	0.12		
	Acute Care Hospitalization	0.73		
Utilization	Readmission	0.17		
Utilization	Outpatient ED Use	0.63		
	Emergency Department Visits	0.39		
	Total Parts A & B	0.55		
	Total Part A ⁵	0.57		
	Part A Hospital ⁵	0.60		
	Part A LTCH, IRF ⁵	0.16		
	Other Part A ⁵	0.59		
No. Para	Total Part B	0.39		
Medicare Payments (PPPM)	Part B Dialysis	0.67		
rayinents (FFFIVI)	In Center Dialysis	0.23		
	Home Dialysis	0.53		
	Home Hemodialysis	0.48		
	Peritoneal Dialysis	0.43		
	Other Part B	0.49		
	Total Part D ⁵	0.26		
	Peritonitis ⁶	0.89		
	ESRD complications	0.52		
Quality (%)	VA complications	0.55		
	Vascular Infection ⁷	0.74		
	Kt/V	0.77		

Notes: ED = Emergency Department; ESRD = End Stage Renal Disease; HD = Hemodialysis; LTCH = Long-Term Care Hospital; PPPM = Per-Patient Per-Month; VA = Vascular Access. Transplant and waitlisting measures restricted to patients less than 75 years old.

- 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 (see Exhibit B-3 for details). Shading means p-value < 0.1.
- * 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). Shading means p-value < 0.1.



Exhibit B-18. Unadjusted Trends of Select Measures That Failed Parallel Trends
Assumption



Note: ETC = ESRD Treatment Choices. H1: Half year 1, H2: Half year 2. Linear trend test coefficients for gain from established patients is 0.07% (p = 0.05), for gain from new ESRD patient is -0.05% (p = 0.02) and for home dialysis any loss -0.04% (p = 0.43)



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 minus the difference in outcomes between the two groups in the pre-ETC period, as shown in **Exhibit B-19**. $Y_{E,i}$ 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 relies on the assumption 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 $(Y_{E,I} - Y_{C,i}) - (Y_{E,b} - Y_{C,b})$

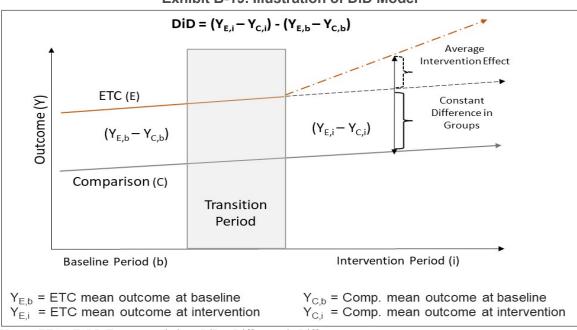


Exhibit B-19. Illustration of DiD Model

Note: ETC = ESRD Treatment Choices; DiD = Difference in Differences.



We used repeated cross-sectional regression models to estimate the effects of the ETC Model on patient outcomes for 2021-2023, the first three years of the model. We also calculated the aggregate (cumulative) estimate (CY 2021-2023) 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.

For the ETC model, we estimated the following DiD regression model for the outcome Y as

$$Y_{i,t} = a_0 + a_1 ETC_i + \sum_{j=1}^3 \beta_j Year_j + \sum_{j=1}^3 \delta_j ETC_i * Year_j + \omega P_{Cov} + \epsilon_{it}$$

where subscripts i t denote patient and months respectively. The variable "ETC" is an indicator that identifies whether a patient belongs to an ETC HRR in a given month. Calendar years are represented by $Year_j$, j = 1,2,3 correspond to the post-ETC years 2021, 2022 and 2023, respectively. P_{Cov} denotes a vector of patient-, provider-, and market level covariates included in the regression model to adjust for residual imbalance despite randomization. The coefficient α_1 is the average difference between the ETC and comparison group over the pre-ETC period. The coefficient β_j captures changes in the ETC and comparison groups between the pre-ETC period and CY_i . The model impacts are captured by the coefficients of the treatment indicator- year interaction terms with δ_j , j = 1,2,3 for years 2021-2023 capturing the regression adjusted differential change in the ETC group relative to the comparison group during the intervention years. 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.⁶

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.

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



B-31

B.5.1. Covariate Adjustments

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

- Relationship with impact measures of interest. Factors found to have a relatively strong relationship with impact measures of interest were given greater emphasis for covariate adjustment in impact analyses, provided they also satisfy other criteria. For example, factors such as patient age and pre-existing comorbidities are often strongly associated with health outcomes like hospitalization, transplants and mortality and hence were considered for covariate adjustment.
- 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 (e.g., such as with a public health event). 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 that may be influenced by the QoC provided by ESRD facilities and Managing Clinicians (e.g., infections related to dialysis access) 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.
- *KCC Model impact:* 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. With the ETC Model overlapping with the KCC Model in 2022 and 2023, we accounted for both the KCC provider effect and year-specific model effects. Using the unduplicated NPI list



provided by the KCC implementation contractor, we created a KCC provider indicator to identify patient months aligned with clinicians participating in the KCC Model. For pre-ETC years, this meant alignment with clinicians who later volunteered for the KCC Model in 2022 or 2023. Since KCC is a voluntary model where clinicians can opt in or out over time, we controlled for the KCC Model's impact separately for 2022 and 2023.

To address the issue that transplant patients may have missing NPI information in a given month, potentially leading to missing KCC status even if their Managing Clinician is a KCC participant, we implemented a six-month look-back period to backfill KCC status for months with missing NPI data. ⁷ Since the missing data may not be random, we categorized all KCC variables into three groups: "Yes" (KCC participant), "No" (not a KCC participant), and "Missing" (no NPI information available, even after applying the six-month look-back method).

■ 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. The COVID-19 PHE may influence outcomes of interest based on individual patients. To account for potential confounding due to the COVID-19 PHE on utilization in the ETC Model, we included four patient month-level risk-adjustment 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 (see Exhibit B-20).

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-20**. 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.

⁷ KCC status remained the same 96% of the times within a 6 month look back period



B-33

Exhibit B-20. Covariate Adjustments Included in the DiD Models

Patient-Level	Facility-Level	Market-Level
 Age categories¹ Female Patient demographics BMI at ESRD incidence ESRD vintage categories² (that is, time on dialysis) Indicator for dually eligible (full or partial Medicaid benefits) status (monthly) Indicator Original Reason for Entitlement Code: age, disabled, ESRD, ESRD and Disabled Indicator for primary cause of ESRD: diabetes, glomerulonephritis, hypertension, other Indicators for comorbidities: Cancer (annual), acute myocardial infarction I, diabetes, pneumonia, rheumatoid arthritis Indicators of health status at incidence of ESRD: Atherosclerotic Heart Disease, Peripheral Vascular Disease, other cardiac disease, Congestive Heart Failure, Chronic Obstructive Pulmonary Disease, tobacco user, alcohol and drug dependence, inability to ambulate and transfer, prior employment status. Indicators for alignment with: CEC, NGACO, Medicare Shared Savings Program. Year specific alignment with Kidney Care Choice (KCC) model, KCC provider effect³ Pre-ESRD nephrology care Indicators for presence of COVID-19: during the month, within the last 30 days, 31-60 days, 61-90 days)⁴ 	 Census Region Indicator: North, East South, West Rural Urban Indicator: Metro, Urban, Rural Facility chain/ownership indicator categories⁵ Facility patient count (annual) 	 Poverty indicator Education attainment⁶ CBSA MA penetration (annual) CBSA geographic rate of primary care providers per 10,000 population (annual) Key demographics of interest⁷ Percent of ACO beneficiaries in the market Percent of CEC beneficiaries in the market

Notes: ACO = Accountable Care Organizations; BMI = Body Mass Index; CBSA = Core-Based Statistical Area; CEC = Comprehensive End-Stage Renal Disease Care; DiD = Difference in Differences; ESRD = End Stage Renal Disease; KCC = Kidney Care Choices Model; MA = Medicare Advantage.

- ¹ Age categories: 18-25 years, 25-35 years, 35-45 years, 45-55 years, 55-65 years, 65-75 years, > 75 years.
- ² Time on dialysis categories: <6 months, 6-12 months, 1-2 years, 2-3 years, 3-6 years, 6-10,10 years and higher.
- ³ 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.
- ⁴ COVID-19 indicators not applicable for checking pre-ETC trends.
- ⁵ Facility chain/ownership categories: Fresenius, DaVita, independent for profit, other for profit, non-profit, missing/unknown chain.
- ⁶ Percent of persons in the facility county of residence who are ages 25 years and older with less than a high school diploma.
- ⁷ Key demographics of interest based on the University of Wisconsin's publicly available values (<u>https://www.neighborhoodatlas.medicine.wisc.edu/</u>).



B.5.2. Modality Transitions

New in this report, we characterized the sources of home dialysis gains (accrual) and losses (referred to collectively as transitions). In addition to the current analysis that focusses on (point) prevalence of home dialysis, the gain/loss transitions analysis will quantify the sources of home dialysis gains (e.g., new dialysis patients, modality changes for existing dialysis patients, resumption of dialysis after a failed transplant) and losses (e.g., modality changes, death, transplantation, recovery, withdrawal from dialysis, loss to follow-up). The analysis may reveal important differences between the current proportion of patients using home dialysis and gain/loss patterns. For example, one may imagine two patient groups with similar proportions of home dialysis. However, one group may show higher rates of accrual and loss than the other, resulting in similar prevalence. Furthermore, home dialysis losses may occur for that may be considered desirable (e.g., transplantation) or undesirable (e.g., death, withdrawal, modality switches). These analyses have the potential to provide important insights into home dialysis care patterns for disadvantaged and historically underrepresented patient populations.

See Section 3 for a detailed analysis of underlying home dialysis gain and loss patterns for patient subpopulations of interest. We compared home dialysis gain and loss patterns based on dual eligibility for Medicare and Medicaid and Part D Low Income Subsidy eligibility.

Methods. Beneficiary months where the primary dialysis modality was home hemodialysis or peritoneal dialysis were included in the modality transition analysis. Home dialysis gains were defined as the first month of home dialysis for a beneficiary, or the first month following a month with an unknown or in-center hemodialysis (ICHD) modality. Home dialysis losses were defined as the last month of home dialysis, or the last month before a transition to an unknown or ICHD modality.

- Data fields from EQRS Form 2744, including admission reason, admission date, discharge dates, discharge reason, treatment type and treatment start date, were used to supplement claims data to determine the cause of each gain or loss.
- Home dialysis gains were categorized as follows:
 - Gain from a new ESRD patient (no previous dialysis claim and no prior treatment types = 'DIALYSIS'),
 - Gain from a transition from ICHD (two consecutive months of home dialysis required to confirm transition),
 - Gain from a return to dialysis after a failed transplant (as a home dialysis gain within a month of having patient admission reason = '4' or 'Dialysis after Transplant Failed').
- Home dialysis losses were categorized as:
 - Loss due to death (defined as a home dialysis loss within a month of having a patient discharge reason = '1' or 'Death'),
 - Loss due to transplantation (evidence of living or deceased transplant),
 - Loss due to transition to ICHD (two consecutive months of ICHD following the home dialysis loss),



- Loss due to follow-up (defined as a home dialysis loss within a month of having a patient discharge reason = '3' or 'Loss to Follow Up'),
- Loss due to recovery (home dialysis loss within a month of having a patient discharge reason = '4' or 'Recover Function').
- Beneficiary months where no specific gain or loss reason could be identified were excluded from the modality transition analysis.

B.5.3. 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-21**. In **Exhibit B-22**, we show the yearly and cumulative (CY 2021 through CY 2023) impact estimates along with risk-adjusted pre-ETC and post-ETC means and estimates of the relative change for all the outcomes.



Exhibit B-21. Unadjusted Means of Outcome Measures Used to Evaluate the ETC Model

			ET	·c			Compa	rison		SMD (ETC vs.	SMD (ETC vs.
		Pre	-ETC	Post	-ETC	Pre-	-ETC	Post	-ETC	Comparison)	Comparison)
Outcomes		N = 3,1	16,487	N = 2,172,797		N = 6,165,610		N = 4,2	67,259	Pre-ETC	Post-ETC
		Mean	SD	Mean	SD	Mean	SD	Mean	SD	period	period
	Home Dialysis	12.0%	32.5%	15.6%	36.3%	12.7%	33.3%	16.3%	36.9%	-0.02	-0.02
	Peritoneal Dialysis	2.2%	14.5%	3.3%	17.8%	2.0%	14.0%	3.0%	17.1%	0.01	0.02
Dialysis	Home HD	9.9%	29.8%	12.4%	32.9%	10.7%	31.0%	13.3%	33.9%	-0.03	-0.03
Modality	In-Center HD	87.9%	32.6%	84.2%	36.5%	87.1%	33.5%	83.5%	37.1%	0.02	0.02
Measures ¹ (%)	In-Center hemodialysis	87.6%	33.0%	84.0%	36.6%	86.7%	34.0%	83.4%	37.2%	0.03	0.02
	In-Center Self-Dialysis	0.04%	1.9%	0.03%	1.8%	0.09%	2.9%	0.03%	1.7%	-0.02	0.002
	Nocturnal HD	0.28%	5.3%	0.12%	3.5%	0.34%	5.8%	0.14%	3.8%	-0.01	-0.01
	Home Dialysis Training	0.75%	8.6%	0.97%	9.8%	0.77%	8.8%	0.92%	9.6%	-0.003	0.005
	Home dialysis gains	3.1%	17.5%	3.2%	17.5%	3.1%	17.3%	3.0%	17.0%	0.004	0.011
	Gain from New ESRD patient	1.4%	11.6%	1.6%	12.5%	1.4%	11.7%	1.5%	12.2%	-0.002	0.006
	Gain from return to dialysis after failed transplantation	0.05%	2.3%	0.06%	2.4%	0.07%	2.6%	0.06%	2.3%	-0.005	0.000
	Gain from In-center Hemodialysis switch	1.7%	13.0%	1.5%	12.3%	1.6%	12.7%	1.4%	11.8%	0.007	0.009
Modality Transition	Home dialysis losses	2.9%	16.7%	3.1%	17.3%	2.8%	16.6%	3.0%	17.0%	0.003	0.007
Hansition	Loss to In-center Hemodialysis switch	1.7%	13.1%	1.7%	12.8%	1.7%	12.7%	1.6%	12.5%	0.006	0.006
	Loss to transplantation	0.59%	7.7%	0.74%	8.6%	0.62%	7.8%	0.69%	8.3%	-0.004	0.005
	Loss to death or withdrawal	0.68%	8.2%	0.72%	8.5%	0.69%	8.3%	0.73%	8.5%	-0.001	-0.001
	Loss to other types (Recovery and Loss to follow-up)	0.02%	1.2%	0.01%	1.2%	0.01%	1.0%	0.01%	1.0%	0.004	0.004
	Overall	18.8%	39.1%	18.4%	38.8%	21.2%	40.9%	20.1%	40.0%	-0.06	-0.04
Waitlisting	Active Status	11.9%	32.3%	10.5%	30.6%	13.5%	34.2%	11.8%	32.3%	-0.05	-0.04
(%)	Inactive Status	6.9%	25.4%	8.0%	27.1%	7.7%	26.6%	8.2%	27.5%	-0.03	-0.01



			ET	·c			Compa	rison		SMD (ETC vs.	SMD (ETC vs.
		Pre	-ETC	Post	-ETC	Pre-	-ETC	Post	-ETC	Comparison)	Comparison)
Outcomes		N = 3,1	16,487	N = 2,172,797		N = 6,165,610		N = 4,2	67,259	Pre-ETC	Post-ETC
		Mean	SD	Mean	SD	Mean	SD	Mean	SD	period	period
	Total ²	3.7	61.1	5.2	71.8	3.9	62.4	5.0	70.5	-0.003	0.003
Transplant	Deceased Donor ²	3.2	56.3	4.5	67.3	3.3	57.1	4.3	65.6	-0.002	0.003
(per 1000 Patient	Living Donor ²	0.56	23.7	0.63	25.2	0.64	25.4	0.67	25.9	-0.003	-0.002
Months)	Living Donor (Dialysis and Pre-emptive) ³	0.56	23.7	0.63	25.2	0.64	25.4	0.67	25.9	-0.003	-0.002
	Acute Care Hospitalization	9.7%	29.6%	9.4%	29.2%	9.8%	29.8%	9.5%	29.3%	-0.004	-0.004
Utilization	Readmission	29.9%	44.8%	29.3%	44.5%	29.9%	44.8%	29.5%	44.6%	0.001	-0.005
(%)	Outpatient ED Use	11.4%	31.8%	9.8%	29.8%	11.1%	31.4%	9.7%	29.5%	0.01	0.01
	Emergency Department Visits	0.24	0.62	0.21	0.58	0.23	0.61	0.21	0.57	0.007	0.004
	Total Parts A & B	\$5,666	\$6,333	\$6,168	\$7,157	\$5,722	\$6,467	\$6,211	\$7,280	-0.01	-0.01
	Total Part A	\$1,579	\$6,088	\$1,796	\$6,971	\$1,649	\$6,293	\$1,869	\$7,156	-0.01	-0.01
	Part A Acute Care Hospitalization	\$1,359	\$5,532	\$1,532	\$6,456	\$1,399	\$5,659	\$1,568	\$6,576	-0.01	-0.01
	Part A LTCH, IRF	\$100	\$1,785	\$129	\$2,136	\$119	\$1,945	\$149	\$2,302	-0.01	-0.01
Medicare	Other Part A	\$120	\$626	\$147	\$556	\$133	\$657	\$165	\$587	-0.02	-0.03
Payments	Total Part B	\$4,136	\$2,213	\$4,425	\$2,415	\$4,135	\$2,231	\$4,406	\$2,423	0.000	0.008
(PPPM)	Part B Dialysis	\$2,899	\$782	\$3,022	\$702	\$2,882	\$786	\$3,003	\$707	0.02	0.03
	In Center Dialysis	\$2,662	\$771	\$2,715	\$646	\$2,649	\$778	\$2,707	\$654	0.02	0.01
	Home Dialysis	\$2,796	\$843	\$2,997	\$887	\$2,770	\$831	\$2,950	\$870	0.03	0.05
	Home Hemodialysis	\$3,393	\$1,231	\$3,784	\$1,196	\$3,408	\$1,256	\$3,798	\$1,234	-0.01	-0.01
	Peritoneal Dialysis	\$2,649	\$675	\$2,769	\$649	\$2,635	\$670	\$2,741	\$636	0.02	0.04
	Other Part B	\$1,237	\$2,157	\$1,403	\$2,404	\$1,253	\$2,178	\$1,403	\$2,409	-0.01	0.000
	Total Part D	\$867	\$1,531	\$812	\$1,666	\$901	\$1,549	\$848	\$1,693	-0.02	-0.02



			ET	·c		Comparison				SMD (ETC vs.	SMD (ETC vs.
Outcomes		Pre-E		Post-	-ETC	Pre-	ETC	Post	-ETC	Comparison)	Comparison)
Outcomes		N = 3,1	N = 3,116,487		N = 2,172,797		N = 6,165,610		67,259	Pre-ETC	Post-ETC
		Mean	SD	Mean	SD	Mean	SD	Mean	SD	period	period
	Peritonitis ⁴	4.4%	20.4%	4.4%	20.4%	4.2%	20.0%	4.3%	20.3%	0.01	0.003
	Hospitalization with ESRD complications	0.84%	9.5%	0.82%	9.4%	0.80%	9.3%	0.80%	9.3%	0.005	0.002
Quality	Hospitalization with VA complications	0.77%	9.1%	0.84%	9.5%	0.83%	9.5%	0.89%	9.8%	-0.01	-0.005
	Vascular Infection ⁵	1.0%	9.9%	0.89%	9.4%	1.0%	10.1%	0.92%	9.6%	-0.005	-0.003
	Kt/V ⁶	96.0%	19.5%	95.9%	19.9%	95.9%	19.8%	95.5%	20.6%	0.006	0.02

Note: ED = Emergency Department; ESRD = End Stage Renal Disease; ETC = ESRD Treatment Choices; SD = Standard Deviation; SMD = Standardized Mean Difference; VA = Vascular Access.



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.

⁶ Percent of patients who have a Kt/V \geq 1.2 (for HD patients) or Kt/V \geq 1.7 (for PD patients), obtained through EQRS.

Exhibit B-22. Estimated Impacts of the ETC Model for CY 2021 - 2023

0		Calendar	ETC		Compa	rison		DiD Model Esti	mates	% Relative
Outcomes		Year	Pre-ETC Mean	CY Mean	Pre-ETC Mean	CY Mean	DiD	Lower 90% CI	Upper 90% CI	Change
		CY 2021-23	11.8%	15.0%	12.8%	16.2%	-0.07	-0.49	0.35	-0.57%
	Harris Diabreia	CY 2021	11.8%	14.6%	12.8%	15.8%	-0.11	-0.48	0.27	-0.89%
	Home Dialysis	CY 2022	11.8%	15.1%	12.8%	16.3%	-0.09	-0.55	0.38	-0.75%
		CY 2023	11.8%	15.5%	12.8%	16.5%	0.01	-0.54	0.56	0.07%
		CY 2021-23	9.8%	11.9%	10.8%	13.1%	-0.13	-0.50	0.24	-1.4%
	Doniton and Dialysis	CY 2021	9.8%	11.8%	10.8%	12.9%	-0.14	-0.48	0.19	-1.5%
	Peritoneal Dialysis	CY 2022	9.8%	12.0%	10.8%	13.2%	-0.16	-0.57	0.25	-1.6%
		CY 2023	9.8%	12.0%	10.8%	13.1%	-0.09	-0.56	0.38	-0.92%
		CY 2021-23	2.0%	3.1%	2.0%	3.1%	0.07	-0.16	0.29	3.3%
	Hama HD	CY 2021	2.0%	2.9%	2.0%	2.9%	0.04	-0.16	0.23	1.9%
	Home HD	CY 2022	2.0%	3.1%	2.0%	3.1%	0.07	-0.17	0.31	3.6%
		CY 2023	2.0%	3.5%	2.0%	3.4%	0.10	-0.19	0.39	4.9%
		CY 2021-23	88.1%	84.8%	87.0%	83.7%	0.05	-0.37	0.47	0.06%
	In-Center HD	CY 2021	88.1%	85.2%	87.0%	84.1%	0.10	-0.28	0.48	0.11%
Dialysis		CY 2022	88.1%	84.7%	87.0%	83.6%	0.07	-0.40	0.54	0.08%
Modality		CY 2023	88.1%	84.4%	87.0%	83.3%	-0.04	-0.59	0.51	-0.04%
Measures ¹	In-Center	CY 2021-23	87.8%	84.6%	86.6%	83.5%	-0.01	-0.46	0.44	-0.02%
(%)		CY 2021	87.8%	85.1%	86.6%	83.8%	0.09	-0.32	0.50	0.10%
	Hemodialysis	CY 2022	87.8%	84.6%	86.6%	83.4%	0.0005	-0.49	0.49	0.001%
		CY 2023	87.8%	84.2%	86.6%	83.2%	-0.17	-0.75	0.40	-0.20%
		CY 2021-23	0.04%	0.02%	0.10%	0.04%	0.04	-0.02	0.10	113.2%
	In-Center Self-	CY 2021	0.04%	0.006%	0.10%	0.05%	0.02	-0.04	0.08	51.5%
	Dialysis	CY 2022	0.04%	0.000%	0.10%	0.02%	0.04	-0.02	0.09	91.2%
		CY 2023	0.04%	0.07%	0.10%	0.04%	0.09*	0.001	0.17	220.9%
		CY 2021-23	0.28%	0.15%	0.33%	0.17%	0.02	-0.05	0.09	7.2%
	Nocturnal HD	CY 2021	0.28%	0.15%	0.33%	0.21%	-0.01	-0.08	0.06	-4.7%
	Nocturnal HD	CY 2022	0.28%	0.15%	0.33%	0.16%	0.04	-0.04	0.12	12.8%
		CY 2023	0.28%	0.14%	0.33%	0.14%	0.05	-0.03	0.13	16.7%
		CY 2021-23	0.72%	0.83%	0.75%	0.80%	0.07***	0.03	0.11	10.0%
	Home Dialysis	CY 2021	0.72%	0.84%	0.75%	0.80%	0.08***	0.03	0.12	10.5%
	Training	CY 2022	0.72%	0.81%	0.75%	0.79%	0.06*	0.003	0.11	8.0%
		CY 2023	0.72%	0.85%	0.75%	0.81%	0.08**	0.03	0.14	11.4%



0		Calendar	ETC	2	Compa	rison		DiD Model Esti	mates	% Relative
Outcomes		Year	Pre-ETC Mean	CY Mean	Pre-ETC Mean	CY Mean	DiD	Lower 90% CI	Upper 90% CI	Change
		CY 2021-23	3.0%	2.7%	3.0%	2.6%	0.07	-0.03	0.17	2.3%
	Home dialysis	CY 2021	3.0%	2.9%	3.0%	2.7%	0.13*	0.01	0.25	4.3%
	gains	CY 2022	3.0%	2.7%	3.0%	2.6%	0.05	-0.09	0.19	1.6%
		CY 2023	3.0%	2.6%	3.0%	2.5%	0.02	-0.12	0.16	0.59%
		CY 2021-23	1.3%	1.2%	1.3%	1.1%	0.05	-0.02	0.12	4.2%
	Gain from New	CY 2021	1.3%	1.2%	1.3%	1.2%	0.005	-0.07	0.08	0.38%
	ESRD patient	CY 2022	1.3%	1.2%	1.3%	1.1%	0.07	-0.02	0.15	5.2%
		CY 2023	1.3%	1.2%	1.3%	1.1%	0.09	0.00	0.19	7.5%
	Gain from return	CY 2021-23	0.05%	0.06%	0.06%	0.06%	0.01**	0.004	0.02	28.4%
	to dialysis after	CY 2021	0.05%	0.06%	0.06%	0.05%	0.02**	0.01	0.04	44.2%
	failed	CY 2022	0.05%	0.06%	0.06%	0.06%	0.01	-0.01	0.03	18.5%
	transplantation	CY 2023	0.05%	0.06%	0.06%	0.07%	0.01	-0.01	0.03	20.0%
		CY 2021-23	1.7%	1.5%	1.7%	1.4%	0.003	-0.07	0.08	0.16%
	Gain Switched	CY 2021	1.7%	1.7%	1.7%	1.5%	0.10*	0.01	0.20	6.0%
	from In-center Hemodialysis	CY 2022	1.7%	1.5%	1.7%	1.4%	-0.03	-0.13	0.08	-1.6%
Modality	Tremoularysis	CY 2023	1.7%	1.3%	1.7%	1.3%	-0.09	-0.19	0.02	-5.0%
Transition		CY 2021-23	2.9%	3.0%	2.9%	2.9%	0.08	-0.02	0.18	2.8%
	Home dialysis	CY 2021	2.9%	3.0%	2.9%	2.9%	0.08	-0.04	0.19	2.6%
	losses	CY 2022	2.9%	3.0%	2.9%	2.9%	0.09	-0.06	0.23	2.9%
		CY 2023	2.9%	3.0%	2.9%	2.9%	0.08	-0.06	0.23	2.9%
		CY 2021-23	1.7%	1.6%	1.7%	1.6%	-0.002	-0.07	0.07	-0.12%
	Loss Switched to	CY 2021	1.7%	1.6%	1.7%	1.6%	0.01	-0.09	0.10	0.33%
	In-center Hemodialysis	CY 2022	1.7%	1.6%	1.7%	1.6%	-0.01	-0.11	0.10	-0.46%
	Tremoularysis	CY 2023	1.7%	1.6%	1.7%	1.6%	-0.01	-0.10	0.09	-0.34%
		CY 2021-23	0.57%	0.77%	0.60%	0.72%	0.08**	0.03	0.14	14.6%
	Loss to	CY 2021	0.57%	0.70%	0.60%	0.68%	0.05	-0.02	0.12	8.8%
	transplantation	CY 2022	0.57%	0.79%	0.60%	0.74%	0.08*	0.01	0.15	14.4%
		CY 2023	0.57%	0.86%	0.60%	0.76%	0.13***	0.05	0.21	23.2%
		CY 2021-23	0.74%	0.68%	0.74%	0.69%	-0.01	-0.05	0.04	-0.77%
	Loss to death or	CY 2021	0.74%	0.76%	0.74%	0.78%	-0.01	-0.06	0.05	-1.1%
	withdrawal	CY 2022	0.74%	0.67%	0.74%	0.66%	0.02	-0.04	0.08	2.9%
		CY 2023	0.74%	0.58%	0.74%	0.62%	-0.04	-0.11	0.03	-5.1%



0		Calendar	ETC		Compa	rison		DiD Model Esti	mates	% Relative
Outcomes		Year	Pre-ETC Mean	CY Mean	Pre-ETC Mean	CY Mean	DiD	Lower 90% CI	Upper 90% CI	Change
		CY 2021-23	19.4%	18.8%	21.1%	19.7%	0.81	-0.14	1.8	4.2%
	0 112	CY 2021	19.4%	18.8%	21.1%	19.8%	0.78	-0.04	1.6	4.0%
	Overall ²	CY 2022	19.4%	19.0%	21.1%	19.9%	0.88	-0.13	1.9	4.5%
		CY 2023	19.4%	18.5%	21.1%	19.5%	0.77	-0.45	2.0	4.0%
		CY 2021-23	12.1%	10.9%	13.4%	11.7%	0.44	-0.43	1.3	3.6%
Waitlisting	Astiva Ctatus?	CY 2021	12.1%	11.3%	13.4%	12.2%	0.37	-0.32	1.1	3.1%
(%)	Active Status ²	CY 2022	12.1%	10.9%	13.4%	11.6%	0.54	-0.43	1.5	4.5%
		CY 2023	12.1%	10.4%	13.4%	11.3%	0.42	-0.73	1.6	3.5%
	Inactive Status ²	CY 2021-23	7.2%	7.8%	7.7%	8.0%	0.37	-0.28	1.0	5.1%
		CY 2021	7.2%	7.5%	7.7%	7.6%	0.40	-0.14	0.95	5.6%
		CY 2022	7.2%	8.0%	7.7%	8.2%	0.34	-0.42	1.1	4.7%
		CY 2023	7.2%	8.1%	7.7%	8.2%	0.35	-0.44	1.1	4.8%
		CY 2021-23	3.9	5.2	4.0	5.0	0.35**	0.06	0.64	9.0%
	Total ²³	CY 2021	3.9	4.9	4.0	4.6	0.38*	0.04	0.72	9.8%
	Total	CY 2022	3.9	5.3	4.0	5.1	0.28	-0.06	0.61	7.2%
		CY 2023	3.9	5.6	4.0	5.3	0.39*	0.03	0.76	10.2%
		CY 2021-23	3.3	4.6	3.3	4.3	0.32*	0.03	0.61	9.8%
	Deceased	CY 2021	3.3	4.3	3.3	4.0	0.38*	0.05	0.71	11.6%
	Donor ^{2, 3}	CY 2022	3.3	4.7	3.3	4.5	0.25	-0.09	0.58	7.6%
Transplant		CY 2023	3.3	4.9	3.3	4.6	0.33	-0.05	0.70	10.0%
(per 1,000 Patient		CY 2021-23	0.60	0.60	0.66	0.63	0.03	-0.03	0.09	4.7%
Months)	Living Donor ^{2, 3}	CY 2021	0.60	0.55	0.66	0.61	-0.0002	-0.07	0.07	-0.04%
Wionitins,	LIVING DONOI	CY 2022	0.60	0.59	0.66	0.62	0.03	-0.05	0.11	4.8%
		CY 2023	0.60	0.68	0.66	0.67	0.07	-0.03	0.17	11.2%
	Living Donor	CY 2021-23	0.60	0.60	0.66	0.63	0.03	-0.03	0.09	4.5%
	(among Both	CY 2021	0.60	0.55	0.66	0.61	0.001	-0.07	0.07	0.09%
	Dialysis Patients and Pre-emptive	CY 2022	0.60	0.59	0.66	0.62	0.03	-0.06	0.11	4.5%
T	Transplant Recipients) 2,4	CY 2023	0.60	0.68	0.66	0.67	0.07	-0.03	0.17	10.8%



0 1		Calendar	ETC		Compa	rison		DiD Model Esti	mates	% Relative
Outcomes		Year	Pre-ETC Mean	CY Mean	Pre-ETC Mean	CY Mean	DiD	Lower 90% CI	Upper 90% CI	Change
		CY 2021-23	10.1%	9.1%	10.1%	9.1%	0.01	-0.14	0.16	0.05%
	Acute Care	CY 2021	10.1%	9.0%	10.1%	9.0%	0.09	-0.07	0.25	0.92%
	Hospitalization (%)	CY 2022	10.1%	9.0%	10.1%	9.0%	0.02	-0.16	0.20	0.22%
	(70)	CY 2023	10.1%	9.4%	10.1%	9.5%	-0.13	-0.30	0.04	-1.3%
		CY 2021-23	30.1%	28.9%	30.1%	29.1%	-0.18	-0.67	0.31	-0.59%
	December (0/)	CY 2021	30.1%	28.9%	30.1%	29.4%	-0.49	-1.0	0.01	-1.6%
	Readmission (%)	CY 2022	30.1%	29.0%	30.1%	28.9%	0.06	-0.55	0.67	0.20%
		CY 2023	30.1%	28.8%	30.1%	28.8%	-0.03	-0.75	0.69	-0.10%
Utilization		CY 2021-23	11.4%	9.6%	11.2%	9.6%	-0.13	-0.29	0.03	-1.2%
	Outpatient ED	CY 2021	11.4%	9.4%	11.2%	9.4%	-0.13	-0.30	0.05	-1.1%
	Use (%)	CY 2022	11.4%	9.5%	11.2%	9.6%	-0.16	-0.34	0.02	-1.4%
		CY 2023	11.4%	9.9%	11.2%	9.9%	-0.11	-0.30	0.09	-0.94%
	_	CY 2021-23	0.24	0.20	0.24	0.20	-0.002	-0.01	0.002	-0.77%
	Emergency	CY 2021	0.24	0.20	0.24	0.20	0.0001	-0.004	0.004	0.02%
	Department Visits (counts)	CY 2022	0.24	0.20	0.24	0.20	-0.002	-0.01	0.002	-0.89%
	(counts)	CY 2023	0.24	0.21	0.24	0.21	-0.004	-0.01	0.000004	-1.7%
	Total Parts A & B	CY 2021-23	\$5,721	\$6,078	\$5,796	\$6,137	\$16	-\$24	\$55	0.27%
		CY 2021	\$5,721	\$5,944	\$5,796	\$6,030	-\$11	-\$49	\$28	-0.19%
		CY 2022	\$5,721	\$6,045	\$5,796	\$6,080	\$40	-\$8	\$87	0.69%
		CY 2023	\$5,721	\$6,293	\$5,796	\$6,345	\$24	-\$27	\$75	0.42%
		CY 2021-23	\$1,656	\$1,726	\$1,713	\$1,781	\$3	-\$43	\$49	0.17%
	Total Part A ⁵	CY 2021	\$1,656	\$1,678	\$1,713	\$1,740	-\$5	-\$49	\$39	-0.28%
	TOTAL PAIL A	CY 2022	\$1,656	\$1,729	\$1,713	\$1,767	\$19	-\$31	\$68	1.1%
Medicare Payments		CY 2023	\$1,655	\$1,788	\$1,713	\$1,852	-\$5	-\$61	\$51	-0.32%
(PPPM)		CY 2021-23	\$1,420	\$1,474	\$1,446	\$1,490	\$10	-\$5	\$24	0.68%
(,	Part A Hospital ⁵	CY 2021	\$1,420	\$1,444	\$1,446	\$1,462	\$8	-\$11	\$26	0.53%
	rait A riospitai	CY 2022	\$1,420	\$1,464	\$1,446	\$1,472	\$18	-\$2	\$37	1.3%
		CY 2023	\$1,420	\$1,526	\$1,446	\$1,550	\$3	-\$17	\$24	0.22%
		CY 2021-23	\$103	\$123	\$125	\$141	\$3	-\$1	\$7	3.2%
	Part A LTCH, IRF⁵	CY 2021	\$104	\$104	\$125	\$132	-\$7**	-\$11	-\$2	-6.3%
	rail A LICH, IKF	CY 2022	\$103	\$133	\$125	\$142	\$13***	\$7	\$18	12.2%
		CY 2023	\$102	\$135	\$125	\$152	\$6	-\$0.4	\$12	5.8%



0.1		Calendar	ETC		Compa	rison		DiD Model Estir	mates	% Relative
Outcomes		Year	Pre-ETC Mean	CY Mean	Pre-ETC Mean	CY Mean	DiD	Lower 90% CI	Upper 90% CI	Change
		CY 2021-23	\$129	\$147	\$136	\$157	-\$3*	-\$7	-\$0.02	-2.6%
	0.1 5 . 45	CY 2021	\$129	\$147	\$136	\$157	-\$2	-\$5	\$2	-1.4%
	Other Part A ⁵	CY 2022	\$129	\$148	\$136	\$158	-\$2	-\$6	\$1	-1.7%
		CY 2023	\$129	\$144	\$136	\$158	-\$7***	-\$10	-\$3	-5.1%
		CY 2021-23	\$4,124	\$4,388	\$4,160	\$4,407	\$18	-\$3	\$39	0.43%
	T-+- D+ D	CY 2021	\$4,124	\$4,299	\$4,160	\$4,341	-\$6	-\$29	\$17	-0.16%
	Total Part B	CY 2022	\$4,124	\$4,355	\$4,160	\$4,365	\$27*	\$2	\$52	0.65%
		CY 2023	\$4,124	\$4,544	\$4,160	\$4,541	\$40**	\$13	\$66	0.96%
		CY 2021-23	\$2,878	\$3,016	\$2,882	\$3,018	\$2	-\$9	\$13	0.06%
		CY 2021	\$2,878	\$2,966	\$2,882	\$2,969	\$0.6	-\$11	\$12	0.02%
	Part B Dialysis	CY 2022	\$2,878	\$3,002	\$2,882	\$3,006	\$0.2	-\$12	\$12	0.01%
		CY 2023	\$2,878	\$3,100	\$2,882	\$3,098	\$5	-\$7	\$18	0.19%
	In Center Dialysis	CY 2021-23	\$2,645	\$2,712	\$2,647	\$2,718	-\$4	-\$16	\$8	-0.16%
		CY 2021	\$2,645	\$2,661	\$2,647	\$2,669	-\$5	-\$18	\$8	-0.20%
		CY 2022	\$2,645	\$2,695	\$2,647	\$2,704	-\$7	-\$20	\$6	-0.26%
PPPM		CY 2023	\$2,645	\$2,800	\$2,647	\$2,802	-\$0.2	-\$14	\$13	-0.01%
(cont.)		CY 2021-23	\$2,768	\$2,992	\$2,764	\$2,974	\$15	-\$3	\$34	0.55%
		CY 2021	\$2,768	\$2,942	\$2,764	\$2,917	\$22.0*	\$3	\$41	0.80%
	Home Dialysis	CY 2022	\$2,768	\$2,986	\$2,764	\$2,965	\$17	-\$2	\$37	0.63%
		CY 2023	\$2,768	\$3,059	\$2,764	\$3,051	\$5	-\$18	\$27	0.17%
		CY 2021-23	\$3,377	\$3,760	\$3,416	\$3,808	-\$9	-\$82	\$64	-0.27%
	Home	CY 2021	\$3,377	\$3,749	\$3,416	\$3,771	\$17	-\$59	\$93	0.50%
	Hemodialysis	CY 2022	\$3,377	\$3,761	\$3,416	\$3,795	\$5	-\$71	\$80	0.14%
		CY 2023	\$3,377	\$3,771	\$3,416	\$3,864	-\$54	-\$134	\$26	-1.6%
		CY 2021-23	\$2,626	\$2,774	\$2,625	\$2,760	\$13	-\$1	\$28	0.51%
	Devitement Dielusie	CY 2021	\$2,626	\$2,727	\$2,625	\$2,709	\$17**	\$4	\$29	0.64%
	Peritoneal Dialysis	CY 2022	\$2,626	\$2,768	\$2,625	\$2,754	\$13	-\$3	\$29	0.49%
		CY 2023	\$2,626	\$2,838	\$2,625	\$2,827	\$10	-\$8	\$28	0.37%
		CY 2021-23	\$1,246	\$1,372	\$1,278	\$1,388	\$16	-\$2	\$33	1.3%
	Other Death D	CY 2021	\$1,246	\$1,333	\$1,278	\$1,373	-\$7	-\$27	\$13	-0.56%
	Other Part B	CY 2022	\$1,246	\$1,353	\$1,278	\$1,359	\$27**	\$6	\$47	2.1%
		CY 2023	\$1,246	\$1,444	\$1,278	\$1,443	\$34**	\$11	\$58	2.8%



Outcomes		Calendar	ETC	:	Compa	Comparison		DiD Model Estimates		
		Year	Pre-ETC Mean	CY Mean	Pre-ETC Mean	CY Mean	DiD	Lower 90% CI	Upper 90% CI	Change
		CY 2021-23	\$871	\$823	\$894	\$849	-\$3	-\$24	\$18	-0.38%
PPPM	T	CY 2021	\$871	\$781	\$894	\$797	\$7	-\$11	\$25	0.81%
(cont.)	Total Part D	CY 2022	\$871	\$824	\$894	\$857	-\$9	-\$32	\$14	-1.1%
		CY 2023	\$871	\$877	\$894	\$911	-\$10	-\$39	\$18	-1.2%
		CY 2021-23	4.3%	4.3%	4.2%	4.3%	-0.10	-0.35	0.15	-2.4%
	Di+ i+i -6	CY 2021	4.3%	4.3%	4.2%	4.4%	-0.15	-0.46	0.16	-3.5%
	Peritonitis ⁶	CY 2022	4.3%	4.4%	4.2%	4.4%	-0.02	-0.34	0.30	-0.42%
		CY 2023	4.3%	4.2%	4.2%	4.2%	-0.13	-0.43	0.18	-3.0%
		CY 2021-23	0.85%	0.82%	0.80%	0.79%	-0.02	-0.06	0.02	-2.6%
	Hospitalization	CY 2021	0.85%	0.79%	0.80%	0.75%	-0.01	-0.05	0.03	-1.2%
	with ESRD complications	CY 2022	0.85%	0.81%	0.80%	0.78%	-0.02	-0.07	0.02	-2.6%
		CY 2023	0.85%	0.87%	0.80%	0.86%	-0.04	-0.09	0.01	-4.5%
		CY 2021-23	0.79%	0.84%	0.82%	0.87%	-0.002	-0.03	0.03	-0.22%
O 111 (0/)	Hospitalization	CY 2021	0.79%	0.82%	0.82%	0.84%	0.01	-0.02	0.05	1.7%
Quality (%)	with VA complications	CY 2022	0.79%	0.83%	0.82%	0.87%	-0.01	-0.05	0.03	-1.3%
	complications	CY 2023	0.79%	0.88%	0.82%	0.93%	-0.01	-0.05	0.03	-1.6%
		CY 2021-23	0.97%	0.88%	1.03%	0.91%	0.03	-0.03	0.08	2.8%
	Vascular	CY 2021	0.97%	0.86%	1.03%	0.91%	0.01	-0.05	0.07	0.73%
	Infection ⁷	CY 2022	0.97%	0.90%	1.03%	0.91%	0.05	-0.02	0.11	4.7%
		CY 2023	0.97%	0.90%	1.03%	0.92%	0.03	-0.03	0.10	3.4%
		CY 2021-23	96.1%	96.1%	96.0%	95.8%	0.17	-0.13	0.47	0.18%
	1/4 // /	CY 2021	96.1%	96.2%	96.0%	96.0%	0.18	-0.29	0.65	0.19%
	Kt/V	CY 2022	96.1%	95.7%	96.0%	95.4%	0.25	-0.07	0.57	0.26%
		CY 2023	96.1%	96.2%	96.0%	96.0%	0.07	-0.23	0.38	0.08%

Note: CI = Confidence Interval; CY = Calendar Year; DiD = Difference in Differences; ED = Emergency Department; ESRD = End Stage Renal Disease; ETC = ESRD Treatment Choices; HD = Hemodialysis; IRF = Inpatient Rehabilitation Facility; LTCH = Long-term Care Hospital; VA = Vascular Access. 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% CIs. Significance of the DiD impact estimates is indicated for each outcome where * implies significance at the 10% level, ** at the 5% level, and *** at the 1% level assuming a two-tailed test. Cumulative (CY 2021-23) 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).

⁴ Among dialysis patients and pre-emptive transplant recipients.



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.

- ⁵ Estimates obtained from a two-part model. Note that pre-ETC means in the ETC group vary across the years due to the non-linearity adjustment of the two-part models and inclusion of the unadjusted post-ETC mean for each specific year.
- ⁶ Among PD patients.
- ⁷ Among HD patients.



B.6. Net Impact on Medicare Payments

The net impact of the ETC Model on Medicare fee-for-service (FFS) payments depends in part on the net effect of the performance-based payment adjustments that are made to ETC participants. The ETC Model incorporates two distinct types of payment adjustments to ETC participants, the HDPA and the PPA (see **Exhibit B-23**).

Exhibit B-23. Overview of ETC Model Payment Adjustments

Home Dialysis Payment Adjustment (HDPA)	 Positive adjustment applied to Medicare payments to ETC participants for FFS beneficiaries with ESRD undergoing home dialysis Represented a 3% adjustment during CY 2021, a 2% adjustment during CY 2022, and a 1% adjustment during CY 2023
Performance Payment Adjustment (PPA)	 Positive or negative adjustment applied to Medicare payments to participating ESRD facilities and Managing Clinicians for FFS beneficiaries with ESRD Determined by rates of home dialysis, waitlisting, and living donor transplants among attributed beneficiaries starting on January 1, 2021, and used to adjust payments starting on July 1, 2022 Initially ranged from up to a 5% reduction to up to a 4% increase, with the maximum payment adjustments becoming larger over time
New Payment Adjustments	 Includes changes to the PPA that were effective on January 1, 2022 Introduced a modified payment adjustment that enables ETC participants to earn more favorable PPAs when demonstrating significant improvements in home dialysis and 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) Assessed the performance of 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

Note: CY= Calendar Year.

The HDPA was in effect during the entire 2021-2023 period and represents a positive Medicare payment adjustment to participating ESRD facilities and Managing Clinicians for services provided to home dialysis patients. The PPA was used to adjust Medicare payments to ETC participants starting in July 2022 and can be either a positive or negative payment adjustment depending on their performance on a combination of measures of home dialysis, transplant waitlisting, and living donor transplant rates. The range of potential PPAs increases over time for both ESRD facilities and Managing Clinicians (see **Exhibit B-24**).

Exhibit B-24. Measurement Years (MYs) and Range of Potential PPAs, by PPA Period

PPA MY		Time Period for	ESRD F	acilities	Managing Clinicians	
Period	IVIT	Payment Adjustments	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	-5.0%	+4.0%	-5.0%	+4.0%
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	-0.0%	+5.0%	-0.0%	+5.0%
5	1/1/2023 – 12/31/2023	7/1/2024 – 12/31/2024	7.00/	+6.0%	7.00/	+6.0%
6	7/1/2023 – 6/30/2024	1/1/2025 - 6/30/2025	-7.0%	+6.0%	-7.0%	+6.0%
7	1/1/2024 – 12/31/2024	7/1/2025 – 12/31/2025	-9.0%	+7.0%	-8.0%	+7.0%

Note: ESRD = end-stage renal disease; MY = measurement year; PPA = Performance Payment Adjustment. The Model is proposed to end December 31, 2025, which eliminates PPA periods 8, 9, 10.

Source: CMS (February 2023). End-Stage Renal Disease Treatment Choices (ETC) Model Performance Payment Adjustment Report User Guide (Measurement Years 5-6) (cms.gov)



Additionally, the ETC Model was amended in the second year (CY 2022) to provide additional support to health care providers who treat people dually eligible for Medicare and Medicaid, as well as Medicare beneficiaries who are eligible to receive assistance with prescription drug costs through the Part D program (also known as the Low-Income Subsidy). This included 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 potential bonus points towards the Modality Performance Score (MPS) of ETC participants that reward them for higher levels of improvement among their attributed dually eligible patients and Part D LIS recipients (see **Exhibit B-23**). These new payment adjustments affected the ETC payment adjustments starting in July 2023.

The total HDPA amounts declined each year from 2021 to 2023, for both ESRD facilities and Managing Clinicians (see **Exhibit B-25**).

HDPA period	Provider Type	N (percent) of ETC beneficiary months with HDPA	Total Medicare payment adjustments
Jan-Dec 2021	ESRD facility	137,265 (13.7%)	\$14,804,532
Jan-Dec 2021	Managing Clinician	102,104 (10.2%)	\$1,056,721
Jan-Dec 2022	ESRD facility	127,982 (14.8%)	\$9,418,908
Jan-Dec 2022	Managing Clinician	94,443 (10.9%)	\$655,535
Ion Doc 2022	ESRD facility	119,902 (15.7%)	\$4,535,835
Jan-Dec 2023	Managing Clinician	87,551 (11.4%)	\$305,312

Exhibit B-25. Analysis of HDPA Amounts for ETC Participants, CYs 2021-2023

The positive PPA adjustments were more common than the negative PPA adjustments for both ESRD facilities and Managing Clinicians (MCs), in both 2022 and 2023. Similarly, the total positive PPA adjustment amounts exceeded the total negative PPA adjustment amounts (See **Exhibit B-26**).

Exhibit B-26. Analysis of PPA Amounts for ETC Participants, CYs 2022-2023

PPA period Provider Type and PPA Direction		N (percent) of ETC beneficiary months with PPA	Total Medicare payment adjustments
	ESRD facility, positive PPA	172,299 (40.5%)	\$12,602,439
July Doc 2022	ESRD facility, negative PPA	56,188 (13.2%)	(\$5,244,722)
July-Dec 2022	MC, positive PPA	166,468 (39.1%)	\$1,293,282
	MC, negative PPA	32,532 (7.6%)	(\$358,558)
	ESRD facility, positive PPA	171,065 (43.6%)	\$12,659,607
Jan-Jun 2023	ESRD facility, negative PPA	47,032 (12.0%)	(\$4,371,923)
Jan-Jun 2025	MC, positive PPA	144,611 (36.9%)	\$1,125,574
	MC, negative PPA	36,329 (9.3%)	(\$398,271)
	ESRD facility, positive PPA	176,129 (47.2%)	\$21,860,559
July-Dec 2023	ESRD facility, negative PPA	73,730 (19.8%)	(\$8,435,236)
July-Dec 2025	MC, positive PPA	162,297 (43.5%)	\$2,034,637
	MC, negative PPA	29,188 (7.8%)	(\$391,951)



To calculate estimates of the net impact to Medicare of the ETC Model for CY 2021-2023, we combined the effects which included payments made to the model participants during CY 2021-2023 as well as our estimation of the change in total Medicare payments for the same period. The net impact estimate consists of two components: (a) estimated changes in payments for Total Medicare Parts A & B services payments; and (b) costs of the ETC Model based on the net ETC payment adjustment amounts, as shown below:

Net Impact = Estimated Change in Total Medicare Payments for Parts A and B Payments + Total Costs of the ETC Model (net ETC Payment Adjustments paid by CMS)

The DiD estimate of \$16 PPPM reported in **Exhibit B -27** represents the PPPM change in Total Medicare Parts A & B payments for CY 2021-2023. Because we used standardized payments for our DiD estimation, to reduce bias from regional variation in prices, we applied a ratio of nonstandardized-to-standardized payments to calculate the nonstandardized impact estimate which can be combined with the ETC payment adjustment amounts. To calculate the total annual estimated change in total Medicare payments, we multiplied the nonstandardized impact estimate by the number of eligible and attributable patient months included in the analytical sample. This calculation yielded an estimated change (gross impact) of \$35.6 million (90% CI: –\$53.4 million, \$122.4 million). Accounting for both the HDPA and PPA, the net ETC payments adjustments to model participants amounted to \$63.1M for CY 2021-2023. Combining these two components together, this resulted in an estimated net increase in total Medicare payments of \$98.8 million during 2021-2023 with a 90% confidence interval ranging from \$9.7 million to \$185.6 million.

Exhibit B-27. Calculation of Net Impact of ETC Model on Total Medicare Payments

	Calculation Process	90% Lower Confidence Limit	DID estimate	90% Upper Confidence Limit	
	Change in Medicare Payments PPPM Due to ETC Model	-\$24	\$16	\$55	
Change from Total Parts A & B Payments for	Times: 1 + Ratio Adjustment for Nonstandardized Medicare Payments	1.1	1.1	1.1	
CY 2021-2023	Times: Patient-months in CY 2021-2023 (N)	2,023,901	2,023,901	2,023,901	
	Equals: Total Change in Medicare Payments	-\$53.4M	\$35.6M	\$122.4M	
Net ETC payments	Add: The Total Costs of the ETC Model (HDPA + PPA)	\$63.1M	\$63.1M	\$63.1M	
Net Impact of ETC Model	Sum equals: Change in Total A & B payments and Total Cost of the Model (Net ETC Payment Adjustments)	\$9.7M	\$98.8M	\$185.6 M	

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



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).8

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.

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% 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 2023 (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.⁹

Assessment of TDAPA/TPNIES claims for ETC and the comparison group. Exhibit B-28 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 2023) 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 2023. We found similar usage of each item in both groups. We used standardized mean difference (SMD) to assess balance (see Appendix B, Section B.4.1.) and using a threshold

⁹ AX modifier is not specific for TDAPA and TPNIES items.



8

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

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-28. TDAPA and TPNIES Claims for ETC and Comparison Groups (shown as % of overall beneficiary months)

Years	Program	Item	ETC			Comparison			SMD
Tears		item	N	Mean	SD	N	Mean	SD	סואוכ
		Cinacalcet	3,116,487	15.25%	35.95%	6,165,610	14.23%	34.93%	0.029
Pre-ETC	TDAPA	Etelcalcitide	3,116,487	3.87%	19.30%	6,165,610	4.02%	19.64%	-0.007
(2017- 2019)		Korsuva	3,116,487	0	0	6,165,610	0	0	-
,	TPNIES	Tablo System	3,116,487	0	0	6,165,610	0	0	-
		Cinacalcet	2,172,797	0.01%	0.79%	4,267,259	0.01%	1.11%	-0.006
ETC	TDAPA	Etelcalcitide	2,172,797	0.02%	1.50%	4,267,259	0.02%	1.33%	0.003
(2021- 2023)		Korsuva	2,172,797	0.26%	5.10%	4,267,259	0.25%	4.97%	0.003
	TPNIES	Tablo System	2,172,797	0.02%	1.35%	4,267,259	0.04%	1.96%	-0.012

Note: ETC = ESRD Treatment Choices; SD = Standard Deviation; SMD = Standardized Mean Difference; TDAPA = Transitional Drug Add-on Payment Adjustment; TPNIES = Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies.

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.

B.8. Analyses of Patient Subpopulations of Interest

The PPA scoring methodology was modified in CY 2022 to provide additional support to ETC participants treating patients who are dually eligible for Medicare and Medicaid, as well as Medicare beneficiaries who are eligible to receive assistance with prescription drug costs through the Part D program (also known as the Low-Income Subsidy). ¹⁰ 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% or 50% or more. ¹⁰

Also effective January 1, 2022, CMS allows ETC participants to receive a higher improvement score towards their MPS 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. Prior to this modification, ETC participants could earn maximum home dialysis and transplant improvement scores of 1.5 points. With this modified payment adjustment in place, ETC participants have the opportunity to earn a bonus of 0.5 points to be added to their improvement

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.



score, thereby increasing the maximum improvement score to 2.0. With the potential for ETC participants to earn these bonus points for improvements among their attributed dually eligible patients and Part D LIS recipients, the MPS was calculated as follows starting in CY 2022:

 $MPS = 2 * (Higher of the home dialysis achievement score^{11} or (home dialysis improvement score + bonus points)) + (Higher of the transplant achievement score^8 or (transplant improvement score + bonus points)).$

For CY 2021-CY 2023, the MPS for ETC participants ranged from 0 to 6 points.

To assess whether the ETC Model had differential impacts among patient subgroups, we examined whether the impacts of the Model during CY 2021-CY 2023 differed for patient subpopulations of interest. This included dually eligible beneficiaries, beneficiaries enrolled in Part D plans who are recipients of the Part D LIS, and beneficiaries residing in rural/urban/metro counties based on beneficiary mailing address. 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. We hypothesized that younger patients might be more inclined to choose home dialysis due to its advantages in flexibility, independence, and employment opportunities.

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 beneficiary age, and whether the beneficiary received treatment at an ESRD facility with an established home dialysis program.

Achievement scores range from 0 to 2.0 points. The bonus points do not apply to the achievement scores.



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To assess if the ETC Model had differential impacts among patient subpopulations of interest, we examined select outcomes:

- Home dialysis use; Home dialysis gains and losses
- Waitlisting
- Overall transplantation and Living Donor Transplantation among dialysis patients
- Utilization and quality of care: acute care hospitalizations; hospital readmissions; outpatient ED use; peritonitis among PD patients; hospitalization with ESRD complications; hospitalization with VA complications; vascular infection; Kt/V
- 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)
- Rural/Urban Location: rural, urban, and metropolitan subgroups based on the beneficiary's mailing address

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

Home dialysis use

based on:

- Age (subgroups defined as 18-44, 45-64, >65 years)
- Facility with an established home dialysis program ¹² (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 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.

We only examined home dialysis use for this subgroup analyses.



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, ¹³ subject to the constraint that the coefficients on risk-adjustment variables were the same for both subpopulations.

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

- β_6 : DiD for the reference subgroup
- \blacksquare β_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, rural/urban/metro location, 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-20** for the entire list of covariates). Like DiD analyses, we calculated both yearly (CY 2021, CY 2022 and CY 2023) 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 **Appendix B, 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 **Exhibit B-49**.

The primary analyses were adjusted for the same set of patient, facility, and market characteristics as the overall impact analyses described in **Section 3**. 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. 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 influence variations in ESRD patient care.

Listed below are the two approaches for risk adjustment:

- Fully adjusted model: As specified for overall impact analyses (Exhibit B-20)
- Parsimonious model: Patient age, sex, primary cause of ESRD, comorbidities and BMI at onset of ESRD, and duration of ESRD. These analyses included no adjustments for other patient characteristics or for any facility or market characteristics.

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



Findings were generally not sensitive to which risk adjustment approach was used but details are discussed in **Section 4.** All the DDD results included in the main report and appendix were adjusted for a full set of covariates as specified in **Exhibit B-20.**

We compared the overlap and impact among patient subgroups used in the subgroup analyses for both ETC and comparison groups (see <u>Exhibit B-29</u> – <u>Exhibit B-51</u>). We noted that there was a high level of overlap between dual eligibility and Part D LIS status (see <u>Exhibit B-29</u>).

Exhibit B-29. Distribution of Patient Months by Dual Eligibility and Part D LIS, for ETC and Comparison Areas

Part D LIS Recipient	E.	гс	Comparison		
Part D LIS Recipient	Dually Eligible ¹	Non-Dually Eligible	Dually Eligible ¹	Non-Dually Eligible	
Yes	99.6%	40.9%	99.6%	39.2%	
No	0.39%	59.1%	0.43%	60.8%	

Note: ETC = ESRD Treatment Choices; LIS = Low Income Subsidy. lIncludes dually eligible beneficiaries with full Medicaid benefits.

Exhibit B-30. Distribution of Patient Months by Dual Eligibility and Rural/Urban, for ETC and Comparison Areas

Rural/Urban	Eī	гс	Comparison		
Rui ai/ Oi baii	Dually Eligible ¹	Non-Dually Eligible	Dually Eligible ¹	Non-Dually Eligible	
Rural	1.6%	1.5%	1.4%	1.8%	
Metro	80.5%	82.8%	86.7%	83.0%	
Urban	18.0%	15.8%	11.9%	15.2%	

Notes: ETC = ESRD Treatment Choice.

Exhibit B-31. Distribution of Patient Months by Part D LIS and Rural/Urban, for ETC and Comparison Areas

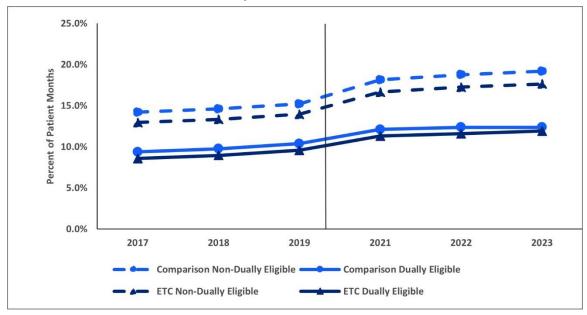
	ET	гс	Comparison		
Rural/Urban	Part D LIS Recipient: Yes	Part D LIS Recipient: No	Part D LIS Recipient: Yes	Part D LIS Recipient: No	
Rural	1.6%	1.5%	1.6%	1.9%	
Metro	80.5%	82.6%	84.8%	82.0%	
Urban	17.9%	15.9%	13.6%	16.1%	

Note: ETC = ESRD Treatment Choices; LIS = Low Income Subsidy.



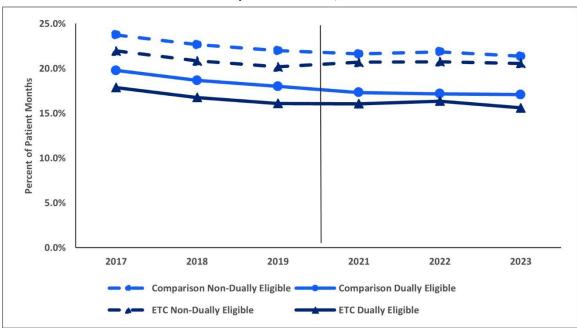
¹ Includes dually eligible beneficiaries with full Medicaid benefits.

Exhibit B-32. Adjusted Trends in Home Dialysis Use by Patient Dual Eligibility, for ETC and Comparison Areas, CY 2017-CY 2023



Note: CY = Calendar Year; ETC = ESRD Treatment Choices.

Exhibit B-33. Adjusted Trends in Waitlisting by Patient Dual Eligibility, for ETC and Comparison Areas, CY 2017-CY 2023



Note: CY = Calendar Year; ETC = ESRD Treatment Choices.



7.0 6.0 Rate per 1,000 Patient Months 5.0 4.0 2.0 1.0 0.0 2017 2018 2021 2022 2023 2019 Comparison Non-Dually Eligible Comparison Dually Eligible **ETC Non-Dually Eligible** ETC Dually Eligible

Exhibit B-34. Adjusted Trends in Transplant Rates by Patient Dual Eligibility, for ETC and Comparison Areas, CY 2017-CY 2023

Note: CY = Calendar Year; ETC = ESRD Treatment Choices.

Exhibit B-35. Patient Subgroup DDD Model Impact Estimates for Home Dialysis Gains, CY 2021–CY 2023

Patient Subgroup		Cumulative DiD1	% Relative Change	DDD¹ (vs. Ref)	Pre-ETC Gap in ETC areas (vs. Ref)	% Change in Pre-ETC Gap
Dually	Yes	0.01	0.40%	-0.08	0.20%	-38.8%
Eligible ²	No (Ref)	0.09	3.0%	-	-	-
Part D LIS	Yes	-0.02	-0.74%	-0.13	0.16%	-86.4%
Recipient	No (Ref)	0.11	3.7%	-	-	-
	Rural	-0.07	-2.3%	-0.13	0.10%	-133.8%
Beneficiary location	Urban	0.13	4.2%	0.07	-0.02%	-341.1%
	Metro (Ref)	0.06	1.9%	-	-	-

Notes: CY = Calendar Year; ETC = ESRD Treatment Choices; LIS = Low Income Subsidy. Ref corresponds to reference subgroup. Results are based on DDD models of cumulative impacts in CY 2021 through CY 2023, adjusted for the full set of patient, facility, and market characteristics (for the list of covariates see Exhibit B-20). 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. No DiD or DDD estimates are statistically significant at p-value <0.1.

Exhibit B-36. Patient Subgroup DDD Model Impact Estimates for Home Dialysis Losses, CY 2021–CY 2023

Patient Subgroup		Cumulative DiD ¹	% Relative Change	DDD¹ (vs. Ref)	Pre-ETC Gap in ETC areas (vs. Ref)	% Change in Pre-ETC Gap
Dually	Yes	-0.03	-1.06%	-0.15	0.02%	-631.4%
Eligible ²	No (Ref)	0.12*	4.1%	-	-	-
Part D LIS	Yes	0.06	2.0%	-0.001	0.03%	-5.2%
Recipient	No (Ref)	0.06	2.1%	-	-	-
	Rural	-0.41	-13.3%	-0.50	0.16%	-306.1%
Beneficiary location	Urban	0.13	4.5%	0.04	-0.01%	-542.9%
	Metro (Ref)	0.08	2.9%	-	-	-

Notes: CY = Calendar Year; ETC = ESRD Treatment Choices; LIS = Low Income Subsidy. Ref corresponds to reference subgroup. Results are based on DDD models of cumulative impacts in CY 2021 through CY 2023, adjusted for the full set of patient, facility, and market characteristics (for the list of covariates see Exhibit B-20). 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. *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-37. Patient Subgroup DDD Model Impact Estimates for Living Donor Transplantation, CY 2021–CY 2023

Patient Subgroup		Cumulative DiD ¹	% Relative Change	DDD¹ (vs. Ref group)	Pre-ETC Gap in ETC Areas (vs. Ref group)	% Change in Pre-ETC Gap
Dually	Yes	-0.02	-5.1%	-0.08	-0.24	33.0%
Eligible ²	No (Ref)	0.06	8.2%	-	-	-
Part D LIS	Yes	-0.01	-2.4%	-0.10	-0.35	28.5%
Recipient	No (Ref)	0.09	11.5%	-	-	-
	Rural	0.02	3.5%	-0.01	0.08	-19.3%
Rural and Urban	Urban	0.01	1.6%	-0.03	0.18	-14.9%
	Metro (Ref)	0.04	6.6%	-	-	-

Notes: CY = Calendar Year; DDD = Division of Developmental Disabilities; DiD = Difference in Differences; ETC = End-Stage Renal Disease Treatment Choices; LIS = Low-Income Subsidy. Ref corresponds to reference subgroup. Results are based on DDD models of cumulative impacts in CY 2021 through CY 2023, with adjustment for patient, facility, and market characteristics. DDD estimates correspond to the relative impact of the ETC Model for the patient subgroup relative to the reference subgroup. The pre-ETC period includes CY 2017–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.

¹ Corresponds to transplants per 1,000 patient months.

² Includes dually eligible beneficiaries with full Medicaid benefits. No DiD or DDD estimates are statistically significant at p-value <0.1.

Exhibit B-38. Subgroup DDD Model Impact Estimates for Acute Care Hospitalization, CY 2021–CY 2023

Patient Subgroup		Cumulative DiD ¹	% Relative Change	DDD¹ (vs. Ref)	Pre-ETC Gap in ETC areas (vs. Ref)	% Change in Pre-ETC Gap
Dually	Yes	-0.03	-0.3%	-0.03	1.0%	-3.3%
Eligible ²	No (Ref)	-0.001	0.0%	-	-	-
Part D LIS	Yes	0.07	0.70%	0.29**	0.35%	82.7%
Recipient	No (Ref)	-0.21**	-2.1%	-	-	-
Beneficiary location	Rural	0.11	1.3%	0.09	-1.2%	-7.5%
	Urban	-0.01	-0.08%	-0.03	-0.69%	4.3%
	Metro (Ref)	0.02%	0.21%	-	-	-

Notes: CY = Calendar Year; DDD = Difference-in-difference-in-differences; DiD = Difference in Differences; ETC = ESRD Treatment Choices; LIS = Low Income Subsidy. Ref corresponds to reference subgroup. Results are based on DDD models of cumulative impacts in CY 2021 through CY 2023, adjusted for the full set of patient, facility, and market characteristics (for the list of covariates see Exhibit B-20). 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. *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-39. Patient Subgroup DDD Model Impact Estimates for Hospital Readmission, CY 2021–CY 2023

Patient Subgroup		Cumulative DiD ¹	% Relative Change	DDD¹ (vs. Ref)	Pre-ETC Gap in ETC areas (vs. Ref)	% Change in Pre-ETC Gap
Dually	Yes	-0.06	-0.18%	0.21	2.6%	8.3%
Eligible ²	No (Ref)	-0.27	-0.93%	-	-	-
Part D LIS	Yes	-0.12	-0.40%	0.42	1.8%	22.9%
Recipient	No (Ref)	-0.54	-1.8%	-	-	-
- 0.	Rural	-0.27	-0.91%	-0.12	-0.27%	44.5%
Beneficiary location	Urban	-0.22	-0.75%	-0.06	-1.5%	4.2%
Tocation	Metro (Ref)	-0.15	-0.50%	-	-	-

Notes: CY = Calendar Year; DDD = Difference-in-difference-in-differences; DiD = Difference in Differences; ETC = ESRD
Treatment Choices; LIS = Low Income Subsidy. Ref corresponds to reference subgroup. Results are based on DDD models of
cumulative impacts in CY 2021 through CY 2023, with adjustment for patient, facility, and market characteristics. DDD
estimates correspond to the relative impact of the ETC Model for the patient subgroup relative to the reference subgroup. The
pre-ETC period includes CY 2017-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.

¹ Corresponds to percentage point change.

² Includes dually eligible beneficiaries with full Medicaid benefits. No DiD or DDD estimates are statistically significant at p-value <0.1.</p>

Exhibit B-40. Patient Subgroup DDD Model Impact Estimates for Outpatient ED Use, CY 2021–CY 2023

Patient Subgroup		Cumulative DiD ¹	% Relative Change	DDD¹ (vs. Ref)	Pre-ETC Gap in ETC areas (vs. Ref)	% Change in Pre-ETC Gap
Dually	Yes	-0.20	-1.5%	-0.06	3.1%	-1.8%
Eligible ²	No (Ref)	-0.15	-1.4%	-	-	-
Part D LIS	Yes	-0.18	-1.4%	0.07	2.9%	2.4%
Recipient	No (Ref)	-0.25**	-2.5%	-	-	-
Beneficiary location	Rural	0.21	1.7%	0.36	0.92%	38.6%
	Urban	-0.15	-1.1%	0.003	1.8%	0.15%
	Metro (Ref)	-0.15	-1.3%	-	-	-

Notes: CY = Calendar Year; DDD = Difference-in-difference-in-differences; DiD = Difference in Differences; ED = Emergency Department; ETC = ESRD Treatment Choices; LIS = Low Income Subsidy. Ref corresponds to reference subgroup. Results are based on DDD models of cumulative impacts in CY 2021 through CY 2023, adjusted for the full set of patient, facility, and market characteristics (for the list of covariates see Exhibit B-20). 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. *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-41. Patient Subgroup DDD Model Impact Estimates for Hospitalizations with ESRD Complications, CY 2021–CY 2023

Patient Subgroup		Cumulative DiD ¹	% Relative Change	DDD¹ (vs. Ref)	Pre-ETC Gap in ETC areas (vs. Ref)	% Change in Pre-ETC Gap
Dually	Yes	-0.08**	-7.2%	-0.08**	0.33%	-25.0%
Eligible ²	No (Ref)	0.01	0.86%	-	-	-
Part D LIS	Yes	-0.04	-3.6%	-0.01	0.24%	-2.4%
Recipient	No (Ref)	-0.03	-4.0%	-	-	-
Beneficiary location	Rural	0.19*	33.8%	0.21*	-0.33%	-64.4%
	Urban	-0.01	-1.3%	0.02	-0.19%	-10.3%
	Metro (Ref)	-0.03	-3.3%	-	-	-

Notes: CY = Calendar Year; DDD = Difference-in-difference-in-differences; DiD = Difference in Differences; ETC = ESRD Treatment Choices; LIS = Low Income Subsidy; ESRD = End Stage Renal Disease. Ref corresponds to reference subgroup. Results are based on DDD models of cumulative impacts in CY 2021 through CY 2023, adjusted for the full set of patient, facility, and market characteristics (for the list of covariates see Exhibit B-20). 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. *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.



¹ Corresponds to percentage point change.

² Includes dually eligible beneficiaries with full Medicaid benefits.

¹ Corresponds to percentage point change.

² Includes dually eligible beneficiaries with full Medicaid benefits.

Exhibit B-42. Patient Subgroup DDD Model Impact Estimates for Hospitalizations with VA Complications, CY 2021–CY 2023

Patient Subgroup		Cumulative DiD ¹	% Relative Change	DDD¹ (vs. Ref)	Pre-ETC Gap in ETC areas (vs. Ref)	% Change in Pre-ETC Gap
Dually	Yes	0.01	1.1%	0.02	0.08%	20.6%
Eligible ²	No (Ref)	-0.01	-0.94%	-	-	-
Part D LIS	Yes	0.01	0.90%	0.04	0.01%	316.9%
Recipient	No (Ref)	-0.03	-3.8%	-	-	-
- C: :	Rural	-0.12	-16.1%	-0.12	-0.06%	219.5%
Beneficiary location	Urban	-0.03	-3.3%	-0.03	0.04%	-87.8%
	Metro (Ref)	0.01	0.90%	-	-	-

Notes: CY = Calendar Year; DDD = Difference-in-difference-in-differences; DiD = Difference in Differences; ETC = ESRD Treatment Choices; LIS = Low Income Subsidy; VA = Vascular Access. Ref corresponds to reference subgroup. Results are based on DDD models of cumulative impacts in CY 2021 through CY 2023, adjusted for the full set of patient, facility, and market characteristics (for the list of covariates see Exhibit B-20). 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.

Exhibit B-43. Patient Subgroup DDD Model Impact Estimates for Peritonitis among PD Patients, CY 2021–CY 2023

Patient Subgroup		Cumulative DiD ¹	% Relative Change	DDD¹ (vs. Ref)	Pre-ETC Gap in ETC areas (vs. Ref)	% Change in Pre-ETC Gap
Dually	Yes	0.11	2.5%	0.29	0.46%	61.5%
Eligible ²	No (Ref)	-0.17	-4.1%	-	-	-
Part D LIS	Yes	-0.03	-0.70%	0.12	0.57%	20.9%
Recipient	No (Ref)	-0.15	-3.7%	-	-	-
Beneficiary location	Rural	-1.5	-23.1%	-1.4	2.1%	-68.8%
	Urban	-0.36	-7.9%	-0.34	0.31%	-112.0%
	Metro (Ref)	-0.01	-0.30%	-	-	-

Notes: CY = Calendar Year; DDD = Difference-in-difference-in-differences; DiD = Difference in Differences; ETC = ESRD Treatment Choices; LIS = Low Income Subsidy; PD = Peritoneal Dialysis. Ref corresponds to reference subgroup. Results are based on DDD models of cumulative impacts in CY 2021 through CY 2023, with adjustment for patient, facility, and market characteristics. DDD estimates correspond to the relative impact of the ETC Model for the patient subgroup relative to the reference subgroup. The pre-ETC period includes CY 2017-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. No DiD or DDD estimates are statistically significant at p-value <0.1.

¹ Corresponds to percentage point change.

² Includes dually eligible beneficiaries with full Medicaid benefits. No DiD or DDD estimates are statistically significant at p-value <0.1.</p>

Exhibit B-44. Patient Subgroup DDD Model Impact Estimates for Vascular Infection, CY 2021–CY 2023

Patient Subgroup		Cumulative DiD ¹	% Relative Change	DDD¹ (vs. Ref)	Pre-ETC Gap in ETC areas (vs. Ref)	% Change in Pre-ETC Gap
Dually	Yes	0.04	3.6%	0.02	0.17%	10.6%
Eligible ²	No (Ref)	0.02	2.3%	-	-	-
Part D LIS	Yes	0.03	3.0%	0.01	0.13%	10.0%
Recipient	No (Ref)	0.02	2.0%	-	-	-
Beneficiary location	Rural	-0.13	-12.5%	-0.17	0.07%	-224.1%
	Urban	-0.02	-1.5%	-0.06	0.20%	-28.7%
	Metro (Ref)	0.04	4.3%	-	-	-

Notes: CY = Calendar Year; DDD = Difference-in-difference-in-differences; DiD = Difference in Differences; ETC = ESRD Treatment Choices; LIS = Low Income Subsidy. Ref corresponds to reference subgroup. Results are based on DDD models of cumulative impacts in CY 2021 through CY 2023, adjusted for the full set of patient, facility, and market characteristics (for the list of covariates see Exhibit B-20). 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.

Exhibit B-45. Patient Subgroup DDD Model Impact Estimates for Kt/V, CY 2021-CY 2023

Patient Subgroup		Cumulative DiD ¹	% Relative Change	DDD¹ (vs. Ref)	Pre-ETC Gap in ETC areas (vs. Ref)	% Change in Pre-ETC Gap
Dually	Yes	0.11	0.12%	-0.08	0.50%	-17.1%
Eligible ²	No (Ref)	0.20	0.21%	-	-	-
Part D LIS	Yes	0.10	0.11%	-0.19	0.62%	-30.7%
Recipient	No (Ref)	0.29	0.30%	-	-	-
Beneficiary location	Rural	-0.05	-0.05%	-0.24	0.58%	-41.5%
	Urban	0.05	0.06%	-0.14	-0.53%	26.4%
	Metro (Ref)	0.19	0.20%	-	-	-

Note: CY = Calendar Year; DDD = Difference-in-difference-in-differences; DiD = Difference in Differences; ETC = ESRD
Treatment Choices; LIS = Low Income Subsidy. Ref corresponds to reference subgroup. Results are based on DDD models of cumulative impacts in CY 2021 through CY 2023, adjusted for the full set of patient, facility, and market characteristics (for the list of covariates see Exhibit B-20). 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. No DiD or DDD estimates are statistically significant at p-value <0.1.

¹ Corresponds to percentage point change.

² Includes dually eligible beneficiaries with full Medicaid benefits. No DiD or DDD estimates are statistically significant at p-value <0.1.

Exhibit B-46. Patient Subgroup DDD Model Impact Estimates for
Total Medicare Parts A & B Payments PPPM, CY 2021-CY 2023

Patient Subgroup		Cumulative DiD	% Relative Change	DDD (vs. Ref)	Pre-ETC Gap in ETC areas (vs. Ref)	% Change in Pre-ETC Gap
Dually	Yes	\$4	0.06%	-\$10	\$142	-6.9%
Eligible ¹	No (Ref)	\$13	0.23%	-	-	-
Part D LIS	Yes	\$13	0.23%	\$22	-\$92	-24.3%
Recipient	No (Ref)	-\$9	-0.16%	-	-	-
	Rural	-\$85	-1.5%	-\$103	-\$107	96.0%
Beneficiary location	Urban	\$23	0.41%	\$5	-\$38	-13.9%
location	Metro (Ref)	\$18	0.32%	-	-	-

Note: CY = Calendar Year; DDD = Difference-in-difference-in-differences; DiD = Difference in Differences; ETC = ESRD Treatment Choices; LIS = Low Income Subsidy. Ref corresponds to reference subgroup. Results are based on DDD models of cumulative impacts in CY 2021 through CY 2023, with adjustment for patient, facility, and market characteristics. DDD estimates correspond to the relative impact of the ETC Model for the patient subgroup relative to the reference subgroup. The pre-ETC period includes CY 2017-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.

Exhibit B-47. Age DDD Model Impact Estimates for Home Dialysis Use, CY 2021–CY 2023

Patient sub-group: Age	Cumulative DiD ¹	% Relative change	DDD¹ (vs. Ref)	Pre-ETC Gap in ETC areas (vs. Ref)	% Change in Pre-ETC Gap
18 - 45	0.20	1.2%	0.26	7.1%	3.7%
45 - 65	-0.07	-0.52%	-0.005	3.1%	-0.15%
>65	-0.06	-0.64%	-	-	-

Notes: CY = Calendar Year; DDD = Difference-in-difference-in-differences; DiD = Difference in Differences; ETC = ESRD Treatment Choices. Ref corresponds to reference subgroup. Results are based on DDD models of cumulative impacts in CY 2021 and CY 2023, with adjustment for patient, facility, and market characteristics. DDD estimates correspond to the relative impact of the ETC Model for the patient subgroup relative to the reference subgroup. The pre-ETC period includes CY 2017-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.

Exhibit B-48. Facility Characteristics DDD Model Impact Estimates for Home Dialysis Use, CY 2021–CY 2023

Facility Subgroup: Size of home dialysis program	Number of Facilities	Cumulative DiD ¹	% Relative Change	DDD¹ (vs. Ref)	Pre-ETC Gap in ETC areas (vs. Ref)	% Change in Pre-ETC Gap
Large	818	-0.14	-0.38%	-0.10	31.3%	-0.31%
Small or none (Ref)	7,538	-0.04	-0.73%	-	-	-

Notes: CY = Calendar Year; DDD = Difference-in-difference-in-differences; DiD = Difference in Differences; ETC = ESRD Treatment Choices. Ref corresponds to reference subgroup. Results are based on DDD models of cumulative impacts in CY 2021 and CY 2023, with adjustment for patient, facility, and market characteristics. DDD estimates correspond to the relative impact of the ETC Model for the patient subgroup relative to the reference subgroup. The pre-ETC period includes CY 2017-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.

¹ Corresponds to percentage point change. No DiD or DDD estimates are statistically significant at p-value <0.1.



¹ Includes dually eligible beneficiaries with full Medicaid benefits. No DiD or DDD estimates are statistically significant at p-value <0.1.

¹ Corresponds to percentage point change. No DiD or DDD estimates are statistically significant at p-value <0.1.

Exhibit B-49. Patient Subgroup DDD Falsification and Dynamic Trend Test Results

Patient		Falsification Parallel	Dynamic Trend Test	
Subgroups	Outcomes	DDD Estimate ^a	p-value	Joint F-test p-value
	Home Dialysis	-0.03	0.88	0.37
	Home dialysis gains	-0.02	0.90	0.30
	Home dialysis losses	0.19	0.22	0.45
	Overall Waitlisting	-0.37	0.25	0.39
	Total Transplant ¹	0.27	0.19	0.38
	Living Donor Transplant ¹	0.003	0.96	0.40
	Acute Care Hospitalization	-0.06	0.56	0.84
Dually Eligible: Yes vs. No	Total Parts A & B Medicare Payments (PPPM)	\$6	0.82	0.79
	Readmission	-0.34	0.56	0.84
	Emergency department visit	-0.07	0.63	0.03
	Peritonitis	0.19	0.54	0.70
	ESRD complications	-0.03	0.45	0.30
	Vascular complications	-0.01	0.86	0.38
	Vascular infection	-0.01	0.91	0.16
	KtV	-0.07	0.60	0.76
	Home Dialysis	0.41	0.13	0.10
	Home dialysis gains	-0.17	0.29	0.24
	Home dialysis losses	0.08	0.62	0.54
	Overall Waitlisting	-0.23	0.55	0.82
	Total Transplant ¹	0.40	0.18	0.41
	Living Donor Transplant ²	-0.03	0.72	0.86
	Acute Care Hospitalization	-0.06	0.62	0.62
Part D LIS Recipient:	Total Parts A & B Medicare Payments (PPPM)	\$12	0.71	0.10
Yes vs. No	Readmission	0.22	0.68	0.81
	Emergency department visit	-0.12	0.40	0.01
	Peritonitis	0.01	0.98	0.87
	ESRD complications	0.002	0.96	0.28
	Vascular complications	-0.02	0.49	0.24
	Vascular infection	-0.08	0.11	0.14
	KtV	-0.08	0.57	0.85
	Home Dialysis	1.0	0.21	0.17
	Home dialysis gains	0.39	0.45	0.30
	Home dialysis losses	-0.76	0.18	0.39
	Overall Waitlisting	-0.43	0.76	0.15
	Total Transplant ¹	-0.53	0.47	0.76
Beneficiary	Living Donor Transplant ¹	-0.28	0.33	0.58
location:	Acute Care Hospitalization	-0.31	0.37	0.64
Rural vs. Metro	Total Parts A & B Medicare Payments (PPPM)	-\$55	0.55	0.34
	Readmission	0.87	0.66	0.58
	Emergency department visit	-0.58	0.24	0.10*
	Peritonitis	-0.36	0.77	0.50
	ESRD complications	-0.02	0.86	0.97



Patient	Outcomes	Falsification Parallel	Trend Test	st Dynamic Trend Test		
Subgroups	Outcomes	DDD Estimate ^a	p-value	Joint F-test p-value		
Beneficary loc.:	Vascular complications	-0.14	0.21	0.17		
Rural vs. Metro	Vascular infection	-0.15	0.40	0.66		
(cont.)	KtV	-0.45	0.42	0.27		
	Home Dialysis	0.15	0.64	0.86		
	Home dialysis gains	-0.13	0.51	0.26		
	Home dialysis losses	-0.15	0.45	0.65		
	Overall Waitlisting	-0.42	0.43	0.73		
	Total Transplant ¹	-0.48	0.07*	0.17		
	Living Donor Transplant ¹	-0.05	0.67	0.16		
Barra Calama	Acute Care Hospitalization	-0.03	0.83	0.94		
Beneficiary location: Urban vs. Metro	Total Parts A & B Medicare Payments (PPPM)	-\$27	0.46	0.76		
Orban vs. Metro	Readmission	-1.1	0.15	0.17		
	Emergency department visit	-0.16	0.40	0.56		
	Peritonitis	-0.08	0.83	0.34		
	ESRD complications	-0.04	0.48	0.47		
	Vascular complications	-0.04	0.42	0.53		
	Vascular infection	0.07	0.51	0.70		
	KtV	-0.11	0.69	0.84		

Notes: DDD = Difference-in-difference-in-differences; ESRD = End Stage Renal Disease; LIS = Low Income Subsidy; PPPM = Per=Patient Per-Month. Transplant and waitlisting measures restricted to patients less than 75 years old.

Exhibit B-50. Patient age DDD Falsification and Dynamic Trend Test Results

Patient sub-group: Age	Outcomos	Falsification Parallel Tr	Dynamic Trend Test	
Patient sub-group: Age	Outcomes	DDD Estimate for 2019	p-value	Joint F-test p-value
18-45	Llomo Dialusis	-0.02	0.95	0.97
45-65	Home Dialysis	-0.08	0.73	0.81

Note: DDD = Difference-in-differences

Exhibit B-51. Facility Characteristics DDD Falsification and Dynamic Trend Test Results

Facility Subgroups	Outcomos	Falsification Paral	Dynamic Trend Test	
Facility Subgroups	Outcomes	DDD Estimate ^a	p-value	Joint F-test p-value
Large vs. Small Home Dialysis Program	Home Dialysis	0.11	0.84	0.90

Notes: DDD = Difference-in-difference-in-differences.



^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.

^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.9. Performance of ETC Participants by Patient Subpopulations of Interest

A potential unintended consequence of the ETC Model is that lower performance among participating ESRD facilities and Managing Clinicians serving disproportionate numbers of patient subpopulations of interest leads to a pattern of ETC payment adjustments that may systematically increase or decrease available resources from these providers, which may hamper or bolster their future efforts to encourage home dialysis and transplantation among these patient subgroups. To explore this possibility, we compared Modality Performance Scores among ETC participants based on the dual eligibility status, Part D LIS status, and rural/urban status of their attributed beneficiaries.

Using the ETC performance reports for MY1 through MY4 obtained from the Model Implementation Contractor, we defined three groups of facilities/Managing Clinicians based on their Modality Performance Score (MPS): (1) Lower MPS, based on the lowest quartile of MPS values among facilities/ Managing Clinicians in the MY; (2) Middle MPS, which includes all other facilities/ Managing Clinicians (i.e., the middle two quartiles of MPS values in the MY); and (3) Higher MPS, based on being in the highest quartile of MPS values among facilities/Managing Clinicians in the MY. We compared ETC participants in the three MPS categories based on the dual eligibility status, Part D LIS status, and rural/urban status of their attributed patients. More specifically, we conducted unadjusted univariate regression models for each of the patient characteristics to examine differences among the three MPS categories of ESRD facilities and Managing Clinicians, using the lower MPS category as the reference group. While MPS ranges from 0 – 6 in all the 4 MYs, over 80% of facilities received a MPS ranging between 3 and 5 in MY1 and MY2, and about 50% of facilities received a MPS ranging between 3 and 5 in MY3 and MY4 (see Exhibit B-52). Similar patterns are observed for clinicians (see Exhibit B-53).

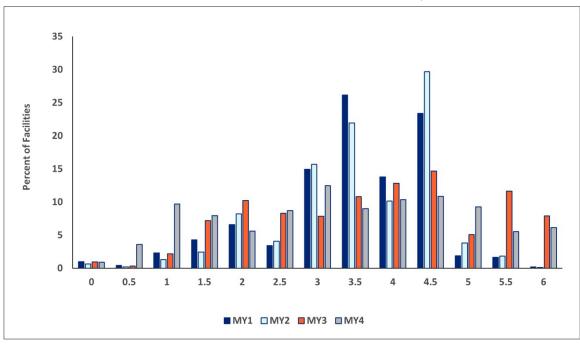


Exhibit B-52. MPS Distribution for ETC Facilities, MY1-MY4

Note: ETC = ESRD Treatment Choices; MPS = Modality Performance Score.



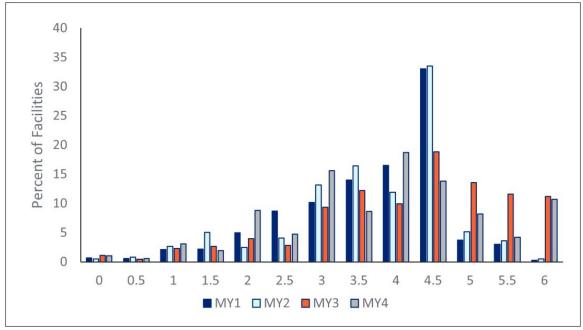


Exhibit B-53. MPS Distribution for ETC Managing Clinicians, MY1-MY4

Note: ETC = ESRD Treatment Choices; MPS = Modality Performance Score.

Exhibit B-54. Subpopulations of Interest by Facility MPS Group, MY1-MY4

Measurement Period	Facility MPS group	# of Bene- months	Dually Eligible	Part D LIS Recipient	Rural
Baya	Lower MPS	144,537	36.6%	66.7%	1.4%
MY1 (1/1/2021 – 12/31/2021)	Middle MPS	425,499	32.3%*	62.2%**	1.2%
(1/1/2021 - 12/31/2021)	Higher MPS	244,309	37.5%	62.8%	2.0%
BAV2	Lower MPS	120,675	35.2%	65.2%	1.0%
MY2 (7/1/2021 – 6/30/2022)	Middle MPS	353,754	32.4%	62.1%*	1.9%*
(7/1/2021 - 6/30/2022)	Higher MPS	276,229	37.6%	61.2%*	1.2%
BAV2	Lower MPS	141,710	33.4%	59.6%	1.0%
MY3 (1/1/2022 – 12/31/2022)	Middle MPS	287,194	37.7%	63.9%*	1.6%
(1/1/2022 – 12/31/2022)	Higher MPS	266,777	33.0%	58.8%	1.5%
BAVA	Lower MPS	147,534	30.5%	59.0%	0.64%
MY4 (7/1/2022 – 6/30/2023)	Middle MPS	296,540	39.2%**	62.3%	1.1%
(//1/2022 - 0 /30/2023)	Higher MPS	208,252	32.2%	57.3%	2.5%**

Note: ETC = ESRD Treatment Choices; LIS = Low Income Subsidy; MPS = Modality Performance Score. Analyses of Part D LIS recipients are limited to patients enrolled in Part D. Dually eligible is defined as beneficiaries with full Medicaid benefits. Statistical significance is based on unadjusted univariate regression model for each patient characteristic to examine differences among the three MPS categories of ETC facilities, using the lower MPS category as the reference group.

*Indicates statistical significance of estimate difference at p-value <0.1. **Indicates statistical significance of estimate difference at p-value <0.05.



Exhibit B-55. Subpopulations of Interest by Managing Clinician MPS Group, MY1-MY4

Measurement Period	Clinician MPS group	# of Bene- months	Dually Eligible	Part D LIS Recipient	Rural
B.0V4	Lower MPS	129,795	36.5%	65.7%	1.3%
MY1 (1/1/2021 – 12/31/2021)	Middle MPS	307,428	34.8%	63.5%	1.6%
(1/1/2021 – 12/31/2021)	Higher MPS	277,409	32.9%*	59.9%**	1.7%
NAVO	Lower MPS	108,840	35.1%	63.8%	1.2%
MY2 (7/1/2021 – 6/30/2022)	Middle MPS	275,242	34.0%	62.0%	1.6%
(//1/2021 - 0/30/2022)	Higher MPS	271,703	34.2%	59.9%**	1.7%
NAVO	Lower MPS	148,951	39.7%	63.8%	1.3%
MY3 (1/1/2022 – 12/31/2022)	Middle MPS	238,559	31.8%	57.8%	1.9%
(1/1/2022 – 12/31/2022)	Higher MPS	210,857	34.1%	60.8%	1.5%
	Lower MPS	115,523	33.5%	57.7%	2.1%
MY4 (7/1/2022 – 6/30/2023)	Middle MPS	248,472	35.6%	60.6%	1.3%
(7/1/2022 - 0/30/2023)	Higher MPS	192,068	33.6%	58.9%	1.8%

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



Appendix C: Power Calculation Methodology

The sensitivity of a model to detect differences 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.¹⁴

We conducted power calculations for three main outcomes: home dialysis, waitlisting, and overall transplantation. 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, a 1.9 percentage points difference for transplant waitlisting, and a 0.30 transplantation per 1,000 patient months difference for overall transplantation.

We also conducted power analyses separately for each of the subgroups: Dually eligible (yes and no), Part D LIS recipient (yes and no), as well as rural and urban residing patients (rural, metro, and urban) for the same three main outcomes: home dialysis, waitlisting, and overall transplantation. Using a two-tailed test at 0.1 level of significance, the evaluation has 80% power to detect a minimum effect size ranging between 1.5 to 2.4 percentage points for home dialysis for dually eligible subgroup, and Part D LIS Recipient subgroup. The minimum detectable effect size was 3.4 percentage points for the Hispanic subgroup, and 6.8 and 4.2 percentage points for the rural subgroup and urban subgroup, respectively. 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 2.5 percentage points, except for the Hispanic subgroup where the minimum detectable effect size was 3.7 percentage points and for the rural subgroup where the minimum detectable effect size was 4.0 percentage points. For the overall transplantation measure, the minimum effect size for each of the subgroups ranged between 0.26 to 0.42 transplant per 1,000 patient months, except for the rural subgroup where the minimum detectable effect size was 1.80 patient months.

Home Dialysis Care Experience Survey. We conducted power analyses for Home-DCE survey for the three measures: dialysis staff rating, dialysis center rating, and quality of dialysis center care and operations. Using a two-tailed test at 0.1 level of significance, the evaluation has 80% power to detect a minimum effect size of 3 percentage points for the two global rating measures (dialysis staff rating and dialysis center rating). For the quality of dialysis center care and operations measure using exact same criteria as above, the minimum effect size was 1.8 percentage points.

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.



C-1

PROMIS-29 Quality of Life Survey. For each of the three modalities, we conducted power analyses for the QoL survey for all eight outcomes: physical function T-score, anxiety T-score, depression T-score, fatigue T-score, sleep disturbance T-score, ability to participate in social roles and activities T-score, pain interference T-score, and global pain intensity score. Using a two-tailed test at 0.1 level of significance, the evaluation has 80% power to detect a minimum effect size of at least 1.55 points for all T-score outcomes, and 0.43 points for the global pain intensity score for the home dialysis sample. For the IC HD sample, the evaluation has 80% power to detect a minimum effect size of at least 1.49 points for all T-score outcomes and 0.43 points for the global pain intensity score; and 1.53 for all T-score outcomes and 0.43 points for the global pain intensity score for the transplant sample.

All these power calculations indicate that the ETC Model is sufficiently powered to detect important differences in key outcomes.



Appendix D: Mortality

This appendix defines the methodology used to conduct mortality analyses. We used the same beneficiary month file (see <u>Appendix B, Section B.1.</u> and <u>B.2.</u>) and reconstructed it to perform survival analysis at the patient level rather than at the beneficiary month level. 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 (<u>Exhibit B-3</u>).

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 the ETC or the comparison group, thus counting as an observed event. 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. Unadjusted death rates increased from 13.7 to 17.0 per 100 patient years at risk for the ETC group and from 14.1 to 17.3 for the comparison group between 2017 and 2023 (see **Exhibit D-1**). Death rates peaked in 2022, reaching 18.9 for comparison and 18.6 for ETC in 2022. Overall, death rates in ETC group remained lower than the comparison group throughout this period.



20 18.9 Deaths per 100 Patient Years at Risk 17.8 18 17.3 16.0 15.9 17.1 17.0 16 15.7 15.6 14 13.7 12 Pre-ETC Post-ETC 10 2017 2018 2019 2021 2022 2023 ETC Comparison

Exhibit D-1. Unadjusted Mortality Rates by ETC Status, 2017-2023

Note: ETC = ESRD Treatment Choices.

We used Cox proportional hazards model to evaluate the impact of the ETC Model accounting for patients and provider characteristics. ¹⁵ We used the same set of covariates as used for the DiD model (see **Exhibit B-20**) and conducted separate baseline and intervention period analyses. We compared survival in the ETC group relative to the comparison group. ETC was considered a time dependent covariate, so if a patient changed groups during follow-up their ETC status was updated and their time at risk was attributed to the corresponding ETC or 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 the ETC group has a lower (or higher) risk of death relative to the comparison group. If the 90% confidence interval for the hazard ratio doesn't include a value of one that means it is statistically significant at the 10% 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 2022. ¹⁶ 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, 2017-2022

Group	2017	2018	2019	2020	2021	2022
ETC	0.98	0.98	0.99	0.99	0.94	0.99
Comparison	1.02	1.01	1.00	1.03	0.97	1.02

Note: ETC = ESRD Treatment Choices; SMR = Standardized Mortality Ratio.

¹⁶ Obtained SMR from publicly available Dialysis Facility Report.



D-2

¹⁵ Cox (1972). Regression models and life tables (with discussion). J R Statist Soc B 34: 187–220.

Appendix E: In-Center Hemodialysis (ICH) Consumer Assessment of Healthcare Providers (CAHPS) Survey Analysis Supplement

E.1. Data Sources

We used the ICH CAHPS survey data for 2017-2019 (pre-ETC) and CY 2021-2023 (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). 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. 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.¹⁹ 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 reflect 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**). ²⁰ 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; difficulty

²⁰ CMS (2024). Patient-Mix Coefficients and Star Ratings for the In-Center Hemodialysis CAHPS (ICH CAHPS) Survey Results Publicly Reported in October 2024.
Patient-Mix Coefficients and Star Ratings for the In-Center Hemodialysis CAHPS (ICH CAHPS) Survey Results Publicly Reported in October 2024.



E-1

¹⁷ CMS (February 2025). *ICH CAHPS Survey: Survey Administration and Specifications Manual Version 13.0*. https://ichcahps.org/Portals/0/SurveyMaterials/ICH_SurveyAdminManual.pdf.

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.

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.

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.

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

Note: HD = Hemodialysis; ICH CAHPS = In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems Source: CMS (February 2025). ICH CAHPS Survey: Survey Administration and Specifications Manual Version 13.0. 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							
Nephrologists' Communication and	Q3: In the last 3 months, how often did your kidney doctors listen carefully to you?						
Caring	Q4: In the last 3 months, how often did your kidney doctors explain things in a way that was easy for you to understand?	This composite measure reflects					
This corresponds to the following measure reported	Q5: In the last 3 months, how often did your kidney doctors show respect for what you had to say?	the percentage of patients who					
on CMS' Care Compare website: "Patients who	Q6: In the last 3 months, how often did your kidney doctors spend enough time with you?	provided the most favorable ratings to the corresponding					
reported that kidney doctors "always"	Q7: In the last 3 months, how often did you feel your kidney doctors really cared about you as a person?	six ICH CAHPS questions.					
communicated well and cared for them 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
	Q10: In the last 3 months, how often did the dialysis center	
	staff listen carefully to you?	
	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?	
Quality of Dialysis Center	Q16: In the last 3 months, did dialysis center staff keep	
Care and Operations	information about you and your health as private as possible	
This corresponds to the	from other patients?	This composite
following measure reported on CMS' Care Compare	Q17: In the last 3 months, did you feel comfortable asking the dialysis center staff everything you wanted about dialysis	measure reflects
website: "Patients who	care?	the percentage of
reported that dialysis center	Q21: In the last 3 months, how often did dialysis center staff	patients who
staff "always"	insert your needles with as little pain as possible?	provided the most
communicated well, kept	Q22: In the last 3 months, how often did dialysis center staff	favorable ratings to the corresponding
patients as comfortable and	check you as closely as you wanted while you were on the	17 ICH CAHPS
pain-free as possible,	dialysis machine?	questions.
behaved in a professional manner, and kept the	Q24: In the last 3 months, how often was the dialysis center staff able to manage problems during your dialysis?	
center clean"	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
	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?	
	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?	
Providing Information to Patients	Q30: Has dialysis center staff ever told you what to do if you experience a health problem at home?	This composite
This corresponds to the following measure reported	Q31: Has any dialysis center staff ever told you how to get off the machine if there is an emergency at the center?	measure reflects the percentage of
on CMS' Care Compare website: "Patients who reported that YES their kidney doctors and dialysis center staff gave them the	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?	patients who provided the most favorable ratings to the corresponding nine ICH CAHPS questions.
information they needed to take care of their health"	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?	questions.
	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?	

Note: HD = Hemodialysis; ICH CAHPS = In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems. Source: CMS (February 2025). *ICH CAHPS Survey: Survey Administration and Specifications Manual Version 13.0.* https://ichcahps.org/Portals/0/SurveyMaterials/ICH SurveyAdminManual.pdf.

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 (i.e., the ETC group) and comparison HRRs (i.e., the comparison group). CMS does not report ICH CAHPS data for facilities with fewer than 30 completed surveys in the two most recent survey periods and also suppresses ICH CAHPS data for facilities that have fewer than 10 completed surveys. 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% of ESRD facilities having ICH CAHPS data in the pre-ETC period (CY 2017-CY 2019) with similar declining shares between the ETC and the comparison group (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% of facilities having ICH CAHPS data in the spring 2021 wave and only 28% to 31% in the fall 2021 wave (see Exhibit E-4). The proportion of ESRD facilities with ICH CAHPS data increased in the second and third CYs of the ETC model but remained below the pre-ETC level

²¹ CMS (February 2025). *ICH CAHPS Survey: Survey Administration and Specifications Manual Version 13.0*. https://ichcahps.org/Portals/0/SurveyMaterials/ICH SurveyAdminManual.pdf.



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(e.g., 56% in spring 2023 and 52% to 53% in fall 2023). The percentage of facilities with ICH CAHPS data was similar between the ETC and the comparison group for all years, with a small but larger share among comparison facilities for almost all waves (for example, 63% versus 66% for the spring 2017 wave).

Like the percentage of facilities with ICH CAHPS data, response rates of surveyed patients also decreased, dropping from 33% in spring 2017 to 29% in spring 2019, to a low of 20% in fall 2021. The response rate increased for survey waves in 2022 and 2023 to about a quarter but continued to be lower than in the pre-ETC period (i.e., 25% and 24% in spring and fall 2023, 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. 3,717) and of completed surveys (98,202 vs. 66,024; see **Exhibit E-3** and **Exhibit E-4**).



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

						Pre	-ETC					
Characteristic	Spring 2017		Fall 2017		Sprin	g 2018	Fall 2018		Spring 2019		Fall 2019	
Characteristic	ETC	Non- ETC	ETC	Non- ETC	ETC	Non- ETC	ETC	Non- ETC	ETC	Non- ETC	ETC	Non- ETC
ESRD Facilities*	2,174	4,411	2,174	4,411	2,266	4,646	2,266	4,646	2,334	4,784	2,334	4,784
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	63.4%	66.5%	61.9%	63.9%	56.0%	58.1%	59.0%	60.8%	56.8%	57.9%	56.3%	57.5%
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: ESRD = End-Stage Renal Disease; ETC = ESRD Treatment Choices; ICH CAHPS = In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems.



^{*} 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

						Post	-ETC					
Characteristic	Spring 2021		Fall 2021		Spring 2022		Fall 2022		Spring 2023		Fall 2023	
Characteristic	ETC	Non- ETC	ETC	Non- ETC	ETC	Non- ETC	ETC	Non- ETC	ETC	Non- ETC	ETC	Non- ETC
ESRD Facilities*	2,387	4,906	2,387	4,906	2,362	4,882	2,362	4,882	2,306	4,763	2,306	4,763
ESRD Facilities with ICH CAHPS Data	1,089	2,314	675	1,498	1,272	2,571	980	2,113	1,282	2,665	1,203	2,514
Percent with ICH CAHPS Data	45.%	47.2%	28.3%	30.5%	53.9%	52.7%	41.5%	43.3%	55.6%	56.0%	52.2%	52.8%
Number of ICH CAHPS Sampled Patients across Facilities	74,744	164,714	53,993	122,767	87,296	182,128	68,099	150,624	90,080	193,692	86,551	187,547
ICH CAHPS Survey Responses across Facilities	19,042	41,852	10,703	24,046	22,554	46,957	16,493	36,177	23,139	49,172	21,121	44,903
Response Rate	25.5%	25.4%	19.8%	19.6%	25.8%	25.8%	24.2%	24.0%	25.7%	25.4%	24.4%	23.9%

Note: ESRD = End-Stage Renal Disease; ETC = ESRD Treatment Choices; ICH CAHPS = In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems.



^{*} 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 six survey waves (spring 2021-fall 2023) 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 **Appendix B, 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, 77% for ETC and 65% for comparison group in 2023), a lower percent of Asian patients among ETC facilities relative to comparison facilities (i.e., 3.4% vs. 5.1%, respectively in 2023), and a lower percentage of patients who are Hispanic in ETC facilities than comparison facilities (i.e., 11% and 18%, respectively, in 2023; 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 **Appendix B, Section B.4.**). Our DiD analyses included 44,829 facility-survey wave observations for 5,880 unique ESRD facilities.



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

Characteristic				Pre-ETC			CY 2021			CY 2022		CY 2023		
Characteristic			ETC	Comparison	SMD									
Number of Facil	lities		4,421	9,273	N/A	1,129	2,401	N/A	1,341	2,754	N/A	1,440	2,998	N/A
Number of Surv	reys	Spring	3,972	8,404	N/A	1,089	2,314	N/A	1,272	2,571	N/A	1,282	2,665	N/A
per Wave		Fall	3,997	8,391	N/A	675	1,498	N/A	980	2,113	N/A	1,203	2,514	N/A
		Northeast	15.3 (36.0)	14.3 (35.0)	0.03	17.4 (38.0)	16.0 (36.7)	0.04	16.4 (37)	14.9 (35.6)	.04	16.0 (36.6)	15.2 (35.9)	0.02
Census Region		South	49.3 (50)	44.7 (49.7)	0.09	45.8 (49.8)	40.2 (49.0)	0.11	47.1 (49.9)	42.7 (49.5)	.09	48.5 (50)	43.4 (49.6)	0.10
(% in Each Region	on)	Midwest	17.0 (37.6)	18.0 (38.4)	-0.03	16.4 (37.0)	17.3 (37.9)	-0.03	16.8 (37.4)	17.2 (37.8)	01	16.8 (37.4)	17.3 (37.9)	-0.01
		West	18.4 (38.7)	23.0 (42.1)	-0.12	20.4 (40.3)	26.4 (44.1)	-0.14	19.7 (39.8)	25.1 (43.4)	13	18.8 (39)	24.1 (42.8)	-0.13
Number of Patie	ents at	t ESRD Facility	534,970	1,167,388	N/A	128,737	287,481	N/A	155,395	332,138	N/A	176,631	381,239	N/A
Hospital-Owned	d (%)		2.4 (15.4)	2.2 (14.8)	0.01	2.6 (15.8)	2.8 (16.5)	-0.01	2.3 (15)	2.5 (15.5)	01	2.4 (15.2)	2.7 (16.1)	-0.02
	DaVit	ta	38.2 (48.6)	41.4 (49.3)	-0.06	35.1 (47.7)	38.4 (48.7)	-0.07	36.0 (48.0)	38.6 (48.7)	05	35.8 (47.9)	38.0 (48.5)	-0.05
	Frese	enius	41.9 (49.3)	37.5 (48.4)	0.09	45.3 (49.8)	38.1 (48.6)	0.15	44.9 (49.8)	39.4 (48.9)	.11	45.5 (49.8)	39.9 (49)	0.11
Facility Chain/ Ownership (%)		pendent/NonC For-Profit	1.8 (13.2)	2.6 (15.9)	-0.06	1.6 (12.5)	3.3 (17.8)	-0.11	1.2 (10.9)	2.8 (16.6)	12	1.7 (12.8)	3.1 (17.4)	-0.10
	Othe	r For-Profit	10.7 (30.9)	8.6 (28.1)	0.07	9.8 (29.8)	8.9 (28.4)	0.03	10.7 (30.9)	8.9 (28.5)	.06	11.0 (31.3)	9.3 (29.1)	0.05
	Non-Profit		7.4 (26.2)	9.9 (29.9)	-0.09	8.1 (27.4)	11.3 (31.7)	-0.11	7.2 (25.9)	10.2 (30.3)	-0.11	6.1 (24)	9.6 (29.5)	-0.13
Me	Metr	0	84.1 (36.5)	86.3 (34.3)	-0.06	86.2 (34.5)	89.3 (30.9)	-0.10	85.3 (35.4)	88.3 (32.2)	-0.09	85.8 (34.9)	87.3 (33.3)	-0.04
Facility RUCC (%)		n	15.5 (36.2)	13.4 (34.0)	0.06	13.6 (34.2)	10.5 (30.6)	0.10	14.5 (35.2)	11.3 (31.7)	0.09	13.9 (34.6)	12.5 (33)	0.04
Rura		l T	0.4 (6.0)	0.3 (5.5)	0.01	0.3 (5.2)	0.2 (4.6)	0.01	0.2 (4.7)	0.4 (6.0)	-0.03	0.3 (5.3)	0.3 (5.2)	<0.01



Characteristic			Pre-ETC			CY 2021			CY 2022			CY 2023	
Characteristic		ETC	Comparison	SMD	ETC	Comparison	SMD	ETC	Comparison	SMD	ETC	Comparison	SMD
Medicare Shared Savings Program		99.7 (5.4)	99.5 (7.2)	0.04	99.6 (5.9)	99.5 (7.3)	0.03	99.7 (5.5)	99.4 (7.6)	0.04	99.9 (3.7)	99.4 (7.7)	0.08
APMs (%)	CEC	77.3 (41.9)	67.0 (47.0)	0.23*	79.9 (40.1)	68.3 (46.5)	0.27*	78.7 (41.0)	67.3 (46.9)	0.26*	76.8 (42.2)	65.4 (47.6)	0.25*
	NGACO	56.6 (49.6)	57.1 (49.5)	-0.01	58.0 (49.4)	60.6 (48.9)	-0.05	57.4 (49.5)	58.2 (49.3)	-0.02	56.1 (49.6)	56.9 (49.5)	-0.02
	al Percentage of ns with COVID-19	0 (0)	0 (0)		1.4 (1.0)	1.4 (1.0)	02	1.4 (1.2)	1.5 (1.1)	02	1.5 (1.2)	1.5 (1.2)	01
Key Demogra	y Demographics of Interest ¹		56.2 (23.1)	0.16	58.0 (20.9)	53.7 (23.7)	0.19	58.5 (20.6)	54.5 (23.2)	0.18	58.4 (20.4)	54.6 (22.8)	0.17
Dually Eligible Medicaid %	for Medicare and	46.5 (15.6)	48.5 (17.1)	-0.12	46.0 (15.5)	49.1 (17.7)	-0.18	46.1 (15.6)	48.4 (17.6)	-0.14 45 (15		47.9 (17.7)	-0.14

Notes: APMs = Alternative Payment Models; CEC = Comprehensive ESRD Care; CY = calendar year; ESRD = End-Stage Renal Disease; ETC = ESRD Treatment Choices; ICH CAHPS = In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems; NGACO = Next Generation ACO; RUCC = Rural-Urban Continuum Code; SMD = Standardized Mean Difference. Pre-ETC includes spring 2017-fall 2019 survey waves. CY 2021, CY 2022 and CY2023 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.



¹ Key demographics of interest were based on the University of Wisconsin's publicly available values (https://www.neighborhoodatlas.medicine.wisc.edu/).

Exhibit E-6. Annual Means (and Standard Errors) for Selected Characteristics of ESRD Facilities Used in ICH CAHPS Analyses

			Pre-ETC			CY 2021			CY 2022			CY 2023	
Characteristic	C	ETC	Comparison Group	SMD									
Number of Fa	acilities	4,421	9,273	N/A	1,129	2,401	N/A	1,341	2,754	N/A	1,440	2,998	N/A
Offer Home [Dialysis (%)	42.0 (49.4)	45.1 (49.8)	-0.06	44.8 (49.8)	47.0 (49.9)	-0.04	44.3 (49.7)	46.7 (49.9)	-0.05	45.6 (49.8)	46.6 (49.9)	-0.02
Average Age (Years)	of Patients	62.4 (3.7)	62.6 (3.7)	-0.06	62.5 (3.7)	62.7 (3.7)	-0.05	62.5 (3.7)	62.8 (3.7)	-0.08	62.7 (3.8)	62.9 (3.7)	-0.07
LIS patients (%)	53.5 (15.6)	55.2 (16.6)	-0.11	52.8 (15.6)	55.4 (17.0)	-0.16	52.7 (15.7)	54.8 (16.9)	-0.12	51.7 (15.6)	53.7 (17)	-0.12
MD	Facilities (%)	8.1	0.0	N/A	9.1	0.0	N/A	8.4	0.0	N/A	8.4	0.0	N/A
MD	Patients (%)*	4.3	0.0	N/A	5.5	0.0	N/A	4.6	0.0	N/A	4.6	0.0	N/A

Note: CY = calendar year; ESRD = End-Stage Renal Disease; ETC = ESRD Treatment Choices; ICH CAHPS = In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems; LIS = Low Income Subsidy; MD = Maryland; SMD = Standardized Mean Difference. Pre-ETC includes spring 2017-fall 2019 survey waves. CY 2021, CY 2022, and CY 2023 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 **Appendix B, 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 beginning in 2022)
- ESRD facility's average annual percentage of patient months with COVID-19 diagnosis
- Key demographics of interest related to the location of the ESRD facility
- Percentage of ESRD facility's patients who are dually eligible for Medicare and Medicaid
- 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

			Joint Test				
ICH CAHPS M	1easures	Spring 2017	Fall 2017	Spring 2018	Fall 2018	Fall 2019	p-value
	Rating of Kidney Doctors	0.24	0.21	0.03	-0.22	0.28	0.86
	Rating of Dialysis Center Staff	0.39	-0.11	-0.63	-0.28	-0.36	0.61
Patient	Rating of Dialysis Center	0.33	-0.04	-0.23	-0.32	0.15	0.74
Experience of Care	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

Note: DiD = Difference in Differences; ICH CAHPS = In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems. 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 three 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 (3,618) 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

		Performance	ΕΊ	r C	Compariso	n Group		Mod	el Estimates	5	% Relative
ICH CAHPS IV	H CAHPS Measures		Pre-ETC Mean	CY Mean	Pre-ETC Mean	CY Mean	DiD	p- value	Lower 90% CI	Upper 90% CI	% Relative Change
		CY 2021-23	59.4	58.9	60.6	59.9	0.15	0.72	-0.55	0.86	0.26
	Rating of	CY 2021	59.4	60.0	60.6	61.2	0.03	0.96	-0.82	0.87	0.04
	Kidney Doctors	CY 2022	59.4	58.3	60.6	59.5	0.07	0.89	-0.73	0.87	0.12
		CY 2023	59.4	58.5	60.6	59.4	0.32	0.56	-0.57	1.2	0.53
		CY 2021-23	62.5	63.6	62.9	63.9	0.18	0.66	-0.49	0.85	0.29
	Rating of Dialysis Center Staff	CY 2021	62.5	63.6	62.9	64.7	-0.65	0.18	-1.5	0.16	-1.04
		CY 2022	62.5	63.5	62.9	63.3	0.62	0.21	-0.19	1.4	1.0
		CY 2023	62.5	63.7	62.9	63.8	0.37	0.48	-0.49	1.2	0.59
	Rating of Dialysis Center	CY 2021-23	67.6	68.0	68.0	68.3	0.08	0.84	-0.62	0.79	0.13
		CY 2021	67.6	68.1	68.0	68.8	-0.29	0.55	-1.1	0.51	-0.43
		CY 2022	67.6	68.1	68.0	67.9	0.56	0.28	-0.29	1.4	0.82
Patient		CY 2023	67.6	67.9	68.0	68.4	-0.07	0.89	-0.95	0.80	-0.11
Experience of Care		CY 2021-23	67.2	66.7	67.7	66.8	0.45	0.19	-0.11	1.0	0.67
OI Care	Nephrologists'	CY 2021	67.2	67.1	67.7	67.5	0.19	0.61	-0.42	0.81	0.29
	Communicatio n and Caring	CY 2022	67.2	66.5	67.7	66.5	0.58	0.12	-0.04	1.2	0.87
	II allu Carilig	CY 2023	67.2	66.6	67.7	66.7	0.51	0.24	-0.21	1.2	0.75
	Quality of	CY 2021-23	62.5	63.2	62.9	63.5	0.18	0.53	-0.30	0.66	0.29
	Dialysis Center	CY 2021	62.5	63.0	62.9	63.6	-0.18	0.60	-0.74	0.38	-0.28
	Care and	CY 2022	62.5	63.2	62.9	63.0	0.57	0.10	0.00	1.1	0.91
	Operations	CY 2023	62.5	63.4	62.9	63.8	0.08	0.81	-0.48	0.64	0.13
		CY 2021-23	80.0	79.1	80.2	79.1	0.20	0.35	-0.15	0.55	0.25
	Providing	CY 2021	80.0	79.7	80.2	80.0	-0.01	0.96	-0.36	0.34	-0.01
	Information to	CY 2022	80.0	78.9	80.2	78.7	0.49	0.09	0.01	0.97	0.61
	Patients	CY 2023	80.0	78.8	80.2	79.0	0.09	0.73	-0.35	0.53	0.11

Note: CI = Confidence Interval; CY = calendar year; DiD = Difference in Differences; ETC = ESRD Treatment Choices; ICH CAHPS = In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems. Sample size = 44,829 facility-survey wave observations. Pre-ETC includes spring 2017-fall 2019 survey waves. Post-ETC includes spring 2021-fall 2023 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

		Dou's annual of	ET	С	Comparis	on Group		Model	Estimates		O/ Deletion
ICH CAHPS N	Measures	Performance - Year	Pre-ETC Mean	CY Mean	Pre-ETC Mean	CY Mean	DiD	p-value	Lower 90% CI	Upper 90% CI	% Relative Change
		CY 2021-23	59.4	58.8	60.8	60.1	0.13	0.77	-0.57	0.82	0.21
	Rating of Kidney	CY 2021	59.4	59.9	60.8	61.3	-0.01	0.98	-0.83	0.81	-0.02
	Doctors	CY 2022	59.4	58.4	60.8	59.5	0.18	0.72	-0.66	1.0	0.31
		CY 2023	59.4	58.4	60.8	59.6	0.18	0.75	-0.73	1.1	0.30
		CY 2021-23	62.4	63.5	62.9	63.9	0.13	0.75	-0.55	0.81	0.21
	Rating of Dialysis	CY 2021	62.4	63.3	62.9	64.5	-0.72	0.13	-1.5	0.07	-1.15
	Center Staff	CY 2022	62.4	63.4	62.9	63.5	0.42	0.41	-0.43	1.3	0.68
		CY 2023	62.4	63.9	62.9	63.9	0.53	0.31	-0.34	1.4	0.85
	Rating of Dialysis Center	CY 2021-23	67.5	67.8	68.0	68.2	0.06	0.89	-0.68	0.81	0.09
		CY 2021	67.5	67.7	68.0	68.6	-0.36	0.44	-1.1	0.42	-0.54
Button.		CY 2022	67.5	67.7	68.0	67.8	0.45	0.41	-0.45	1.4	0.67
Patient		CY 2023	67.5	67.8	68.0	68.3	0.03	0.96	-0.93	0.98	0.04
Experience of Care		CY 2021-23	67.2	66.6	67.8	66.9	0.38	0.27	-0.18	0.94	0.56
or care	Nephrologists' Communication	CY 2021	67.2	67.2	67.8	67.6	0.27	0.47	-0.34	0.87	0.40
	and Caring	CY 2022	67.2	66.4	67.8	66.5	0.52	0.19	-0.13	1.2	0.77
	and Caring	CY 2023	67.2	66.3	67.8	66.7	0.33	0.46	-0.40	1.1	0.49
	Quality of	CY 2021-23	62.4	63.0	62.9	63.5	0.09	0.75	-0.39	0.58	0.15
	Dialysis Center	CY 2021	62.4	62.8	62.9	63.6	-0.25	0.48	-0.82	0.33	-0.40
	Care and	CY 2022	62.4	63.0	62.9	63.1	0.46	0.19	-0.12	1.0	0.74
	Operations	CY 2023	62.4	63.3	62.9	63.8	0.01	0.98	-0.59	0.62	0.02
	Descriptions	CY 2021-23	80.1	79.2	80.4	79.2	0.28	0.20	-0.08	0.65	0.35
	Providing Information to	CY 2021	80.1	79.9	80.4	80.1	0.12	0.58	-0.24	0.49	0.15
	Patients	CY 2022	80.1	79.0	80.4	78.7	0.56	0.05	0.09	1.0	0.70
	Tatients	CY 2023	80.1	78.8	80.4	79.0	0.14	0.64	-0.35	0.62	0.17

Note: CI = Confidence Interval; CY = calendar year; DiD = Difference in Differences; ETC = ESRD Treatment Choices; ICH CAHPS = In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems. Sample size = 36,953 facility-survey wave observations among 3,618 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 2023 survey waves. Values reflected weighted adjusted measure values.



Appendix F: Home Dialysis Patient Experience Survey

F.1. The Home-DCE Survey Instrument

We fielded the Home Dialysis Care Experience (Home-DCE) survey to examine the impact of the ETC model on patient's experience with home dialysis. Developed in 2020 by researchers at the University of Washington,²² the Home-DCE survey is a validated instrument that captures ESRD patient experience with home dialysis. The 46-item survey is publicly available for use in clinical practice in both English and Spanish, and its care domains (captured in 26 survey questions) largely overlap with the ICH CAHPS instrument, including items that assess the quality of communication, concern, helpfulness, shared decision making, and overall rating of dialysis center staff. The survey developers also constructed measures from the survey instrument which were used in our analyses.²³ The Home-DCE also includes demographic questions, including language spoken at home, education, and presence of selected health conditions. We omitted the Home-DCE survey questions for age and sex since we were able to obtain the information from administrative data. We also added a question to identify potential patients for future interviews.

F.2. Sample Design

To construct our survey sample, we began with all patients aligned with the ETC treatment and comparison groups as of December 2022, which was the most current data available at the time of drawing the sample. As part of our contract with CMS, we are also examining the impact of the KCC model on patient's experience with home dialysis. We exploited the overlap in patients eligible for both models to obtain larger survey sample sizes, thereby increasing efficiency in our data collection. We restricted to all home dialysis patients (46,000) and then applied exclusion criteria informed by the Home-DCE survey developers shown in **Exhibit F-1**.²⁴

We randomly selected ETC treatment and comparison patients from an eligible pool of 18,941. Due to fewer than expected eligible KCC patients, we added preliminary Performance Year 2023 data to improve the eligible KCC pool for sampling and subsequently preserve the sample's power. The final distribution included 9,143 home dialysis patients (**Exhibit F-2**). The sample size was determined using a power analysis based on recent results from the ICH CAHPS to achieve 80% statistical power to detect a 5-percentage point difference between two proportions with a baseline rate of 60% top box scores.

For the KCC patients drawn from Performance Year 2023 preliminary data, their eligibility for ETC in 2023 was not able to be determined until June 2024 (i.e., after the survey fielding concluded). After applying the ETC eligibility criteria (see **Appendix B, Section B.2.**), we determined 677 of these patients were ineligible for the ETC Model and therefore excluded from the analysis.



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²² Rivara MB, Edwards T, Patrick D, Anderson L, Himmelfarb J, Mehrotra R. Development and Content Validity of a Patient-Reported Experience Measure for Home Dialysis. Clin J Am Soc Nephrol 2021;16(4):588-598.

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

Assessing Patient-Reported Experience of Care for Home Dialysis (ASPD) ClinicalTrials.gov identifier: NCT04435873. Updated December 2, 2021. Accessed May 2, 2023. https://www.clinicaltrials.gov/study/NCT04435873.

Exhibit F-1. Exclusion Criteria Applied to the Home Dialysis Patient Population

- Deceased as of November 21, 2023
- In both treatment and comparison groups of the same model in 2022
- Affiliated practice provides care for fewer than 3 patients in 2022
- Patient is < 18 years old as of December 31, 2022
- Patient was institutionalized as of December 31, 2022
- Patient was in hospice as of December 31, 2022
- Patient had a dementia diagnosis in the current or preceding 12 months
- Had incomplete contact information (e.g., missing name or address)
- Did not have a home dialysis claim June-September 2023

Exhibit F-2. Distribution of the ETC Home-DCE Patient Sample

	ETC Group	Comparison Group	Total
ETC status based on Performance Year 2022	3,633	4,752	8,385
ETC status based on Performance Year 2023	208	550	758
Total	3,841	5,302	9,143

Note: DCE = Dialysis Care Experience; ETC = ESRD Treatment Choices.

F.3. Fielding

We fielded the Home-DCE survey to a sample of home dialysis patients in the ETC and comparison areas (described above) from January through May 2024. The survey was administered over an 11-week period using a multi-modal approach – mail and phone, with phone follow-up initiated for non-respondents by interviewers trained on computer-assisted telephone interview (CATI) (**Exhibit F-3**). Materials were available in English and Spanish. We obtained patient addresses from Medicare administrative data. The first survey packet included a cover letter from CMS, a paper survey, and a prepaid return envelope. Patients who had not yet responded to the survey were resent the materials in week 4 followed by up to five call attempts in the final five weeks of the fielding period (i.e., weeks 7-11).

Exhibit F-3. Timeline for Fielding the Home-DCE Survey



F.4. Data Sources

We merged the survey data with patient-level data from the analytic file (described above) to obtain variables used in our analyses (e.g., patient sex and age; provider characteristics).



F.5. Study Sample

We used respondents' ETC attribution status as defined in the sampling frame (**Exhibit F-2**). We defined our study sample as respondents who self-reported in the survey that they dialyzed at home for at least 3 months and had completed at least one of the core survey questions that were used to generate the outcomes. Among the 3,654 respondents, 85.5% indicated they dialyzed at home for at least 3 months (N=3,126; 1,299 ETC group and 1,827 comparison group).

F.6. Description of Home Dialysis Patient Experience Survey Measures

We analyzed three patient experience measures constructed by the Home-DCE survey developers:²³ Global Rating of Dialysis Center; Global Rating of Dialysis Staff; and Quality of Home Dialysis Center Care and Operations. The two global rating measures are derived from a single Home-DCE survey question and reflect the percentage of patients who reported a "top box" score; i.e., nine or ten on a scale of one (worst) to 10 (best) (**Exhibit F-4**). The composite measure (Quality of Home Dialysis Center Care and Operations) is derived from twelve Home-DCE survey questions and reflects the percentage of patients who reported the most favorable response to the individual survey question (**Exhibit F-4**).

Exhibit F-4. Home-DCE Measures and their Corresponding Survey Questions

Measure		Home-DCE Question	Interpretation		
Global Measures	Rating of Dialysis Center	Q26: Using a number from 1 to 10, where 1 is the worst home dialysis center possible and 10 is the best home dialysis center possible, what number would you use to rate your current dialysis center?	This global measure reflects the percentage of patients who gave a score of 9 or 10 on a scale of 1 (worst possible) to 10 (best possible).		
	Rating of Dialysis Center Staff	Q17: Using a number from 1 to 10, where 1 is the worst home dialysis staff possible and 10 is the best home dialysis staff possible, what number would you use to rate your current dialysis staff?	This global measure reflects the percentage of patients who gave a score of 9 or 10 on a scale of 1 (worst possible) to 10 (best possible).		
		Q4: In the last 6 months, how often did the home dialysis staff listen carefully to you?			
	Quality of Dialysis Center Care and Operations	Q5: In the last 6 months, how often did the home dialysis staff explain things in a way that was easy for you to understand?			
Composite		Q6: In the last 6 months, how often did the home dialysis staff show respect for what you had to say?	The composite measure reflects the percentage of patients who provided the most favorable		
Measure		Q7: In the last 6 months, how often did the home dialysis staff spend enough time with you?	rating to nine of the twelve questions (Q4-Q12), "yes" to two questions (Q13, Q18), and		
		Q8: In the last 6 months, how often did you feel supported when you called the home dialysis staff for help?	"no" to one question (Q23)		
		Q9: In the last 6 months, if you asked for help from the home dialysis staff, how often did you get help as soon as you needed it?			



Measure		Home-DCE Question	Interpretation
Composite Quality of Dialysis Measure (cont.) Operations (cont.)		Q10: In the last 6 months, how often did you notice problems with communication among the home dialysis staff?	
	Q11: In the last 6 months, how often did the home dialysis staff and your kidney doctor work well together as a team?		
		Q12: In the last 6 months, how often were the home dialysis staff able to help you deal with problems that you encountered with your home dialysis?	The composite measure reflects the percentage of patients who provided the most favorable
		Q13: In the last 6 months, did the home dialysis staff talk to you about what you should eat and drink?	rating to nine of the twelve questions (Q4-Q12), "yes" to two questions (Q13, Q18), and "no" to one question (Q23)
		Q18: In the last 6 months, did the home dialysis staff and your kidney doctor make sure that your home dialysis treatment plan works for you?	
		Q23: In the last 6 months, were you ever unhappy with the care you received at the home dialysis center?	

Note: DCE = Dialysis Care Experience.

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

F.7. Analytic Methods

F.7.1. Assessing Balance on the Home-DCE Survey Sample

For SMDs, we used a threshold value of 0.2 to understand the extent of any difference between the ETC and comparison group. With few exceptions, the survey respondents are representative of the ETC home dialysis population eligible for the survey (**Exhibit F-5**). Survey respondents were slightly older and had been on home dialysis longer (i.e., SMDs were outside of the 0.2 threshold for both characteristics). These patterns were similar for the ETC and comparison groups. There were also fewer comparison patients from the Midwest compared to the ETC home dialysis population.



Exhibit F-5. Characteristics of Eligible Patients and Survey Respondents, by ETC Treatment and Comparison

Characteristic		ETC Population Eligible for the Home-DCE Survey		Survey Respondents			SMD			
		Total	ETC	Comparison	Total	ETC	Comparison	Total	ETC	Comparison
Number of h	ome dialysis patients	19,641	6,376	13,265	3,126	1,299	1,827	N/A	N/A	N/A
Beneficiary a	ige (average years)	61.4 (14.9)	61.0 (15.2)	61.7 (14.8)	64.5 (13.3)	64.7 (13.4)	64.3 (13.2)	-0.21*	-0.26*	-0.19
Female		42.6% (49.5%)	42.5% (49.4%)	42.7% (49.5%)	41.7% (49.2%)	41.9% (49.5%)	41.5% (49.1%)	0.02	0.01	0.02
Beneficiary d	lual eligibility	32.2% (46.7%)	32.4% (46.8%)	32.1% (46.7%)	30.5% (45.9%)	30.2% (46%)	30.6% (45.9%)	0.04	0.05	0.03
Beneficiary months on home dialysis		9.1 (3.8)	9.0 (3.8)	9.1 (3.8)	11.2 (2.0)	11.4 (1.8)	11.2 (2.1)	-0.70*	-0.76*	-0.67*
	Northeast	12.5% (33%)	14.2% (34.9%)	11.6% (32.1%)	18.2% (38.5%)	17.6% (38.2%)	18.4% (38.6%)	-0.16	-0.09	-0.19
Facility	South	43.3% (49.6%)	46.6% (49.9%)	41.8% (49.3%)	44.1% (49.6%)	47.6% (50.1%)	42.5% (49.3%)	-0.02	-0.02	-0.01
geographic location	Midwest	18.7% (39%)	17.7% (38.2%)	19.2% (39.4%)	10.8% (30.9%)	12% (32.6%)	10.2% (30.1%)	0.23*	0.16	0.26*
	West	25.5% (43.6%)	21.5% (41.1%)	27.4% (44.6%)	26.9% (44.3%)	22.7% (42%)	28.9% (45.2%)	-0.03	-0.03	-0.03
	Metro	88.4% (32%)	86.6% (34%)	89.3% (30.9%)	88.7% (31.6%)	86.4% (34.4%)	89.7% (30.3%)	-0.01	0.01	-0.01
Facility rurality	Urban	11.4% (31.8%)	13.2% (33.9%)	10.5% (30.7%)	11.3% (31.6%)	13.4% (34.1%)	10.3% (30.3%)	0.00	-0.01	0.01
	Rural	0.2% (4.4%)	0.2% (4.2%)	0.2% (4.4%)	0.1% (2.8%)	0.2% (4.9%)	0% (0%)	0.03	-0.01	0.06

Note: CATI = Computer assisted telephone interviewing; DCE = Dialysis Care Experience; ETC = ESRD Treatment Choices; SMD = Standardized mean difference. Standard deviations are included in parentheses below the means. Results for survey respondents are weighted. *Indicates SMD exceeds the 0.2 threshold, suggesting a meaningful difference between eligible population and survey respondents.



We also assessed balance of the patients included in the analyses by calculating SMDs between the ETC and comparison groups for characteristics used in the analyses (**Exhibit F-6**). While there was balance in most of the characteristics assessed, we observed that the ETC group had, on average, lower Medicare Advantage penetration and lower percentage of MSSP patients (i.e., SMDs were outside of the 0.2 threshold for these characteristics).

Exhibit F-6. Means (and Standard Deviations) for Covariates Used in the Home-DCE Analysis

Characteristic		ETC	Comparison	SMD*
N		1,299	1,827	N/A
	Age (average years)	65.7 (13.4)	65.3 (13.2)	.03
Patient Characteristics	Female	41.9% (49.5%)	41.5% (49.1%)	.01
	Beneficiary dual eligibility	30.2% (46%)	30.6% (45.9%)	01
Town of distorts	Peritoneal	72.5% (44.7%)	77% (42%)	10
Type of dialysis	Home dialysis	26.6% (44.3%)	22.5% (41.6%)	.10
	3 months - 1 year	3.1% (17.3%)	3.4% (17.9%)	02
Time on home dialysis	1-5 years	71.5% (45.2%)	75.8% (42.7%)	10
	More than 5 years	25.4% (43.6%)	20.8% (40.5%)	.11
Treated for high b	plood pressure	78.6% (41.1%)	76.8% (42.1%)	.04
Treated for diabe	tes	40.4% (49.2%)	- ()	
Treated for heart	problems	39.6% (49%)	41.5% (49.1%)	04
Difficulty hearing	/deaf	14.9% (35.7%)	16.5% (37%)	04
Difficulty seeing/	olind	8.7% (28.3%)	10.7% (30.8%)	07
Difficulty concent	rating	11.4% (31.9%)	9.1% (28.6%)	.08
Difficulty dressing	g/bathing	13.1% (33.8%)	14.9% (35.5%)	05
	Less than high school	10.2% (30.4%)	9% (28.5%)	.04
	High school graduate or GED	28.8% (45.4%)	27.3% (44.4%)	.03
Education	Some college or 2-year degree	30.8% (46.3%)	32.7% (46.7%)	04
	4-year college graduate	12.1% (32.7%)	13.8% (34.3%)	05
	More than 4-year college degree	14.1% (34.9%)	14.1% (34.7%)	.00
	Missing	4% (19.6%)	3.1% (17.3%)	.05



Characteristic			ETC	Comparison	SMD*	
	e itali		87.5%	82.5%		
	English		(33.2%)	(37.9%)	.14	
	Chanich		3.7%	6.5%	13	
Language	Spanish		(18.9%)	(24.6%)	15	
spoken at home	Other		3.3%	5.1%	09	
	Other		(17.9%)	(21.9%)	09	
	Missing		5.5%	5.9%	02	
	1411331118		(22.9%)	(23.6%)	.02	
Received help cor	mpleting surv	ey	17.1%	20.6%	09	
			(37.7%) 92.4%	(40.3%) 93%		
	Paper		(26.6%)	(25.4%)	02	
Survey mode			7.6%	7%		
	CATI		(26.6%)	(25.4%)	.02	
			17.6%	18.4%	0.0	
		Northeast	(38.2%)	(38.6%)	02	
		South	47.6%	42.5%	.10	
	Census	South	(50.1%)	(49.3%)	.10	
	region	Midwest	12%	10.2%	.06	
		Midwest	(32.6%)	(30.1%)	.00	
		West	22.7%	28.9%	14	
	11000		(42%)	(45.2%)		
	Facility size	(Number of patients at facility)	98.8	98.8	001	
			(49.9)	(54.2)		
	Facility Rurality	Metro	86.4% (34.4%)	89.7% (30.3%)	10	
			13.4%	10.3%		
		Urban	(34.1%)	(30.3%)	.10	
			0.2%	0%	07	
		Rural	(4.9%)	(0%)	.07	
		Chain: DaVita	34.9%	38.2%	07	
		Cildiii. Davita	(47.8%)	(48.4%)	07	
Facility/Market		Chain: FMC	44.3%	37.1%	.15	
Characteristics	Facility		(49.8%)	(48.1%)	.13	
	Chain/	Chain: Independent/non chain	2.6%	3.4%	04	
	Ownership	for-profit	(16%)	(17.9%)	.07	
	Ownership	Chain: Other for-profit	9.5%	9.4%	.01	
		Chain. Other for-profit	(29.4%)	(29%)	.01	
		Chain: Non-profit	8.7%	11.9%	10	
		1	(28.3%)	(32.3%)		
	Hospital-ow	ned	2.9%	2.4%	.03	
			(16.7%) 11.7%	(15.2%) 12.3%		
	COVID indica	ator	(32.2%)	(32.7%)	02	
			33.7%	38.3%	22.5	
MA penetration			(15%)	(13.2%)	32*	
	MSSP			23.9%	20*	
	IVISSP		(36.8%)	(42.5%)	20	
	Key demogr	aphics of interest ¹	49.7	45.6	.15	
	Key delllogi	apmes of interest	(28.1)	(28.5)	.10	
	48.6%	39.2%	.19			
	KCC particip	none interviewing: DCE = Dialysis Care Ev	(50.1%)	(48.6%)	. 61 .	

Note: CATI = Computer assisted telephone interviewing; DCE = Dialysis Care Experience; ETC = ESRD Treatment Choices; FMC = Fresenius Kidney Care; KCC = Kidney Care Choices Model; MA = Medicare Advantage; MSSP = Medicare Shared Savings Program; SMD = Standardized mean difference. COVID reflects the share of patients who, as of December 2023, had a COVID diagnosis in the past 12 months. Results are weighted. ¹Key demographics of interest were based on the



University of Wisconsin's publicly available values (https://www.neighborhoodatlas.medicine.wisc.edu/).

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

F.7.2. Regression to Assess the Impact of ETC on Patient Experience with Home Dialysis

We used linear regression to assess the experience of home dialysis patients in the ETC Model with the three outcomes (<u>Exhibit F-4</u>) compared to home dialysis patients in the comparison group. We adjusted for the covariates listed in <u>Exhibit F-6</u> to control for potential differences in ETC and comparison group (see <u>Appendix B, Section B.1.</u> for additional information about how the covariates were derived).

Observations are weighted to reflect the probability of selection by treatment group (i.e., ETC vs. comparison) into the survey sample and adjusted for the different nonresponse propensities to compensate for potential nonresponse bias. Post-stratification adjustments by region, sex, and dual eligibility were also applied that ensured the weights summed to population totals. Similar to the other analyses in this report, we clustered standard errors at the HRR level. We performed the regression analysis on all observations with non-missing outcome values for each of the three outcome measures. "Missing" responses included patients who had not responded to the survey question, responded "don't know" or refused to answer, or had duplicate responses.

F.7.3. Regression Findings and Sensitivity Analyses

As noted in the main report, we found no impact of the ETC Model on the three patient experience of care measures derived from the Home-DCE survey. We also conducted sensitivity analyses to assess the robustness of our findings, including restricting to survey respondents who were aligned with the ETC treatment and comparison groups as of December 2022 only (i.e., excluding patients aligned to the ETC Model in 2023 only but were included in the survey sample as part of the supplemental KCC Performance Year 2023 data to bolster the KCC sample [see

Section F.1. The Home-DCE Survey Instrument]). Secondly, instead of using Performance Year 2022 (i.e., what was current at the time the sample was pulled) to define the treatment group status (i.e., ETC or comparison), we instead used ETC status in 2023 for all respondents (i.e., the most recent treatment status at the time of fielding the survey). Findings for both sensitivity analyses were similar to our main results (Exhibit F-7).



Exhibit F-7. Sensitivity Analysis: Impact of the ETC Model on the Home-DCE Measures

Measures	Model Estimate	p- value	Lower 90% CI	Upper 90% CI	
Panel 1: restricting to	Rating of Dialysis Center Staff	1.5%	0.29	-0.83%	3.9%
patients aligned with the model (i.e., ETC treatment	Rating of Dialysis Center	2.2%	0.16	-0.36%	4.8%
or comparison group) in Payment Year 2022	Quality of Home Dialysis Center Care and Operations	0.22%	0.81	-1.3%	1.8%
Panel 2: used ETC status in 2023 to define treatment group (i.e., ETC or	Rating of Dialysis Center Staff	2.0%	0.17	-0.41%	4.3%
	Rating of Dialysis Center	2.2%	0.14	-0.28%	4.7%
comparison) for all respondents	Quality of Home Dialysis Center Care and Operations	0.04%	0.96	-1.5%	1.6%

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



Appendix G: Patient Quality of Life Survey

G.1. The PROMIS-29 Survey Instrument

To assess whether the ETC Model affects patient quality of life (QoL), we fielded the PROMIS-29 survey, which has been validated in several chronic disease patient populations and captures seven primary domains of health-related QoL.²⁶ The PROMIS-29 survey instrument is a collection of short-form items used to assess eight outcomes (seven domains and one global scale for pain intensity) of health-related QoL:

- 1. Physical function
- 2. Anxiety
- 3. Depression
- 4. Fatigue
- 5. Sleep disturbance
- 6. Ability to participate in social roles and activities
- 7. Pain interference
- 8. Pain intensity

All outcomes assess health-related QoL in the past seven days with the exception of the physical function domain, which is not timeframe specific. Four questions are included in each of the seven domains, whereas the Pain intensity measure is a single, global scale from 0 to 10. Lower scores are interpreted as being better for all measures except physical function and ability to participate in social activities.

G.2. Sample Design

To construct our survey sample, we first identified in-center hemodialysis patients, home dialysis patients, and transplant recipients in the ETC treatment and comparison group areas as of December 2022, which was the most current data available at the time of drawing the survey sample. We then applied the set of restrictions shown in **Exhibit G-1**.

Exhibit G-1 Exclusion Criteria Applied to the Patient QoL Analysis Sample

- Deceased as of December 31, 2023
- In both treatment and comparison groups of the same model in 2022
- Patient had a dementia diagnosis in the current or preceding 12 months
- Had incomplete contact information (e.g., missing name or address)
- Had a dialysis claim after transplant
- Ineligible for ETC in December 2022

²⁶ The PROMIS-29 survey instrument



G-1

After applying these exclusion criteria, we randomly selected patients for the survey sample. As part of our contract with CMS, we are also examining the impact of the KCC model on patient's quality of life. We exploited the overlap in patients eligible for both models to obtain larger survey sample sizes, thereby increasing efficiency in our data collection. Given the relatively large and geographically diverse patient population in the selected ETC Model areas, the eligible pool of ETC patients had considerable overlap with transplant and dialysis patients eligible for the KCC patient QoL survey sample such that we were able to survey additional patients from the remaining pool of eligible patients, with a final survey sample size of 13,162 (Exhibit G-2).

Exhibit G-2. Patient QoL Survey Sample for the ETC Model

Modality	ETC	Comparison	Total
In-center HD	2,212	1,907	4,119
Home dialysis	2,551	2,072	4,623
Transplant	2,481	1,939	4,420
Total	7,244	5,918	13,162

Note: ETC = ESRD Treatment Choices.

G.3. Fielding

We fielded the PROMIS-29 survey to a sample of patients in the ETC and comparison areas (described above) from March through June 2024. The survey was administered over an 11-week period using a multi-mode approach that included mail and phone, with phone follow-up initiated for non-respondents by interviewers trained on computer-assisted telephone interview (CATI) (**Exhibit G-3**). Materials were available in English and Spanish. We obtained patient addresses from Medicare administrative data. The first survey packet included a cover letter from CMS, a paper survey, and a prepaid return envelope. Patients who had not yet responded to the survey were resent the materials in week 4 followed by up to five call attempts in the final five weeks of the fielding period (i.e., weeks 7-11).

Exhibit G-3. Timeline for Fielding the QoL Survey

Week 0	Week 1		Week 2		Week 4	/	Weeks 7-11	
Pre-notification	> First survey	->	Reminder		Second		Telephone	
letter /	packet		postcard	/	survey packet	/	follow up	

G.4. Data Sources

We merged the survey data with patient-level data from the analytic file (described above) to obtain additional variables used in our analyses (e.g., patient sex and age; provider characteristics).

G.5. Study Sample

We defined our sample as survey respondents who were eligible for either the ETC Model treatment group or comparison group as of December 2022 and had a Medicare FFS claim in 2022 for in-center HD, home dialysis, or a transplant. Overall, the response rate among the 13,162 patients surveyed was 26.4% (N=3,471). Response rates were slightly higher for ETC



patients than comparison patients, a pattern that was similar across the three modality types (**Exhibit G-4**).²⁷

Exhibit G-4. Patient QoL Survey Response Rate

Modality	Respondents file			Response Rate			
iviouality	ETC	Comparison	Total	ETC	Comparison	Total	
Home Dialysis	534	607	1,141	31.8%	24.1%	27.7%	
In-Center HD	517	650	1,167	31.4%	20.3%	25.2%	
Transplant	515	648	1,163	33.4%	20.8%	26.3%	
Total	1,566	1,905	3,471	32.2%	21.6%	26.4%	

Note: ETC = ESRD Treatment Choices; QoL = Quality of life.

G.6. Description and Scoring of PROMIS-29 Survey Measures

Responses to the PROMIS-29 survey instrument were scored using the HealthMeasures Scoring Service, which uses response pattern scoring and yields more precise T-scores versus manual scoring. ²⁸ In response pattern scoring, a survey participant can choose to skip questions and still receive a score. The raw survey scores are converted into a T-score (M=50, SD=10); T-scores above 60 indicate above-average health-related QoL whereas T-scores below 40 indicate poor health-related QoL, compared to the average score for respondents in the reference population of US adults.

For each of the three patient modalities, patient-level T-scores for each domain were summed and then averaged for the respective ETC treatment and comparison groups. For comparisons of T-scores between ETC and comparison groups, we used a threshold of 3 points to assess a clinically meaningful difference, a threshold that PROMIS has indicated is applicable for most contexts.²⁹

To supplement the extant Medicare enrollment data we added several demographic questions at the end of the PROMIS-29 survey instrument, such as:

- Is someone helping to complete the survey? (with sub-questions)
- What is the highest grade or level of school that you have completed?
- Do you have a care partner that we may contact for future interviews?

²⁹ https://www.healthmeasures.net/score-and-interpret/interpret-scores/promis/meaningful-change



G-3

Given the 15-month lag between data used to define the sample and fielding the survey, we examined the concordance of modality type for each respondent between 2022 (i.e., when the sample was defined) and the last quarter of 2023 (the most recent data available). Overall, most respondents' modality did not change over the 12-month period. For example, 88% of respondents in the home dialysis group had a claim for home dialysis in the last quarter of 2023, and 99% of in-center dialysis respondents had a claim for in-center dialysis in the most recent quarter (not shown).

https://www.healthmeasures.net/explore-measurement-systems/promis

G.7. Analytic Methods

G.7.1. Assessing Balance of the Patient QoL Survey Sample

For SMDs, we used a threshold value of 0.2 to understand the extent of any difference between the ETC and comparison group. Survey respondents were older on average than the ETC population (i.e., SMDs were outside of the 0.2 threshold for both ETC and comparison groups). Otherwise, the survey respondents are representative of the underlying ETC population eligible for the survey (**Exhibit G-5**).



Exhibit G-5. Characteristics of Eligible Patients and Survey Respondents, by ETC Treatment and Comparison

Characteristic		ETC Pop	ulation Eli QoL Surv	gible for the ey	Survey respondents		SMD			
		Total	ETC	Comparison	Total	ETC	Comparison	Total	ETC	Comparison
Number of P	atients	176,023	58,990	117,033	13,162	5,918	7,244	N/A	N/A	N/A
Dialysis	Home Dialysis	15.2% (35.9%)	14.9% (35.6%)	15.4% (36.1%)	20.0% (40.0%)	18.3% (38.7%)	21.3% (41.0%)	-0.12	-0.09	-0.15
Modality	In-Center HD	80.1% (40.0%)	80.3% (39.8%)	79.9% (40.0%)	76.0% (42.7%)	77.2% (42.0%)	75.1% (43.3%)	0.10	0.08	0.12
Transplant		4.6% (21.0%)	4.7% (21.2%)	4.6% (20.9%)	4.0% (19.6%)	4.5% (20.7%)	3.6% (18.7%)	0.03	0.01	0.05
Beneficiary A	Age (average years)	61.6 (14.4)	61.5 (14.4)	61.7 (14.4)	65.0 (13.0)	64.9 (12.9)	65.1 (13.0)	25*	-0.25*	-0.25*
Female		42.0% (49.4%)	42.2% (49.4%)	41.9% (49.3%)	43.1% (49.5%)	42.1% (49.4%)	43.9% (49.6%)	-0.02	0.00	-0.04
Beneficiary o	dual eligibility	49.0% (50.0%)	47.5% (49.9%)	49.7% (50.0%)	43.4% (49.6%)	43.7% (49.6%)	43.0% (49.5%)	0.11	0.08	0.13
	Northeast	15.4% (36.1%)	17.3% (37.9%)	14.4% (35.1%)	16.8% (37.3%)	15.1% (35.8%)	18.1% (38.5%)	-0.04	0.06	-0.10
Facility	South	43.4% (49.6%)	47.0% (49.9%)	41.6% (49.3%)	44.6% (49.7%)	50.4% (50.0%)	39.8% (49.0%)	-0.02	-0.07	0.04
geographic location	Midwest	17.0% (37.6%)	15.1% (35.8%)	18.0% (38.4%)	14.7% (35.4%)	13.8% (34.5%)	15.4% (36.1%)	0.06	0.04	0.07
	West	24.2% (42.8%)	20.5% (40.4%)	26.0% (43.9%)	23.8% (42.6%)	20.3% (40.3%)	26.6% (44.2%)	0.01	0.00	-0.01
Facility rurality	Metro	86.9% (33.7%)	85.6% (35.1%)	87.6% (33.0%)	86.8% (33.8%)	85.5% (35.2%)	87.9% (32.7%)	0.00	0.00	-0.01
	Urban	12.7% (33.3%)	14.1% (34.8%)	12.0% (32.5%)	12.5% (33.1%)	13.8% (34.5%)	11.4% (31.8%)	0.01	0.01	0.02
	Rural	0.35% (5.9%)	0.30% (5.5%)	0.38% (6.1%)	0.45% (6.7%)	0.25% (5.0%)	0.62% (7.85%)	-0.02	0.01	-0.03

Note: ETC = ESRD Treatment Choices; SMD = Standardized Mean Difference. Standard deviations are included in parentheses below the means. Results for survey respondents are weighted. * Indicates SMD exceeds the 0.2 threshold, suggesting a meaningful difference between the survey sample and respondents.



We also assessed balance between the ETC and comparison groups of survey respondents by calculating SMDs for patient and facility characteristics (**Exhibit G-6**). While there was balance in most of the characteristics assessed, we observed that the ETC group had, on average, lower Medicare Advantage penetration, a lower percentage of MSSP patients, and a higher percentage of KCC participants (i.e., SMDs were outside of the 0.2 threshold for these characteristics).

Exhibit G-6. Means (and Standard Deviations) for Covariates Used in the Patient QoL Analysis

Characteristics			Total	ETC	Comparison	SMD
N			3,471	1,566	1,905	N/A
	Home Dialysis		20.0% (40.0%)	18.3% (38.7%)	21.3% (41.0%)	-0.08
	In-Center HD		76.0% (42.7%)	77.2% (42.0%)	75.1% (43.3%)	0.05
Dialysis	Transplant	4.0% (19.6%)	4.5% (20.7%)	3.6% (18.7%)	0.04	
Modality	Age (average years	Age (average years)			65.1 (13.0)	-0.01
	Female		43.1% (49.5%)	42.1% (49.4%)	43.9% (49.6%)	-0.04
	Beneficiary dual eli	43.4% (49.6%)	43.7% (49.6%)	43.0% (49.5%)	0.01	
	High school or less		48.2% (50.0%)	46.8% (49.9%)	49.4% (50.0%)	-0.05
	Some college or 2-	28.9% (45.3%)	29.5% (45.6%)	28.4% (45.1%)	0.02	
Education	4-year college grad	11.6% (32.0%)	12.4% (33.0%)	11.0% (31.2%)	0.05	
	More than 4-year o	8.0% (27.2%)	8.2% (27.4%)	7.9% (27.0%)	0.01	
	Missing	3.2% (17.7%)	3.1% (17.3%)	3.4% (18.1%)	-0.02	
Mode type	CATI		6.3% (24.3%)	6.7% (25.1%)	6.0% (23.7%)	0.03
would type	Mail		93.7% (24.3%)	93.3% (25.1%)	94.0% (23.7%)	-0.03
		Northeast	16.8% (37.3%)	15.1% (35.8%)	18.1% (38.5%)	-0.08
Provider Characteristics	Census region	South	44.6% (49.7%)	50.4% (50.0%)	39.8% (49.0%)	0.21*
	Census region	Midwest	23.8% (42.6%)	20.3% (40.3%)	26.6% (44.2%)	-0.15
		West	14.7% (35.4%)	13.8% (34.5%)	15.4% (36.1%)	-0.05
	Facility size (Number of patients at facility)		92.9 (52.0)	91.6 (48.2)	93.9 (54.9)	-0.05



Characteristics			Total	ETC	Comparison	SMD	
		Metro	86.8% (33.8%)	85.5% (35.2%)	87.9% (32.7%)	-0.07	
	Facility rurality	Urban	12.5% (33.1%)	13.8% (34.5%)	11.4% (31.8%)	0.07	
		Rural	0.5% (6.7%)	0.3% (5.0%)	0.6% (7.8%)	-0.06	
		Chain: DaVita	36.7% (48.2%)	35.4% (47.8%)	37.9% (48.5%)	-0.05	
		Chain: FMC	40.1% (49.0%)	45.7% (49.8%)	35.5% (47.9%)	0.21*	
Provider Characteristics	Facility Chain/ Ownership		Chain: Independent/ non-chain for-profit	3.0% (17.1%)	2.0% (14.1%)	3.8% (19.2%)	-0.11
		Chain: Other for-profit	10.0% (30.0%)	11.2% (31.5%)	9.0% (28.6%)	0.07	
(cont.)		Chain: Non-profit	9.9% (29.9%)	5.3% (22.3%)	13.7% (34.4%)	-0.29*	
		Hospital-owned	3.7% (19.0%)	2.8% (16.4%)	4.5% (20.8%)	-0.09	
	COVID indica	ator	9.5% (29.3%)	12.1% (32.6%)	7.4% (26.1%)	0.16	
	MA penetrat	tion	36.0% (13.9%)	es8% (14.4%)	37.8% (13.2%)	-0.29*	
	MSSP		17.5% (38.0%)	12.6% (33.2%)	21.5% (41.1%)	-0.24*	
	Key demographics of interest ¹		48.6 (29.7)	49.9 (29.7)	47.5 (29.7)	0.08	
	KCC participa	ation	30.1% (45.9%)	37.0% (48.3%)	24.5% (43.0%)	0.27*	

Note: CATI = Computer assisted telephone interviewing; ETC = ESRD Treatment Choices; FMC = Fresenius Kidney Care; KCC = Kidney Care Choices; MA = Medicare Advantage; MSSP = Medicare Shared Savings Program; QoL = Quality of life; SMD = Standardized Mean Difference. COVID reflects the share of patients who, as of December 2023, had a COVID diagnosis in the past 12 months. Results are weighted.

G.7.2. Regression Analysis to Assess the Impact of the ETC Model on Patient OoL

We used linear regression to assess the potential impact of the ETC Model on patient QoL on each of the eight outcomes from the PROMIS-29 survey, overall and by the three ESRD modalities. We adjusted for the covariates listed in **Exhibit G-6** to control for potential differences between the ETC and comparison groups (see **Appendix B, Section B.1.** for additional information about how the covariates were derived). Treatment group status (i.e., ETC or comparison) was defined using 2022 data (i.e., what was current at the time the sample was pulled).

Observations are weighted to reflect the probability of selection by treatment group (i.e., ETC vs. comparison) into the survey sample and adjusted for the different nonresponse propensities to compensate for potential nonresponse bias. Post-stratification adjustments by region, sex, and dual eligibility were also applied that ensured the weights summed to population totals. Similar to the



¹ Key demographics of interest were based on the University of Wisconsin's publicly available values (https://www.neighborhoodatlas.medicine.wisc.edu/).

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

other analyses in this report, we clustered standard errors at the HRR level. We performed the regression analysis on all observations with non-missing outcome values for each of the eight outcome measures. "Missing" responses included patients who had not responded, responded "don't know" or refused to answer, or had duplicate responses to all of the questions for a given outcome.

G.7.3. Regression Analysis Findings

As noted in the main report, overall, we found no clinically meaningful differences between the ETC and comparison groups in the eight patient QoL measures derived from the PROMIS-29 survey. Similar to the overall results, there were no clinically meaningful differences by modality (**Exhibit G-7**). Regression results for home dialysis patients show no statistically significant difference for any of the outcomes (**Exhibit G-7**). For in-center HD patients and transplant recipients, we observed statistically significant but not clinically meaningful (i.e., less than a 3-point threshold) differences in the physical function and sleep disturbance measures, respectively (**Exhibit G-8** and **Exhibit G-9**).

Exhibit G-7. Impact of the ETC Model on Patient QoL: Home Dialysis Patients

Outcome	Model Estimate	p-value	Lower 90% CI	Upper 90% CI
Physical function	0.78	0.43	-0.83	2.4
Anxiety	0.34	0.74	-1.3	2.0
Depression	0.37	0.69	-1.2	1.9
Fatigue	-0.17	0.86	-1.8	1.5
Sleep Disturbance	0.66	0.53	-1.1	2.4
Social Activities	0.29	0.76	-1.3	1.9
Pain Interference	-1.1	0.29	-2.9	0.61
Pain Intensity	-0.26	0.37	-0.74	0.22

Note: CI = Confidence interval; ETC = ESRD Treatment Choices; QoL = Quality of life. Results are weighted. Model estimates were adjusted for patient, facility, and market characteristics. Analyses were performed at the patient level. All rows except pain intensity are T-scores scaled to have a mean of 50 and a standard deviation of 10 for the reference population. Pain intensity was rated on a scale from 0 to 10, with 10 being the worst.

Exhibit G-8. Impact of the ETC Model on Patient QoL: In-center Hemodialysis Patients

Outcome	Model Estimate	p-value	Lower 90% CI	Upper 90% CI
Physical function	-1.7	0.004	-2.6	-0.73
Anxiety	-0.01	0.99	-1.2	1.1
Depression	0.27	0.69	-0.86	1.4
Fatigue	0.89	0.18	-0.2	2.0
Sleep Disturbance	-0.51	0.46	-1.7	0.63
Social Activities	-0.71	0.28	-1.8	0.37
Pain Interference	-0.20	0.78	-1.4	1.0
Pain Intensity	-0.23	0.34	-0.62	0.16

Note: CI = Confidence interval; ETC = ESRD Treatment Choices; QoL = Quality of life. Results are weighted. Model estimates were adjusted for patient, facility, and market characteristics. Analyses were performed at the patient level. All rows except



pain intensity are T-scores scaled to have a mean of 50 and a standard deviation of 10 for the reference population. Pain intensity was rated on a scale from 0 to 10, with 10 being the worst.

Exhibit G-9. Impact of the ETC Model on Patient QoL: Transplant Recipients

Outcome	Model Estimate	p-value	Lower 90% Cl	Upper 90% Cl
Physical function	0.19	0.77	-0.89	1.3
Anxiety	1.2	0.16	-0.19	2.5
Depression	0.80	0.25	-0.35	2.0
Fatigue	0.12	0.86	-1.0	1.3
Sleep Disturbance	1.7	0.03	0.40	3.0
Social Activities	-0.36	0.60	-1.5	0.80
Pain Interference	0.15	0.82	-0.94	1.2
Pain Intensity	-0.37	0.16	-0.81	0.07

Note: CI = Confidence interval; ETC = ESRD Treatment Choices; QoL = Quality of life. Results are weighted. Model estimates were adjusted for patient, facility, and market characteristics. Analyses were performed at the patient level. All rows except pain intensity are T-scores scaled to have a mean of 50 and a standard deviation of 10 for the reference population. Pain intensity was rated on a scale from 0 to 10, with 10 being the worst.

We also conducted three sensitivity analyses to assess the robustness of our findings, including 1) an unadjusted model, and 2) a more parsimonious model that controlled for provider characteristics only. Additionally, for our third sensitivity analysis, instead of using 2022 data to define the treatment group status, we instead used ETC status in 2023 (i.e., the most recent treatment status at the time of the survey fielding the survey). Findings for all three sensitivity analyses were similar to our main findings overall and by modality (not shown).



Appendix H: Case Studies of Patient Access to Care

H.1. Case Study Area Selection

For the case studies, we initially selected two rural counties in Mississippi, two rural counties in Georgia, and two urban counties (Washington, D.C., and San Diego, California) that include a disproportionately high percentage of dually eligible patients. To identify these candidates, we considered the rural/urban composition of counties (for example, largely urban or largely rural population) based on the classification of census tracts within each county. We classified counties with a Rural-Urban Continuum Code (RUCC) of 1–2 as urban and 5–9 as rural. RUCC are used to classify counties based on their degree of urbanization and proximity to metropolitan areas. Within each of these categories, we selected one county with a high proportion of ETC participants (both End-Stage Renal Disease (ESRD) facilities and Managing Clinicians) consistently performing poorly during the first 2 years of the model and a county with a high proportion of participants consistently performing well. To measure performance, we considered rates of home dialysis use, waitlisting, and living donor transplants.

Due to recruitment challenges, we expanded case study area selection beyond the originally selected counties. Among rural Managing Clinicians and ESRD facility participants, we expanded recruitment to providers located in rural counties that were within two counties of the original Georgia and Mississippi case study counties. We expanded patient recruitment to patients located in urban and rural counties nationwide. Thus, our provider case studies continued to be geographically bound, but our patient case studies were ultimately demographically bound. Please see **Exhibit H-1** for more detail on market-level characteristics in our four provider case study areas. Given that there are fewer potential ESRD facilities and Managing Clinicians in rural areas than in urban areas, we have not specified the specific county names to protect participant anonymity in rural areas. See **Appendix H, Section H.2.** for more detail on the characteristics of the specific patients and providers in our sample.



Exhibit H-1. Provider Case Study Area Characteristics: Patient, Facility, and Market Characteristics and Patient Outcomes

Case Study Area	Characteristics			San Diego, CA	Washington, DC	GA counties*	MS counties*
	Age, Continuous (Years)				61.5	60.2	57.2
	Duration of ESR	D (Yea	irs)	5.8	7.0	4.4	5.4
	Female (%)			42.9	43.5	43.5	48.2
	Dual Medicare/	Medic	aid Enrollment (Full Benefits) (%)	64.1	53.2	34.9	40.2
Patient	Part D Low Inco	me Su	bsidy (Where Enrolled in Part D Benefits) (%)	64.6	73.8	56.1	65.0
Characteristics			Not under Care of Nephrologist prior to ESRD	15.6	20.0	16.4	24.3
	Patient-Months		Unknown Whether under Care of Nephrologist	18.5	29.3	16.3	17.9
	under Care of Nephrologist pri	ior to	< 6 Months under Care	16.3	17.6	27.2	12.6
	ESRD Therapy (%		6-<12 Months under Care	23.0	18.6	19.4	29.1
			12 Months or Longer under Care	26.7	14.5	20.8	16.1
	Facility Chain/ Ownership (%)	Larg	e Dialysis Organization (Fresenius Medical Care, DaVita)	75.6	85.7	40.0	100.0
		Inde	Independent/Non-Chain For-Profit		0.0	20.0	0.0
Facility Characteristics		Othe	er For-Profit	4.9	0.0	0.0	0.0
Characteristics		Non	profit	9.8	14.3	40.0	0.0
	Fac		ity Size	20.3	19.1	16.2	27.0
	Key Demographics of Interest ¹			20.2	24.3	87.1	90.9
Market	Poverty			10.0%	13.5%	21.3%	21.0%
Characteristics	Persons > 25 Yea	ars Old	d with Less Than High School Diploma	9.8%	7.8%	11.7%	11.8%
	Medicare Advantage Penetration			49.0	20.4	42.1	16.9
Bullion I	Home Dialysis (9	Home Dialysis (%)			10.2	28.1	13.7
Patient Outcomes	Overall Waitlisti	ing (%)		21.4	12.9	12.0	8.4
odtcomes	Living Donor Tra	nspla	nt (per 1000 patient months)	0.91	0.13	0.0	0.0

Note: ESRD = End-Stage Renal Disease. See Exhibit B-2 for data sources to obtain information on patient, facility, and market characteristics and patient outcomes.



¹ Key demographics of interest were based on the University of Wisconsin's publicly available values (https://www.neighborhoodatlas.medicine.wisc.edu/).

H.2. Sample Selection

Patients. We selected patients who were dually eligible for Medicare and Medicaid and/or Part D LIS recipients associated with ETC Model Participants in either urban or rural counties nationwide.

Managing Clinicians. We selected clinicians in each rural and urban county who are participants in the ETC Model and whose contact information was available via the Innovation Center's 4innovation (4i) web platform. We restricted the sample to those who provided service to at least five patients monthly on average. We used Medicare claims data to assess how many Medicare FFS patients were served. We identified practices serving a disproportionately high percentage of dually eligible patients and prioritized them for recruitment. Recognizing that Managing Clinicians may serve patients in more than one county, particularly in rural areas, Managing Clinicians did not need to primarily work or reside in the case study counties themselves but needed to see patients who sought care at ESRD facilities in those counties.

ESRD Facility Staff. We selected facilities in each rural and urban county with a high percentage of dually eligible patients served, based on tertiles of ETC Model Participants. We also restricted the sample to those who provided service to at least five Medicare FFS patients monthly on average.

H.3. Recruitment

Patients. We primarily recruited patients via phone and email using contact information from the ETC and KCC home dialysis patient experience survey, which was fielded January –April 2024 and the ETC and KCC patient quality of life surveys fielded in March–June 2024. Each survey included a question asking whether individuals were willing to be contacted about participating in other evaluation activities. We limited the number of outreach attempts to three emails and three phone calls per patient. Additionally, we asked participating Managing Clinicians to refer us to patients who might be interested in participating in interviews, and we asked ESRD facilities to post or distribute flyers with information about the interviews to recruit patients. However, recruiting patients via Managing Clinicians and ESRD facilities was unsuccessful.

Managing Clinicians. We used CMS 4i contact information to conduct phone and email outreach to Managing Clinician practices. We limited the number of outreach attempts to each practice to three emails and three phone calls.

ESRD Facility Staff. We used contact information from the CMS 4i database, from the Center for Clinical Standards and Quality (CCSQ) ESRD Networks, and from Large Dialysis Organizations (LDOs). We reached out to ESRD facility staff via email, phone, or both. We limited the number of outreach attempts to each facility to three emails and three phone calls.

H.4. Data Collection

Between May and July 2024, two interviewers conducted a total of 28 interviews via phone or video conference with participants (16 patients, 5 Managing Clinicians and 7 ESRD facilities) across urban and rural locations. See **Appendix H, Section H.5.** for further detail on sample characteristics. Interviews with patients and Managing Clinicians were all individual interviews, and interviews with ESRD facility staff were attended by one to two participants. The interviewers used a semi-structured interview guide for all interviews. Mean interview times were as follows:



33 minutes for patients, 37 minutes for Managing Clinicians, and 34 minutes for ESRD facility staff. All interviews were recorded with participant consent and professionally transcribed.

Patient Interviews. Interviews focused on patient experiences with choosing and maintaining a treatment option based on location. Specific topics included:

- Experiences choosing a dialysis modality, including why they chose a specific modality, whether they had assistance choosing, and any challenges they experienced when choosing
- Impact of urban or rural location on choosing and maintaining a modality
- Any resources available to help start and maintain their chosen modality type
- Experiences learning about and seeking transplantation, including referral and evaluation processes, barriers, and resources available to help overcome these barriers

Managing Clinician and ESRD Facility Staff Interviews. Interviews focused on identifying barriers to treatment options linked to geographic and social context and resources or strategies to overcome these barriers, as well as impacts of the ETC Model and the modified payment adjustments providing additional support to ETC participants treating patients who are dually eligible for Medicare and Medicaid or enrolled in a Part D plan and receive the Part D Low Income Subsidy (LIS). Specific topics included:

- Barriers to home dialysis and transplant within their patient populations
- Strategies and resources to help patients overcome these barriers
- Policy recommendations for improving access to home dialysis and transplantation
- Impacts of the ETC Model and the modified payment adjustments on providing patient care and availability of resources to improve care
- Unintended consequences of the ETC Model and the modified payment adjustments

H.5. Sample Description

Patients. The patient sample includes individuals located in urban counties in California, Louisiana, Minnesota, Missouri, New York, and North Carolina, and in rural counties in Alaska, Georgia, Indiana, Iowa, Maryland, New Mexico, New York, and Virginia. See **Exhibit H-2** for more information on the patient sample characteristics. Because most of the patient participants were recruited via the patient experience survey, which focused only on home modalities, findings may be more representative of the experiences of patients on home dialysis rather than in-center dialysis.

Characteristic Category Total (n=16) 7 Urban Location 9 Rural 10 Peritoneal dialysis 3 Home hemodialysis **Treatment Type** 2 In-center dialysis 1 Transplant

Exhibit H-2. Patient Sample Characteristics



Characteristic	Category	Total (n=16)
	30–40	3
	41–50	3
Age (years)	51–60	3
Age (years)	61–70	3
	71–80	3
	No response	1
	High school diploma or less	10
Education Level	Associate's degree	2
Education Level	Bachelor's degree	3
	Master's degree	1
KCC Participation	Yes	7
Rec Participation	No	9

Note: KCC = Kidney Care Choices Model. See **Exhibit B-2** for data sources to obtain information on RUCC classification based on beneficiary zip code and KCC participation. RUCC classification was used to define urban or rural location. Patient characteristics for treatment type, age, and education level were self-reported by patients in interviews.

Managing Clinicians. The urban Managing Clinician sample includes ETC Model Participants located in San Diego, California, and Washington, D.C. Both areas are large metropolitan centers with an urban population of more than 1 million individuals and an RUCC of 1. The rural Managing Clinician sample includes participants serving patients in a Georgia county, a non-metro area with an RUCC of 7. We were unable to recruit Managing Clinicians serving patients in or near our target county in Mississippi. Two of the Managing Clinicians were also participants in the KCC Model.

ESRD Facilities. The urban ESRD facility sample includes facilities located in San Diego, California, and Washington, D.C. The rural ESRD facility sample includes facilities located in two nearby counties in Georgia and two nearby counties in Mississippi. These counties are also nonmetro areas with RUCCs ranging from 5 to 8. Five facilities were part of LDOs, and two were part of non-LDOs. Three facilities were also participants in the KCC Model. Most facility interview participants were social workers, nurses, and/or facility managers.

H.6. Analysis

The interviewers analyzed interview transcripts using inductive coding in MAXQDA, a qualitative data analysis software, to identify themes. The codebook was collaboratively developed based on the interview guide topics and initial findings. Findings were compared across participant types (patient, Managing Clinician, ESRD facility staff) and urban or rural location. Patient findings were further analyzed and compared across age, education, modality type, and KCC Model participation, while provider findings were further analyzed and compared according to high/low performance and KCC Model participation. Potentially due to small sample sizes, only analyses across urban versus rural location and education level yielded differences; thus, we have reported on those variables only. To increase rigor and aid in data interpretation, themes were discussed across the Lewin Team.

