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Comprehensive End-Stage Renal Disease Care (CEC) Model

Performance Year 1 Annual Evaluation Report

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Executive Summary

A. Introduction

Medicare beneficiaries with end-stage renal disease (ESRD) are a medically complex group that requires significantly more resources than the general Medicare population. While only 399,455 Medicare beneficiaries (or 1%) had ESRD in 2014, they accounted for over 7% of fee-for-service (FFS) Medicare spending.[2] Beneficiaries with ESRD have more and longer hospitalizations than other beneficiaries (1.64 admissions, averaging over 10.9 days per patient-year) and their readmission rates average 34.6%, more than twice the rate of the general Medicare population.

In an effort to provide better care for Medicare beneficiaries with ESRD, the Centers for Medicare & Medicaid Services (CMS) launched the Comprehensive ESRD Care (CEC) Model in 2015 under the authority of the Center for Medicare & Medicaid Innovation (CMMI). The CEC Model is an alternative payment model (APM) that creates financial incentives for dialysis facilities, nephrologists, and other Medicare providers to coordinate care for Medicare beneficiaries with ESRD. The model is designed to improve clinical and patient-centered outcomes for Medicare beneficiaries with ESRD, while promoting value and reducing per-capita spending. The CEC Model expands the reach of recent value-based payment initiatives targeting dialysis-related care such as the ESRD Prospective Payment System (ESRD PPS) and the ESRD Quality Incentive Program (ESRD QIP). Under the CEC Model, dialysis facilities, nephrologists, and other providers may partner to form ESRD seamless care organizations (ESCOs), specialty-oriented accountable care organizations (ACOs), which assume financial responsibility for the quality of care and Medicare Part A and Part B spending of their aligned beneficiaries.

This first annual report provides early findings on the impact of the CEC Model based on an evaluation of the first performance year (PY1) from October 1, 2015 through December 31, 2016. It summarizes findings from mixed quantitative and qualitative research to address several core questions. Qualitative research addresses the questions of which organizations chose to participate, why they entered the model, and how they implemented the model, including perceived successes and challenges. Quantitative research complements the qualitative data by measuring the effects of participation in the CEC Model on costs, utilization and quality as follows:

- **A difference-in-differences (DiD) design was implemented to estimate the impact of the model on claims-based outcomes.** The DiD design estimates the differential change from baseline to PY1 for ESCO aligned beneficiaries with ESRD compared to those who received services at matched comparison dialysis facilities.
- **The Kidney Disease and Quality of Life (KDQOL-36) questionnaire was used to assess the relationship between CEC participation and quality of life.** We analyzed several dimensions of quality of life including physical and mental health, burden of kidney disease, symptoms and problems, and effects of kidney disease. The comparison only included post-CEC data (from June 2016 to August 2016) for the beneficiaries aligned to ESCOs and from a matched comparison group.

[2] United States Renal Data System, 2016 Annual Data Report: Atlas of Chronic Kidney Disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2016.

B. Overview of Findings

The key findings of the PY1 evaluation are summarized in **Exhibit ES-1**, followed by a detailed discussion of findings relating to each research question.

Exhibit ES-1. Summary of Evaluation Findings

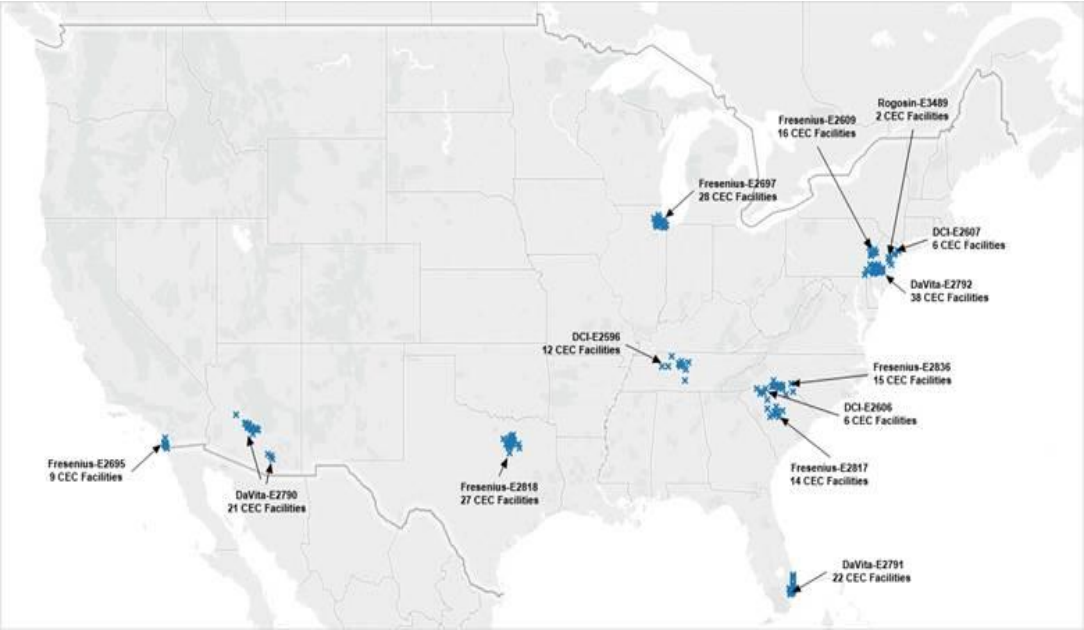
Evaluation Measures		CEC Model Effect (Impact Estimate)*	CEC vs. Comparison Group	Focus Area Reported by ESCOs
Spending per Beneficiary per Month (PBPM)	Total Part A and Part B	⬇ Decrease		● Focus Area
	Acute Inpatient	⬇ Decrease		● Focus Area
	Readmissions	N.S.		● Focus Area
	Home Health	N.S.		
	Hospice	N.S.		● Focus Area
	Post-Acute Institutional Care	⬇ Decrease		
	Hospital Outpatient	N.S.		
	Office Visits	⬇ Decrease		
	Other Part B	N.S.		
	Total Dialysis	⬆ Increase		● Focus Area
Utilization	Hospitalizations	⬇ Decrease		● Focus Area
	Readmissions	N.S.		● Focus Area
	Emergency Department (ED) Visits	N.S.		● Focus Area
	Observational Stays	N.S.		
	ED Visits Within 30 days of an Acute Hospitalization	N.S.		● Focus Area
	Length of Stay (LOS)	⬆ Increase		
	Hemodialysis	N.S.		
	Peritoneal Dialysis	N.S.		● Focus Area
	Office Visits	⬇ Decrease		
	Home Hemodialysis	N.S.		
Quality	Fistula	N.S.		
	Catheter	⬇ Decrease		● Focus Area
	Vascular Access (VA) Complications	⬇ Decrease		
	ESRD Complications	⬇ Decrease		
	Pre-ESRD care	N.S.		
	Hospice	N.S.		● Focus Area
	Flu Vaccinations	N.S.		
	Standardized Hospitalization Ratio (SHR)		CEC below	● Focus Area
	Standardized Readmission Ratio (SRR)		CEC below	● Focus Area
	Standardized Mortality Ratio (SMR)		same	
	Quality of Life (QoL)		same	
Unintended Consequences	Part D Cost Shifting	N.S.		

Notes: ⬆ Significant Increase; ⬇ Significant Decrease; N.S. = not statistically significant; ● focus area reported by ESCOs during site visits. Each impact estimate is based on a DiD analysis, and reflects the difference in the regression-adjusted average outcome for beneficiaries in CEC facilities for PY1 with baseline relative to the same difference over time for beneficiaries in matched comparison facilities. Significance identified with p-values ≤ 0.10.

1. Who participates in the CEC Model?

Thirteen ESCOs representing three large dialysis organizations (LDOs) (i.e., DaVita, Fresenius, and Dialysis Clinic Inc. [DCI]) and one small dialysis organization or non-LDO (Rogosin) participated in the CEC Model as of January 2016. (See **Exhibit ES-2**.) Collectively, these ESCOs had 216 dialysis facilities and were spread across 12 states.

Exhibit ES-2. Location of CEC Dialysis Facilities



Dialysis organization representation. The group of ESCOs in PY1, totaling 13 participants, was diverse along several important dimensions, including geographic region, ownership and size. In general, ESCOs covered a wide range of markets in terms of Medicare Part A and Part B costs, with no apparent selection into high cost markets. However, they tended to operate in larger urban markets, likely reflecting the requirement to have at least 350 patients. In particular, ESCOs were located in many of the largest population centers in the United States (U.S.), with the average CEC core-based statistical area (CBSA) having a population six times larger than the average non-CEC CBSA and substantially more Medicare ESRD beneficiaries than non-CEC CBSAs (mean 1,851 vs. 122).

2. Why did participants join the CEC Model and how did they prepare?

Reasons for joining the CEC Model. ESCO representatives reported a number of reasons for joining the model as well as a number of barriers. ESCO participants wanted to explore new opportunities and build upon existing organizational strengths. ESCO participants highlighted the potential for improving patient care in their own organizations while also influencing future payment models. They also cited the potential for financial gains, but generally expected the magnitude of any gains to be modest. ESCO participants often cited the importance of building upon existing good relationships between dialysis providers and nephrologists and developing or strengthening relationships with other providers such as hospitals and vascular surgeons. Staff at LDOs noted that markets where they had the strongest relationships with nephrologists were the ones they selected for ESCOs. Additionally, ESCO participants believed that nephrologist

participation would be encouraged by the CEC Model's qualification as an APM under the Quality Payment Program.

New or Enhanced Partnerships. Each dialysis organization and associated ESCO established formal financial risk-sharing partnerships with a nephrologist, as required for participation in the CEC Model. The nephrologist partners were often members of larger group practices and indicated willingness to collaborate on care redesign initiatives. Non-owner nephrologists were sometimes seen as creating barriers to care redesign, partly due to misaligned incentives. Some nephrologist owners expressed concerns about their lack of knowledge regarding the CEC Model, potential financial risks and potential unintended consequences.

Many ESCOs supplemented the required risk-sharing agreements with other providers across the care spectrum, beyond dialysis facilities and nephrologists. These included vascular surgeons, hospitals and associated health systems including their emergency department (ED) staff, an ACO, and hospice/palliative care providers.

Hospital system partners were reported by many interviewees to be critical to the success of the CEC Model. Many ESCO officials reported having a formal relationship with a hospital system, and ESCOs without formal partnerships also consistently reported informal efforts to improve communication and coordination with local hospitals. ED providers were seen as particularly important gatekeepers, as they could potentially arrange for patients to be transferred to a dialysis facility and thereby avoid an admission. Interviewees described that obtaining patients' records after discharge was crucial for preventing readmissions, and they noted that good relationships with care coordinators, discharge planners, and other staff helped improve the flow of discharge summary information.

Use of CEC Model Waivers. The CEC Model offers a number of waivers under which ESCOs can apply to be allowed to provide extra services for their organizations or patients. ESCO staff varied in their reported use of or interest in these waivers, and they reported that utilizing certain waivers could be cumbersome. The waivers most often discussed were those for patient incentives (e.g., transportation services, nutritional supplements, or patient information technology [IT]); there was little to no discussion of waivers regarding care coordination arrangements, performance-based payments to physicians, or remuneration furnished by the dialysis corporation to the ESCO.

3. How did ESCOs change care delivery to meet CEC Model goals?

Investments in Case Management and Information Technology. Dialysis organizations and their ESCOs made investments in new staff and in education for staff about the model. Enhanced case management and care coordination activities were the most frequently noted changes in care delivery. Another major area of investment was IT to support case coordination and care transformation efforts. Examples of IT investments include clinical software to improve use of evidence-based guidelines for dialysis care, case management software to improve communication among ESCO staff members, and IT tools to allow patients to be treated at any available facility in the same LDO on short notice.

Care Transformation Strategies. Model participants implemented strategies to transform care for CEC beneficiaries. They reported efforts to improve access to dialysis care (e.g., contacting

patients to reschedule missed dialysis appointments), to increase ESCO staff members' discussion and follow-up with patients regarding important non-ESRD care (e.g., outpatient visits with other specialists), to more frequently reconcile patients' medication lists, and to improve case management. Some particular strategies that were cited as likely to have affected patient cost and clinical outcomes included enhanced identification and focus on patients at high risk of adverse outcomes, proactive monitoring of dialysis treatment adherence, efforts to reduce ED use and hospital readmissions, greater focus on care transitions, and enhanced patient and caregiver education. Overall, there was a perception among many ESCO staff members that these interventions had started to impact some of the key outcomes.

Implementation Challenges. ESCO staff also noted several challenges in implementing the model, including delayed attribution of beneficiaries resulting in missed opportunities near the start of dialysis, limits on the transportation waiver, regulatory limits on the ability to deliver non-nephrology care in the dialysis unit, and inability of the non-LDO participant to aggregate their patients with other non-LDOs.

4. What are beneficiaries' perceptions of the CEC Model?

Beneficiary Awareness of the CEC Model. Most beneficiaries had positive impressions of the care received but only vague knowledge of the CEC Model. The participants that had the most favorable impressions of ESCOs were generally new patients, patients with a higher comorbidity burden, and patients in need of support services (e.g., transportation, and help with medications or scheduling appointments).

5. What were CEC's impacts on quality of life?

Impact on Quality Composite Scores. CEC respondents scored higher than the comparison group on all five quality of life composite measures in the KDQOL survey: physical health, mental health, burden of kidney disease, symptoms and problems, and effects of kidney disease. However, the differences were small in magnitude and only the physical component score attained marginal statistical significance. Furthermore, surveys response rates were low in both the CEC and comparison groups.

6. What were CEC Model's impacts on spending, utilization, and quality?

Exhibit ES-3 presents a detailed summary of the estimated impacts associated with spending, utilization, and quality.

Exhibit ES-3. Summary of DiD Impact of CEC on Spending, Utilization, and Quality; PY1

Measure		CEC		Comparison		Difference-in-Differences Estimate			
		Baseline Mean	PY1 Mean	Baseline Mean	PY1 Mean	DiD	90% Lower CI	90% Upper CI	Percent Change
Expenditures ($) PBPM by type of service (Standardized allowed charges)	Total Part A and Part B	$7,486	$7,365	$7,618	$7,655	-$159 **	-$291	-$26	-2.12%
	Acute Inpatient	$1,601	$1,628	$1,663	$1,793	-$102 ***	-$163	-$42	-6.40%
	Readmission	$310	$319	$332	$366	-$24	-$50	$2	-7.78%
	Home Health	$189	$180	$168	$166	-$6	-$14	$2	-3.38%
	Hospice	$18	$15	$16	$14	-$1	-$4	$3	-3.60%
	Post-Acute Institutional Care	$561	$544	$605	$647	-$59 **	-$107	-$12	-10.56%
	Hospital Outpatient	$460	$457	$501	$490	$8	$10	$27	1.84%
	Office Visits	$369	$377	$374	$396	-$13 *	-$24	-$2	-3.58%
	Other Part B	$838	$699	$887	$762	-$14	-$77	$49	-1.68%
	Total Dialysis	$3,328	$3,335	$3,311	$3,305	$12 *	$1	$23	0.36%
Utilization Measures	Hospitalizations	10.80%	10.67%	11.08%	11.60%	-0.65 ***	-1.03	-0.26	-5.99%
	Readmissions	29.03%	29.04%	30.20%	30.97%	-0.76	-2.07	0.55	-2.61%
	Emergency Department (ED) Visits	10.97%	11.16%	11.10%	11.56%	-0.26	-0.61	0.09	-2.37%
	Observational Stays	2.54%	2.75%	2.37%	2.66%	-0.08	-0.24	0.08	-3.15%
	Length of Stay (LOS)	5.84	5.81	5.94	5.74	0.16 *	0.00	0.32	2.78%
	ED Visits Within 30 days of an Acute Hospitalization	2.40%	2.42%	2.53%	2.63%	-0.08	-0.25	0.08	-3.42%
	Hemodialysis	93.76%	93.03%	94.92%	94.13%	0.07	-0.57	0.72	0.08%
	Home Hemodialysis	1.98%	2.16%	1.53	1.57%	0.14	-0.22	0.51	7.20%
	Peritoneal Dialysis	6.50%	7.12%	5.33%	5.98%	-0.04	-0.70	0.62	-0.54%
	Office Visits	0.85	0.87	0.89	0.93	-0.03 ***	-0.05	0.00	-2.94%
Quality Measures	Fistula	62.75%	63.45%	63.19%	63.08%	0.80	-0.22	1.82	1.28%
	Catheter	8.48%	8.84%	9.40%	10.49%	-0.72 *	-1.38	-0.05	-8.46%
	VA Complications	0.60%	0.60%	0.66%	0.76%	-0.09 **	-0.16	-0.02	-14.95%
	ESRD Complications	1.72%	1.67%	1.81%	1.96%	-0.21 ***	-0.35	-0.08	-12.41%
	Percent Starting Dialysis Without Prior ESRD-Nephrology Care	25.42%	23.22%	30.78%	28.08%	0.50	-4.61	5.61	1.97%
	Hospice	0.64%	0.53%	0.59%	0.49%	0.00	-0.10	0.10	-0.18%
	Flu Vaccinations	29.50%	38.60%	28.93%	38.34%	-0.32	-4.61	3.97	-1.09%
Unintended Consequences	Total Part D Drug Cost	$826	$1,082	$858	$1,132	-$17	-$46	$11	-2.11%

Notes: PY1 covers the period from October 2015-December 2016. Each impact estimate is based on a DiD analysis, and reflects the difference in the regression-adjusted mean outcome for beneficiaries in CEC facilities for PY1 with baseline relative to the same difference over time for beneficiaries in matched comparison facilities. Medicare allowed charges outcomes are standardized to remove the effect of geographic and other adjustments. CI= confidence interval, ***p<0.01, **p<0.05, *p<0.1. ~Readmission allowed charges are included in the overall acute inpatient spending.

Medicare Spending. Early data shows ESCOs have been able to reduce costs mainly through a reduction in spending on hospitalizations, although the overall impact has been modest. Average total Medicare Part A and Part B standardized allowed charges, our overall measure of Medicare spending, increased slightly from the baseline to PY1 for the comparison group beneficiaries, while it decreased for the CEC group, resulting in a relative reduction of $159 per beneficiary per month (PBPM) ($p<0.10$) for CEC beneficiaries, or an aggregate savings of $29.9 million during PY1.[3] A similar pattern (i.e., relative declines in spending for CEC beneficiaries) was found in all Part A settings, with statistically significant relative declines in spending for post-acute institutional care (-$59 PBPM; $p<0.05$) and acute inpatient stays (-$102 PBPM; $p<0.01$). Among Part B services, spending for office visits showed a marginally statistically significant decline relative to the comparison group. Additionally, there are early signs that ESCOs reported increased efforts to promote dialysis adherence has been successful, as payments for dialysis increased slightly ($12 PBPM, $p<0.1$) for CEC beneficiaries relative to beneficiaries in the comparison group.

Utilization. Utilization results were consistent with the spending results. For most service types, utilization rates increased slightly for both CEC and comparison group beneficiaries, but they increased at a slower rate for CEC beneficiaries. Relative to the comparison group, CEC beneficiaries saw statistically significant relative reductions in hospitalizations and office visits. In particular, relative to the baseline, CEC beneficiaries were 6% less likely to have a hospitalization in a given month in PY1. We observed a small relative decline in the percent of CEC beneficiaries having at least one readmission, ED visit, observational stay, or ED visit within 30 days of a hospitalization, but these changes were not statistically significant. At the same time, the average length of stay among those beneficiaries who were hospitalized increased for CEC beneficiaries relative to comparison beneficiaries by 0.16 days (2.8%). This increase was not explained by a change (from the pre-CEC to the post-CEC period) in the average Medicare Severity-Diagnosis Related Group (MS/DRG) corresponding to CEC beneficiaries' hospital admissions to that in the comparison group. Additional analyses will be conducted if the difference persists with greater longitudinal follow-up to assess what clinical behaviors might be contributing to this increase.

Quality. There is no evidence that relative reductions in cost and utilization compromised quality. Among the CEC beneficiaries relative to the comparison group, use of fistulas (the preferred type of vascular access for hemodialysis) showed a small but insignificant increase, while use of catheters (the non-preferred form of vascular access) declined slightly ($p<0.10$).

For the most part, CEC beneficiaries experienced fewer hospitalizations associated with complications related to poor dialysis care. CEC beneficiaries experienced fewer hospital admissions due to ESRD complications ($p<0.01$) and vascular access complications ($p<0.10$). Finally, the standardized mortality rate (SMR) in 2016 is very similar for both the ESCOs and the comparison group. The result for SMR implies that the number of adverse events associated with ESCOs is in line with national averages across all dialysis facilities.

[3] Estimates are based on standardized allowable charges, which combine Medicare and beneficiary payments. In addition, allowed charges are standardized to remove the effects of wage differences and for teaching status and other policy adjustments. Finally, these estimates do not account for payments between ESCOs and CMS resulting from PY1 reconciliation.

C. Discussion

The CEC Model is designed to create incentives for dialysis facilities and nephrologists to coordinate care for Medicare beneficiaries with ESRD across settings by making the ESCO responsible – financially and clinically – for care delivered in other institutional and professional settings. Overall, the first fifteen months under the CEC Model showed promising results, with lower spending and improvements on some utilization and quality measures. Results from the first performance period suggest that savings for ESCO patients have primarily been generated through a reduction in total hospitalizations and readmissions.

Findings presented in this report are limited in two ways. First, the thirteen ESCOs which joined in PY1 and are summarized in this report, are not representative of the population of Medicare providers, limiting our ability to generalize the results presented here. The influx of 24 new ESCOs joining in PY2 will add three non-LDO organizations to the population of CEC participants and cover additional markets, therefore improving our ability to generalize findings. Second, although the analysis employs matching methods to select an appropriate comparison group to infer counterfactual outcomes for the ESCOs, the characteristics we selected for matching and the specificity of the data may not adequately account for all differences between ESCOs and comparison facilities.

I. Introduction

The Centers for Medicare & Medicaid Services (CMS) launched the Comprehensive End-Stage Renal Disease (ESRD) Care (CEC) Model in 2015 under the authority of the Center for Medicare & Medicaid Innovation (CMMI). The CEC Model is designed to improve clinical and patient-centered outcomes for Medicare beneficiaries with ESRD, while promoting value and reducing per capita spending. Under the CEC Model, dialysis facilities, nephrologists, and other providers can partner to form ESRD Seamless Care Organizations (ESCOs). ESCOs act as specialty-oriented accountable care organizations (ACOs), which assume responsibility for the complete care and costs of their aligned Medicare fee-for-service (FFS) beneficiaries with ESRD. The CEC Model is designed to encourage ESCOs to create interdisciplinary care teams and implement patient-centered care approaches to promote comprehensive and coordinated care and improve access to services. The CEC Model expands the reach of recent value-based payment initiatives targeting dialysis-related care such as the ESRD Prospective Payment System (ESRD PPS) and the ESRD Quality Incentive Program (ESRD QIP).

The Lewin Group, Inc. (Lewin), along with its partners, the University of Michigan's Kidney Epidemiology Cost Center (UM) and General Dynamics Information Technology (GDIT), are under contract to CMS to evaluate the first five years of the CEC Model. The goal of the evaluation is to assess the impact of the CEC Model on the care quality, health outcomes, and Medicare spending of Medicare beneficiaries with ESRD.

This is the first of four annual reports and covers the 13 ESCOs operating in performance year (PY1) from October 1, 2015 through December 31, 2016. An additional 24 ESCOs joined on January 1, 2017 at the start of PY2 and will be covered in subsequent reports.

A. Overview of the CEC Model

ESCOs consist of dialysis facilities, nephrologists, and other Medicare and community-based providers interested in collaborating to deliver comprehensive care to Medicare beneficiaries with ESRD. CMS mandates that ESCO participant-owners include at least one dialysis facility and one nephrologist/nephrology practice. ESCO participant non-owners can include other (non-dialysis facility or nephrologist/nephrologist practice) Medicare-enrolled providers and suppliers (durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers; ambulance suppliers; or drug/device manufacturers). Other community-based organizations, referred to as partners, may also be part of an ESCO.[4] There are two types of ESCOs: large dialysis organizations (LDOs), comprised of the chain dialysis organizations DaVita, Fresenius, and Dialysis Clinic, Inc. (DCI) and small dialysis organizations (also called non-LDOs), which are organizations with fewer than 200 dialysis facilities that are not owned by an LDO.

Each ESCO is located in a specific market area, restricted to no more than two contiguous Medicare core-based statistical areas (CBSAs) with exceptions for rural ESCOs. Each ESCO is required to have a governing body and provide care for a minimum of 350 beneficiaries over the course of the PY.

[4] https://innovation.cms.gov/Files/x/cec-py2-rfa.pdf

Under the CEC Model, ESCOs are also required to develop a care model with comprehensive and coordinated care delivery, enhanced patient-centered care and communication, and improved access to services.

The key design features of the CEC Model include:

- **An exclusive focus on Medicare beneficiaries with ESRD.** The CEC Model only enrolls Medicare beneficiaries with ESRD, who are clinically complex and require coordination from an interdisciplinary care team led by a nephrologist.
- **Shared savings and shared losses payment model**, which rewards ESCOs for improved quality of care and reduced costs. ESCOs assume responsibility for the complete care and costs of their aligned Medicare FFS beneficiaries with ESRD. In ESCOs with a two-sided payment arrangement, participant owners must assume downside risk for at least 50% of their contribution to the ESCO's total expenditures multiplied by the ESCO's total losses. This requires nephrologists to bear financial risk, which cannot be covered by the broader ESCO or other participants within the ESCO. Compared to other ACO programs, which only require repayment from the ACO as a whole, the CEC Model is unique as it requires individual participants to bear downside financial risk. This is important as it gives nephrologists and other participants a vested interest in the ultimate success of the model. CEC includes two financial payment tracks depending on whether the participating dialysis facility is an LDO or non-LDO. ESCOs from LDOs are required to participate in a two-sided payment arrangement where they are eligible for both sharing in cost savings and responsible for any losses. ESCOs from non-LDOs have the option of participating in a one-sided payment track where they do not bear the risk of any losses or, alternatively, participating in two-sided arrangements by aggregating with other non-LDOs. If non-LDOs choose to participate in a one-sided track, with less risk, they are also eligible for a lower share of savings relative to the two-sided payment track.
- **Quality performance measures.** In PY1, ESCOs will be eligible for shared savings if they have complete, accurate, and timely reporting for a set of hybrid quality measures that use both claims and medical record data. Starting in PY2, all ESCOs will only be eligible for sharing in the savings resulting from reductions in care costs if they also achieve a set of quality standards.[5] The broader accountability for both outcomes and costs also further incentivizes dialysis providers to improve these measures using patient-centered approaches (for example, enhanced communication and education). The CEC Model incorporates patient-reported measures, a practice unique to the model, using the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) and the Kidney Disease Quality of Life (KQDOL) beneficiary surveys in their quality metrics. Shared savings/losses will also depend on an ESCO's total quality score (TQS). The TQS rates the ESCO's overall performance based on the CEC Quality Measure Set, which is a set of standardized quality performance measures used to determine eligibility for shared savings.[6]

[5] List of quality measures included in the CEC Model can be found here: https://innovation.cms.gov/Files/x/cec-qualityperformance-ldo.pdf

[6] Because the TQS will not be available in time for PY1 reconciliation, in PY1, ESCOs will be eligible for shared savings if they have complete, accurate, and timely reporting for the hybrid quality measures.

- **"First touch" approach and prospective matching for beneficiary alignment.** To limit opportunities for patient selection by the ESCOs, while maintaining beneficiary choice, patients are attributed to ESCOs prospectively, using a "first touch" methodology. Eligible beneficiaries are prospectively aligned to an ESCO after their first visit to a dialysis facility participating in an ESCO. Beneficiaries continue to be aligned to that ESCO unless: they receive less than 50% of their dialysis—following alignment—in the aligned facility's market; they have no eligible first touch in the year at any facility in an ESCO to which the beneficiary was aligned; they are aligned to another shared savings program, receive a transplant, or die. This alignment procedure stands in contrast to that used in Medicare's general ACO models, which rely on a retrospective alignment system based on the plurality of primary care services delivered in the prior year.

In addition, to give ESCOs greater flexibility in redesigning care, the CEC Model does not require a set approach to care but instead allows ESCOs to give performance-based payments to participating physicians for conducting certain medically necessary procedures or providing certain care and services that improve outcomes for CEC beneficiaries. ESCOs distribute these payments based on quality metrics; they are not funded from the shared savings pool. ESCOs are also allowed to provide in-kind items or services to CEC beneficiaries, generally under a waiver of regular program rules. These waivers apply to services that include oral nutrition supplements when needed to maintain serum albumin levels, non-emergency transportation to obtain medically necessary care in selected situations, and technology support for health services. Technological devices may be provided to beneficiaries if the beneficiary does not already own similar technology and it is considered "medically necessary" because it will improve a beneficiary's communication with his/her providers, improve adherence to medications or allow the beneficiary to access telehealth services. We provide additional detail on the CEC Model waivers in **Appendix A.**

B. Research Questions in First Annual Report

The first annual report is organized to address several core research questions as detailed below. These research questions were generated based on the conceptual framework, or logic model, of the CEC Model shown in **Exhibit 1**.

Exhibit 1. CEC Evaluation Logic Model (Abbreviated Version)

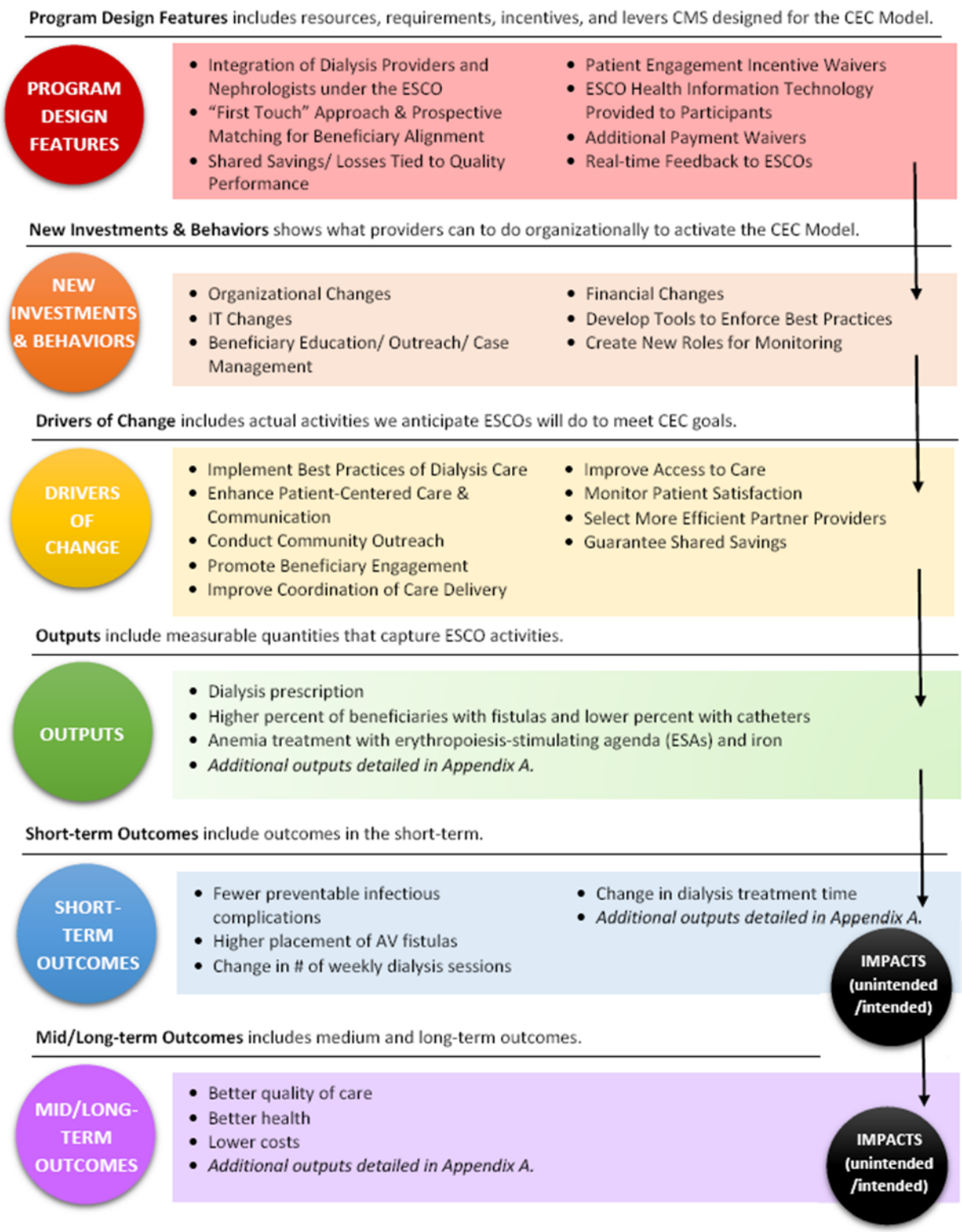


Exhibit 1 and Appendix B provide the conceptual framework which describes the evaluation team's understanding of the resources participants bring to the CEC Model, the design features

and incentives that are put in place under the CEC Model, the actions and behaviors that participants may take, and the outcomes that may be achieved.

Formative evaluation research questions focus on characteristics of participants, entry decisions, investments by participants, care redesign approaches, implementation challenges and stories of success. Summative evaluation research questions assess impact in the following areas: better care, better health, cost and utilization, and unintended consequences.

1. Who participates in the CEC Model?

To provide context for the CEC Model, we describe its participants and the markets they serve and compare them to non-CEC participants and markets. We develop market profiles using data from the Provider of Service (POS), Dialysis Facility Compare (DFC), Area Health Resource Files (AHRF), and other secondary data. We also compare ESCO aligned beneficiaries to non-CEC beneficiaries to understand differences in demographic, clinical, and utilization characteristics that may influence the impact of the CEC Model on outcomes.

2. How did participants prepare for the CEC Model?

We assessed participants' goals for joining the CEC Model and their readiness to implement changes. Data from site visits and interviews with ESCO representatives were used to investigate the decision-making process as to why certain providers and markets were chosen by the LDOs for the CEC Model, and the motivations behind participation in the model. We evaluated how program design and incentives motivated participating providers to change behaviors, information flows, and investments. Finally, we provide information about the types of partnerships (formal and informal) dialysis organizations made to form and operate their ESCOs.

3. How did ESCOs change care delivery to meet CEC Model goals?

We explored ESCOs' strategies for reducing costs, improving quality, and coordinating care. The strategies included activities to improve care and value, increase engagement of beneficiaries and caregivers, coordinate interdisciplinary care across settings, and align financial incentives. We used data from application materials, site visits, and calls with ESCOs to identify the most common approaches for care redesign and case management, detail why they were chosen, and how they were implemented during the PY1. Additionally, we discussed commonalities and differences in approaches across ESCOs.

Furthermore, the CEC Model seeks to encourage better coordination among providers across the continuum of care. Facilitating such coordination requires a number of structural changes in the organization of care. These include the strategic selection of partners (e.g., hospitals, primary care providers, specialists) most willing and able to deliver efficient, high quality care to a dialysis population; enhanced information flows among all partners (through health information technology [HIT] and other communication pathways); and financial arrangements that support the achievement of the model's goals (i.e., provider payment mechanisms and shared savings distributions).

4. What are beneficiaries' perceptions of the CEC Model?

We gauged beneficiaries' perceptions of the CEC Model from focus groups with ESRD patients receiving services at selected ESCO dialysis facilities. We assessed patients' level of awareness

of the CEC Model and patients' impressions of their care and whether they noticed changes in the quality of their care since the start of the CEC Model.

5. What were CEC's impacts on quality of life?

We used data from the KDQOL-36 beneficiary survey to assess the impact of the CEC Model on self-reported measures of health-related quality of life (HRQOL). The KDQOL instrument is designed to collect data on general health, perceived burden of kidney disease, kidney disease symptoms or problems, and effects of kidney disease on quality of life and function. We analyzed physical and mental composite scores constructed based on these domains. The KDQOL-36 questionnaire was administered to both CEC participants and a matched comparison group of beneficiaries.

6. What were CEC Model's impacts on Medicare spending, utilization, and quality?

We evaluated the impact of the CEC Model on the rate of Medicare spending per beneficiary per month (PBPM), utilization of various services, and quality for Medicare beneficiaries with ESRD during PY1.

First, ESCOs are expected to redesign care and adopt cost savings strategies that will change the use of health care services and reduce the cost of care of ESRD aligned beneficiaries. This first annual report examines changes in the costs of care using Medicare standardized allowed charges for total Part A and Part B services and by type of services.[7] The analysis accounts for differences in patients' need for services through risk adjustment based on patient characteristics.

Second, we examined changes in utilization of distinct services received by ESRD patients. Since ESRD patients often have co-occurring conditions and thus may require a comprehensive array of health care services, changes in both ESRD-related care and non-ESRD care are measured. As with the measures of better care, analyses examined changes in the cost of services most directly dialysis-related (e.g., dialysis modality) as well as a broader set of services that encompass the continuum of care and health services (e.g., hospitalizations, length of stay, readmissions, emergency department (ED) use, and primary care).

As for quality, we first explored indicators related to dialysis treatment. Since dialysis facilities and nephrologists were the main points of care prior to the CEC Model, it is natural to consider the technical quality of dialysis-related care that is centered in the facility and how the model affected it. This involved meeting and improving basic standards of care widely accepted by the dialysis community. Multiple evidence-based clinical metrics were used to assess the quality of care delivered by dialysis facilities and nephrologists (e.g., establishment of vascular access with low rates of vascular access complications). We also looked at flu vaccinations as a measure of appropriate preventive care and hospice use as a measure of appropriate care at the end of life, given the high mortality rate in the ESRD population and the fact that several ESCOs focused specifically on hospice referral.

[7] These amounts combine the Medicare payments with the patient coinsurance and copayment amounts. Then, these amounts are standardized to remove the effects of wage differences and for teaching status and other policy adjustments.

Perhaps most significant to improved quality is the management of hospitalizations and the facilitation of effective transitions from inpatient to outpatient care after discharge, often identified as an area for needed improvement in ESRD care. To assess the success in this area, we analyzed outcome measures such as standardized hospitalization ratio (SHR) and the standardized readmission ratio (SRR).

7. Are there unintended consequences?

ESCOs may employ multiple approaches to reduce their costs of care under the CEC Model. Strategies to deliver care more efficiently or coordinate care across providers may improve quality of care and health outcomes while reducing costs. However, strategies such as stinting on care, postponing care, or substituting inferior or inappropriate services could result in worse care or health. Still other strategies could reduce the cost of care for CEC beneficiaries while increasing costs to other payers, including other parts of the Medicare program (Medicare Part D) or Medicaid.

The first annual report only focuses on the impact of the CEC Model on Part D costs. When Medicaid, transplant, and ICH CAHPS data become available in PY2, other outcomes, including cost shifting to Medicaid, wait listing for transplantations,[8] and patient satisfaction, will be measured and analyzed in concert with Part D and overall costs. In PY2, we will also use Medicare claims data to assess referral patterns for dialysis to explore whether nephrologists are selectively referring healthier patients to ESCO facilities.

[8] Transplant wait list information is not included in the first annual report due to a delay in receiving transplant data from the Scientific Registry of Transplant Recipients (SRTR). This information will be provided in a supplemental report at a later date and will be included in future annual reports.

II. Who Participates in CEC?

Participation in the CEC Model was voluntary and included requirements based on market area and minimum number of Medicare beneficiaries treated at each ESCO. These program rules led to differences between CEC and non-CEC facilities and the markets in which they reside.

A. Key Findings

CEC facilities tend to be larger with both more dialysis stations and more patients than non-CEC facilities. Patients treated at CEC facilities have lower total Medicare Part A and Part B spending than their non-CEC counterparts. Markets with CEC participating facilities are much larger on average and are more racially diverse. CEC markets have a higher median income and their Medicare beneficiaries with ESRD have higher total Medicare Part A and Part B spending.

B. Methods

CEC facilities were identified through participation data collected from Salesforce, a software tool maintained by CMS to track model participants. We constructed a dialysis facility-level dataset that included facility level characteristics from the 2015 DFC database and 2014 Medicare claims, and market (Medicare CBSA) level characteristics from 2014 based on the AHRF and Census American Community Survey (ACS). We aggregated county level characteristics to the Medicare CBSA market level by weighting individual county observations by population. CEC markets were defined as those CBSAs that had at least one CEC facility, while non-CEC CBSAs were those without CEC facilities.

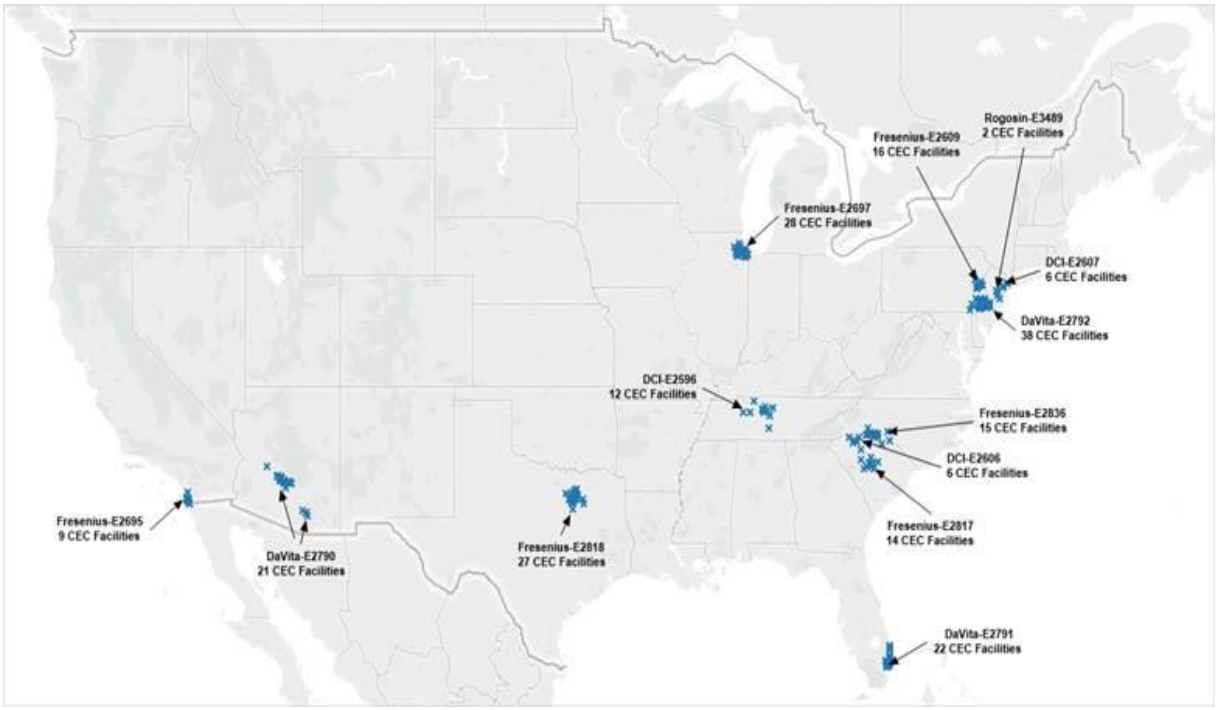
C. Results

The discussion below details findings based on the comparison of the characteristics of CEC facilities and non-CEC facilities and the comparison of markets with CEC participants to markets without CEC participants.

1. Characteristics of CEC Facilities

Thirteen ESCOs representing three LDOs (i.e., DaVita, Fresenius, and DCI) and one non-LDO (Rogosin) participated in the CEC Model as of October 2015. Collectively, the ESCOs starting on or prior to October 2015 signed up 216 dialysis facilities to the model and were spread across 12 states, the map in **Exhibit 2** provides a visualization of the location of participating facilities.

Exhibit 2. Location of PY1 CEC Dialysis Facilities



Source: CEC Model participation data extracted from Salesforce on 4/10/2017.

CEC facilities represented about 3% of all dialysis facilities nationally in PY1. **Exhibit 3** compares the characteristics of PY1 facilities and non-CEC facilities in 2014. CEC facilities were associated with four organizations DaVita, DCI, Fresenius, and Rogosin. Respectively, these organizations represented 38%, 11%, 50%, and 1% of the CEC facilities. DaVita, DCI, Fresenius, and non-LDOs represented 37%, 3%, 27%, and 33% of the non-CEC facilities. On average, ESCOs had 16.6 facilities each, ranging from 2 to 38 facilities per ESCO. LDO ESCOs had a larger number of facilities per ESCO than did the non-LDO ESCO. Compared to non-CEC facilities, CEC facilities had, on average, 4.3 more dialysis stations and treated around 17 more Medicare beneficiaries. Average Medicare spending per month was slightly lower for beneficiaries aligned to CEC facilities.

Exhibit 3. Characteristics of PY1 CEC Facilities and Non-CEC Facilities in 2014

Characteristics	PY1 CEC Facilities[9] (N=216)				Non-CEC Facilities[10] (N=6,025)			
	Mean	25th Percentile	Median	75th Percentile	Mean	25th Percentile	Median	75th Percentile
For Profit Facility	88%	1	1	1	88%	1	1	1
Chain Owned Facility	98%	1	1	1	85%	1	1	1
Number of Dialysis Stations	21.4	16	21	25	17.1	12	16	21
Late Shift (i.e. facility is open after 5pm)	18%	0	0	0	16%	0	0	0
Peritoneal Service Offered	37%	0	0	1	55%	0	1	1
Medicare Beneficiary Count	77.5	51.0	70.5	100.0	60.1	30.0	53.0	81.0
Hemodialysis Beneficiary Count	72.8	47.0	68.0	95.0	55.5	28.0	50.0	77.0
Peritoneal Dialysis Beneficiary Count	6.3	0.0	1.0	6.0	6.4	0.0	1.0	8.0
Percent of Patients with Hemodialysis	94%	94%	100%	100%	92%	90%	99%	100%
Percent of Patients with Peritoneal Dialysis	8%	0%	2%	8%	11%	0%	3%	14%
Percent Patients with Vascular Catheter	8%	5%	8%	10%	10%	6%	9%	14%
Percent Patients with Arteriovenous Fistula	62%	55%	63%	70%	64%	57%	65%	72%
Standardized Hospitalization Ratio	0.98	0.80	0.96	1.13	0.98	0.78	0.96	1.17
Standardized Readmission Ratio	0.99	0.84	1.01	1.16	0.97	0.80	0.99	1.18
Standardized Mortality Ratio	0.93	0.80	0.94	1.08	1.01	0.84	0.99	1.17
Average Monthly Total Part A and Part B Allowed Charges per Beneficiary	$7,485	$6,846	$7,318	$7,938	$7,585	$6,676	$7,336	$8,093
Standardized Average Total Part A and Part B Allowed Charges	0.97	0.90	0.96	1.04	1.00	0.90	0.99	1.08

Source: Lewin analysis on the 2014 AHRF, DFC data from 2014, CEC Model participation data extracted from Salesforce on 4/10/2017, and Medicare Claims in 2014.

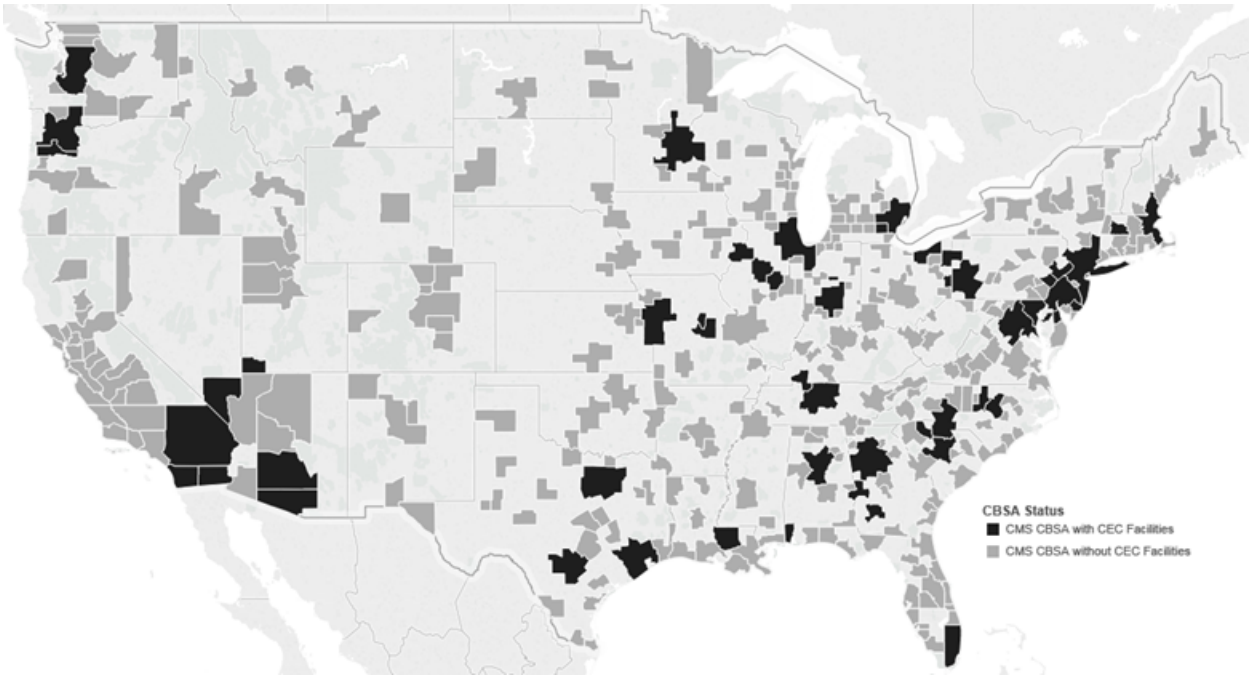
2. Characteristics of PY1 CEC Markets

We examined whether the CBSAs where ESCOs were located were typical or atypical of other CBSAs containing dialysis facilities, across the United States (U.S.). In 2014, 384 of the 389 Medicare CBSAs had at least one dialysis facility. CEC facilities were located in 19 Medicare CBSAs, as illustrated by the map in **Exhibit 4**. CEC program rules in PY1 allowed ESCOs to include facilities in up to two contiguous Medicare CBSAs.

[9] Data was not available for select characteristics for 12 of the 216 CEC facilities. Reported mean values are based on all non-missing values.

[10] Dialysis facilities that joined the CEC Model in PY2 (January 2017) are excluded.

Exhibit 4. Medicare CBSAs with PY1 CEC Facilities



Source: DFC data from 2014 and CEC Model participation data extracted from Salesforce on 4/10/2017.

Markets with CEC facilities—or CEC CBSAs—differed from those without CEC facilities, non-CEC CBSAs, in many ways including population characteristics, race and ethnicity, age, and types of providers, the chart in **Exhibit 5** compares the market characteristics of CBSAs with and without CEC facilities. First, CEC CBSAs included many of the largest population centers in the U.S. The average CEC CBSA had a population six times larger than the average non-CEC CBSA. CEC CBSAs had a higher proportion of Black and Hispanic residents. CEC CBSAs tended to have a higher rate of specialists per 10,000 residents relative to non-CEC CBSAs. Median income was higher in CEC CBSAs and ESRD patients enrolled in Medicare spent more on medical care. CEC CBSAs also had fewer dialysis facilities per capita even though they had a similar prevalence of ESRD.

Exhibit 5. Characteristics of Markets with and without PY1 CEC Facilities

Characteristic	CEC Medicare CBSAs (N=19)				Non-CEC Medicare CBSAs (N=310)			
	Mean	25th Percentile	Median	75th Percentile	Mean	25th Percentile	Median	75th Percentile
CBSA Population	2,738,694	827,171	1,815,137	4,050,793	449,946	138,695	215,868	468,233
Median Household Income	54,474	$48,415	$54,076	$59,241	48,677	$42,187	$46,519	$52,963
Percent White	59%	52%	59%	69%	72%	63%	77%	85%
Percent Black	16%	7%	17%	21%	10%	2%	6%	13%
Percent Hispanic	17%	7%	13%	26%	12%	3%	6%	13%
Percent 65 & Older	13%	11%	13%	15%	14%	12%	14%	16%
PCP's Per 10,000	7.53	6.57	7.70	8.54	7.40	6.08	7.25	8.56
Specialists Per 10,000	10.35	8.31	9.86	13.20	8.23	5.26	6.82	9.59
Skilled Nursing Facility Beds Per 10,000	45.07	33.78	43.36	55.42	55.73	36.90	51.27	70.77
Percent Dual Eligible	0.03	0.02	0.03	0.03	0.03	0.02	0.03	0.04
Hospitals with Kidney Transplant Services per 10,000	0.006	0.000	0.006	0.010	0.005	0.000	0.000	0.000
Percent with No High School Diploma	14%	13%	14%	16%	14%	11%	13%	17%
Average Total A&B Allowed Charges	$73,062	$67,592	$71,752	$78,700	$67,026	$61,160	$66,790	$71,321
Percent ESRD	0.12%	0.11%	0.12%	0.14%	0.13%	0.09%	0.12%	0.16%
Percent of ESRD with Medicare & Medicaid	49%	45%	49%	54%	48%	41%	48%	55%
Dialysis Facilities	60.11	24	43	86	13.45	5	9	15
Dialysis Facilities per 10,000	0.26	0.20	0.26	0.30	0.41	0.22	0.32	0.51

Source: Lewin analysis on the 2014 AHRF, DFC data from 2014, CEC Model participation data extracted from Salesforce on 4/10/2017, and Medicare Claims in 2014.

III. Why Did Participants Join the CEC Model and How Did They Prepare?

In an effort to understand the factors that motivated dialysis organizations and nephrologists to establish ESCOs, we conducted a series of phone interviews and site visits with PY1 CEC participants. Information was collected regarding participants' organizational goals, expectations, perceptions and use of resources offered by the model.

A. Key Findings

Key findings on participants' reasons for joining the CEC Model, their preparations, nephrologists' payment arrangements, and use of waivers are highlighted below:

- **Reasons for Joining**. ESCO representatives described joining the CEC Model to improve patient care, learn about and possibly influence future renal payment models, and potentially realize financial gains. Interviewees also noted that ESCOs leveraged existing resources and relationships, and they felt that ESCOs aligned with missions of their respective dialysis organization.
- **Preparations.** Dialysis organizations and associated ESCO staff reported preparing for the CEC Model by developing or strengthening relationships with several types of optional owners and non-owner partners.
    - Optional owners are entities (other than the nephrologists and dialysis organizations) at risk for shared savings and losses, whereas non-owner partners are not at risk.
    - Key types of partners reported by respondents included vascular surgeons, hospitals and associated health systems, ED staff, and hospice/palliative care providers.
- **Payment Arrangements.** Interviewees had relatively few comments about their shared savings or pay-for-performance (P4P) arrangements with nephrologists and other owners, perhaps because they either considered the information to be proprietary, the financial arrangements were still under development, or they did not yet have enough experience to report. However, most dialysis organizations' staff reported expecting positive but small shared savings while nephrologist owners anticipated little or no shared savings.
- **Waivers.** Dialysis organization and ESCO participants described utilizing a number of the waivers allowed under the CEC Model. Respondents mentioned frequently using the patient engagement incentive waivers (i.e., transportation, nutritional supplements, and patient information technology [IT]), while interviewees had relatively few or no comments about the P4P, ESCO remuneration, and care coordination waivers.

B. Methods

The first round of site visits occurred between August 23, 2016 and November 10, 2016. A total of 74 individual or small group interviews were conducted at dialysis organization corporate- and ESCO-level site visits, with one to seven staff members participating in each interview. A single corporate-level site visit was conducted with staff members at each dialysis organization (DaVita, DCI, Fresenius, and Rogosin). All 13 PY1 ESCOs were visited, with two to three facilities visited

per ESCO, for a total of 31 dialysis facility site visits. **Appendix C** provides additional detail on the criteria used to select facilities and interview protocols used in the site visits.

C. Results

1. Why Did CEC Participants Join the Model?

To identify and illustrate the relative importance of various reasons for participating in the CEC Model, **Exhibit 6** below shows a "heat map" of entry determinants. Colors in the heat map indicate the relative frequency with which each topic was mentioned by interviewees in response to several open-ended questions about motivations for joining the CEC Model, providing a "quasi-statistic" or measure of their relative importance.

Exhibit 6. Most Frequently Mentioned Reasons for Participating in the CEC Model

Organization	New Opportunities in the CEC Model				CEC Model Aligned with Organization Strengths		
	Improve patient care	Influence future payment models	Potential financial gains	Learn about new payment models	Existing resources & relationships	Prior integrated care experience	Model aligns with mission
DaVita							
DCI							
Fresenius							
Rogosin							

Legend: 0% | 1-10% | 11-30% | 31-50% | 51-70% | 71-90% | >90%

Notes: Colors in the heat map indicate the relative frequency with which each topic was mentioned by interviewees. The values were calculated by measuring the total number of times interviewees in an organization discussed a specific entry decision topic and dividing that number by the total number of corporate- and ESCO-level interviews in which the protocol examined participants' reasons for joining the CEC Model.

As shown in **Exhibit 6**, interviewees explained that they joined the CEC Model both to pursue new opportunities and because the model aligned well with aspects of their organizations that were already in place. Concerning new opportunities, interviewees from all four dialysis organizations most frequently cited opportunities to improve patient care and to influence future renal payment models as reasons for joining the model. These two reasons for joining the CEC Model were more commonly noted among non-profit organizations (DCI and Rogosin) than among the for-profit LDOs. DCI uniquely reported having a strategy to develop new clinical best practices in ESCO facilities and then disseminate them to non-ESCO facilities. Potential financial gains were discussed only slightly less frequently than the other two primary reasons among staff from DaVita, DCI, and Fresenius. Rogosin staff did not discuss potential financial gains at all. In contrast, Rogosin staff regularly discussed how the opportunity to gain experience with new payment models influenced their decision to join the CEC Model.

Representatives also described organizational strengths, prior experience, or goals of their organizations that both encouraged and prepared them to join the CEC Model and be successful within the model. All organizations referred to existing resources and relationships that equipped them to join the model. For instance, DaVita staff described how they specifically selected the

Phoenix market for an ESCO because they had a strong relationship with a major nephrology practice in the area (Southwest Kidney Institute), which had substantial experience with ACOs, managed care, and other performance- and risk-based payment models. DaVita representatives also cited organizational competencies from their prior experience with integrated care and that this strength encouraged them to join the CEC Model. Fresenius also reported prior experience with integrated care but to a lesser degree, while no representatives from DCI or Rogosin mentioned this as a reason for joining the model.

In response to a specific question about the impact of the Medicare Access and Children's Health Insurance Program (CHIP) Reauthorization Act (MACRA) on CEC Model participation, corporate staff members from DaVita, DCI, and Fresenius noted that for PY2, nephrology practices were more motivated to join the model because it qualified as an advanced alternative payment model (APM). However MACRA did not go into effect in time to influence the initial round of ESCOs.

2. What New or Enhanced Partnerships Did CEC Model Participants Develop?

Each dialysis organization and associated ESCO established formal financial risk-sharing partnerships with nephrologists, as required by participation in the CEC Model, and many created additional risk-sharing partnerships with other organizations. These optional owners included hospitals and hospital systems, vascular surgery practices, and hospice/palliative care organizations. Non-owner partners included a broad set of stakeholders including additional nephrologists and vascular surgeons, hospitals, an ACO, home health agencies, IT service providers, consumer advocates and other community partners.

Although partnerships with nephrologists were a mandatory part of the CEC Model, all dialysis organizations emphasized the importance of good relationships with these owner nephrologists. Dialysis organization interviewees reported that nephrology practices that opted to participate in the CEC Model were typically the larger practices in the market, were forward-thinking, and were willing to collaborate on ESCO care redesign programs.

In contrast, non-owner nephrologists were typically in relatively small practices in the market and were sometimes less willing to engage in care redesign and improvement efforts. One ESCO staff member described, *"When a physician is not involved [in the ESCO] and a patient is in the ER, if [the nephrologist] gets called and [is told by the ESCO case managers] that, 'We arranged for this patient to go to the dialysis center,' the doctor says, 'Just admit them [to the hospital].' That's the reality of it. They're not as incentivized or concerned about the cost as much."* Despite the relatively active engagement by nephrology practice owners in the ESCOs, some individual nephrologists within these practices nonetheless reported concerns about participating in the CEC Model. Their concerns centered on a lack of knowledge about the CEC Model, potential financial risks, and the possibility of negative unintended consequences for patient safety. For example, one nephrologist in a Fresenius ESCO noted, *"I remember the day I was given the [ESCO agreement] form to sign. I almost decided not to sign it. I almost decided to raise my hand and say hey, you guys signed it, but I won't because I don't know what I am diving into."*

Second, many ESCOs partnered with local vascular surgeons to enhance availability of vascular access services and to improve the quality of care. For example, one DCI corporate respondent commented, *"We wanted to pick surgeons that dedicated their practice to better care for*

patients on dialysis." Some respondents noted that they were more likely to refer a patient to a surgeon at a greater distance if it produced better beneficiary outcomes; this change created a completely new referral pattern for many nephrologists.

Third, hospital system partners were reported by many interviewees to be critical to the success of the CEC Model. The DaVita Phoenix ESCO had a hospital system (Banner Health) as an optional owner, and two other ESCOs (Rogosin and DCI Palmetto) had hospital systems as formal non-owner partners. However, even ESCOs without formal partnerships consistently reported informal efforts to improve communication and coordination with local hospitals. ED providers were seen as particularly important gatekeepers as they could potentially arrange for patients to be transferred to a dialysis facility and thereby avoid an admission. Interviewees described that obtaining patients' records after discharge was crucial for preventing readmissions, and they noted that good relationships with care coordinators, discharge planners, and other staff helped ensure the flow of discharge summary information.

Lastly, ESCO interviewees reported developing other partnerships to acquire or enhance competencies they otherwise lacked. One example was described by a DCI corporate interviewee who explained, "W*hen we asked [care coordinators] who was comfortable having conversations [regarding end-of-life care], about a third of them said they were comfortable, but when we asked how many of them could think of a patient in their dialysis clinic who would benefit from having this conversation; everyone raised their hand - so we know there's a need [for more training]."* Recognizing need for improvement in end-of-life care, DCI leaders engaged hospice and palliative care providers in their home city (Nashville, TN) as optional participant owners in the Music City ESCO. This partnership resulted in new training for ESCO staff members and reportedly increased rates of patient referral for palliative care and hospice services.

3. What Financial Arrangements were developed with Nephrologist Owners?

Under the CEC Model, ESCOs may alter the way they pay nephrology owners to align their financial incentives with the ESCO and encourage the kinds of behavior changes and care redesigns necessary to reduce cost and improve quality. In general, ESCO interviewees had relatively few and/or only general comments regarding the structure of their financial arrangements or P4P programs with nephrologist owners.

DCI corporate staff noted that their P4P program incentivizes nephrologists to speak with each ESCO patient at least once quarterly about dialysis access type (e.g., catheter, fistula), use of in-center versus home dialysis, and kidney transplant. They reported one instance of a patient opting to switch to home dialysis because of this discussion, but they noted it was too early to draw definitive conclusions on how these physician P4P parameters would influence cost and quality. A Fresenius corporate representative explained that their P4P programs were scheduled to start in 2017, so they did not yet have experience to report. DaVita staff did not discuss the P4P waiver, and Rogosin reported not using this waiver because its nephrologists are Rogosin employees.

4. What Were CEC Participants' Expectations Regarding Risk Arrangements?

Interviewees had varied expectations regarding the potential to realize shared savings. Dialysis organization staff typically anticipated positive shared savings, particularly in the early years of the CEC Model, but they thought that the net savings after investments over the five year period

would be low. A Fresenius corporate interviewee anticipated savings in the *"mid to high single-digit [percent]"* during the first 12 to 15 months. DaVita corporate interviewees expected modest shared savings during the first two to three years but stated *"the long term [CEC Model] economic structure is very, very challenging"* in terms of achieving continued long-term savings.

In contrast, most nephrologists reported expecting zero or minimal shared savings. *"It's not college tuition money,"* as one nephrologist said, *"but maybe a semester at a community college."* This nephrologist stated the goal of the nephrology practice involvement in the ESCO was to learn about alternative payment models and that shared savings were incidental. *"[Nephrologists] do have some shared gain in this, but the numbers are relatively small. In July 2017, if we end up with $2,000 in our pocket it would be kind of nice, but I don't think anybody is looking at it that way. We're all with our eye on 3-5 years down the road, [asking] what is CMS going to be doing, and how will we fit into that?"*

5. What Waivers Did CEC Model Participants Use?

Exhibit 7 below displays the utilization of CEC Model waivers by dialysis organization, as reported by interviewees during the first round of ESCO calls.

Exhibit 7. ESCO Waiver Use

Organization	Patient Engagement Incentives Waiver			Pay-for-Performance (P4P)	Remuneration to ESCO	ESCO IT
	Transportation	Nutritional Supplements	Patient IT			
DCI	#/+	#	#	+		
DaVita	#	-			+	-
Fresenius	+	+	#/-		+	#/-
Rogosin	-	-	+	-		+

Key: (+) Waiver in use (#) Under consideration (-) No plans to use (blank) Not discussed by interviewees
Data Source: ESCO Calls, December 2015-March 2016

During site visits, interviewees claimed to have used the patient engagement incentive waivers (i.e., transportation, nutritional supplements, and patient IT). All ESCOs identified lack of transportation as a frequent cause of missed dialysis treatments, hospitalizations, and associated unnecessary expenses. Staff at all dialysis organizations regularly coordinated transportation for patients to and from the dialysis clinic.

Staff at Fresenius reported frequently using the waiver for transportation services, especially when utilizing the Care Navigation Unit (CNU): *"The Care Navigation Team helped [because] a lot of patients don't have transportation. Care Navigation has money allotted per patient. It doesn't go very far, but it gets patients to a couple of extra treatments."* Fresenius interviewees noted the waiver was a valuable tool for reducing avoidable costs, several respondents reflected the sentiment that *"It is easier to pay for a $50 cab ride than an expensive hospital stay."* Interviewees at more rural Fresenius facilities noted that limited public transportation in their regions made the waiver especially useful. DCI ESCOs used the transportation waiver to a lesser degree, while neither DaVita nor Rogosin reported using the waiver.

Site visit interviewees identified several limitations to the transportation waiver. Interviewees described the dollar amount as too low, especially for patients whose transportation needs were chronic. Many staff noted a preference for *"one pool of [transportation] money"* that staff could disburse to patients with the highest needs. Several staff noted that only a small fraction of patients need the waiver and that funds allotted to other patients are wasted. The waiver only funds transportation to and from ESCO providers, so patients may not use it for specialists that are not ESCO owners. At least two ESCOs reported not using the waivers due to logistical challenges, such as finding the right transportation vendors and developing a waiver accounting system. One person at the DaVita Fort Lauderdale ESCO noted, *"It's incredibly challenging with regards to logging of data - where [the patient] went, the mileage, costs associated. We have to track they didn't exceed that $500 per member per year limit. We're nervous about even starting it. It's so nuanced and so legally driven that it's stifling in a way."*

Fresenius staff described that the waiver for oral nutritional supplements (ONS) was a highly valued benefit of the CEC Model. DCI staff indicated that they are evaluating use of the waiver for ONS, while DaVita declined to use the waiver as they reported already providing equivalent nutritional services and they disliked what they perceived to be administrative burdens of the waiver. Interviewees described occasional waiver use for patient IT services. For example, a Rogosin ESCO representative explained that home dialysis equipment services rely on internet connectivity to send important information to the dialysis organization and that one patient was starting home dialysis but was unable to afford internet service. *"Send[ing] him home on home dialysis - that wouldn't have been possible without the waiver,"* one staff member noted. However, the patient eventually opted to receive his dialysis in the facility, so the waiver use was discontinued. One ESCO reported that use of the waiver for patient IT devices was unnecessary due to the stable socioeconomic status of its patients.

Staff members had limited comments about the P4P waiver (Section III.C.3.), and other interviewees did not address the ESCO remuneration waiver or the care coordination waiver during the site visits.

IV. How Did ESCOs Change Care Delivery to Meet CEC Model Goals?

A. Key Findings

Investments in Case Management Staff and Information Technology. Dialysis organizations and their ESCOs reported key investments in two major areas:

- Hiring new staff, particularly case managers, and providing new staff education about the model. Enhanced case management activities were the most frequently noted changes in care delivery in response to the CEC Model.
- Information technology was another major area of investment, including software to improve communication and data sharing among ESCO staff, to rapidly identify available dialysis chairs and reschedule appointments, to manage non-ESRD chronic diseases; to track patient hospitalizations, and to access hospital discharge summaries.

Care Transformation Strategies. Model participants implemented three primary strategies to transform care:

- **Increase access to care.** Two organizations added new dialysis capacity, including new stations reserved for patients who need urgent treatment (e.g., to avoid hospitalization). Fresenius developed IT tools to allow patients to be treated at any available Fresenius facility on short notice. Improved coordination of transportation was identified as another approach to improving access. Finally, staff identified patients' non-dialysis health needs and expedited appointments with medical and mental health specialists.
- **Improve care for ESCO beneficiaries.** DaVita adopted clinical software to improve use of evidence-based guidelines for dialysis and other chronic diseases common among ESRD patients. Fresenius and DCI providers reported using the CEC Model waiver for oral nutritional supplements, which they thought would decrease hospitalizations. DCI and DaVita used renal pharmacists to review patient medications, especially after hospital discharge, which could prevent adverse events.
- **Provide enhanced case management services.** Interviewees reported an increased emphasis on educating patients and family members at ESCO admission, with a goal of reducing avoidable risks (e.g., catheter use, missed treatments). Staff also identified new efforts to risk-stratify patients and to provide intensive services to high-risk patients to optimize care and prevent hospitalizations. ESCOs also reported monitoring patient compliance with dialysis treatment. Fresenius case managers identify patients who are more than 15 minutes late for appointments and contact them to quickly reschedule. ESCO staff also communicate more frequently with hospital staff to identify changes in patient needs, medications, or specialist follow-up care after discharge.

Greater Use of Utilization and Quality Data. ESCO staff reported that CMMI now provides CEC participants with additional data that allows them to better track patients' utilization of non-dialysis related services, which allows providers to be more strategic in their care redesign. Moreover, staff described using this data to more frequently analyze service utilization and quantifiable outcomes such as ED visits, hospitalizations, hospital days, and readmissions.

B. Methods

The same methods described in Section III.B. above were used in the analyses described in this chapter.

C. Results

Dialysis organizations made major investments in the areas of human resources and IT and focused on improving access to dialysis and non-dialysis care, enhancing care for patients, and improving case management as care redesign strategies.

1. What Investments Did Participants Initiate for the CEC Model?

The CEC Model provides incentives (e.g., through shared savings) for better coordination of services, with the aim of reducing per capita or total Medicare payments while maintaining or improving quality. To be successful in achieving these goals, ESCOs need to make investments in care delivery infrastructure and processes including new or enhanced staff dedicated to case management, enhanced information sharing among partners, and/or enhanced partnerships.

a. New Staff Investments and Staff Education

All ESCOs made human resource investments for the CEC Model, including funding new facility-level care coordination and program management positions, remote (e.g., telephonic) case management teams, and regional program managers. Most ESCOs located case managers in dialysis facilities. In contrast, Fresenius established its CNU, which used remotely-based case managers who could observe details of dialysis facility operations by computer and communicate with local staff members by telephone. DCI and DaVita hired pharmacists to support medication therapy management (MTM) programs.

All ESCOs provided staff education about the CEC Model when the program began, but some respondents indicated additional training was needed, especially on non-dialysis-related topics that arose such as depression, nutrition, and palliative care. A few staff reported that patients received a letter about the ESCO program before staff were educated about it, which caused confusion for both staff and patients. Interviewees from all organizations noted staff have historically been uncomfortable discussing palliative or hospice services with patients and indeed several participants at DCI, Rogosin, and DaVita noted ESCO-related opportunities for new training related to end-of-life care. For instance, DCI partnered with a palliative care organization, Alive, to develop a training program for DCI staff. In addition, DCI and Rogosin arranged for Rogosin staff to participate in DCI's training program.

b. Information Technology Investments

IT resources required a major investment for most organizations in the CEC Model. Electronic health record (EHR) and related health information exchange (HIE) upgrades included new tools to allow case managers to track hospitalizations and communicate with non-dialysis providers. Fresenius revamped the entire organization's EHR to improve data sharing across facilities. Interviewees described this investment as critical because it allowed patients to receive care beyond their home facility, such as at "safety net" facilities for a rescheduled appointment or while on vacation. DCI shifted its entire IT department focus to services needed for the CEC Model and accordingly updated its software platforms and EHR to facilitate ESCO care redesign.

Rogosin contracted with DCI to use DCI's EHR (Darwin) and case management software platform (RoundingWell).

While interviewees at nearly all ESCOs reported efforts to improve communication among ESCO staff members, DCI specifically invested in case management software (RoundingWell) to improve communication and coordination regarding clinical tasks, such as a nephrologist requesting (and reviewing) an evaluation by a nutritionist or social worker. One respondent at the DCI Corporate site visit explained, *"If you're only covering one patient, it's easy to remember what I need to do today, but when you're covering two locations and 50 to 100 patients, it's hard to remember who needs what. RoundingWell provides a task list in chronological order so that I can come in and see what's overdue, what's due today, what's due tomorrow. It also gives us the ability to communicate with other members of the team; if we load social workers and dieticians in the system, we can assign tasks to these people specifically."*

Interviewees also described other types of IT investments. DaVita invested in clinical management software (Capella) to record patient clinical data (e.g., lab results, current medications), provide reminders to clinicians about the management of chronic diseases beyond ESRD (e.g., cardiac or eye care), and track performance on ESCO-relevant quality measures. They also adopted a Health Insurance Portability and Accountability Act (HIPAA)-compliant text messaging system (Cureatr) to improve communication among nephrologists and nurses. Rogosin developed interactive e-books for patient education and provided iPads that patients could use during dialysis to access these resources. However, many interviewees reported that the lack of EHR interoperability and lack of effective HIE remained major barriers to effective patient care. Several staff members speculated it would take years to solve the IT barriers between the dialysis facility and outside organizations such as hospitals.

2. How Did CEC Model Participants Transform Care?

Most care redesign for the CEC Model took place at the level of the dialysis organization. All LDOs rolled out large-scale investments and related interventions (e.g., additional EHR capabilities, new communication tools, new case management models with enhanced staffing, new staff training) and these interventions were implemented at the organization's ESCO(s). The major strategies to redesign care for the CEC Model included efforts to improve access to care, enhance care for CEC beneficiaries, and improve case management. At the market level, ESCOs increased coordination with local hospital systems and other providers, as well as invested in HIE and communication technology.

a. Improved Access to Care

CEC Model participants sought to generate savings by reducing ED visits and hospital admissions that can be prevented with adequate dialysis and appropriate management of chronic diseases. Interviewees discussed several strategies to reduce missed dialysis appointments and to improve chronic disease management as described below.

Added Dialysis Capacity

Organizations adopted different strategies for increasing the number of available chairs in order to minimize missed dialysis treatments. Fresenius and DaVita both added a few extra dialysis chairs for their ESCOs. Interviewees at Fresenius described these investments as "safety net chairs" that

would be available for patients who needed an urgent treatment or who rescheduled a missed appointment; certain facilities also added new staff shifts (e.g., late night) to provide greater access to these additional dialysis stations. The investment in these additional chairs was expected to result in savings over time through reduction of avoidable ED visits. A Fresenius ESCO staff member noted, *"In the old days before ESCO, patients with a clotted access had to go to the hospital or get back [to the facility] the next morning, but then you're crossing your fingers through the night that their potassium's okay, hope they don't have any cardiac event. The ability to go from the vascular access center to a dialysis unit that's open odd hours and the middle of the night is a blessing because we can keep our patients out of the hospital."*

To leverage its new capacity, Fresenius worked proactively with patients to reschedule missed appointments. Fresenius added software (Schedule Wise) to simplify appointment scheduling, improve visibility of available chairs, and eliminate barriers to rescheduling appointments for a different time or location. Separate investments in the nationwide Fresenius EHR improved scheduling by creating tools that enabled staff to easily access a patient's dialysis records at more than one facility. One Fresenius ESCO interviewee explained, *"If you dialyze here and you want to go to Florida on vacation and you want to dialyze at a Fresenius in Florida; in the old days your paper records were faxed. Now because of this process of the EMR, they can just open up the [patient record] in the EMR and document directly. When [the patient] is coming back to me, I can see what happened in Florida. Before, we just had to rely on the patient to say, 'It went great,' but maybe something happened or maybe you went to the hospital or you went to the emergency room and you forgot to tell me."*

Scheduling and Expediting Specialty Care Appointments

CEC Model participants implemented strategies to improve access to care beyond dialysis. Interviewees at all dialysis organizations reported that they helped CEC beneficiaries arrange appointments with specialists such as cardiologists, podiatrists, or ophthalmologists. One DCI ESCO staff member noted, *"I've had incidents where patients needed an urgent appointment with a specialist, and [there was] a 2-3 month waiting period. I'll call the office manager and [describe] what's going on. I can fax over test results so the specialist can make an educated decision on [whether] this is an urgent case."* Two DCI ESCOs reported hiring dedicated vascular access coordinators who functioned as schedulers and communication liaisons between the ESCO nephrologists and the vascular surgeon.

Interviewees at nearly all ESCOs reported that ESRD patients frequently suffer from mental health conditions such as anxiety and depression. Many staff described the availability of mental health providers in their community as grossly inadequate, especially for patients on Medicaid. ESCO representatives attempted to arrange patient appointments with mental health resources in the community. Occasionally, staff members also reported working directly with patients to help them identify and address psychosocial needs during dialysis. For example, one interviewee at the Fresenius corporate site visit explained that that *"we have a program [for] those high-risk patients with psychosocial needs that are preventing them from being adherent to their treatments. The social worker works with them intensively to do some cognitive behavioral counseling, because we find that often patients don't have the transportation or they don't want to go to another appointment, although that's what they need."*

b. How Did CEC Model Participants Enhance Clinical Care?

Interviewees reported several approaches to enhance the way dialysis care is delivered and promote best practices in response to the CEC Model. For example, DaVita adopted evidence-based clinical management software (Capella) to improve the quality and coordination of dialysis care (e.g., fluid management, standardizing use of diabetes medications, replacing dialysis catheters with fistulas) and the care for other chronic diseases. However, the "gap" between prior care and current care was not clearly described, nor did they have objective data to demonstrate that there were clear improvements in quality of dialysis care. Staff at a Fresenius ESCO reported more closely monitoring clinical metrics such as albumin, blood pressure, and weight to prevent hospitalizations. Nutritionists at several Fresenius facilities expected that improvements in patient nutrition, such as through use of the ONS waiver, would likely decrease hospitalization rates but that it was too early to see those results.

Both DCI and DaVita reported using renal pharmacists to review ESCO patient medications. The DCI program is staffed remotely by pharmacists. One DCI interviewee explained, *"We have a pharmacist who reviews medications on every ESCO patient quarterly and after every transition of care. Medications have been checked [in the past], but not as thoroughly, and the more we do it, the more we realize patients come out of the hospital and their medication lists are different because of a hospital formulary, and they're taking double the same medications."* Pharmacists may also meet with patients virtually using video teleconferencing software. Staff members at DCI attributed to the MTM program a tenfold reduction in patient falls due to fewer adverse effects from medications.

Home dialysis was mentioned at length by DCI and to a lesser degree by DaVita and Rogosin; in contrast, it was not frequently addressed by Fresenius staff. In general, interviewees reported observing relatively little impact of the CEC Model on home dialysis operation or adoption thus far. Staff members at one DaVita ESCO noted that home peritoneal dialysis is *"better for both the patient and the system"* in terms of infection rates, cost, and convenience; other representatives noted that increasing home dialysis is a goal regardless of the ESCO. As noted in Section III.C.3., the DCI P4P program incentivizes nephrologists to discuss home dialysis with patients at least once per quarter, although several staff members reported expecting that only a small proportion of in-center dialysis patients would consider home dialysis. One interviewee at a DCI ESCO believed that patients who were interested in home dialysis were likely to sign up irrespective of the additional education the ESCO provided patients about home dialysis. In their view, patients who were uncomfortable with home dialysis would not become more likely to sign up, even if the ESCO offered increased patient education on the topic.

c. How Did CEC Model Participants Improve Case Management and Care Coordination?

Case management and, more specifically care coordination, is one of the key focus areas for the CEC Model. Each organization reported investing heavily in these areas and had their own unique models for case management services. Major aspects of case management included beneficiary education, identifying and focusing on high-risk patients, monitoring adherence with dialysis, increasing coordination with hospitals and diverting patients from the ED, and coordinating transitions of care or other related supportive services (e.g., transportation, nutritional supplements).

Early and Ongoing Patient and Caregiver Education

Each ESCO emphasized the importance of educating and engaging patients and caregivers as early as possible. The period immediately after a patient's entry into the ESCO was identified as a key time to educate patients with information about the dialysis process, as described by staff at a DCI ESCO: *"When new admissions come in, we sit with family members and the patient, and we tell them we're a non-catheter clinic. [We] more or less tell them, 'We're not going to let you sit here with something that could kill you.' If [education] starts from the beginning and you have the attention of the caregivers, it's going to make a huge difference."* Staff members noted that this early education was now a higher priority than it had been prior to the ESCO.

ESCOs had educational programs ranging from a series of educational pamphlets and fliers to a 120-day structured curriculum. Some ESCOs used more advanced tools such as eBooks, podcasts, and smartphone applications. Interviewees noted informal patient education had improved due to more frequent face-to-face "rounding" by nephrologists and new care coordinators at the facilities. Staff members noted that ongoing education was effective at reducing hospitalization. Staff at the Fresenius corporate site visit explained that "*the number one thing that we can do is keep the patient adherent to their treatment because probably 30% of admissions are for some sort of treatment-related problem. If they had gotten their dialysis treatment they wouldn't be there."*

Identifying and Focusing on High-Risk Patients

All dialysis organizations reported stratifying CEC beneficiaries based on risk of hospitalization. Interviewees described these decisions as based on clinical judgment or on algorithms that examined patients' comorbidities, prior hospitalizations, and psychological needs. ESCO representatives explained that additional support would be provided to those patients identified as high-risk. For instance, DaVita ESCO staff used dedicated case managers from Village Health (DaVita's disease management service) to provide these high-risk patients with more intensive services and to develop plans to reduce the chance of hospitalization. Interviewees at one DaVita ESCO described efforts to identify *"the most vulnerable patients, these that have been going to the ER for years and being admitted 15-20 times per year. These are the patients that [intensive care coordination] services can have the greatest impact on outcomes and the total cost of care."* Fresenius interviewees from one ESCO noted that their staff members help high-risk patients *"[look] at shared decision-making, advanced directives, advanced care planning, [and] palliative care referrals."*

Proactive Monitoring of Adherence to Dialysis Treatment

Three of the four participating dialysis organizations reported efforts to increase monitoring of patients' ongoing adherence to dialysis treatment. Fresenius was most active in this area. For example, Fresenius ESCO representatives tried to improve treatment adherence by tracking patient arrivals at dialysis appointments. Facility staff reported that before the CEC Model, dialysis organizations were not involved in locating patients who missed treatments. Since starting the ESCO, Fresenius established an electronic system that will proactively inform CNU staff when patients are more than 15 minutes late for appointments. The case managers can then contact patients and immediately reschedule the appointment. ESCO interviewees using this system reported that there was a steep early learning curve in working together with the CNU, but they noted that the collaboration has since improved. Rogosin and DaVita staff also reported monitoring

adherence to dialysis but did so less frequently or intensively than Fresenius. Respondents from DCI did not mention this strategy.

Reducing ED Visits and Avoidable Hospital Admissions

Representatives from all dialysis organizations reported efforts to reduce ED visits among CEC beneficiaries and some described initiatives to reduce avoidable hospital admissions that could follow ED visits. To reduce ED visits, Rogosin staff educated patients to contact the dialysis facility before going to the hospital. One Rogosin staff member explained, *"One of the things that we've done is educating our patients that if you're feeling a certain way, call us, because we may be able to treat you quicker than running to the ER."* Fresenius staff were able to accommodate patients by arranging a treatment on short notice at their home clinic or by finding a nearby dialysis facility with an open chair, thereby preventing an ED visit or hospitalization. One interviewee at a Fresenius ESCO noted that since joining the CEC Model the *"facilities are much more agreeable to taking patients and will even stay late to dialyze them and get patients their treatment."*

Interviewees at Fresenius and DaVita ESCOs described efforts to prevent unnecessary hospital admissions of CEC beneficiaries from the ED. They noted that patients who go to the ED might only need dialysis but that the emergency physicians often admit the patients to the hospital to ensure they receive care. ESCO staff members, particularly nephrologists, stated that they sometimes can reach out to the emergency physicians to suggest alternatives to admission. A nephrologist at a Fresenius ESCO explained, *"My first discussion with the ER physicians is about the patient's condition. If it looks like the patient just missed dialysis, there's a 50% chance the patient may avoid admission. If I'm in the hospital, I would go to the ER, assess the patient myself, and if I feel comfortable then I can try to convince the ER physician, 'Let us see if you can send him back to the clinic.'"* Other ESCO representatives reported developing a protocol in which ED physicians may call the dialysis facility when evaluating an ESCO patient, although no interviewees had objective data documenting the actual use of such an arrangement.

Transitions of Care

Interviewees at all ESCOs emphasized the importance of care transitions, especially for patients recently discharged from the hospital. Staff at a Fresenius ESCO noted, *"We really need hospitals to communicate more with us, especially around discharge. If they let us know that a patient's getting discharged soon, we can make sure that everything is in place for their return [to the facility]."* Case managers were described as crucial in obtaining hospital records after discharge, especially at ESCOs without electronic access to hospital record systems. DCI and DaVita staff noted that medication reconciliation errors often occur during hospital discharge and that their MTM programs aimed to prevent complications during these transitions.

With the exception of ESCOs that had hospital systems as partners (e.g., DaVita's Phoenix-Tucson ESCO), staff members at most dialysis facilities did not report receiving real-time notifications of patients' hospital admission or discharge. However, interviewees at one Fresenius ESCO reported that one of their nephrologists developed an automated tool (based on patient registration data from an affiliated hospital system) to inform nephrologists when their patients are admitted to or discharged from local hospitals.

3. Utilization and Quality Data

Interviewees at most ESCOs reported that the CEC Model did not change the quality data they track for dialysis-specific care. However, they noted that CMS/CMMI now provides CEC participants with utilization data for non-dialysis related services and therefore the ESCO may conduct more frequent review and discussion of key utilization and quality outcomes such as hospitalizations, hospital days, readmission rate, and ED visits. Staff at one Fresenius ESCO described quality meetings as an opportunity to *"do a deep dive into metrics"* and that the ESCO now has resources to make changes based on these utilization and quality data.

All dialysis organization had EHRs before the CEC Model, but DCI and Rogosin both enhanced their EHR capabilities to collect and use data on non-ESRD conditions and other quality metrics (e.g., immunization rates). ESCOs were generally positive about future possibilities of data sharing with hospitals and other local providers, but they noted the substantial technical and legal barriers to establishing data-sharing agreements.

4. Early Implementation Challenges

Interviewees reported facing several early challenges with ESCO implementation, such as the beneficiary attribution mechanism and the transportation waiver.

a. Beneficiary Attribution

Fresenius and DaVita interviewees claimed that the current beneficiary attribution mechanism often causes clinics to "miss" (e.g., not provide enhanced services for) new patients during the incident period of the first 90 days after ESRD diagnosis, when they are most vulnerable. One DaVita ESCO interviewee explained, *"A patient could be treated in the facility up to five months before we are notified of them. We can't start managing care for them until they show up on the CMS alignment list. You miss a golden opportunity, that sweet spot when the patient has first presented to the treatment center for their very first treatment and [you can] get them on the right track - and we lose that completely."* Similarly, a staff member at a Fresenius ESCO described the first three months after starting dialysis as *"a really critical time,"* but this individual similarly noted that the ESCO was reluctant to provide additional services for patients until they were confirmed to be in the ESCO. He noted that his team was told by dialysis organization leadership that *"we have got to be careful because if [patients] end up not being [in the ESCO], then technically [the additional service] is an inducement."*

The "first touch" alignment methodology has also reportedly created difficulty in tracking some patients, such as those who visit an ESCO facility on a short-term basis when traveling away from their home facility and are assigned to the ESCO. When a patient returns to dialysis at his or her "home" facility, the ESCO staff members must track patients' financial outcomes because the ESCO is financially responsible for them, yet staff members have found it difficult to maintain contact with the patient and collect the necessary information. Interviewees acknowledged that the ESCO will not be responsible for the patients' costs if the patient does not receive 50% of the dialysis services within the CBSA, but the ESCO will likely not know this until the end of the year, which prevents them from proactively working to manage those costs and the related care.

b. Regulations on Non-nephrologist Providers

Interviewees at several ESCOs described frustration with regulations (typically at the state level) that restrict delivery of care by non-nephrology providers (e.g., podiatrists, ophthalmologists) at the dialysis facilities. Staff noted that allowing other providers on-site would reduce patient appointment burden and ensure that patients received necessary follow-up care for comorbidities.

c. Aggregation of Smaller Dialysis Organizations

As the only small dialysis organization in the CEC Model during PY1, Rogosin staff members expressed interest in aggregating with other similar organizations who join the program, as suggested by CEC Model program rules. When this organization initially signed up for the model they expected they would be able to do so, yet no other small dialysis organizations joined during PY1 so it was not an option.

V. Beneficiary Perceptions of the CEC Model

The purpose of the first round of beneficiary focus groups was to assess how patients perceived being in the ESCO under the CEC Model and to determine if patients noticed changes in the quality and delivery of their care since their facility began participating in the CEC Model.

A. Key Findings

Analysis of qualitative data from the focus groups identified several key themes related to beneficiary perceptions of the ESCO:

- Most beneficiaries had positive impressions of the care received but only vague knowledge of the CEC Model.
- A few beneficiaries in some focus groups had been exposed to components of the model (e.g., ESCO case managers or an organization's pre-dialysis program) without knowing how they came to be included in the group of ESCO patients at their participating facility.
- When participants were given a brief overview of the ESCO design and goals, most thought it sounded good in principle. However, many of the focus group participants were beneficiaries experienced in managing their own dialysis care. These focus group participants indicated they would like to maintain control over their care and did not think the ESCO would have much of an effect on their health.
- The participants that had the most favorable impressions of ESCOs were generally new patients, patients with a higher comorbidity burden, and patients in need of support services (e.g., transportation, and help with medications or scheduling appointments).

B. Methods

Beneficiary focus groups were conducted at a sample of seven ESCO facilities during the site visits that occurred from August 23, 2016 to November 10, 2016. ESCOs selected facilities for focus group participation based on space availability. Although each focus group was conducted at only one facility within the ESCO, participants may have been from any ESCO-participating facility.

A total of 46 beneficiaries participated in the seven focus groups. Each focus group session lasted approximately 90 minutes and was held in the morning or at lunch time. The focus group selection criteria, analysis, structure, and discussion guide is included in **Appendix D**. All focus groups were audio recorded and transcripts were produced from the recordings. To identify the main themes across the focus groups, transcripts were reviewed and summarized by the moderator.

C. Results

Beneficiaries in focus groups showed mostly positive impressions of the care received, but only vague knowledge of the CEC Model. The participants that had the most favorable response to the ESCO were generally those that were new patients, patients with a higher comorbidity burden, and patients in need of support services (e.g., transportation, help with medications, scheduling appointments).

1. What do beneficiaries know about the CEC Model?

The majority of focus group participants reported they were not aware of the ESCO. When the moderator showed or described mailings, previously sent from the ESCOs to participants outlining the purpose and benefits of the ESCO, a few participants recalled the notifications. Additionally, some participants noticed a new person in the facility, the ESCO case manager; however, they did not associate this person with the ESCO.

Participants generally did not think that the ESCO would affect their care. Many participants were already deeply engaged in managing their own care and opined they would rather continue to manage their own care with limited assistance from ESCO staff. They felt like it would be an unwanted buffer between them and their providers. One beneficiary explained, *"If I need to change my appointment, I do what I've always done here. I change my appointment. I don't call Care Navigation…this is a second party, and I would just rather talk to a nurse."* Another participant explained that the ESCO would be helpful for patients who struggle to manage their own health. A few participants thought the ESCO, as described by the moderator, may improve their dialysis care, explaining, *"I think it would be informative…could improve it"* and *"there is always room for improvement."* Of note, the patients who agreed to participate in the focus groups may have been healthier or more engaged in their care than other ESRD patients, and thus these findings may not be generalizable to all ESCO beneficiaries.

Some participants posited that the ESCO is more beneficial for patients beginning dialysis because they do not have experience managing their own care. Participants thought the ESCO care approach would help new patients adjust to living with ESRD and provide the resources necessary to learn about ESRD, treatment options (modality, transplant), and how to maintain health.

2. What do beneficiaries perceive as the strengths of their ESCO?

The participants that had the most favorable response to the ESCO were generally those that were new patients, patients with a higher comorbidity burden, and patients in need of support services (e.g., transportation, help with medications, scheduling appointments). The majority of focus group participants were not aware of the ESCO but were, however, highly satisfied with their care and their facility. Beneficiaries cited several positive attributes and strengths of their facilities, but none were directly attributed to the ESCO. These included competent and helpful nephrologists and the attentive and supportive services provided by nurses and social workers (e.g., finding medication and dental care at reduced costs, working through insurance issues, arranging transportation, arranging treatment in other facilities for patients when they are traveling). Some participants acknowledged that the ESCO may enhance coordination of care and dialysis education. As one patient elaborated, *"My nurse actually gave me her cell phone number, and she was like, 'if you have any questions with anything, you can just call me,' and I might call her for like the simplest things, but she'll help me. That part of this whole experience for me has been very excellent."*

3. What changes have beneficiaries perceived as a result of their facility participation in the ESCO?

Overall, the focus groups revealed that the majority of beneficiaries were not aware their dialysis facility was part of an ESCO. A few beneficiaries saw the ESCO as an added benefit, while

others believed their facility already provided the described ESCO services and were satisfied with the care they already received.

During the site visits, many clinic staff members shared that they treat both ESCO and non-ESCO beneficiaries the same; some staff members from DCI and Rogosin ESCOs described how nurses and social workers often take on the ESCO case management role and initiatives for non-ESCO beneficiaries. As explained by one DCI staff member, *"We treat our patients the same. [Non-ESCO beneficiaries] don't get left out and we have made that very very clear when we first started that we didn't want any patient to be left out because, no matter what we're doing, our goal is for our patients to receive the same care."* A Rogosin staff member expressed a similar sentiment, *"[None of] the staff on the floor knows who's an ESCO patient. So nobody is treated any different. […] I know if I look up the list, but other than that nobody else really knows who they are and we want to keep it that way because nobody should be treated different."* Staff concern about all patients receiving the same quality of care may be why many focus group participants were not aware they were a part of an ESCO. It may also indicate that ESCO dialysis facilities are taking extra steps to improve care for all of their patients and, therefore, ESCO beneficiaries may be unable to attribute improvements to the ESCO or the model.

VI. What is the Association between Alignment in CEC Model and Quality of Life?

This section presents findings of the association of the CEC Model with HRQOL during PY1. The analysis uses survey data from both CEC participants and a matched comparison group of beneficiaries collected through the KDQOL-36 questionnaire.[11] The KDQOL-36 is a validated 36-item survey with five subscales including physical and mental health, burden of kidney disease, symptoms and problems, and effects of kidney disease.[12,13] Because there was no pre-CEC data collected, a cross-sectional study design was used to compare CEC respondents against a matched comparison group.

A. Key Findings

Within the PY1 of the CEC Model, there was no evidence of a statistically significant or clinically meaningful association of the model with patient quality of life.

- Overall, the estimated associations for patients participating in the CEC Model on the five subscale summary measures were small in magnitude suggesting no clinically meaningful associations with patients' overall HRQOL.
- For the physical component summary measure, there was a small but statistically significant difference, at the 10% significance level, of a 1.4% increase in the mean score for the CEC versus the comparison group.

B. Methods

The association between participation in the CEC Model and quality of life was estimated for CEC beneficiaries, relative to the matched control group of ESRD beneficiaries, using multivariate regression methods (**Appendix E** describes the methods for selecting beneficiaries in the comparison group and for estimating regression models).

The KDQOL-36, which has been administered to thousands of patients since 2002, is estimated to take less than 30 minutes to complete. The KDQOL-36 survey consists of the Short Form 12 (SF-12) generic core of general quality of life questions, four questions related to the perceived burden of kidney disease, twelve questions addressing kidney disease symptoms or problems, and eight questions addressing effects of kidney disease. These items are used to compute the following five scales according to established methods:[14] physical component summary (PCS), mental component summary (MCS), burden of kidney disease, symptoms and problems, and effects of kidney disease. Individual questions are shown in **Appendix E**, **Exhibits E-1** and **E-2**.

[11] The KDQOL-Short Form underwent extensive psychometric testing (e.g., Joshi VD, Mooppil N, Lim JF. Validation of the Kidney Disease Quality of Life-Short Form: a cross-sectional study of a dialysis-targeted health measure in Singapore. *BMC Nephrology*. 2010;11(36). doi:10.1186/1471-2369-11-36.).

[12] Yang et al. Validation of the English version of the Kidney Disease Quality of Life questionnaire (KDQOL-36) in hemodialysis patients in Singapore. *Patient*. 2013;6(2):135-41

[13] Ricardo et al. and CRIC Investigators. Validation of the Kidney Disease Quality of Life Short Form 36 (KDQOL-36) US Spanish and English versions in a cohort of Hispanics with chronic kidney disease. *Ethn Dis*. 2013 Spring;23(2):202-9

[14] https://www.rand.org/health/surveys_tools/kdqol.html

C. Results

For the KDQOL survey, the response rate among CEC beneficiaries was about 36%, (5,098 of 14,256 responded) and lower for the comparison group at 24% (responses from 2,435 of 10,153). Response rates stratified by select characteristics (e.g., demographics) are available in **Exhibit E-3** in **Appendix E**. A sufficient sample size was achieved for estimating the association of the CEC Model with each of the five respective composite scores. In other words, each of the five subscale models achieved the minimum sample size required to detect an increase in the average score of 5 points, with 80% power and acceptable level of a type 1 error set to be 10% for a one-sided hypothesis test. There is no single accepted absolute target in determining a clinically meaningful change (increase or decrease) in quality of life scores.[15] However, multiple clinical trials reported statistically significant and implied meaningful results in varying ranges (e.g., <1 to about 5 points) in the PCS or MCS or other HRQOL subscales, pre/post intervention.[16] Therefore, as a rule of thumb, we consider that a 5-point difference is reasonably clinically meaningful.

Exhibit 8a & 8b shows the distribution of select characteristics across CEC and comparison respondents (also see **Exhibit E-4a** and **E-4b** in **Appendix E**). CEC beneficiaries that responded to the survey are slightly older, slightly more likely to be White, and have a lower health risk score relative to the entire CEC group that was sent the survey. Similarly, the comparison group respondents are older, more likely to be White, and have a lower health risk score than the entire comparison group surveyed. The impact of these differences on the results were minimized by using sample-balancing weights to match the distribution by age, sex, and race for the total surveyed and respondent groups (see **Exhibit E-4a** and **E-4b** in **Appendix E**). Finally, respondents across the CEC and matched comparison groups exhibit extremely similar distributions for sex and hierarchical condition category (HCC) score. However, CEC respondents are less likely to be younger than 65, and less likely to be White than comparison respondents.

[15] See Hays and Cooley on the limits of applying an absolute threshold for determining clinically meaningful differences in HRQoL scores (The Concept of Clinically Meaningful Difference in Health-Related Quality of-Life Research: How Meaningful is it? Pharmacoeconomics 2000 Nov; 18 (5): 419-423).

[16] Dwyer, Johanna T & Larive, Brett & Leung, June & Rocco, Michael & Burrowes, Jerrilynn D & Chumlea, Wm Cameron & Frydrych, Anne & Kusek, John W & Uhlin, Leigh. Nutritional status affects quality of life in Hemodialysis (HEMO) Study patients at baseline. Journal of Renal Nutrition: the official journal of the Council on Renal Nutrition of the National Kidney Foundation. 2002 12 (4): 213-23

Unruh, Mark & Benz, Robert & Greene, Tom & Yan, Guofen & Beddhu, Srinivasan & DeVita, Maria & Dwyer, Johanna T & Kimmel, Paul L & Kusek, John W & Martin, Alice & Rehm-McGillicuddy, Josephine & Teehan, Brendan P & Meyer, Klemens B. Effects of hemodialysis dose and membrane flux on health-related quality of life in the HEMO Study. Kidney international. 2004 66 (1): 355-66.

Garg et al., Patients receiving frequent hemodialysis have better health-related quality of life compared to patients receiving conventional hemodialysis. Kidney International (2017) 91, 746–754).

FREEDOM, a prospective cohort study reported a range of score changes (most between 2 and 4 points) at different follow-up time points: Finkelstein, Fredric O & Schiller, Brigitte & Daoui, Rachid & Gehr, Todd W & Kraus, Michael A & Lea, Janice & Lee, Yoojin & Miller, Brent W & Sinsakul, Marvin & Jaber, Bertrand L. At-home short daily hemodialysis improves the long-term health-related quality of life. Kidney International. 2012 82 (5): 561-9.

Exhibits 8a & 8b. Characteristics by Respondent Group

Characteristics		CEC Beneficiaries				Matched Comparison Beneficiaries			
		All Surveyed		Respondents		All Surveyed		Respondents	
		N	%	N	%	N	%	N	%
Age	<65	7,276	51.1	2,392	47.0	5,216	51.4	912	37.5
	65 to 85	6,044	42.4	2,339	45.9	4,261	42.0	1,289	53.0
	85 +	927	6.5	363	7.1	674	6.6	233	9.6
Sex	Female	6,230	43.7	2,274	44.6	4,400	43.3	1,078	44.3
	Male	8,023	56.3	2,822	55.4	5,753	56.7	1,357	55.7
Race	Black	6,726	47.2	2,315	45.5	4,947	48.7	995	40.9
	White	5,412	38.0	2,121	41.6	3,969	39.1	1,222	50.2
	Hispanic	1,013	7.1	330	6.5	506	5.0	75	3.1
	Other	1,096	7.7	328	6.4	729	7.2	142	5.8

	CEC Beneficiaries				Matched Comparison Beneficiaries			
	All Surveyed		Respondents		All Surveyed		Respondents	
	N	Mean	N	Mean	N	Mean	N	Mean
HCC Score	14,238	7.1	5,090	6.8	10,152	7.0	2,435	6.8

Note: Ns do not always sum to total due to missing values.

Exhibit 9 summarizes the empirical association between participation in the CEC Model and quality of life, as measured by KQDOL composite scores. The analysis showed that, within PY1 of the CEC Model, there were no clinically meaningful increases or decreases in -HRQOL among participants in the CEC Model. Overall, the estimated associations between participation in the CEC Model and the five composite scores were generally small in magnitude (i.e., point estimates amounting to composite score changes of 0.6%-1.6% relative to the mean). Only the PCS measure had a statistically significant difference of 0.50 (a 1.4% increase in the mean score) for the CEC versus the comparison group.[17] **Exhibit E-6** in **Appendix E** displays the regression results for all variables included in the models.

[17] The mean PCS is 34.5 so a 0.5 increase is equivalent to a 1.4% increase relative to the mean in the sample. See **Exhibit E-5** in **Appendix E**.

Exhibit 9. Estimated Associations between the CEC Model Participation and KDQOL Scores

KDQOL Composite Score	N	CEC Estimate ^	90% Lower CI	90% Upper CI	CEC Estimate Relative to CEC Mean Score (Percent Change)+
Physical Component Summary	5,825	0.50*	0.02	0.98	1.4%
Mental Component Summary	5,961	0.27	-0.26	0.80	0.6%
Burden of Kidney Disease	7,066	0.68	-0.60	1.96	1.6%
Symptoms and Problems	7,191	0.76	-0.04	1.56	1.0%
Effects of Kidney Disease	7,079	0.53	-0.56	1.62	0.8%

Notes: (^) The CEC estimate is the ordinary least squares (OLS) regression coefficient, which represents the association between participation in the CEC Model—relative to the comparison group—with the KDQOL scores. CI = confidence interval. (+) the CEC estimate (i.e., regression coefficient) divided by the respective measure's mean within the CEC population and displayed as a percent. *** $p < 0.01$, ** $p < 0.05$, * $p < 0.10$.

These results are generally consistent with the results of CMS's ESRD Managed Care Demonstration[18,19] and the Evaluation of the ESRD Disease Management Demonstration.[20,21] There are a couple of considerations for interpreting the KDQOL survey results. To begin, response rates were generally low relative to these two demonstrations. Consequently, responses may not be representative of the population of CEC aligned beneficiaries. In addition, this study uses cross-sectional differences in risk-adjusted scores to infer associations with the CEC Model. Moreover, survey results prior to the CEC Model were unavailable and this study was unable to assess changes following implementation of the CEC Model. The strength of these results therefore is dependent on how well the comparison group represents what would have happened absent the CEC Model. The characteristics we selected for matching and the regression analysis may not adequately account for all differences between CEC and comparison beneficiaries. Therefore, any observed associations should not be interpreted as causal. Lastly, the KDQOL survey was administered during the first year of the CEC Model, thus there was limited time for ESCOs to affect quality of life.

[18] In the ESRD Managed Care Demonstration there was a statistically significant increase by 1.9 in the overall MCS but this may also not be considered clinically meaningful. This demonstration employed the SF-36 (not KDQOL) survey.

[19] Dykstra et al. Final Report on the Evaluation of CMS's ESRD Managed Care Demonstration. 2013; 128

[20] In the Disease Management Demonstration there was evidence of statistically significant but not clinically meaningful declines in MCS and PCS scores in one Disease Management Organization (DMO). This demonstration utilized either the SF-12 or the SF-36 (not KDQOL) surveys.

[21] Ramirez et al. End-Stage Renal Disease (ESRD) Disease Management Demonstration Evaluation Report: Findings from 2006-2008, the First Three Years of a Five-Year Demonstration. 2010; 85

VII. What Were CEC's Impacts on Medicare Beneficiary Spending, Utilization, and Quality?

This section presents quantitative findings of the impact of the CEC Model on Medicare claim-based outcomes on spending, utilization, and quality during PY1.

A. Key Findings

Exhibit 10 summarizes the direction and statistical significance of the impact estimates of the CEC Model, by measure domain.

Exhibit 10. Summary of DiD Results

Evaluation Measures		CEC Model Effect (Impact estimate)*
Spending PBPM	Total Part A and Part B	⬇ Decrease
	Acute Inpatient	⬇ Decrease
	Readmission	N.S.
	Home Health	N.S.
	Hospice	N.S.
	Post-Acute Institutional Care	⬇ Decrease
	Hospital Outpatient	N.S.
	Office Visit Services	⬇ Decrease
	Other Part B	N.S.
	Total Dialysis	⬆ Increase
Utilization	Hospitalizations	⬇ Decrease
	Readmissions	N.S.
	ED Visits	N.S.
	Observational Stays	N.S.
	ED Visits Within 30 days of an Acute Hospitalization	N.S.
	Length of Stay	⬆ Increase
	Hemodialysis	N.S.
	Peritoneal Dialysis	N.S.
	Office Visits	⬇ Decrease
	Home Hemodialysis	N.S.
Quality	Fistula	N.S.
	Catheter	⬇ Decrease
	VA Complications	⬇ Decrease
	ESRD Complications	⬇ Decrease
	Pre-ESRD care	N.S.
	Hospice	N.S.
	Flu Vaccinations	N.S.
Unintended Consequences	Part D Cost Shifting	N.S.

Notes: ⬆ significant increase; ⬇ significant decrease; N.S. = not statistically significant.
Each impact estimate is based on a DiD analysis, and reflects the difference in the regression-adjusted average outcome for beneficiaries in CEC facilities for PY1 with baseline relative to the same difference over time for beneficiaries in matched comparison facilities. Significance identified with p-values ≤ 0.10.

Notable findings summarized in **Exhibit 10**, include:

- **Medicare Spending**. The broadest measure of Medicare spending effects, total Medicare Parts A and B allowed charges PBPM, was $159 PBPM, resulting in aggregate savings of $29.9 million during PY1. Savings were mostly driven by relative declines in acute inpatient service spending ($102 PBPM; $p<0.01$) and post-acute institutional spending ($59 PBPM; $p<0.05$). Payments for dialysis services increased slightly ($12 PBPM, $p<0.1$) for CEC beneficiaries relative to the comparison group.
- **Utilization.** Relative to the comparison group, CEC beneficiaries used less inpatient care. Specifically, CEC beneficiaries were 6% less likely to be hospitalized (-0.61 percentage points; $p<0.01$).
- **Impacts on quality of care.** Catheter use, which is not a preferred form of vascular access for hemodialysis, declined slightly among ESCO patients relative to the comparison group ($p<0.10$). CEC beneficiaries experienced fewer hospitalizations associated with ESRD complications ($p<0.01$), and vascular access complications ($p<0.10$).

B. Methods

Our evaluation used a DiD approach to infer impacts of the CEC Model on key outcomes depicted in **Exhibit 11**. DiD is a statistical technique that quantifies the impact of the model by comparing changes in CEC beneficiaries before and after CEC to changes in risk-adjusted outcomes in the comparison group before and after CEC. This approach controls for beneficiary-, market-, and facility-level differences between the CEC and comparison populations, minimizes biases from time-invariant differences between the CEC and comparison populations, and controls for secular trends. The DiD analysis uses Medicare Part A and Part B enrollment and claims data from January 2014 to December 2016 in combination with other program, provider, and market data sources. The period of analysis is divided into pre-CEC, transition, and post-CEC periods. The pre-CEC period, defined as January 2014 to April 2015, was followed by a six-month transition period that ran through September 2015. The post-CEC period began on October 2015 and ended December 2016. The transition period took into consideration the delayed start of the CEC Model or "Go Live" date, which was originally scheduled for April 2015. Because ESCOs may have started implementing changes in preparation for the original "Go Live" date, care delivered during the transition was excluded from both the pre-CEC and the post-CEC period. Thus, the DiD compares changes in outcomes between the pre-CEC period and the post-CEC period (PY1). See **Appendix F** for a description of the DiD methodology including data sources, outcomes definitions, methods for identifying comparison populations, and statistical models. **Appendix G** discusses the evaluation's power to detect impacts.

Exhibit 11. Outcome Measures by Domain

Outcome Measure Domain	Evaluation Measure
Spending	• Average Part A and Part B Medicare standardized allowed charges • Average standardized allowed charges PBPM for the following services: inpatient, readmissions, institutional post-acute care, home health, hospice, outpatient, office visits, other Part B, and dialysis care.
Utilization	• Dialysis modality ▪ Percent of beneficiaries receiving hemodialysis in a given month ▪ Percent of beneficiaries receiving peritoneal dialysis in a given month • Percent of beneficiaries receiving home hemodialysis in a given month • Percent of beneficiaries with at least one hospitalization in a given month • Average acute hospital inpatient length of stay (LOS) • Percent of beneficiaries with at least one ED visits in a given month • Percent of beneficiaries with at least one observational stay in a given month • Percent of beneficiaries with at least one ED visit within 30 days of an acute hospitalization • Number of office visits
Quality	• Vascular Access ▪ Fistula- Percentage of adult patients who had a fistula 90 days or longer ▪ Catheter- Percentage of adult patients who had a catheter 90 days or longer • Hospitalizations for complications associated with dialysis care • Vascular Access Complications • ESRD Complications (i.e., volume depletion, hyperpotassemia, fluid overload, heart failure, and pulmonary edema) • Standard Readmission Ratio (NQF#2496) • Standard Hospitalization Ratio (NQF#1463) • Standard Mortality Ratio (NQF#0369) • Percent starting dialysis without prior ESRD-nephrology care – beneficiary had no previous ESRD-nephrology care • Flu vaccinations • Percent of patients receiving hospice services in a given month

Notes: Allowed charges were standardized to remove the effects of Medicare's geographic wage, teaching, and other payment adjustments. (*) Total Part D represents total cost of prescriptions including: ingredients costs, dispensing fee, sales tax, and vaccine administration fee (if applicable).

C. Results

This section presents results from the DiD models for outcomes related to spending, utilization and quality as well as results from the Part D cost shifting analysis.[22]

1. CEC Impact on Medicare Spending

Average total Medicare Part A and Part B standardized allowed charges, our overall measure of Medicare spending, increased slightly from the baseline to PY1 for comparison group beneficiaries, while it decreased for the CEC, resulting in a reduction of $159 PBPM ($p<0.10$)for CEC beneficiaries. This savings estimate represents about 2% of the average PBPM Medicare Part A and Part B allowed charges for CEC beneficiaries at baseline. A similar pattern (i.e., a decline in

[22] Parallel trends for each measure were examined. Results of the test can be found in the Appendix.

spending for CEC beneficiaries relative to the comparison group) was found in all Part A settings, with statistically significant relative declines in spending for post-acute institutional care (-$59 PBPM; p<0.05) and acute inpatient stays (-$102 PBPM; p<0.01).[23] There was not a significant impact in spending for Part B services, except for office visits where there was a small but statistically significant relative decline in allowed charges (-$13 PBPM; p<0.10) for CEC beneficiaries relative to the comparison group. Finally, the CEC Model had a small increase ($12 PBPM, p<0.10) on expenditures related to dialysis services (see **Exhibit 12** for additional details).

Exhibit 12. Impact of the CEC Model on PBPM Medicare Spending, PY1

Spending ($) PBPM by type of service (standardized allowed charges)		CEC		Comparison		DiD Estimate			
		Baseline	PY1 Mean	Baseline	PY1 Mean	DiD	90% Lower CI	90% Upper CI	Percent Change
Total Part A and Part B		$7,486	$7,365	$7,618	$7,655	-159**	-$291	-$26	-2.1%
Part A	Acute Inpatient	$1,601	$1,628	$1,663	$1,793	-102***	-$163	-$42	-6.4%
	Readmissions~	$310	$319	$332	$366	-$24	-$50	$2	-7.8%
	Home Health	$189	$180	$168	$166	-$6	-$14	$2	-3.4%
	Hospice	$18	$15	$16	$14	-$1	-$4	$3	-3.6%
	Post-Acute Institutional Care	$561	$544	$605	$647	-$59**	-$107	-$12	-10.6%
Part B	Dialysis	$3,328	$3,335	$3,311	$3,305	$12*	$1	$23	0.36%
	Hospital Outpatient	$460	$457	$501	$490	$8	-$10	$27	1.8%
	Office Visits	$369	$377	$374	$396	-$13*	-$24	-$2	-3.6%
	Other Part B	$838	$699	$887	$762	-$14	-$77	$49	-1.7%

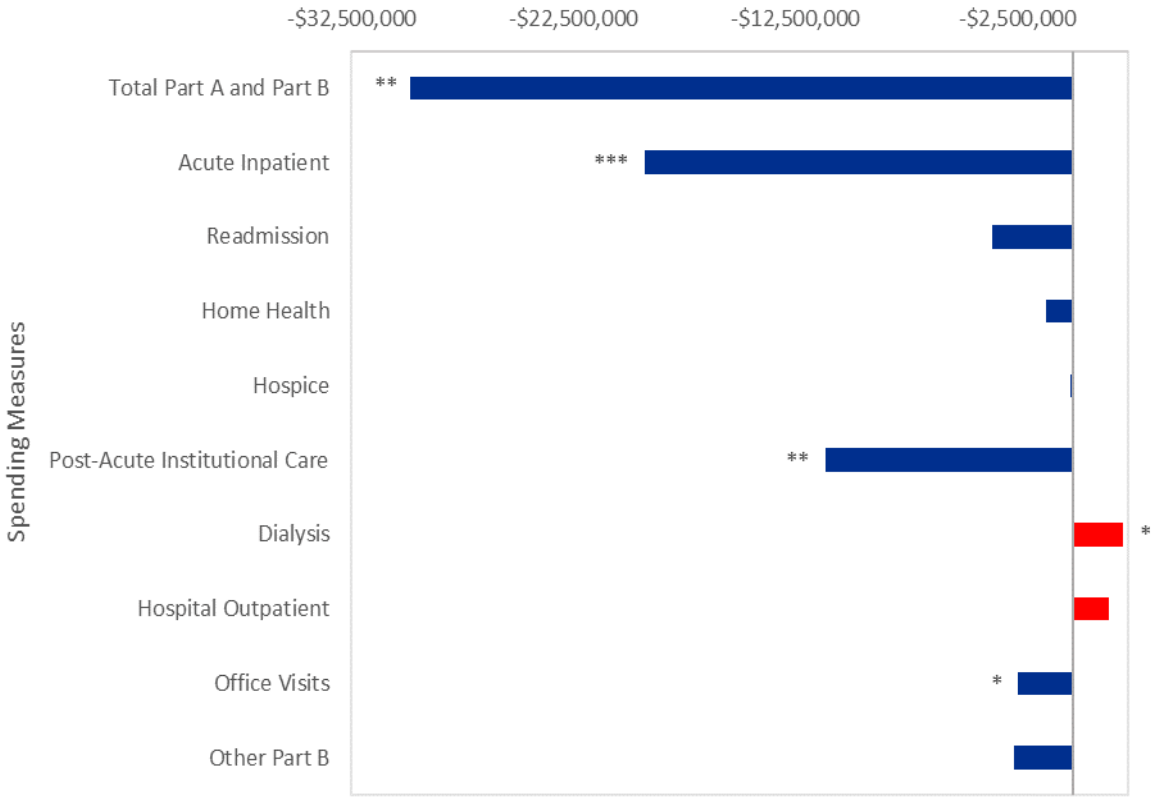
Notes: PY1 covers the period from October 2015-December 2016. Each impact estimate is based on a DiD analysis, and reflects the difference in the regression-adjusted mean outcome for beneficiaries in CEC facilities for PY1 with baseline relative to the same difference over time for beneficiaries in matched comparison facilities. Medicare allowed charges outcomes are standardized to remove the effect of geographic and other adjustments. CI= confidence interval, ***p<0.01, **p<0.05, *p<0.1. ~Readmission expenditures are included in the overall acute inpatient spending.

Exhibit 13 shows the impact on aggregate savings. The impact of the CEC Model on total Part A and Part B allowable charges translates into aggregate reductions in spending of approximately $29.9 million over the 15-month PY1 period.[24] Of these, aggregate reductions in spending for inpatient services was $19.3 million.

[23] Post-acute institutional care, includes allowed charges from inpatient rehabilitation facilities (IRF), skilled nursing facilities (SNF), and long-term care hospitals. Individual analysis of these payments groups identified that savings in post-acute institutional care was primarily driven by long-term care hospital allowed charge reductions.

[24] Estimates are based on standardized allowable charges. Also, these estimates do not account for payments between ESCOs and CMS resulting from PY1 reconciliation.

Exhibit 13. Aggregate Estimates of Medicare Savings by Coverage Type, PY1



Notes: PY1 covers the period from October 2015-December 2016. Each aggregate estimate of savings is based on the regression adjusted DiD impact estimate multiplied by the total number of CEC beneficiary months during PY1. Significance of the DiD impact estimate is indicated along the x-axis along with the outcome title, where * implies significance at the 10% level, ** at the 5% level, and *** at the 1% level assuming a two-tailed test. Blue bars represent favorable decreases and red bars represent unfavorable increases.

2. CEC Impact on Utilization

We examined the impact of the CEC Model on utilization of various types of services in order to understand the payment outcomes summarized above. Consistent with the findings in spending and the strategies to control costs reported by ESCO participants, ESCOs reduced the incidence of hospitalizations during PY1. As shown in **Exhibit 14** below, the percent of beneficiaries that experienced at least one readmission, ED visits, or ED visits within 30 days of hospitalization increased from baseline to PY1 for both groups, but these measures increased less for CEC than for comparison beneficiaries. However, only hospitalizations declined significantly ($p<0.01$). The percentage of CEC beneficiaries who had at least one hospitalization in a 30 day period decreased slightly from 10.8% to 10.7% from baseline to PY1 while it increased from 11.1% to 11.6% for the comparison group, resulting in a net decline of 0.65 percentage points. In terms of the baseline average, this estimate means that CEC beneficiaries were 6% less likely to have a hospitalization in a given month in PY1. The average length of stay among those beneficiaries who were hospitalized remained stable from baseline to PY1 for CEC beneficiaries while it decreased for beneficiaries in the comparison group, resulting in a relative increase of 0.16 days (2.8%). This relative increase was not explained by a change (from the pre-CEC to the post-CEC period) in the average Medicare Severity-Diagnosis Related Group (MS/DRG) corresponding to

CEC beneficiaries' hospital admissions to that in the comparison group. Additional analyses will be conducted if the difference persists with greater longitudinal follow-up to assess what clinical behaviors might be contributing to this increase.

Exhibit 14. Impact of the CEC Model on Inpatient and Emergency Department Use, PY1

Measure		CEC		Comparison		DiD Estimate			
		Baseline mean	PY1 mean	Baseline mean	PY1 mean	DiD	90 % Lower CI	90 % Upper CI	Percent Change
% of Beneficiaries with at least one event in a 30 day period	Hospitalizations	10.80%	10.67%	11.08%	11.60%	-0.65***	-1.03	-0.26	-5.99%
	Readmissions	29.03%	29.04%	30.20%	30.97%	-0.76	-2.07	0.55	-2.61%
	Emergency Department Visits	10.97%	11.16%	11.10%	11.56%	-0.26	-0.61	0.09	-2.37%
	Observational Stays	2.54%	2.75%	2.37%	2.66%	-0.08	-0.24	0.08	-3.15%
	ED Visits Within 30 days of an Acute Hospitalization	2.40%	2.42%	2.53%	2.63%	-0.08	-0.25	0.08	-3.42%
Length of Stay	Length of Stay	5.84	5.81	5.94	5.74	0.16*	0.00	0.32	2.78%

Notes: PY1 covers the period from October 2015-December 2016. Each impact estimate is based on a DiD analysis, and reflects the difference in the regression-adjusted mean outcome for beneficiaries in CEC facilities for PY1 with baseline relative to the same difference over time for beneficiaries in matched comparison facilities. CI = confidence interval at the 10% level. ***p<0.01, **p<0.05, *p<0.1. (*) Average length of stay is derived by dividing number of acute inpatient days by admissions. The point estimate represents a change of the ratio.

Exhibit 15 below, shows that there was no impact on type of modality ESRD patients chose to receive.

Exhibit 15. Impact of the CEC Model on Dialysis Modality, PY1

Measure	CEC		Comparison		DiD Estimate			
	Baseline mean	PY1 mean	Baseline mean	PY1 mean	DiD	90% Lower CI	90% Upper CI	Percent Change
Hemodialysis~	93.76%	93.03%	94.49%	94.13%	0.07	-0.70	0.85	0%
Peritoneal Dialysis	6.50%	7.12%	5.33%	5.98%	-0.04	-0.82	0.75	1%

Notes: PY1 covers the period from October 2015-December 2016. Each impact estimate is based on a DiD analysis, and reflects the difference in the regression-adjusted mean outcome for beneficiaries in CEC facilities for PY1 with baseline relative to the same difference over time for beneficiaries in matched comparison facilities. CI = confidence interval at the 10% level. ***p<0.01, **p<0.05, *p<0.1. ~ includes in-center and home hemodialysis.

We also assessed whether the CEC Model impacted the location in which hemodialysis beneficiaries received their treatment. Previous studies have suggested that home hemodialysis patients report having higher quality of life relative to patients receiving in-center hemodialysis.[25] **Exhibit 16** below, shows the impact estimate on whether a beneficiary received at least one home hemodialysis treatment in a month. There was no significant impact, due to the CEC Model, on the percent of CEC beneficiaries receiving home hemodialysis relative to the comparison group.

[25] https://www.hsrd.research.va.gov/publications/esp/kidney-dialysis-REPORT.pdf

Exhibit 16. Impact of the CEC Model on Hemodialysis Treatment Location, PY1

Measure	CEC		Comparison		DiD Estimate			
	Baseline Mean	PY1 Mean	Baseline Mean	PY1 Mean	DiD	90% Lower CI	90% Upper CI	Percent Change
Home Hemodialysis	1.98%	2.16%	1.53%	1.57%	0.14	-0.22	0.51	7.20%

Notes: PY1 covers the period from October 2015-December 2016. Each impact estimate is based on a DiD analysis, and reflects the difference in the regression-adjusted mean outcome for beneficiaries in CEC facilities for PY1 with baseline relative to the same difference over time for beneficiaries in matched comparison facilities. LCI = lower confidence interval at the 10% level, UCI= upper confidence interval at 10% level. ***p<0.01, **p<0.05, *p<0.1. **Notes:** PY1 covers the period from October 2015-December 2016. Each impact estimate is based on a DiD analysis, and reflects the difference in the regression-adjusted mean outcome for beneficiaries in CEC facilities for PY1 with baseline relative to the same difference over time for beneficiaries in matched comparison facilities. CI = confidence interval at the 10% level. ***p<0.01, **p<0.05, *p<0.1.

Exhibit 17 shows the impact estimate on office visits where we expected an increase. We found a very small statistically significant negative impact on the number of office visits. The number of office visits increased for both the CEC and the comparison group beneficiaries, but they increased slightly less for CEC beneficiaries, resulting in a net decline of 0.03 (p<0.10) office visits PBPM. The DiD estimate translates into a modest 2.9% reduction in the number of visits PBPM for CEC beneficiaries.

Exhibit 17. Impact of the CEC Model on Number of Evaluation and Management Office Visits PBPM, PY1

Measure	CEC		Comparison		DiD Estimate			
	Baseline Mean	PY1 Mean	Baseline Mean	PY1 Mean	DiD	90% Lower CI	90% Upper CI	Percent Change
Number of Office Visits PBPM	0.85	0.87	0.89	0.93	-0.03*	-0.05	0.00	-2.94%

Notes: PY1 covers the period from October 2015-December 2016. Each impact estimate is based on a DiD analysis, and reflects the difference in the regression-adjusted mean outcome for beneficiaries in CEC facilities for PY1 with baseline relative to the same difference over time for beneficiaries in matched comparison facilities. CI = confidence interval at the 10% level. ***p<0.01, **p<0.05, *p<0.1.

3. CEC Impact on Quality

Vascular Access (VA) Type. Measures for VA type were assessed to identify whether dialysis facilities were active in maximizing arterial venous fistula use and minimizing the use of catheters. The results show that catheter use among CEC beneficiaries significantly declined during PY1. The percentage of CEC beneficiaries who used catheters as a means of vascular access for a period over 90 days increased from 8.5% to 8.8% from baseline to PY1, but this increase was 0.7 percentage points lower relative to the increase observed at comparison facilities. For PY1, there was no statistically significant effect on fistula use. Results are shown in **Exhibit 18**.

Exhibit 18. Impact of the CEC Model on Vascular Access Type, PY1

Measure	CEC		Comparison		DiD Estimate			
	Baseline Mean	PY1 Mean	Baseline Mean	PY1 Mean	DiD	90% Lower CI	90% Upper CI	Percent Change
Fistula	62.75%	63.45%	63.19%	63.08%	0.80	-0.22	1.82	1.28%
Catheter	8.48%	8.84%	9.40%	10.49%	-0.72*	-1.38	-0.05	-8.46%

Notes: PY1 covers the period from October 2015-December 2016. Each impact estimate is based on a DiD analysis, and reflects the difference in the regression-adjusted mean outcome for beneficiaries in CEC facilities for PY1 with baseline relative to the same difference over time for beneficiaries in matched comparison facilities. CI = confidence interval at the 10% level. ***p<0.01, **p<0.05, *p<0.1.

Hospital admissions due to VA and ESRD complications. Adverse events such as VA and ESRD complications that resulted in a hospital admission were evaluated.[26] Results are shown in **Exhibit 19**. In both measures, the CEC Model had a statistically significant impact, with effect sizes suggesting that CEC beneficiaries were 14% and 12% less likely relative to comparison beneficiaries, to have a hospital admission for these complications.

Exhibit 19. Impact of the CEC Model on Admissions due to VA and ESRD Complications, PY1

Measure	CEC		Comparison		DiD Estimate			
	Baseline mean	PY1 mean	Baseline mean	PY1 mean	DiD	90% Lower CI	90% Upper CI	Percent Change
VA Complications	0.60%	0.60%	0.66%	0.76%	-0.09**	-0.17	0.00	-14%
ESRD Complications	1.72%	1.67%	1.81%	1.96%	-0.21***	-0.37	-0.05	-12%

Notes: PY1 covers the period from October 2015-December 2016. Each impact estimate is based on a DiD analysis, and reflects the difference in the regression-adjusted mean outcome for beneficiaries in CEC facilities for PY1 with baseline relative to the same difference over time for beneficiaries in matched comparison facilities. CI = confidence interval at the 10% level. ***p<0.01, **p<0.05, *p<0.1.

Exhibit 20 shows the impact estimates for select quality measures, hospice care and flu vaccinations, where we hypothesized an increase due to the CEC Model. We found no impact.

Exhibit 20. Impact of the CEC Model on Selected Quality Measures, PY1

Measure	CEC		Comparison		DiD Estimate			
	Baseline Mean	PY1 Mean	Baseline Mean	PY1 Mean	DiD	90% Lower CI	90% Upper CI	Percent Change
Percent receiving hospice care	0.64%	0.53%	0.59%	0.49%	0.00	-0.10	0.10	-0.18%
Percent vaccinated during flu season (October – March)	29.5%	38.6%	28.93%	38.3%	-0.32	-4.61	3.97	-1.09%

Notes: PY1 covers the period from October 2015-December 2016. Each impact estimate is based on a DiD analysis, and reflects the difference in the regression-adjusted mean outcome for beneficiaries in CEC facilities for PY1 with baseline relative to the same difference over time for beneficiaries in matched comparison facilities. CI = confidence interval at the 10% level. ***p<0.01, **p<0.05, *p<0.1.

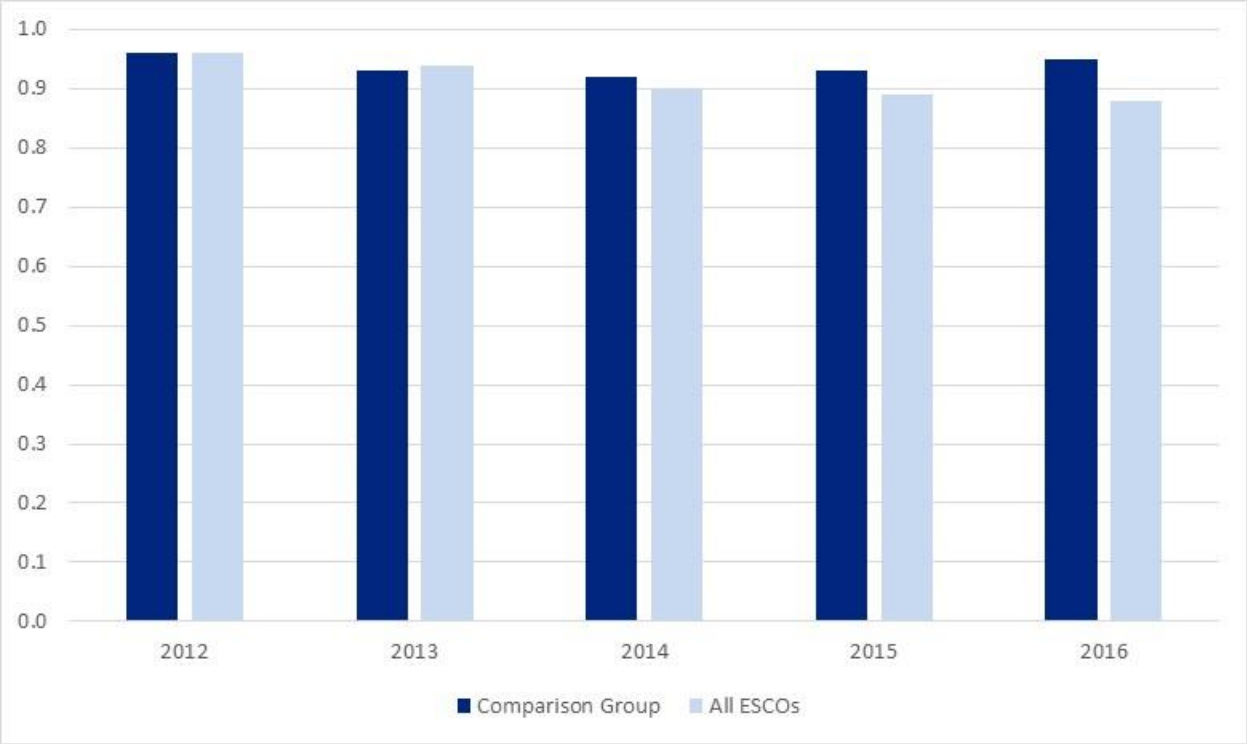
Standard hospitalization, readmission, and mortality ratios. Exhibits 21-23 display all three of the annual standardized measures from 2012 through 2016 for ESCOs and the comparison

[26] The set of diagnoses codes that define each type of complication can be found in **Appendix F, Exhibit F-3.**

group. These standardized measures are useful for examining whether ESCO-specific adverse event rates (i.e., hospitalizations, readmissions, and mortality) are in line with national averages across all dialysis facilities (adjusted for case mix). These measures reflect the number of adverse events for patients in an ESCO, relative to the number of adverse events that would be expected based on overall national rates and the characteristics of the patients at that ESCO as well as the number of discharges.

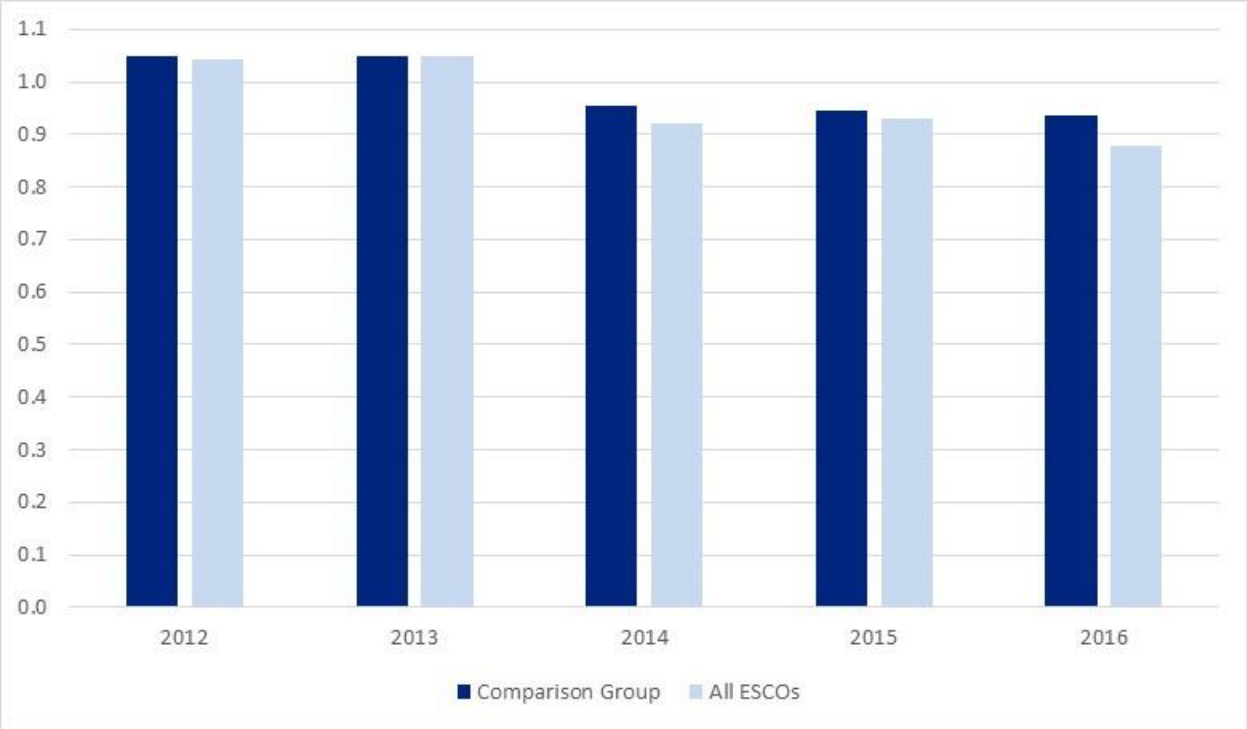
National hospitalization rates for dialysis patients have been declining over time. Beginning in 2014, hospitalization rates, as measured by the SHR, have improved relative to the comparison group, with the greatest differences between the control group and the all ESCO group in calendar year 2016. The chart in **Exhibit 21** presents the SHR for all ESCOs and the comparison group in each year starting in 2012 through 2016.

Exhibit 21. Standardized Hospitalization Ratio for All ESCOs and Comparison Group, 2012-2016



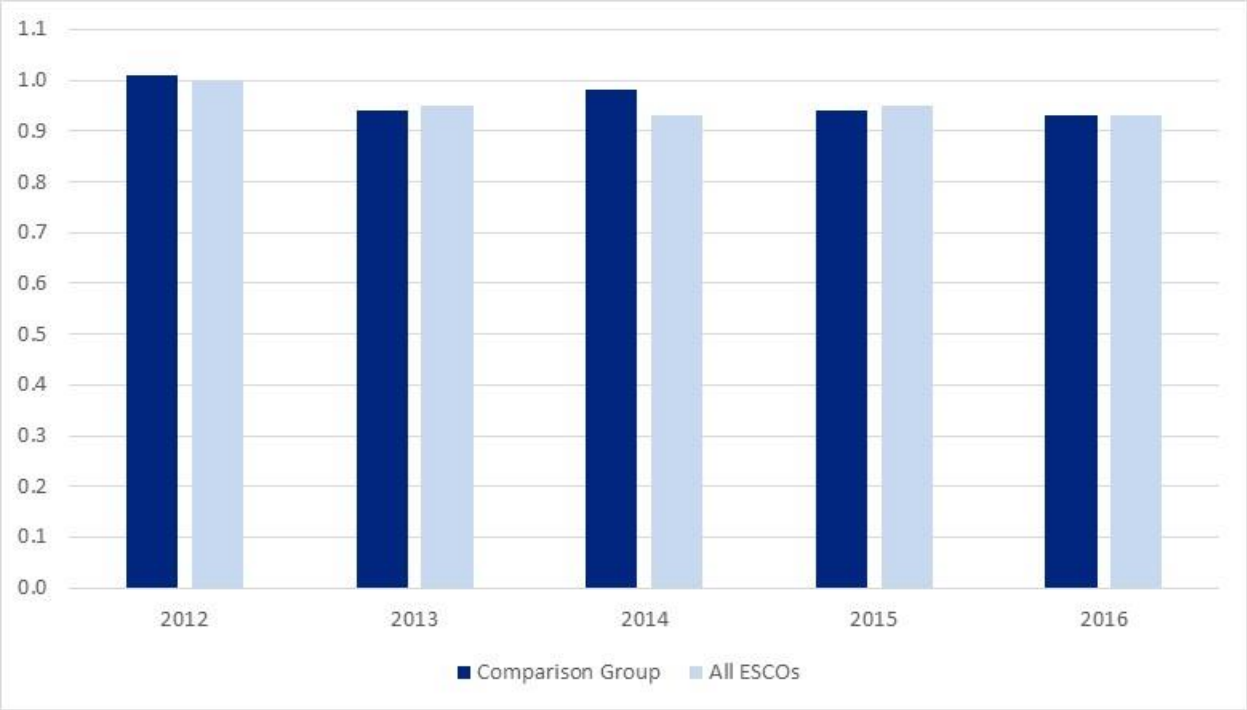
Patterns for the SRR were generally similar to those observed for the SHR. Both the ESCOs and the comparison group showed improvement over time. The combined ESCO SRR exhibited the greatest reduction compared to the comparison group in 2016. The chart in **Exhibit 22** presents the SRR for all ESCOs and the comparison group for each year starting in 2012 through 2016.

Exhibit 22. Standardized Readmission Ratio for All ESCOs and Comparison Group, 2012-2016



Mortality is regarded as one of the primary health outcomes and therefore is an important performance measure for assessing quality of care under any health care delivery model. In the CEC context, the SMR provides additional assurance that the CEC Model is not adversely impacting patient survival. On the SMR, the ESCOs and the comparison group were very similar in 2012-2013. A gradual general reduction in SMR over time is seen, with very similar trends in the ESCOs and the comparison group. The chart in **Exhibit 23** presents the SMR for all ESCOs and the comparison group for each year starting in 2012 through 2016. This decline in mortality is consistent with gradual declines in both unadjusted and adjusted mortality for U.S. ESRD patients reported over the last decade or more in the United States Renal Data System (USRDS) Annual Report. Overall, the mortality trends observed here are generally consistent with ESRD population longitudinal observations. These trends do not support a strong effect of the ESCO model on patient mortality at this time. However, these trends also provide some assurance that the observed reductions in hospitalization rates described above and other potential changes in care motivated by the ESCO incentives have not adversely impacted patient mortality.

Exhibit 23. Standardized Mortality Ratio for All ESCOs and Comparison Group, 2012-2016



Calculation and interpretation of the standardized measures is subject to some limitations. These measures utilize indirect standardization. While statistically appropriate for the data structure encountered with these outcomes, the resulting ambiguity in determining whether observed changes over time are due to changes in risk-adjusted expected events, observed events or both creates some difficulty. In addition, uncertainty about how these complex models, based on multiple years of data, adjust for the generally declining mortality and hospitalization relative to other risk adjusters is uncertain. Comparisons of standardized measures performance between the ESCOs and the comparison group within a given year can give a clearer picture, particularly when matching is used to select comparison groups.

For a detailed description of the standardized measures, as well as of the limitations in the measures, see **Appendix H**.

Pre-ESRD care. ESCOs did not have a statistically significant impact on the percent of beneficiaries who start dialysis without ESRD-nephrology care. From baseline to PY1, the percent of beneficiaries who started dialysis without prior ESRD-nephrology care decreased for both groups, and it decreased less for CEC beneficiaries relative to comparison beneficiaries. However, the difference in growth rates did not reach statistical significance at 10%, as shown in **Exhibit 24**.

Exhibit 24. Impact of the CEC Model on Percent of ESRD Beneficiaries Starting Dialysis without Prior ESRD-Nephrology Care

Measure	CEC		Comparison		DiD Estimate			
	Baseline Mean	PY1 Mean	Baseline Mean	PY1 Mean	DiD	90% Lower CI	90% Upper CI	Percent Change
Percent starting dialysis without prior ESRD-Nephrology Care	25.42%	23.22%	30.78%	28.08%	0.50	-4.61	5.61	1.97%

Notes: PY1 covers the period from October 2015-December 2016. Each impact estimate is based on a DiD analysis, and reflects the difference in the regression-adjusted mean outcome for beneficiaries in CEC facilities for PY1 with baseline relative to the same difference over time for beneficiaries in matched comparison facilities. CI = confidence interval at the 10% level. ***p<0.01, **p<0.05, *p<0.1.

4. Cost Shifting to Part D

Regarding potential unintended consequences of the CEC Model, we assessed the impact of the CEC Model on Part D costs which are not included in the shared savings calculation. We analyzed Part D, PBPM costs for CEC beneficiaries who were also covered under Part D and compared to ESRD beneficiaries in the comparison group who were also enrolled in Part D.[27] **Exhibit 25** shows the DiD estimate corresponding to PY1. There was no statistically significant difference in the rate of change of Part D PBPM costs from baseline to intervention between the CEC and comparison groups.

Exhibit 25. Impact of the CEC Model on PBPM Part D Drug Cost

	CEC		Comparison		DiD Estimate			
	Baseline mean	PY1 mean	Baseline mean	PY1 mean	DiD	LCI	UCI	Percent Change
Total Part D Drug Cost	$826	$1,082	$858	$1,132	-$17	-$51	$17	-2.1%

Notes: PY1 covers the period from October 2015-December 2016. Each impact estimate is based on a DiD analysis, and reflects the difference in the regression-adjusted mean outcome for beneficiaries in CEC facilities for PY1 with baseline relative to the same difference over time for beneficiaries in matched comparison facilities. CI = confidence interval at the 10% level. ***p<0.01, **p<0.05, *p<0.1.

5. Analysis of Subpopulations

We investigated the extent to which the CEC Model had a differential impact on subgroups of Medicare beneficiaries with ESRD varying in their demographic characteristics and their time in dialysis (results reported in **Appendix F, Exhibit F-13**). To this end, we estimated stratified DiD models with the specification described in subsection D of **Appendix F**. The decomposition provides insights to the groups that could be driving the average result.

For most groups, the stratified results are consistent with the reductions in total Part A and Part B spending and hospitalizations found in the pooled sample. However, the stratified results show that average impacts mask important differences across subgroups, with the largest reductions in total PBPM Part A and Part B spending by demographic group found among Medicare ESRD beneficiaries who are non-White and non-Black (-$346; p<0.10), who entered Medicare due to both ESRD and disability (-$350; p<0.01), or who were fully Medicaid eligible (-$278; p<0.05).

[27] On average, 75% of beneficiaries in the ESCO and comparison groups were enrolled in Part D.

The largest difference in results relative to the average impact was found among ESRD patients who had six or fewer months of dialysis, when total PBPM Part A and Part B spending for CEC beneficiaries increased by $485 ($p<0.10$). This result may be due to ESCOs identifying significant clinical needs in new patients starting dialysis. Most dialysis patients in the U.S. start chronic dialysis unprepared and historically this is a very costly time for dialysis facilities. It is possible that the ESCOs have identified non-dialysis resources that may alter the utilization of services in the long term. The differential impact of hospitalizations across groups mirrors the findings on total Part A and Part B spending.

While the average impact on readmissions and ED visits did not reach statistical significance, results show statistically significant declines in readmission rates among non-White (both measures), female (readmissions only), and Medicare beneficiaries with ESRD who became entitled for Medicare for ESRD and disability (ED visits only). Again, the CEC Model had the opposite impact among ESRD patients who had fewer than six months of dialysis, where readmissions increased by 5.57 percentage points ($p<0.05$).

VIII. Discussion

The CEC Model is designed to create financial incentives for dialysis facilities and nephrologists to coordinate care for Medicare beneficiaries with ESRD beyond dialysis care and across their continuum of care. It expands the reach of recent value-based payment initiatives targeting dialysis-related care to address non-dialysis-related care by making the ESCO responsible – financially and clinically – for care delivered in other institutional and professional settings.

Overall, the first fifteen months under the CEC Model showed promising results, with lower spending and improvements on some utilization and quality measures. The CEC Model generated savings of $159 PBPM resulting in aggregate savings of $29.9 million during PY1. Savings were achieved primarily through a reduction in total hospitalizations. This is consistent with the strategies reported by ESCOs during the site visits, which entail targeting patients with high risk of hospitalizations, increasing access to urgent dialysis care at the facilities, and coordinating with EDs to reduce avoidable hospital admissions that could follow ED visits. We also noted a small increase in payments for dialysis services, which is consistent with ESCOs' reported efforts to reduce missed dialysis appointments.

Findings presented in this report are limited in two ways. First, the experience of the thirteen ESCOs who joined in PY1, summarized in this report, is not representative of the population of Medicare providers, which limits our ability to generalize the results presented here. For instance, early participants are heavily concentrated in the Southeast and Northeast regions of the country and include only one non-LDO. The influx of 24 new ESCOs joining in PY2 will add three non-LDO organizations to the population of CEC participants and cover additional markets in the West and Midwest regions, therefore improving our ability to generalize findings. However, they are also concentrated in large urban markets, so the likely impacts of the model on small markets will be difficult to infer from this evaluation. Second, although the analysis relies on matching methods to select an appropriate comparison group of facilities to infer counterfactual outcomes for the ESCOs, the characteristics we selected for matching and the specificity of the data may not adequately account for all differences between ESCOs and comparison facilities.

The stratified results show that average impacts mask important differences across subgroups, with the largest reductions in total Part A and Part B spending by demographic group found among Medicare beneficiaries with ESRD who are non-white, who entered Medicare due to both ESRD and disability, and who were fully Medicaid eligible. On the other hand, Part A and Part B spending for CEC beneficiaries with six of fewer months on dialysis increased relative to the comparison group. Some of the ESCOs expressed concern that they were missing opportunities to intervene at the early stage due to delays in the alignment of beneficiaries. Understanding the patterns of utilization of this group of ESRD patients will be a topic to be addressed on the next report as the program matures and a larger sample becomes available.

Future annual reports will build on these analyses in several ways. First, they will consider the second group of ESCOs, which became operational on January 1, 2017. Second, subsequent annual reports will include analysis of ICH CAHPS data to assess patient-reported experience of care as an additional set of outcomes. Third, with increased sample sizes, as well as extended exposure under the model, the analysis will make more distinctions across ESCOs and

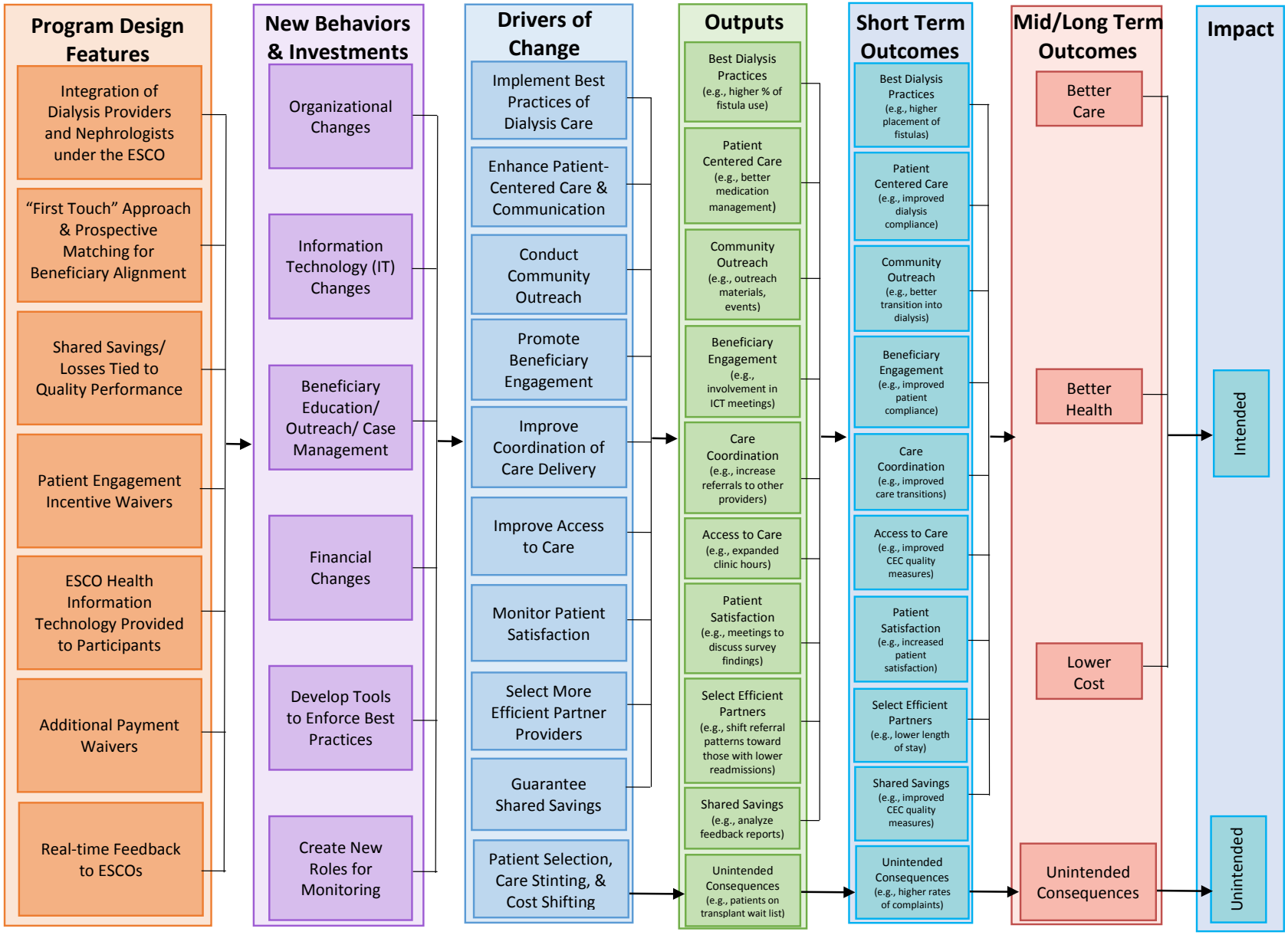
understand the experience of subpopulations that may be more vulnerable to declines in quality. Fourth, more analysis will be presented of the variation in outcomes across ESCOs (e.g., does a subset of ESCOs account for observed effects, or are the effects relatively consistent across ESCOs and dialysis organizations?). Fifth, for a selected set of outcomes, future reports will evaluate whether specialty-oriented ACOs provide better results than general, primary care-oriented ACOs. Finally, future reports will explore impacts on transplant utilization as a potential unintended consequence of the CEC Model.

Appendix A: CEC Waivers

Waivers included in the Comprehensive End-stage Renal Disease (ESRD) Care (CEC) Model:

- **Patient engagement incentive waivers.** These waivers allow ESRD seamless care organizations (ESCOs) to provide in-kind items or services to CEC beneficiaries when related to their medical care. These include technology, oral nutrition supplements (ONS), and non-emergency transportation. Technology may be provided if the beneficiary does not possess or own similar technology and it is considered "medically necessary" in that it will either improve beneficiary-provider communication, health monitoring, or telehealth services; or improve beneficiary adherence to medications, their plan of care (PoC), or their management of chronic conditions and diseases. ONS may be provided free or discounted to beneficiaries only when their serum albumin level falls below the designated target level. Non-emergency transportation can be provided for beneficiaries to access medically necessary care if they meet certain pre-set requirements.
- **Performance-based payments to participant physicians.** ESCOs can provide participant providers incentives for conducting certain medically necessary procedures or providing care that leads to better outcomes to CEC beneficiaries. These payments are based on performance-based metrics and are conditional to accurate reporting on such metrics.
- **ESCO health information technology provided to participants.** Participating providers and facilities may receive health information technology (HIT) but the determination must not take into account referrals and other business generated between the participant and other parties. ESCOs must provide a consistent rationale for providing HIT based on a participant's overall use, quality reporting standards and other performance-based metrics, and care coordination activities.
- **Care coordination arrangements.** Care coordination arrangements include ESCO clinical support services (i.e., case managers, care coordinator, and clinical training), the ability to have care coordination staff onsite at a dialysis facility, and other items or services to improve care coordination (i.e., administrative, quality management, and data services necessary to the delivery, documentation, and assessment of care coordination services).
- **Remuneration furnished by the company/organization to the ESCO.** Remuneration by the dialysis organization (i.e., DaVita, Fresenius, Dialysis Clinic Inc. [DCI], Rogosin) for ESCO support (which includes clinical support services, location and rounding accommodations, and other items or services to improve care coordination), ESCO HIT, and patient engagement incentives can be provided to the ESCO as a whole, not to individuals, participants, or entities.

Appendix B: CEC Evaluation Logic Model



Appendix C: Site Visit Selection and Protocol

A. Selection Criteria and Analysis

Three main criteria were used to select the individual dialysis facilities for each ESCO site visit: average Medicare costs per beneficiary per month (PBPM), patient volume, and quality of patient care according to publicly reported standardized measures[1] (e.g., standardized mortality ratio, standardized readmission ratio, etc.). Most dialysis facilities selected were "typical" cases with average Medicare costs per beneficiary close to the mean. These dialysis facilities varied on patient volume and quality measure performance. The majority of facilities were near the means, but a small proportion of sites were selected for their relatively high or low characteristics regarding volume or quality.

Dialysis organizations and ESCO staff were asked to identify staff members involved in ESCO care redesign, clinical and managerial implementation of the ESCO, development of IT and other administrative infrastructure and support services.

The corporate site visits included two 90-minute interview sessions: one with executive leaders and the other with data, quality, and financial management staff. Each ESCO and/or dialysis facility visit included three 90-minute interview sessions with physician leaders, case managers, and care redesign staff.[2] Each interview was audio recorded. Site visit interview notes and transcripts were managed and analyzed in ATLAS.ti version 7.5.16,[3] a commercially available qualitative data analysis software package. An initial set of codes were developed deductively using the logic model developed for this evaluation (shown in **Appendix B**), site visit protocols, and anticipated question responses prior to the visits. This initial code list was then refined inductively based on coding of a small, diverse set of transcripts, examining content of interviewee comments about various topics or issues, and discussions among the evaluation team in routine post site-visit debrief meetings. A final list of codes was then used to code all remaining interviews and then identify major patterns and themes in interviewees' responses as well as any differences by large dialysis organization (LDO) and/or associated ESCOs and facilities.

B. Protocol Development

Separate interview protocols were developed for each type of respondent, as shown in **Exhibit C-1**. Separate protocols ensure that questions are framed appropriately for each interviewee type, improve consistency in question delivery, and facilitate comparison of interview findings across sites. Protocols were approved by Centers for Medicare & Medicaid Services (CMS) prior to conducting the site visits. Each interview protocol included primary and secondary questions. Primary questions were asked in every interview, and secondary questions were asked if there was still time remaining in the interview. This buffer gave the flexibility to interviewers to engage in deeper discussions of primary topics when it was appropriate to do so.

[1] Measures obtained from Dialysis Facility Compare at https://www.medicare.gov/dialysisfacilitycompare/

[2] Additional information on site visit protocols, including main topics covered in each protocol and example questions for each topic area are included in **Section C**.

[3] ATLAS.ti.

Exhibit C-1. Primary and Secondary Interview Topics

Question Area	Relevant Major Topic	Corporate		Facility Level		
		Executive Leadership	Quality, Data, and Finance	Care Redesign	Case Management	Physician Leadership
Entry Determinants	Entry Determinants	Primary				Primary
Partnership Decisions		Primary				
Investments		Primary				
Goals of the CEC Model	Goals of the CEC Model	Primary		Primary		
Other Implementation Successes and Challenges	ESCO Implementation Feedback	Secondary		Secondary	Secondary	Secondary
Quality Management	ESCO Qualitative Data Collection & Utilization		Primary			
Data Management			Primary			
Financial Management			Primary			
Risk Arrangements for Shared Savings & Losses			Secondary			Secondary
Care Redesign Plans	Care Redesign Plans			Primary	Primary	Primary
Care Redesign Implementation	Other Care Redesign			Secondary		
Care Redesign Outcomes				Secondary		Primary
The Role of Case Management	Case Management in the ESCO Setting				Primary	Secondary
Case Management Operations					Primary	
Case Management Outcomes					Secondary	Secondary

Primary Topic Secondary Topic

Appendix D: Beneficiary Focus Group Structure and Discussion Guide

A. Selection Criteria and Analysis

ESCOs selected facilities for focus group participation based on space availability. The subset of dialysis facilities from which the beneficiary list was drawn reflected the range of CEC facility characteristics (e.g., average Medicare costs, hospital utilization, mortality outcomes, facility size, and dialysis modalities provided). Although each focus group was conducted at only one facility within the ESCO, participants may have been from any ESCO-participating facility. The seven beneficiary focus groups were distributed across ESCOs as follows: two at DaVita ESCOs, two at Fresenius ESCOs, two at DCI ESCOs, and one at the Rogosin ESCO.

To facilitate recruitment, ESCOs provided a list of ESCO beneficiaries who receive dialysis treatment from the facility holding the focus group or from a nearby facility. The ESCO shared this list several weeks prior to the focus group session. A recruiter contacted the beneficiaries via telephone using a screening questionnaire to solicit their interest in participating in the focus group. An attempt was made to schedule participants who were not having dialysis on the day of the focus group. The primary screening criterion for beneficiary recruitment was dialysis modality; the first focus group recruited a larger percentage of home dialysis participants (i.e., home hemodialysis or peritoneal dialysis patients) as the ESCO had a robust home dialysis program. For the remaining six focus groups, the majority of participants were patients who received in-center hemodialysis with zero to two home dialysis patients participating in each of these focus groups.

There was an attempt to recruit ten beneficiaries from each ESCO to ensure six to eight beneficiaries participated in each focus group. Participants were offered a meal before the start of each group and an honorarium of $75 in the form of a prepaid Visa Gift Card. Transportation to and from the focus group location was provided upon request.

Each focus group session lasted approximately 90 minutes and occurred in the morning or at lunchtime.

Research team members observed the focus groups and sat at the periphery of the group. When there was about 10 minutes remaining in the focus group, they were given the opportunity to request additional questions, or clarifications of answers by the moderator.

All focus groups were audio recorded and transcripts were produced from the recordings. The moderator reviewed and summarized focus group transcripts to identify the main themes across the focus groups. Summaries and transcripts were analyzed and key themes and quotes were gleaned.

1. Beneficiary Focus Group Structure

Exhibit D-1 displays the structure of the beneficiary focus group sessions.

Exhibit D-1. Beneficiary Focus Group Discussion Flow

Activity	Descriptions
Welcome and Moderator Introduction	The Facilitator will explain that she works for an independent company and that information is being collected for research purposes only.
Establish Ground Rules	The Facilitator will encourage maximum participation, will remind respondents there are no right or wrong answers as we are obtaining opinions, to speak one at a time so that we can hear and reflect on all comments, and that their anonymity will be preserved.
Participant Introductions	Participants will introduce themselves by first name only and tell one personal thing about themselves.
Open Discussion	The Facilitator will encourage respondents to discuss likes and dislikes about the care they receive (dialysis care and total health care).
Close Discussion	The Facilitator will end the session by summarizing key points heard during the discussion and offer an opportunity for respondents to ask any final questions and then close the group.

B. Beneficiary Focus Group Discussion Guide

***Research Objectives (Timing:** 90 minutes):*

- *To identify and explore the challenges patients face living with ESRD*
- *To obtain insights into how the CEC Model may be affecting the patient care experience*

1. Introduction and General Background (10 minutes)

Goals:

1. *Welcome the respondents*
2. *Inform respondents of confidentiality rights; that we will be audio taping the discussion to share with the broader research team*
3. *Explain the discussion process, objectives and timing, and answer any outstanding questions anyone may have about the group process.*

2. Satisfaction with Current Dialysis Care (35 minutes)

***Goal:** To understand patients' "dialysis experience"*

Part 1: Perceptions

Part 2: Coordination of Care for other Health Conditions

Part 3: Communications with Dialysis Facility Staff

Part 4: Supportive Care

3. Awareness/Understanding of the CEC Model (35 minutes)

4. Impact of the CEC Model (10 minutes)

***Goal:** To understand perceived changes in care or services as a result of implementing the CEC Model*

Appendix E: KDQOL Analysis Supplement

A. Comparison Group Methodology

We used propensity score matching (PSM) to select beneficiaries in the Kidney Disease Quality of Life (KDQOL) comparison sample. Each CEC beneficiary was matched to one ESRD CEC eligible beneficiary with a log odds propensity score absolute difference below a caliper of 1/3 of the standard deviation of the log odds propensity score. The beneficiary-level PSM models were stratified by organizational alignment (DaVita, DCI, Fresenius, and Rogosin) and dialysis history, i.e., new versus existing patients, to reduce possible confounding. The propensity score was based on beneficiary characteristics like demographics and comorbid conditions, facility characteristics, and market characteristics. CEC beneficiaries without a close neighbor (i.e. without a match within the caliper) were excluded from the analysis.[4] Of 13,327 CEC beneficiaries that were included in the PSM models, 12,957 (97%) were matched. The matched pairs of beneficiaries were randomly sampled to select the established target number of comparison beneficiaries (i.e., 10,389, based on sample size power calculations and estimated response rates) while maintaining the balance of markets and organizations in matched pairs identified by each PSM model. The target number of beneficiaries was based on the minimum samples size required to detect an increase in the average score of 5 points, with 80% power, and acceptable level of type 1 error set at 10% for a one-sided hypothesis test. Of the 10,389 comparison beneficiaries selected, 10,153 (98%) were identified with valid address information and were contacted for the survey.

B. KDQOL Administration

The KDQOL survey was administered to two beneficiary groups by separate contractors following the same protocol. The first group included beneficiaries who were aligned to a CEC facility by the end of February 2016, (i.e., including claims through February 2016 available in March 2016). These beneficiaries were surveyed by the CEC implementation contractor. The comparison group was surveyed by the evaluation team following the same survey protocol and included beneficiaries who were matched on important clinical and demographic characteristics as CEC beneficiaries.

To administer the KDQOL, data were collected via a mailed survey with telephone follow-up for non-responders. Beneficiaries received two mailings. An advance-notice letter first informed the beneficiaries that they would receive the KDQOL-36 survey. The survey packet was sent one week later, which included a postage-paid return envelope. Beneficiaries received a toll-free telephone number in the mailing for questions about the survey. Beneficiaries also received a web-address that permitted completion of the survey online. In addition, the mailings included a section in Spanish and a toll-free number to request a Spanish survey. Computer assisted telephone interviews (CATI) began four-weeks after the survey was mailed. A maximum of ten telephone attempts were made—staggering time of day and day of week—prior to discontinuing further contact.

[4] Each CEC beneficiary was matched to the non-CEC beneficiary with the lowest propensity score absolute difference below a caliper of one-third of the standard deviations of the log-odds propensity scores. CEC beneficiaries who did not have a match were excluded from the analysis.

Exhibit E-1 shows the questions used on the KDQOL survey for the physical component score (PCS) and the mental component score (MCS). The SAS code, which is publicly available on the Research and Development Corporation (RAND) website,[5] was used for rescaling responses and deriving the scores.

Exhibit E-1. KDQOL Measures used in the Physical Component Score and the Mental Component Score*

Question	Response
1. In general, would you say your health is:	(1) Excellent, (2) Very good, (3) Good, (4) Fair, (5) Poor
The following items are about activities you might do during a typical day. *Does your health now limit you in these activities? If so, how much?* 2. Moderate activities such as moving a table, pushing a vacuum cleaner, bowling or playing golf 3. Climbing several flights of stairs	(1) Yes, limited a lot, (2) Yes, limited a little, (3) No, not limited at all
During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? 4. Accomplished less than you would like 5. Were limited in the kind of work or other activities	(1) Yes, (2) No
During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)? 6. Accomplished less than you would like 7. Didn't do work or other activities as carefully as usual	(1) Yes, (2) No
8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	(1) Not at all, (2) A little bit, (3) Moderately, (4) Quite a bit, (5) Extremely
These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks… 9. Have you felt calm and peaceful 10. Did you have a lot of energy 11. Have you felt downhearted and blue	(1) All of the time, (2) Most of the time, (3) A good bit of the time, (4) Some of the time, (5) A little of the time, (6) None of the time
12. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?	(1) All of the time, (2) Most of the time, (3) Some of the time, (4) A little of the time, (5) None of the time
https://www.rand.org/health/surveys_tools/kdqol.html	

Notes: * The PCS and MCS measures both use the same twelve questions; different weights are applied to the responses to derive the two scores.

[5] https://www.rand.org/health/surveys_tools/kdqol.html

Exhibit E-2 shows the questions used on the survey for the burden of kidney disease, symptoms and problems, and effects of kidney disease.

Exhibit E-2. KDQOL Measures used in the Burden of Kidney Disease, Symptoms and Problems, and Effects of Kidney Disease Scale Scores

Question	Response
How true or false is each of the following statements for you?	(1) Definitely true,
13. My kidney disease interferes too much with my life*	(2) Mostly true,
14. Too much of my time is spent dealing with my kidney disease*	(3) Don't know,
15. I feel frustrated dealing with my kidney disease*	(4) Mostly false,
16. I feel like a burden on my family*	(5) Definitely false
During the past 4 weeks, to what extent were you bothered by each of the following?	
17. Soreness in your muscles+	
18. Chest pain+	
19. Cramps+	
20. Itchy skin+	(1) Not at all bothered,
21. Dry skin+	(2) Somewhat bothered,
22. Shortness of breath+	(3) Moderately bothered
23. Faintness of breath+	(4) Very much bothered
24. Lack of appetite+	(5) Extremely bothered
25. Washed out or drained+	
26. Numbness in hands or feet+	
27. Nausea or upset stomach+	
28. 28a. Problems with your access site [Hemodialysis] +	
29. 28b. Problems with your catheter site [Peritoneal dialysis] +	
Some people are bothered by the effects of kidney disease on their daily life, while others are not. How much does kidney disease bother you in each of the following areas?	
29. Fluid restriction^	(1) Not at all bothered,
30. Dietary restriction^	(2) Somewhat bothered,
31. Your ability to work around the house^	(3) Moderately bothered,
32. Your ability to travel^	(4) Very much bothered,
33. Being dependent on doctors and other medical staff^	(5) Extremely bothered
34. Stress or worries caused by kidney disease^	
35. Your sex life^	
36. Your personal appearance^	
https://www.rand.org/health/surveys_tools/kdqol.html	

Notes: * denotes the four questions used in the burden of kidney disease measure; + denotes the twelve questions used in the symptoms and problems measure; ^ denotes the eight questions used in the effects of kidney disease measure.

C. Analysis

Associations with the CEC Model were estimated for CEC beneficiaries, relative to the matched comparison group, on each of the five composite score measures (i.e., PCS, MCS, burden of kidney disease, symptoms and problems, and effects of kidney disease) using ordinary least squares (OLS) models. The analysis used sample-balancing weights that were based on age, sex, and race to ensure the distribution of these characteristics among respondents was similar to that

of the original surveyed sample (e.g., account for non-response bias).[6] In addition, models used clustering at the facility level to account for correlation among beneficiaries treated at the same facility, and robust standard errors.[7] Models included controls for beneficiary characteristics (e.g., age, sex, and race), facility characteristics (e.g., if facility had a late shift), and select geographic characteristics (e.g., median household income).[8] The variable selection process contained multiple steps including examining bivariate models and stepwise variable selection. Specifically, these characteristics were explored as covariates in the OLS models to assess independent relationships between each characteristic with each of the five composite score measures. The final selected models were based on a combination of statistical criteria and non-statistical decisions. A characteristic was retained in a final model when the association between the characteristic and a composite score measure was statistically significant ($p < 0.05$). In addition, select characteristics were retained in the final models even in the absence of statistical significance ($p \geq 0.05$); demographic characteristics (i.e., age, race, and sex) and CEC were retained in all models. The association of the CEC Model with each of the composite score measures was of principal interest and was retained in all final regression models accordingly. The demographic characteristics, regardless of significance level, were included for descriptive purposes; the coefficients describe associations with the health related quality of life (HRQOL) composite score measures—albeit not statistically significant—which might be of broader interest (e.g., social determinants of health). Ultimately, the coefficients for the CEC Model in the final regression models show the independent associations of the CEC Model with the composite score measures after adjusting for associations between all other covariates in the models with the composite score measures.

D. Results

Exhibit E-3 shows response rates for CEC and comparison beneficiaries by demographic characteristics.

Exhibit E-3. Response Rates by Demographic Characteristics

Characteristics		CEC (N = 14,256)		Comparison (N = 10,153)	
		N	%	N	%
Age	18 to 54	1,094	28.8	347	12.8
	55 to 64	1,298	37.4	565	22.6
	65 to 74	1,388	38.0	723	28.5
	75+	1,314	39.6	799	33.3
Race	Black	2,315	34.4	995	20.1
	Other	662	31.3	218	17.6
	White	2,121	39.2	1,222	30.8
Sex	Female	2,274	36.5	1,078	24.5
	Male	2,822	35.2	1,357	23.6
Total		**5,098**	**35.8**	**2,435**	**24.0**

Notes: Ns do not always sum to total due to missing values; Lewin computed CEC response rates from raw data provided by IMPAQ.

[6] Deming, W. Edwards (1943), Statistical Adjustment of Data. New York: Wiley.
[7] Robust standard errors were derived using White's correction.
[8] https://datawarehouse.hrsa.gov/topics/ahrf.aspx

Exhibit E-4a & E-4b displays characteristics of respondents by group and weighted respondents.

Exhibit E-4a & E-4b. Characteristics by Respondent Group and Weighted Respondents

Characteristics		TOTAL				CEC					COMPARISON				
		Surveyed		Respondents		Surveyed		Respondents			Surveyed		Respondents		
		N	%	N	%	N	%	N	%	$\%_W$	N	%	N	%	$\%_W$
Age	<65	12,492	51.2	3,304	43.9	7,276	51.1	2,392	47.0	51.1	5,216	51.4	912	37.5	51.4
	65 to 85	10,305	42.2	3,628	48.2	6,044	42.4	2,339	46.0	42.4	4,261	42.0	1,289	53.0	42.0
	85 +	1,601	6.6	596	7.9	927	6.5	363	7.1	6.5	674	6.6	233	9.6	6.6
Sex	Female	10,630	43.6	3,352	44.5	6,230	43.7	2,274	44.6	43.7	4,400	43.3	1,078	44.3	43.3
	Male	13,776	56.5	4,179	55.5	8,023	56.3	2,822	55.4	56.3	5,753	56.7	1,357	55.7	56.7
Race	Black	11,673	47.8	3,310	44.0	6,726	47.2	2,315	45.5	47.2	4,947	48.7	995	40.9	48.7
	White	9,381	38.5	3,343	44.4	5,412	38.0	2,121	41.6	38.0	3,969	39.1	1,222	50.2	39.1
	Hispanic	1,519	6.2	405	5.4	1,013	7.1	330	6.5	7.1	506	5.0	75	3.1	5.0
	Other	1,825	7.5	470	6.2	1,096	7.7	328	6.4	7.7	729	7.2	142	5.8	7.2

	TOTAL				CEC					COMPARISON				
	Surveyed		Respondents		Surveyed		Respondents			Surveyed		Respondents		
	N	Mean	N	Mean	N	Mean	N	Mean	$Mean_W$	N	Mean	N	Mean	$Mean_W$
Hierarchical Condition Category (HCC) Score	24,390	7.0	7,525	6.8	14,238	7.1	5,090	6.8	6.8	10,152	7.0	2,435	6.8	6.8

Notes: Ns do not always sum to total due to missing values. The W subscript (i.e., $\%_W$ and Mean $_W$) denote weighted responses; the analysis used sample-balancing weights to ensure the distribution of these characteristics (i.e., age, sex, and race) was similar to the original surveyed samples to account for non-response.

Exhibit E-5 depicts the five main KDQOL measures and the samples used for each in the final weighted regression models.

Exhibit E-5. Summary Statistics for KDQOL Outcomes based on Regression Sample (Weighted)

Measure	N	Mean	SD	Min	Max
Physical Component Summary (PCS)	5,825	34.5	18.0	11.0	63.3
Mental Component Summary (MCS)	5,961	47.8	20.0	12.7	71.1
Symptoms and Problems	7,191	72.0	32.8	0.0	100.0
Effect of Kidney Disease	7,079	62.9	42.8	0.0	100.0
Burden of Kidney Disease	7,066	43.2	52.0	0.0	100.0

Exhibit E-6 displays regression results for the five main KDQOL measures.

Exhibit E-6. Regression Results for the Five KDQOL Measures

Explanatory Variable	Category	Estimate+				
		Physical Component Summary (N = 5,825)	Mental Component Summary (N = 5,961)	Burden of Kidney Disease (N = 7,066)	Effects of Kidney Disease (N = 7,079)	Symptoms and Problems (N = 7,191)
Intercept		37.0***	46.5***	52.1***	63.1***	81.3***
CEC (vs. Comparison)	CEC	0.5*	0.3	0.7	0.5	0.8
Age (vs. 65 to 85)	< 65	0.6	0.3	-1.5	-2.5***	-0.5
	85 +	-1.7***	-0.4	-1.6	0.5	0.5
Race (vs. White)	Black	2.8***	1.0***	6.5***	4.6***	0.3
	Hispanic	0.7	-1.4*	-6.3**	-2.9*	-4.0***
	Other	2.6***	-1.0	-4.4***	-1.0	-2.1**
Sex (vs. Male)	Female	-2.0***	0.3	1.4*	0.6	-3.2***
Cause of ESRD (vs. Diabetes)	Hypertension	1.2***	n/a	n/a	3.5***	n/a
	Other	1.5***	n/a	n/a	2.7***	n/a
HCC Score	Continuous	-0.5***	-0.1**	-0.9***	n/a	-0.8***
Time on Dialysis (vs. 10+ years)	Less than 1 year	-3.7***	n/a	-12.1***	n/a	-9.5***
	1 to 3 years	-0.6	n/a	-6.1***	n/a	-3.9***
	3 to 6 years	0.1	n/a	-4.1***	n/a	-2.1***
	6 to 10 years	-0.5	n/a	-3.7***	n/a	-2.2***
Medicaid Status (vs. None)	Partial	n/a	-1.6**	n/a	n/a	n/a
	Full	n/a	-2.3***	n/a	n/a	n/a
Medicare Entitlement (vs. ESRD)	Age	0.5	0.5	2.1*	2.7**	3.7***
	Disability	-2.1***	-2.4***	-2.8**	-3.7***	-1.5*
	Disability + ESRD	-0.4	-0.8*	-1.3	-1.8*	-0.2
Median Household Income	Continuous	n/a	0.0***	n/a	n/a	n/a
For Profit (vs. No)	Yes	n/a	-0.2***	n/a	-3.5***	n/a

Notes: * = p < 0.1, ** = p < 0.05, *** p < 0.01. (+) Estimates are the ordinary least squares (OLS) regression coefficients. N/A denotes a variable that was not in a given model. The models retained characteristics when statistically significant associations were found; demographic characteristics (i.e., age, race, and sex) and CEC were retained in all models regardless of statistical significance for descriptive purposes.

An increased score on the PCS measure was associated with ($p<0.1$) CEC participation, Black respondents, respondents categorized by a race of Other (not White, Black, or Hispanic) and respondents whose cause of ESRD was hypertension or other (classified as not diabetes or hypertension). A decreased score on the PCS measure was associated with ($p < 0.1$) respondents at least 85 years of age, respondents who are female, respondents with less than 1 year on dialysis, and respondents whose Medicare entitlement originates from a disability.

An increased score on the MCS measure was associated with ($p<0.1$) Black respondents and median household income of the beneficiary's core-based statistical area (CBSA). A decreased score on the MCS measure was associated with ($p<0.1$) Hispanic respondents, respondents with a higher hierarchical condition categories (HCC) score, full and partial Medicaid respondents, respondents whose Medicare entitlement originates from a disability or both ESRD and a disability, and respondents aligned to a for-profit facility.

An increased score on the burden of kidney disease measure was associated with ($p<0.1$) Black respondents, female respondents, and respondents who aged into Medicare. A decreased score on the burden of kidney disease measure was associated with ($p<0.1$) Hispanic respondents, respondents categorized by a race of Other (not White, Black, or Hispanic), respondents with a higher HCC score, respondents with less than 10 years on dialysis, and respondents whose Medicare entitlement originates from a disability.

An increased score on the effects of kidney disease measure was associated with ($p<0.1$) Black respondents, respondents whose cause of ESRD was hypertension or other (classified as not from diabetes or hypertension), and respondents who aged into Medicare. A decreased score on the effects of kidney disease measure was associated with ($p<0.1$) respondents under the age of 65, Hispanic respondents, respondents whose Medicare entitlement originates from a disability or both ESRD and a disability, and respondents aligned to a for-profit facility.

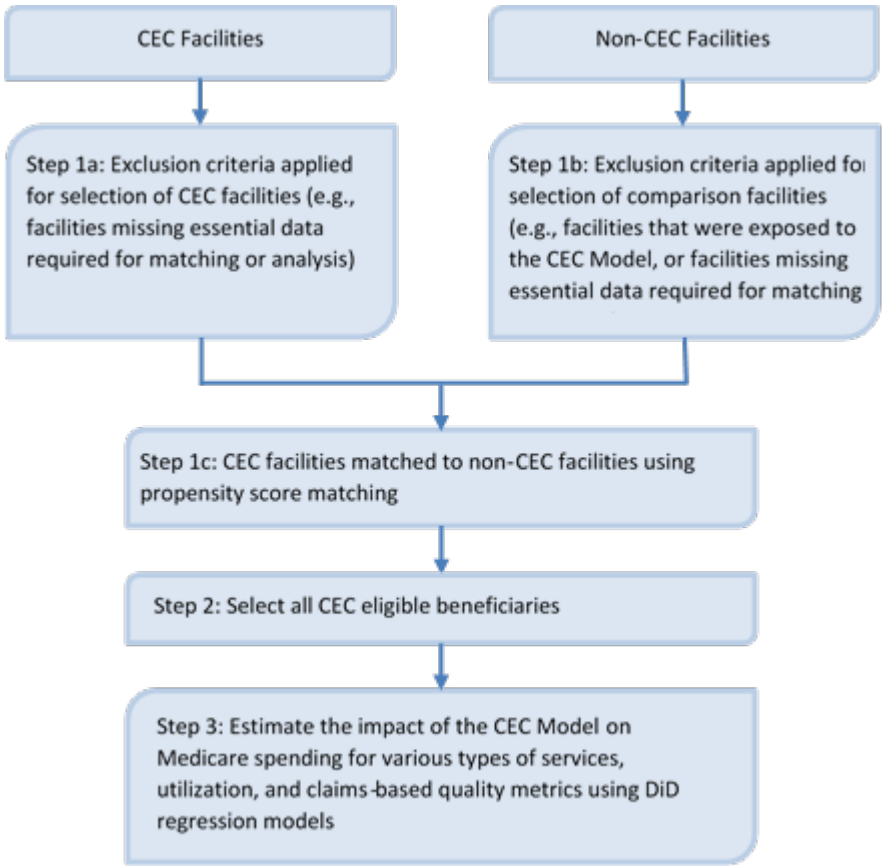
An increased score on the symptoms and problems measure was associated with ($p<0.1$) respondents who aged into Medicare. A decreased score on the symptoms and problems measure was associated with ($p<0.1$) Hispanic respondents, respondents categorized by a race of Other (not White, Black, or Hispanic), female respondents, respondents with a higher HCC score, respondents with less than 10 years on dialysis, and respondents whose Medicare entitlement originates from a disability.

Appendix F: Differences-in-Differences (DiD) Approach

The evaluation model relies on a non-experimental design, which uses a comparison group of non-CEC facilities and beneficiaries who would have been aligned to them under CEC rules, to infer counterfactual outcomes for CEC beneficiaries. The difference-in-differences approach used in the evaluation is a statistical technique that quantifies the impact of an intervention by comparing changes in the intervention group (CEC beneficiaries) to changes in outcomes in the comparison group.

The DiD approach was implemented in several steps, the flow chart in **Exhibit F-1** shows the implementation steps and their succession. First, we used propensity score models to select a comparison group of non-CEC facilities that is similar to the CEC facilities with respect to provider and market characteristics. Second, we applied the CEC Model rules to align eligible beneficiaries to both CEC and matched comparison facilities and assess their CEC eligibility status on a monthly basis. Beneficiaries aligned to either CEC participating or matched comparison facilities were included in our study population for every month they were also eligible for CEC. Finally, we used DiD regression models to identify the impact of the CEC Model on spending, utilization, and quality measures.

Exhibit F-1. DiD Implementation Steps



A. Data and Outcome Measures

Data used to evaluate the CEC Model is listed in **Exhibit F-2**.

Exhibit F-2. Data Sources

Data Source	Data Contents
▪ CEC Model Data	▪ CEC Participating Dialysis Facilities
Master Data Management (MDM) tool	Beneficiary alignment to other shared savings programs
▪ Chronic Conditions Warehouse (CCW) Virtual Research Data Center (VRDC) • Data from the CCW include Medicare claims for services provided between 1/1/2012 and 12/30/2016 that were processed by 4/1/2016[1]	▪ Claims, enrollment, and assessment data
▪ Master Beneficiary Summary File (MBSF) and Long-term Minimum Data Set (MDS)	▪ Beneficiary characteristics, demographics, enrollment status, and chronic condition indicators [2] [3]
▪ CROWNWeb	▪ Complete patient histories at incidence of dialysis including: ▪ Cause for dialysis • Information on dialysis care • Date of first dialysis • Pre-ESRD care
▪ Dialysis Facility Compare (DFC) 2014-2016	▪ Facility Organization characteristics and quality metrics[4]
▪ AHRF (aggregated to CBSA defined by OMB[5])	▪ Market Characteristics: • Population size • Economic and health care supply indicators

Exhibit F-3 defines all the outcome measures evaluated in the report using a DiD methodology.

Exhibit F-3. DiD Measure Outcomes and Definitions

Outcome	Definition of the Outcomes
Total Medicare Part A and Part B Allowed Charges	Monthly standardized allowed charges included under Medicare Part A and Part B. Allowed charges are counted in the month of the claim thru date for all Part A claims (i.e., acute, home health, hospice, skilled nursing facilities, institutional rehabilitation facilities, long-term care hospitals, and other inpatient facilities) and Part B Institutional claims (i.e., hospital outpatient, imaging, therapy, and total dialysis). Allowed charges are counted in the month of the last expense date for all Part B Non-institutional claims (i.e., evaluation and management services, Part B covered drugs, durable medical equipment, etc.). In addition, allowed charges are standardized to remove the effects of wage differences and for teaching status and other policy adjustments.
Total Part D drug cost	Sum of drug costs (i.e., ingredient costs, dispensing fee, sales tax, and vaccination fee if applicable) for all prescription drug events with date of service in the month. These costs are not standardized and they are counted only for Medicare beneficiaries who are enrolled in Part D during the month.

[1] Kidney transplants are an exception, which also included claims that ended in 2011 to assess the kidney transplant exclusion criterion in 2012 (i.e., excluded in the 12 months following the month of a transplant).
[2] The CCW condition indicators are claims-based algorithms that identify beneficiaries with select clinical conditions (e.g., diabetes, hyperlipidemia, hypertension, etc.) https://www.ccwdata.org/web/guest/condition-categories.
[3] The MSBF originates from Medicare's Enrollment Database (EDB), and the Common Medicare Environment (CME) tables
[4] To minimize missing values, a facility's most recent DFC characteristics were used if a facility had no DFC data in a given year
[5] We used the most recent version dated July 2015.

Outcome	Definition of the Outcomes
Total acute Inpatient allowed charges	Monthly standardized allowed charges for acute inpatient services for a Medicare beneficiary with ESRD. Includes claim types 60/61 where 3rd digit of the CMS certification number (CCN)=0 (inpatient prospective payment system {IPPS}) or 3rd/4th digit of CCN=13 (critical access hospital {CAH})
Total readmission allowed charges	Monthly standardized allowed charges for readmissions for a Medicare beneficiary with ESRD. If the beneficiary had a claim from date of a subsequent inpatient stay that was less than or equal to 30 days after the claim through date of a prior stay (i.e., an index hospitalization) then the prior stay is counted as having had a readmission. A hospitalization with a discharge status code of 07 (left against medical advice) or 20 (died) is excluded from being an index admission; hospitalizations that occur within the 30 day period following an excluded index admission are not counted as a readmission.
Total Post-Acute Institutional Care allowed charges	Monthly standardized allowed charges for services incurred during that month at inpatient rehabilitation facilities, skilled nursing facilities, and long-term care hospitals. These correspond to claim types 60/61 where last 4 digits of the CCN are between 3025-3099 or 3rd digit of CCN is R or T, 20/30, 60/61 where 3rd/4th digits of CCN are 20, 21, 22.
Home Health allowed charges	Monthly standardized allowed charges for home health services (claim type 10).
Hospice allowed charges	Monthly standardized allowed charges for hospice services (claim type 50).
Hospital outpatient allowed charges	Monthly standardized allowed charges for Part B outpatient services for a Medicare beneficiary with ESRD. This measure includes all claim type 40 that are not imaging (P_B_IMG), dialysis (P_B_DIALYSIS), or therapy (P_B_THERAPY); this includes hospital outpatient (bill type 13x, 85x), clinics (bill type 71x, 73x, 77x), and all other Part B institutional services (services covered under Part B for inpatients that exhausted Part A coverage {bill type 12x}, skilled nursing facility {22x, 23x}, community mental health center {76x}, other Part B home health services {34x}, home health services {14x}, and Indian health services {83x})
Other Part B allowed charges	Monthly standardized allowed charges for Part B services not included in other Part B outcomes listed above. Includes claim types 71, 72 including other carrier, durable medical equipment, or therapy. This includes ambulatory surgery centers (ASC) (type of service code = F), procedures (first digit of BETOS code is P {excluding P9 dialysis}), labs/tests (first digit of BETOS is D), and other non-institutional (ambulance {BETOS O1A}, chiropractic {O1B}, vision/hearing/speech {O1F}, and other unclassified Part B {Y1, Y2, Z2, and missing BETOS}).
Office visits allowed charges	Monthly beneficiary sum of Part B Non-institutional evaluation and management (E&M) non-standardized payments. Includes claim types 71, 72 (Part B Non-Institutional) and first digit of BETOS is M.
Dialysis allowed charges Part B	Monthly standardized allowed charges for dialysis services included under Medicare Part B for a Medicare beneficiary with ESRD. Includes claim type 40 and bill type 72x (Part B Institutional dialysis) and claim types 71, 72 and first two digits of BETOS=P9 (Part B Non-institutional dialysis).
Total Part B Drugs	Monthly standardized allowed charges of Part B Non-institutional drug amounts. Includes claim types 71, 72 (Part B Non-Institutional) and first two digits of BETOS is O1C, O1D, O1E, or O1G.
Imaging allowed charges	Monthly standardized beneficiary sum of Part B institutional allowed imaging and imaging carrier amounts. Includes claim type 40 (Part B Institutional), bill type 13x or 85x, and first digit of BETOS is I. Also includes claim types 71, 72 (Part B Non-Institutional) and first digit of BETOS is I.
Hospitalization	Binary outcome that indicates a beneficiary was admitted and had at least one inpatient hospital stay in the month. Includes all inpatient claims based on claim type 60.
Percent of patients receiving hospice services in a given month	Binary monthly beneficiary flag indicating a hospice claim (claim type 50).

Outcome	Definition of the Outcomes
Number of office visits	Monthly beneficiary count of office visits. Office visits are based on Part B non-institutional claim lines where the first character of the BETOS code = "M". A visit is a unique revenue center date with an E&M service (i.e., two lines with same date are counted as one visit). The month is based on the last expense date from the claim line.
Percent starting dialysis without prior ESRD-Nephrology Care	Monthly flag if beneficiary crashed into dialysis (i.e., had no prior nephrology) in the beneficiary's first month of dialysis. The month of first dialysis was based on data from the Renal Information Management System (REMIS). Prior dialysis care was based on CMS Form 2728 (i.e., Medical Evidence Report) data for Question 18 (prior erythropoietin in 6+ months, prior nephrologist care in 6+ months, prior kidney dietician care in 6+ months, first access type was a graft or fistula, first access type was not a fistula and had maturing fistula or maturing graft). A "no" response on any of the 6 questions and no "yes" responses defined no prior care (i.e., crashed). A "yes" response on any of the 6 questions defined prior care (i.e., did not crash).
Vascular Access (VA) Complications	Monthly beneficiary flag indicating admission(s) with a principal diagnosis for a vascular access complication. Admission was based on an inpatient claim (i.e., all claim types 60/61). A VA complication was based on ICD-9 diagnosis codes 9961, 99656, 99673 and ICD-10 diagnosis codes T82318A, T82319A, T82328A, T82329A, T82338A, T82339A, T82398A, T82399A, T8241XA, T8242XA, T8243XA, T8249XA, T82510A, T82511A, T82518A, T82520A, T82521A, T82528A, T82529A, T82530A, T82531A, T82538A, T82590A, T82591A, T82598A, T85611A, T85621A, T85631A, T85691A, T82818A, T82828A, T82838A, T82848A, T82858A, T82868A, T82898A.
ESRD Complications	Monthly beneficiary flag indicating admission(s) with a principal diagnosis for ESRD complication. Admission was based on an inpatient claim (i.e., all claim types 60/61). Complications include volume depletion, hyperpotassemia, fluid overload, heart failure, and pulmonary edema. An ESRD complication was based on ICD-9 diagnosis codes 27650, 27651, 27652, 2767, 27669, 40403, 40413, 40493, 5184, 514, 4281, 428x (i.e., first 3 digits are 428) and ICD-10 diagnosis codes E860, E861, E869, E875, E8770, E8779, I132, J810, J811, I50x (i.e., first 3 digits are I50).
Hemodialysis	Monthly binary outcome that indicates a beneficiary received inpatient and or home hemodialysis services and is based on positive non-standardized hemodialysis dialysis payments.
Home Hemodialysis	Monthly binary outcome that indicates a beneficiary received at least one home hemodialysis services. The outcome is conditional on the beneficiary receiving hemodialysis services in the month and is based on positive non-standardized hemodialysis dialysis payments.
Peritoneal Dialysis	Monthly binary outcome that indicates a beneficiary received peritoneal dialysis and is based on positive non-standardized peritoneal dialysis payments.
Flu Vaccinations	Is a seasonal beneficiary influenza vaccination flag that indicates a beneficiary had at least one influenza vaccination during the flu season months (i.e., October through March), Influenza vaccinations are based on Part B institutional and non-institutional claims with a Healthcare Common Procedure Coding System (HCPCS).
Average length of stay (LOS)	Monthly beneficiary average number of acute inpatient days (LOS). LOS is derived by dividing number of acute inpatient days by the number of admissions. If admission=0 then the value is missing. Admission monthly counts include both ever admitted in a month and readmissions.
Readmission within 30 days of Discharge	Binary outcome that indicates a beneficiary had a hospital readmission in the month that was within 30 days after an index discharge.
ED Visits	Binary outcome that indicates a beneficiary had at least one visit to the ED in the month.
AV Fistula Use	Binary outcome that indicates a beneficiary used an arteriovenous (AV) fistula. This outcome is restricted to only hemodialysis Medicare beneficiaries with ESRD with at least three months of hemodialysis.
Catheter Use	Binary outcome that indicates a beneficiary had catheter use for three consecutive months or longer. This outcome is restricted to only hemodialysis Medicare beneficiaries with ESRD with at least three months of hemodialysis.
Observational Stays	Binary outcome that indicates a beneficiary had an observational stay in the month.

Outcome	Definition of the Outcomes
ED Visits Within 30 days of an Acute Hospitalization	Binary outcome that indicates a beneficiary had an outpatient ED claim/visit (i.e., did not result in inpatient hospitalization) within 30 days of an acute inpatient hospital stay. The 30 days is based on the difference between the discharge date on the inpatient hospitalization and the claim from date of the outpatient claim. When an ED visit occurred within 30 days of an inpatient hospitalization, the event is counted in the month of the claim thru date of the hospitalization.

Notes: Allowed charges, besides Total Part D, are standardized and capped at the 99th percentile of all positive expenditure values associated with the outcome.

This appendix describes these steps in detail and provides diagnostic and descriptive statistics that inform the quality of the comparison group.

B. Comparison Group Construction

1. Comparison Group Selection

The construction of the comparison group was performed in two steps. First, eligible facilities were identified by excluding facilities that were exposed to the intervention and those missing essential data. Second, propensity score techniques were used to estimate a matching algorithm that was used to select the final group of comparison facilities. Detailed descriptions of these steps follow below.

a. Selecting Facilities Eligible to be Included in the Comparison Group Pool

After removing 685 dialysis facilities participating in CEC in PY1 or PY2, the preliminary comparison pool contained 6,025 dialysis facilities. A series of eligibility criteria were applied to ensure the comparison facilities could be included in the matching model and would have limited exposure to the CEC Model.

In calendar year (CY) 2016, 272 potential comparison facilities were excluded from matching because they did not have claims. Claims for these providers were not observed either because the facility changed ownership and CCN (CMS Certification Number), the unit at which facilities are identified and associated with claims, or the facility was no longer providing care to Medicare patients.

Remaining facilities were examined to identify those with missing data relevant to the analysis. There were 900 potential comparison facilities excluded because they were missing important facility characteristics used in the matching process. The missing data were mainly for facilities new to Medicare, facilities that focused on peritoneal dialysis and home dialysis, or other facilities that did not regularly perform dialysis within their facility.

Because ESCO facilities were not observed in Alaska, Hawaii, Puerto Rico, or US Territories, an additional 71 potential comparison dialysis facilities in these areas were identified and excluded from the comparison pool.

Dialysis facilities were excluded from the comparison group pool if there was an ESCO from their LDO operating in the same CBSA. This exclusion was implemented because the sources of bias generated by including these facilities likely out-weighed potential benefits. Specifically, a potential benefit of including facilities in the same CBSA as a participating ESCO is that its patients are likely more comparable than patients living in different markets. This is because regional differences in provider practices may lead to variation in utilization and costs among ESRD patients with otherwise similar demographic and clinical characteristics. However, there are important

disadvantages to drawing comparison patients from the same market. For instance, there may be spillover effects given the high market concentration among dialysis organizations or spillover across non-aligned patients in the same market (e.g., Medicare Advantage patients, those receiving less than 50% of their care within the ESCO's CBSA). Spillover effects may lead to a downward biased estimate of the true impact of the CEC Model if (1) non-CEC beneficiaries receive some care from ESCO providers and/or partners, or (2) non-ESCO providers adopt practices similar to ESCO providers as the concentration of ESCO providers/practices in the market grows. If the ESCO practices spill over to non-ESCO providers in the same market or in the same dialysis organization, or if ESCOs preferentially attract certain patients, then comparison groups from the same market or organization would not be representative of the general ESRD population, and the estimate based on this comparison group could be biased. This exclusion reduced the facilities that could potentially be included in the comparison group by 297 out of the remaining 4,782 non-ESCO facilities. The final comparison pool, after the exclusion listed above, included 4,485 dialysis facilities.

Exhibit F-4 shows the data used for the selection of the comparison group of facilities.

Exhibit F-4. Comparison Group Selection Data Sources

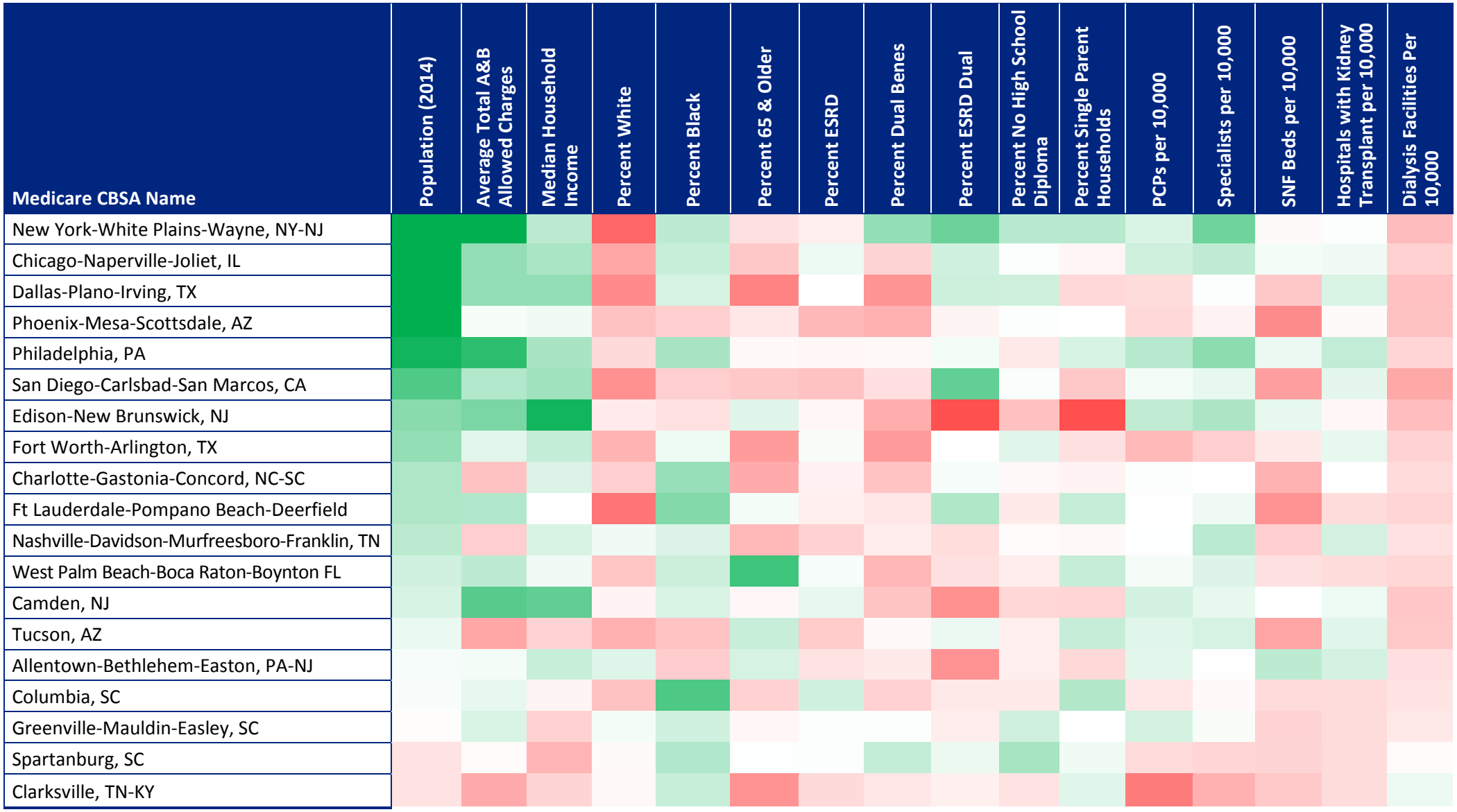
Dataset Name	Date Range	Dataset Contents	Use
Area Health Resource File (AHRF)	2012 – 2015	County-level data on population, environment, geography, health care facilities, and health care professionals	Descriptive analysis of CEC and non-CEC market characteristics. Predictors/characteristics were included in the comparison group selection modeling.
CEC Participant List	Active Participants as of 3/29/2017	ESCO names, IDs, provider names, National Provider Identifiers (NPIs), Taxpayer Identification Numbers (TINs), addresses, start dates, and stop dates	Identification of ESCO facilities and locations
Dialysis Facility Compare (DFC)	2012 – 2016	Dialysis facilities' organizational characteristics and quality measures published on the CMS website	Used to identify facility characteristics incorporated into the DiD models and comparison groups
Master Data Management (MDM)	2012 – 2016	Provider- and beneficiary- level information on participation in Center for Medicare & Medicaid Innovation (CMMI) payment demonstration programs	Used to identify providers who are involved in ACOs and Medicare Shared Savings Program
Chronic Condition Warehouse (CCW)	January 2012 – December 2016	Medicare Part A and Part B claims and beneficiary and enrollment information (MBSF, EDB, CME), including beneficiary unique identifier, address, date of birth/death, sex, race, age, and Medicare enrollment status	Used to create outcome measures such as ED visits and total Medicare Part A and Part B standardized allowed charges, identify eligibility for alignment, beneficiary demographic characteristics, and beneficiary eligibility for inclusion in the denominator for each of the outcome measures
Minimum Dataset (MDS)	2012 – 2016	Information about residence in nursing home	Used to create indicators for long-term institutional status used in risk adjustment
The ZIP Code File-SAS	January 2017	ZIP Codes and CBSAs	Used to link ZIP codes to CBSAs

Dataset Name	Date Range	Dataset Contents	Use
Consolidated Renal Operations in a Web-enabled Network (CROWNWeb)	January 2012 – December 2016	Primary cause of renal failure, cause of renal failure groupings, height, race, dry weight, physician name, dialysis type, and incident comorbidities	Used to obtain patient demographic and medical information were extracted from the CMS ESRD Medical Evidence Report form (2728 form)

Our evaluation accounted for differences between CEC and non-CEC markets, in order to select a comparison group of dialysis facilities that operate in markets that are similar to CEC markets. Accounting for these differences is important so that the comparison group is representative of ESCO providers and patients and it reflects a true counterfactual picture of the nature and costs of care in absence of the CEC Model. **Exhibit F-5** shows a "heat map" for several demographic and utilization indicators. Colors in this map indicate the deviation of CBSA-level characteristics from the mean characteristics of all 384 CBSAs with a dialysis facility as reported in DFC. The mean values are based on 384 Medicare CBSAs identified with dialysis facilities (excluding Puerto Rico, Alaska, Hawaii, and U.S. territories). Exhibit 6 shows that many CEC CBSAs are among the largest CBSAs in the country, but many markets near the mean and below the mean also have CEC dialysis facilities. The composition of CEC CBSAs by median household income is more diverse, since it includes markets at both ends of the socioeconomic distribution, and is correlated with population size. CEC CBSAs have lower proportions of White residents, a possible indicator of ESRD market size, since incidence of ESRD is significantly higher among Blacks and Hispanics compared to Whites.[9] We account for these differences in characteristics when selecting the comparison group and to qualify our ability to generalize the results presented here to all CBSAs.

[9] United States Renal Data System, 2016 Annual Data Report: Atlas of Chronic Kidney Disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2016.

Exhibit F-5. Medicare CBSA-Level Indicators for Markets with a PY1 CEC Facility (Number of Standard Deviations from Mean)



Legend: The color of each cell indicates number of standard deviations (SD) a CBSA characteristic is from the mean.

+3 SD	+2 SD	+1 SD	Mean	-1 SD	-2 SD	-3 SD

Source: Lewin analysis on the 2014 AHRF, DFC data from 2014 and CEC Model participation data extracted from Salesforce on 4/10/2017

b. Statistical Matching Approach

The next step in developing the comparison group involved implementing matching methods. There are many options for matching methods including Mahalanobis distance, Coarsened Exact Matching (CEM), and Propensity Score Model (PSM).[10] The literature guided and the empirical analysis informed the matching methods used to select a comparison group for CEC facilities. Several methods were reviewed but ultimately the PSM approach was selected because it performed best according to multiple balance diagnostics. In the remainder of this section each methodological consideration for PSM is discussed, including a description of the estimated model.

Matching Method. Propensity scores are defined as the probability of receiving treatment, conditional on a set of characteristics and is estimated using a logistic model. For the evaluation of the CEC Model, the key characteristics of interest in the logistic model are defined at the patient, facility, and market levels. Using the coefficients from the logistic regression model, the propensity score for each facility is then constructed as the log odds of the predicted probability of participating in CEC. Each CEC participant facility was matched to a single facility in the comparison group that was the closest in terms of propensity score.

Evidence from the literature indicates that, when matching on many covariates, propensity score matching leads to better balance than other techniques.[11,12] The goal of matching both market and facility level characteristics led to the inclusion of many covariates in the matching model.

Pooled vs. Stratified Models. Selecting comparison facilities in a single-pooled model approach, not models stratified by organizational ownership, uses a single large comparison pool leading to better, smaller differences between treatment and comparison facilities. An important determinant of the success of propensity score modeling are the sizes of the treatment and control pools that enter the model. Stratifying models by organization yielded smaller treatment and control pools and generated weaker overall matches. However, given different practice patterns and cultures across organizations, using organization/organization type as a matching variable was necessary. This resulted in the construction of a pooled dataset for matching models that combined facilities across organization type and ownership (i.e., DaVita, Fresenius, and DCI).[13]

Caliper Selection. For distance matching models, calipers can be applied to limit the absolute distance in propensity scores between matches so that if a neighbor is outside of the caliper, it is not considered a good match. There is no consensus regarding a standard caliper and many caliper widths have been used in literature.[14] For propensity score modeling, many studies use a caliper that is proportional to the standard deviation of the predicted propensity score. After the

[10] Gu, X. S., & Rosenbaum, P. R. (1993). Comparison of multivariate matching methods: Structures, distances, and algorithms. Journal of Computational and Graphical Statistics, 2(4), 405-420

[11] Gu, X. S., & Rosenbaum, P. R. (1993). Comparison of multivariate matching methods: Structures, distances, and algorithms. Journal of Computational and Graphical Statistics, 2(4), 405-420.

[12] Stuart, E. A. (2010). Matching methods for causal inference: A review and a look forward. Statistical science: a review journal of the Institute of Mathematical Statistics, 25(1), 1.

[13] Propensity score models stratified by LDO were attempted, but the stratified models were outperformed by the pooled model in terms of balance diagnostics of the comparison group.

[14] Austin, P. C. (2011). An introduction to propensity score methods for reducing the effects of confounding in observational studies. Multivariate behavioral research, 46(3), 399-424.

propensity score model estimation, all participants could be matched to a unique neighbor that was closer than 0.56 standard deviations of the average propensity score.

Diagnostic Tests. The final step in selecting the comparison group involved using the results from PSM to conduct a series of diagnostic tests for the matched comparison samples to assess whether facilities were similar on observed covariates to the matched comparison sample. Diagnostics included defining the range of common support for the propensity score and for each covariate, evaluating standardized mean differences for all covariates, and examining covariate distributions in quantile-quantile (QQ) plots. A comparison of the distributions of the propensity scores between the CEC and matched comparison facilities was used to assess whether observations in the matched comparison sample should be discarded. Results of the diagnostic tests between the CEC facilities and comparison group are shown in **Exhibits F-6** and **F-7**.

Exhibit F-6 shows standardized differences for key variables included in the PSM. Standardized differences compares the differences in means in relation to the pooled standard deviation. The method that yields the lowest standardized difference of means across the largest number of covariates and that results in the fewest number of "large" standardized differences (i.e., greater than 0.20) is typically preferred.[15] Particular emphasis was given to matching well on performance-related variables: total Medicare payments, standardized hospitalization, readmission, and mortality ratios, unplanned readmission rates, and mortality ratios. Standardized differences below 0.10 were targeted for these variables. Overall, differences remaining between the CEC and comparison facilities after matching were minimal. However, the comparison facilities were in markets with slightly higher proportion of Whites in the population and more single parent households. Additionally, CEC facilities are located in markets with fewer high school graduates, provide care to more patients and have higher proportions of ESRD patients with dual eligibility, and higher average total Medicare Part A and Part B allowed charges. These differences are still relatively small, as no category has a standardized mean difference greater than 0.2.

[15] Stuart, E.A. (2010). Matching methods for causal inference: A review and a look forward. S*tatistical science: a review journal of the Institute of Mathematical Statistics*, 25(1), 1.

Exhibit F-6. Descriptive Statistics and Standardized Mean Differences Pre and Post Matching CEC Facilities and Comparison Facilities

Characteristics		1. CEC Participating Facilities					2. Non-CEC Comparison Pool					3. Standard Difference Before	4. Selected Comparison Group					5. Standard Difference After
		N	Mean	Min	Max	Std Dev	N	Mean	Min	Max	Std Dev		N	Mean	Min	Max	Std Dev	
Market Characteristics	ESRD Beneficiary Population >350 Indicator	204	1.00	0.00	1.00	0.07	4,485	0.80	0.00	1.00	0.40	0.68*	204	1.00	0.00	1.00	0.07	0.00
	Percent 65 and Older	204	0.13	0.09	0.22	0.03	4,485	0.13	0.07	0.36	0.03	-0.16	204	0.13	0.09	0.29	0.03	-0.08
	Percent Race White	204	0.57	0.39	0.77	0.10	4,485	0.63	0.04	0.96	0.18	-0.37*	204	0.59	0.16	0.92	0.15	-0.10
	Percent Race Black	204	0.17	0.03	0.33	0.08	4,485	0.15	0.00	0.52	0.11	0.29*	204	0.18	0.01	0.48	0.11	-0.06
	Percent No HS Diploma	204	0.14	0.10	0.20	0.02	4,485	0.15	0.05	0.40	0.05	-0.12	204	0.14	0.07	0.24	0.04	0.12
	Percent Single Parent Households With Children	204	33.17	20.48	38.37	3.34	4,485	33.88	11.14	54.40	5.62	-0.15	204	34.00	20.48	48.58	5.14	-0.19
	ESRD Percent	204	3.22	0.24	10.05	2.61	4,485	1.93	0.03	10.37	2.74	0.48*	204	2.76	0.11	10.37	2.94	0.16
	Percent ESRD Duals	204	0.50	0.28	0.66	0.07	4,485	0.51	0.26	0.78	0.10	-0.13	204	0.49	0.28	0.77	0.10	0.15
	Median Household Income	204	$55,976	$41,327	$76,290	$6,194	4,485	$52,172	$31,080	$91,681	$10,443	0.44*	204	$55,204	$38,436	$91,681	$11,050	0.09
	Medicare Advantage Penetration (%)	204	27.38	9.74	49.85	11.94	4,485	27.21	0.95	61.52	12.80	0.01	204	27.76	7.66	55.72	11.78	-0.03
	SNF Beds per 10,000	204	45.68	23.07	74.25	14.46	4,485	51.22	13.19	152.62	20.83	-0.31*	204	45.72	18.28	106.60	18.15	0.00
	Hospitals with Kidney Transplant Services per 10,000	204	0.01	0.00	0.01	0.01	4,485	0.01	0.00	0.13	0.01	0.06	204	0.01	0.00	0.04	0.01	0.04
	Average Total A&B Payment (CBSA)	204	$75,289	$59,302	$93,707	$8,811	4,485	$71,043	$48,551	$95,866	$9,078	0.47*	204	$73,630	$54,968	$93,720	$8,945	0.19
	Rural Indicator	204	0.03	0.00	1.00	0.18	4,485	0.17	0.00	1.00	0.37	-0.45*	204	0.04	0.00	1.00	0.19	-0.03
	Extra-Rural Indicator	204	0.00	0.00	0.00	0.00	4,485	0.06	0.00	1.00	0.23	-0.35*	204	0.00	0.00	0.00	0.00	N/A

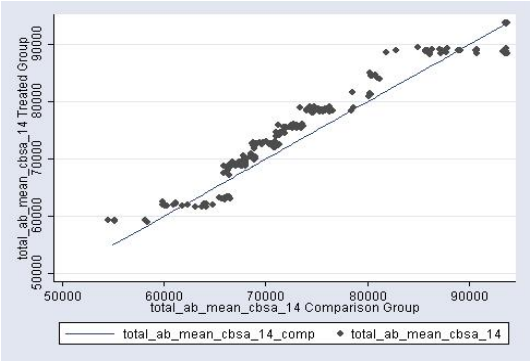
Characteristics		1. CEC Participating Facilities					2. Non-CEC Comparison Pool					3. Standard Difference Before	4. Selected Comparison Group					5. Standard Difference After
		N	Mean	Min	Max	Std Dev	N	Mean	Min	Max	Std Dev		N	Mean	Min	Max	Std Dev	
Facility Characteristics	Facility For Profit Indicator	204	0.88	0.00	1.00	0.33	4,485	0.89	0.00	1.00	0.31	-0.05	204	0.88	0.00	1.00	0.33	0.00
	Late Shift Indicator	204	0.19	0.00	1.00	0.39	4,485	0.18	0.00	1.00	0.39	0.02	204	0.17	0.00	1.00	0.37	0.06
	Peritoneal Indicator	204	0.35	0.00	1.00	0.48	4,485	0.51	0.00	1.00	0.50	-0.32*	204	0.34	0.00	1.00	0.47	0.02
	Beneficiary Count	204	80.51	10.00	275.00	39.55	4,485	65.61	2.00	354.00	39.83	0.38*	204	75.83	3.00	308.00	43.76	0.11
	Percent Peritoneal Dialysis	204	0.06	0.00	0.93	0.12	4,485	0.08	0.00	0.92	0.12	-0.19	204	0.06	0.00	0.41	0.09	0.02
	Percent Patients with Vascular Catheter	204	0.08	0.00	0.25	0.05	4,485	0.10	0.00	0.65	0.06	-0.33*	204	0.08	0.00	0.27	0.05	-0.03
	Percent Patients with Arteriovenous Fistula	204	0.62	0.36	0.95	0.10	4,485	0.65	0.00	1.00	0.11	-0.21*	204	0.63	0.36	0.88	0.11	-0.03
	Standardized Hospitalization Ratio	204	0.98	0.01	1.83	0.28	4,485	0.98	0.01	2.67	0.32	-0.01	204	0.98	0.01	2.47	0.38	-0.01
	Standardized Readmission Ratio	204	1.00	0.01	1.77	0.23	4,485	0.97	0.00	2.27	0.30	0.10	204	1.00	0.00	1.64	0.26	0.00
	Standardized Mortality Ratio	204	0.93	0.01	1.58	0.25	4,485	1.01	0.00	3.35	0.32	-0.27*	204	0.94	0.01	1.89	0.31	-0.03
	Average Total Part A and B Payments	204	$7,456	$5,430	$13,862	$928	4,485	$7,570	$3,487	$22,785	$1,401	-0.10	204	$7,409	$4,017	$12,206	$1,058	0.05
	Standardized Average Total Part A and B Payments	204	0.97	0.70	1.25	0.11	4,485	1.01	0.32	3.07	0.16	-0.26*	204	0.97	0.33	1.49	0.14	0.05
	DaVita Indicator	204	0.37	0.00	1.00	0.48	4,485	0.41	0.00	1.00	0.49	-0.08	204	0.34	0.00	1.00	0.48	0.05
	DCI Indicator	204	0.11	0.00	1.00	0.31	4,485	0.03	0.00	1.00	0.17	0.32*	204	0.11	0.00	1.00	0.31	0.00
	Fresenius Indicator	204	0.51	0.00	1.00	0.50	4,485	0.26	0.00	1.00	0.44	0.55*	204	0.55	0.00	1.00	0.50	-0.07

Notes: The standardized difference is calculated by the following equation: Std. Diff = $(\mu 1 - \mu 2)/\sqrt{(\sigma_t^2 + \sigma_c^2)/2}$. Any value below 0.1 is considered to be a negligible difference. * Indicates a standardized mean difference greater than 0.2 in absolute value. "N/A" indicates that there was no variation in the value of a characteristic and a standardized mean difference cannot be calculated.

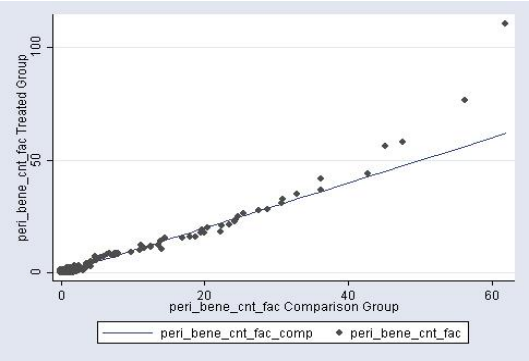
Exhibit F-7 provides an additional metric to assess the quality of the match between the comparison and CEC treatment group. The quantile-quantile (QQ) plot is a graphical technique for determining if two data sets come from populations with common distributions. Points along the 45-degree reference line indicate that the two groups follow a similar distribution.

Exhibit F-7. Quantile-Quantile (QQ) Plots

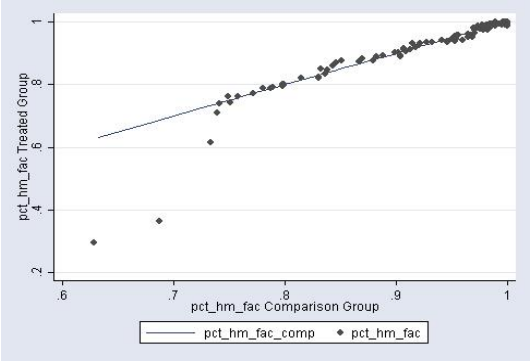
Average Total Part A and Part B Allowed Charges (CBSA)



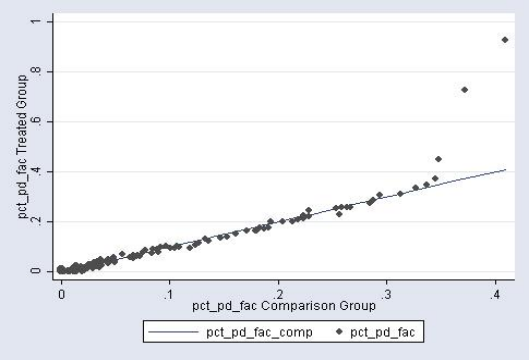
Peritoneal Dialysis Bene Count



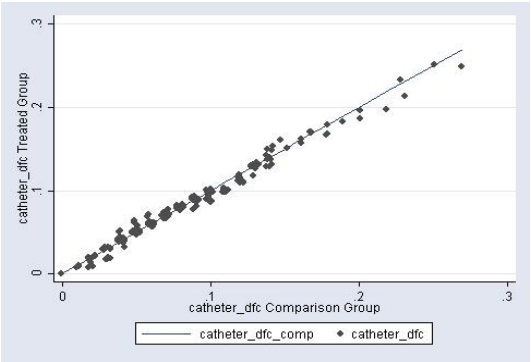
Percent Hemodialysis



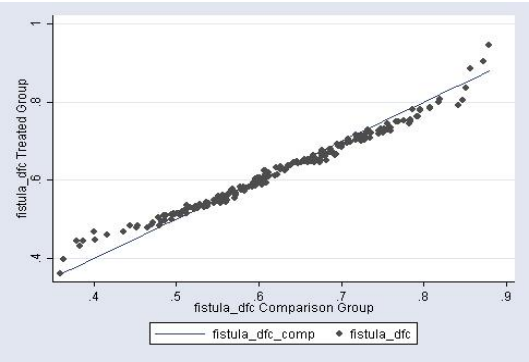
Percent Peritoneal Dialysis



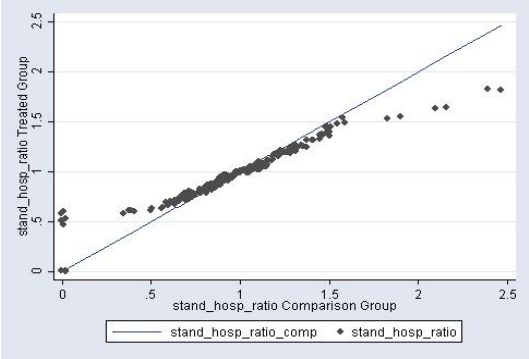
Percent Patients with Vascular Catheter



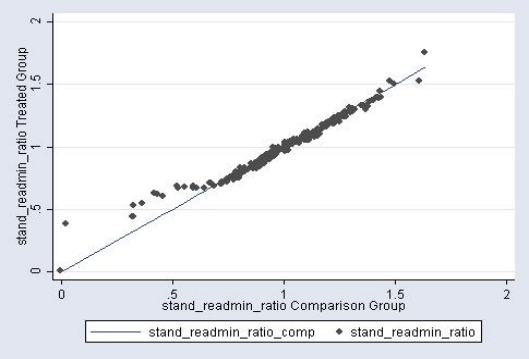
Percent Patients with Arteriovenous Fistula



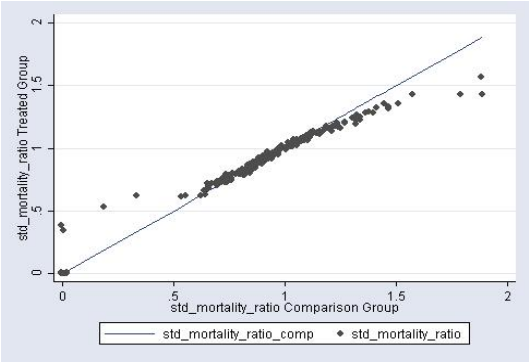
Standardized Hospitalization Ratio



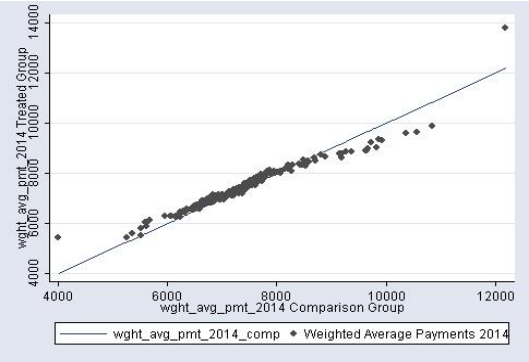
Standardized Readmission Ratio



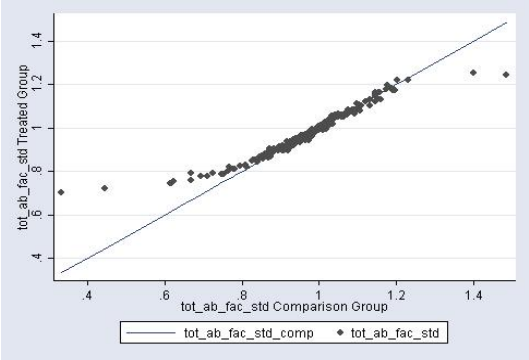
Standardized Mortality Ratio



Average Total Part A and Part B Allowed Charges (Facility)



Standardized Average Total Part A and Part B Allowed Charges (Facility)



The results of the QQ plots show that the differences between the treatment and comparison groups are small. Specifically, for the 11 characteristics shown, the two distributions lie primarily only the 45 degree reference line. Although, there are some outliers at both ends of the distributions the majority of observations cluster alone the reference line, which gives us confidence in the quality of the match between the treatment and comparison group.

C. Beneficiary Alignment and Eligibility

To identify comparison beneficiaries for inclusion in this analysis, we simulated alignment based on the CEC Model rules. We first applied the eligibility criteria (see **Exhibit F-8**) to construct monthly eligibility indicators. This required data from the Enrollment Database (EDB), the Common Medicare Environment (CME), the Master Data Management (MDM) database, and the Chronic Conditions Warehouse (CCW). We combined monthly eligibility indicators with bill type 72X dialysis claims to simulate alignment to ESCOs and comparison group facilities using a two-step approach. First, each month starting in January 2012, CEC eligible beneficiaries were preliminary aligned to an ESCO if the first touch dialysis facility belonged to an ESCO facility and the beneficiary satisfied all monthly eligibility criteria in that month. Beneficiaries are prospectively aligned through December 2016.[16] Beneficiaries could subsequently be de-aligned in the second step of the alignment process, reconciliation, if they no longer meet the criteria to be aligned. This first step was then repeated every month through December 2016 to align new beneficiaries who had their first touch dialysis after January 2012; each monthly alignment was run among beneficiaries not currently aligned. Beneficiaries not aligned to an ESCO facility at any time during the study period (i.e., January 2012 through December 2016) were aligned to a comparison group facility if the first touch provider was in the matched comparison group. The second step simulates the CEC reconciliation process by which beneficiaries who no longer meet the alignment criteria are de-aligned from their ESCO due to death, kidney transplant, the 50% CBSA rule, alignment to another shared saving program, and/or no longer receiving treatment at an ESCO (See **Exhibit F-9**).[17] We applied annual de-alignments after each year. Finally, beneficiaries who were de-aligned could be realigned to any ESCO or facility in the comparison group at a later time if they met the eligibility criteria at the time of first touch.

[16] We simulate alignment of beneficiaries prior to the start of the CEC. This provides information on beneficiaries who would have been aligned—based on identical methods—during this earlier period and allows us to assess changes in ESCOs from before and after CEC implementation.

[17] The simulated reconciliation was applied to calendar years 2012 through 2016. We apply the simulated reconciliation to these previous years to ensure consistency with the program methods (e.g., remove a beneficiary from alignment if they received less than 50% of their dialysis services in the aligned facility's market in that year).

Exhibit F-8. Monthly Eligibility Criteria

- ***Alive (inclusion criterion).*** If a beneficiary had no death date or a validated death date that was on or after the 1st of the month, the beneficiary met the alive criterion for the month of interest.
- ***Enrolled in Medicare Part A and Part B (inclusion criterion)***. A beneficiary met this criterion if he/she was enrolled in both Medicare Part A and Part B in the month.
- ***Not enrolled in Medicare Advantage (i.e., Health Maintenance Organization {HMO}, managed care, or Medicare Part C) (exclusion criterion)***. A beneficiary met this exclusion criterion if he/she was enrolled in a Medicare Advantage (MA) plan during the month.
- ***Over age 18 (inclusion criterion).*** A beneficiary met this criterion if he/she was at least 18 years of age prior to the first day of the month.
- ***Kidney transplant (exclusion criterion).*** A beneficiary met this exclusion criterion during the month of a kidney transplant and the 12 months following that month.
- ***Resided in United States (inclusion criterion***). A beneficiary met this criterion for the month of interest if he/she did not have in their EDB record a residential Social Security Administration (SSA) state code outside of the United States (U.S.) at any time in the month.
- ***Not enrolled in a designated shared savings program (exclusion criterion).*** A beneficiary met this exclusion criterion if he/she was aligned with another shared savings program in a given month, as noted in the MDM. The shared savings program criteria differed for the period prior to calendar year (CY) 2016. For the pre-2016 period, this exclusion encompassed alignment with the Independence at Home (IAH) program (i.e., program code 01), Pioneer Accountable Care Organization (ACO) (i.e., program code 07), and the Medicare-Medicaid Coordination Office (MMCO) Financial Alignment Initiative (FAI) (i.e., program code 11). For the 2016 and later period, this exclusion encompassed alignment with the IAH program, Pioneer ACO, Medicare Shared Savings Program (MSSP) (i.e., program code 08) when the beneficiary was categorized as Track 3, FAI program, and the Next Generation ACO (NGACO) program (i.e., program code 21). MSSP beneficiaries were identified as Track 3 when they were aligned with a Track 3 MSSP ACO.
- ***Medicare as a secondary payer (exclusion criterion).*** A beneficiary met this exclusion criterion if he/she had Medicare as a secondary payer (MSP) at any time during the month.

Exhibit F-9. Reasons for De-alignment

- ***Death.*** An aligned beneficiary who died in the CY was de-aligned at the end of the CY (i.e., alignment ended on December 31 of the CY). For example, a beneficiary who was aligned in January 2012 and died in October 2012, would have an alignment start date of January 1, 2012 and an alignment end date of December 31, 2012.
- ***First touch.*** A first touch is an ESRD claim at an ESCO facility, where the beneficiary is CEC eligible in the month of the claim thru date. For each beneficiary CY, we evaluate if the beneficiary had a first touch at a facility that belongs to the ESCO to which they were preliminarily aligned in the first step. If the beneficiary did not have a first touch in the CY at a facility that belongs to the alignment ESCO, then the beneficiary is de-aligned at the end of the CY.
- ***Kidney transplant.*** An aligned beneficiary who had a kidney transplant in the CY was de-aligned at the end of the CY (i.e., alignment ended on December 31 of the CY). For example, a beneficiary who was aligned in January 2012 and had a kidney transplant in October 2012 would have an alignment start date of January 1, 2012 and an alignment end date of December 31, 2012.
- ***Shared Savings Program.*** If a beneficiary is aligned to a shared savings program that can take beneficiaries from CEC following the start of the preliminary alignment, then the beneficiary is de-aligned from CEC.
- ***Dialysis in provider market (CBSA Rule).*** If a beneficiary has at least one dialysis service in a CY and less than 50% of dialysis services in the CY are from the market of the alignment ESCO, then the beneficiary will be de-aligned due to the 50% CBSA rule. The percentage of dialysis services per CY that occur in the alignment ESCO's market is computed based on (1) total number of dialysis services with claim thru date in that CY and in or after the month that the alignment starts and (2) the total dialysis services that were provided in the market of alignment ESCO, that is the dialysis service occurred in a CBSA that belongs to the alignment ESCO's market, or if CBSA is missing, the county belongs to the alignment ESCO's market.

D. CEC and Comparison Group Populations

Exhibit F-10 compares patient characteristics of the CEC and comparison group beneficiaries for the first month the beneficiary is aligned to the model after facilities are matched. There are more patients aligned and eligible in the CEC group than in the comparison group (N=23,685 vs 22,771). Patient characteristics are well balanced across CEC and comparison groups. Though the differences are small, the comparison group is slightly younger and has on average spent more time on dialysis.

Facility characteristics were also similar between CEC and comparison groups. CEC beneficiaries were more likely to be aligned to a facility that offers late-day services (24% vs 18%). They were also slightly less likely to be aligned to for-profit facilities (88% vs 90%). CEC and comparison patients were aligned to a facility dialysis organization that included DaVita, DCI, Fresenius, Rogosin, or other. The availability of each chain group in the initial comparison pool led to some small differences between the percent of patients aligned to each organization. Rogosin did not have any comparison patients but did provide 3% of CEC beneficiaries. Similarly, Fresenius had a larger share of CEC than the comparison group (56% vs 52%), but DaVita contributed more to the comparison group than the CEC group (32% vs 39%).

CEC beneficiaries were aligned to markets that have higher median incomes ($59,360 vs $57,875). There was a slightly lower proportion of dual eligible beneficiaries per 10,000 in CEC patient-months (258 vs 268). CEC beneficiaries were also aligned to markets with slightly more access to PCPs (7.85 vs 7.73 per 10,000).

Exhibit F-10. CEC and Comparison Population Average Characteristics, PY1

Characteristics		CEC (Mean)	Comparison (Mean)
Patient Characteristics	Age	63.14	62.81
	Female	44%	44%
	Body mass index (kg/m^2)	29.59	29.73
	White	41%	42%
	Black	44%	43%
	Other	14%	14%
	Aged into Medicare	34%	32%
	Disabled into Medicare	21%	22%
	ESRD into Medicare	22%	23%
	Disabled & ESRD into Medicare	22%	23%
	Full Dual Eligibility	36%	35%
	Partial Dual Eligibility	8%	10%
	ESRD Cause: Diabetes	41%	44%
	ESRD Cause: Hypertension	34%	32%
	ESRD Cause: Other	23%	22%
	ESRD Cause: Unknown	2%	2%
	Months on Dialysis	48.21	49.23
	Hemodialysis	93%	94%
	Peritoneal Dialysis	7%	7%
	Both Hemodialysis/Peritoneal Dialysis	1%	2%
	Other Dialysis	1%	1%

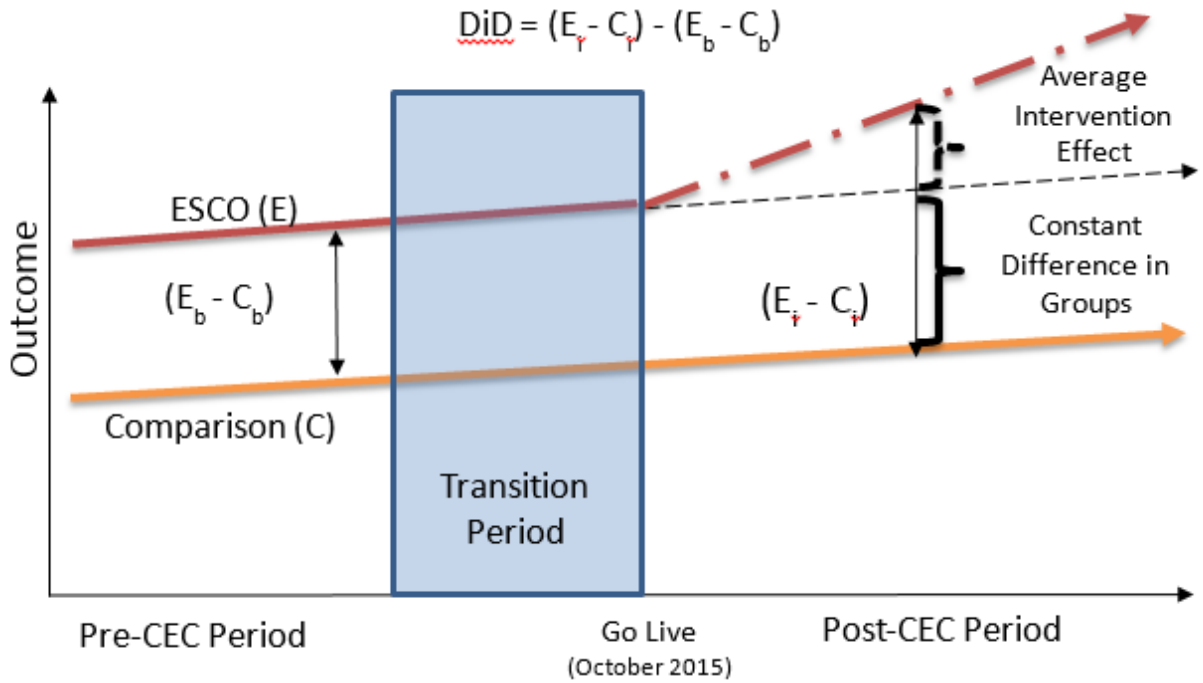
Characteristics		CEC (Mean)	Comparison (Mean)
Facility Characteristics	Beneficiary Count	125.82	124.15
	Late Shift Indicator	24%	18%
	For Profit Indicator	88%	90%
	DaVita	32%	39%
	DCI	9%	9%
	Fresenius	56%	52%
	Other	0%	1%
	Rogosin	3%	0%
Market Characteristics	Median Household Income	$59,360	$57,870
	Medicare Advantage Penetration	30.53	30.74
	Dual Per 10,000	258.11	268.19
	PCPs Per 10,000	7.85	7.73

Notes: Additional controls such as seasonal, region, and CBSA costs decile indicators are not presented in this table.

E. Difference-in-Differences (DiD) Regression Model

The DiD approach quantifies the impact of the CEC Model by comparing changes in outcomes for the CEC population before and after CEC with changes in outcomes for the comparison population before and after CEC. This approach eliminates biases from time invariant differences between the CEC and comparison populations, and controls for trends in the CEC population. The DiD method applied to our outcomes of interest is presented visually in **Exhibit F-11**.

Exhibit F-11. DiD Method Illustration



The DiD model uses data over time from ESRD patients aligned to facilities in the comparison group to obtain an appropriate counterfactual of what would happen to ESRD patients if they had

been aligned to ESCO facilities instead. To estimate a casual effect of the CEC Model, the DiD contrasts changes in outcomes among CEC beneficiaries against this counterfactual. As seen in the exhibit, the DiD model first evaluates the difference between the ESCO (E) and comparison (C) groups over the pre-CEC period (E_b-C_b), depicted by the red and orange lines, for each outcome of interest. The DiD model assumes that if the CEC Model did not exist the two groups would continue to follow the same parallel trends during the post-CEC period (shown by the black dotted (E) and orange line (C), respectively). Therefore, any observed difference in outcomes between the pre-CEC period (E_b-C_b) and post-CEC period (E_i-C_i) is driven by the CEC Model. Thus, the resulting DiD estimate of the average intervention effect is (E_i-C_i) - (E_b-C_b).

Pre-CEC, Transition, and Post-CEC Periods. The period of analysis spans January 2014 through December 2016, divided into pre-CEC, transition, and post-CEC periods. The pre-CEC period, defined as January 2014 to April 2015, followed by a six-month transition period that ran through September 2015. The post-CEC period began on October 2015 and ended December 2016. The transition period took into consideration the delayed start of the CEC Model or "Go Live" date, which was originally scheduled for April 2015. Because ESCOs may have started implementing changes in preparation for the original "Go Live" date, care delivered during the transition was excluded from both the pre-CEC and post-CEC periods. Thus, the DiD compares changes in outcomes between the pre-CEC period and the post-CEC period (PY1). Estimations used eligible monthly beneficiary observations that were aligned to CEC participating facilities or matched comparison facilities at any point during the pre-CEC, transition, or post-CEC periods.

Model Specification. To illustrate the calculation of the DiD in a regression framework, consider the linear regression model shown below:[18]

$$Y_{ikt} = \alpha + Z_t + \delta_1 ESCO_{ik} + \delta_2 (Z_t * ESCO_{ik}) + \lambda' X_{ikt} + \varepsilon_{ikt} \quad (1)$$

where subscripts *i*, *k*, and *t* denote individuals, facilities, and months, respectively. ESCO is an indicator variable that identifies the group of CEC eligible beneficiaries aligned at an ESCO in a given month.[19] Z_t indicates the time period (i.e., pre-CEC, transition, or post-CEC) and captures aggregate factors that could cause changes in outcome Y in the transition and post-CEC period, respectively, relative to the pre-CEC period that are common across beneficiaries aligned to ESCOs and matched comparison facilities. Additionally, Z*ESCO, takes the value of 0 for beneficiaries in the pre-CEC and transition period and 1 for ESCO aligned beneficiaries during or after the "Go Live" date of October 2015. Finally, individuals in the comparison group who do not receive treatment at an ESCO facility will continue to be indicated as 0 in this dummy variable. Thus, δ_2 is the primary coefficient of interest.

The DiD design controls for time-varying changes that are common to all beneficiaries and that occur during the implementation of the CEC Model, as well as time-invariant unmeasured differences between beneficiaries not otherwise captured by the model. **Exhibit F-12** details the

[18] Two-part models were implemented for standardized Medicare allowed charge outcomes when a large share of the sample experienced zero charges. The DiD result, obtained from the two-part models, estimated the unconditional marginal impact of the CEC Model and standard errors are adjusted for the multiple stages of estimation.

[19] Rather than using the list of aligned beneficiaries produced by the implementation contractor, we simulate alignment using the program rules described above. This allows us to align beneficiaries during the pre-CEC period and apply the same methods for CEC and comparison beneficiaries. We validated our alignment methodology by comparing the list of CEC aligned beneficiaries produced by the implementation contractor and by Lewin. The match rate was 98%.

variables we specified in the DiD model to control for time-invariant and time-varying differences in patients, markets, and facilities that are outside the control of ESCOs. Market and facility variables are representative of the facility to which the beneficiary was assigned based on first-touch assignment. The regression model includes only beneficiary health conditions that are not likely to be affected by the CEC Model (i.e., cancer, reason for ESRD) since their inclusion would bias estimates of the impact the CEC Model had on ESRD care. Furthermore, we estimated stratified DiD models similar to the specification described by equation (1) but observations were restricted to our stratified samples of interest. Specifically, we investigated the extent to which the CEC Model had a differential impact on subgroups of Medicare beneficiaries with ESRD varying in their demographic characteristics and their time in dialysis.

Exhibit F-12. Control Variables Included in the DiD Model

Beneficiary Level	Facility Level	Market Level
Original Reason for Entitlement Code: Age, Disabled, ESRD, ESRD and Disabled	DaVita indicator	CBSA median household income (annual)
Reason for ESRD: Hypertension, diabetes, or other	DCI indicator	CBSA Dual enrollees (Medicaid & Medicare) per 100,000 population in CBSA (annual)
Female	Fresenius indicator	CBSA Medicare Advantage penetration (annual)
Age	Rogosin indicator	CBSA geographic rate of primary care providers (PCPs) per 10,000 population (annual)
Body mass index (BMI) at ESRD incidence	Facility beneficiary count (annual)	Average CBSA Medicare payments indicators* (annual)
Months on dialysis	Profit: for profit, not for profit	Region indicators
Seasonal indicators (i.e., the four quarters of the year)	Late shift indicator (facility offers dialysis after 5PM)	
Cancer indicator (annual)		
Type of dialysis indicator: Hemodialysis, peritoneal dialysis, other (monthly)		
Race indicators: White, Black, Other		
Medicaid status indicators: None, full, or partial (monthly)		

Notes: *Average CBSA Medicare payments indicators group CBSAs into 10 groups or deciles based on a CBSA's average annual Medicare Part A and Part B annual payments relative to the national distribution.

Computation of Standard Errors. In general, estimated standard errors of the DiD estimate are calculated using two-way clusters at beneficiary and service facility levels.[20,21] Two-way clusters account for intra-cluster correlation among beneficiaries receiving services from the same facility and correlation across observations from the same beneficiary across time.

[20] Cameron, A., & Gelbach, J. D. Miller, 2011, "Robust Inference with Multiway Clustering". Journal of Business & Economic Statistics, 29(2).

[21] Two-part expenditure models apply one-way cluster methods. Standard errors for these models are clustered by service facility.

Parallel Trends Tests. A pivotal assumption of the DiD model is that the ESCO and comparison groups have the same trend in outcomes prior to the intervention (see **Exhibit F-11** for the illustration of the parallel trends assumption during the pre-CEC period). Formally, the parallel trend tests involved assessing the significance of the coefficient corresponding to the time and treatment dummy interaction term, using data prior to the start of the CEC Model. If the outcome trends between treatment and comparison group are the same prior to the start of the CEC Model, then the interaction coefficient should be near zero and insignificant, i.e., the difference in trends is not significantly different between the two groups in the pre-CEC period. Similar to equation (1), the parallel trend test includes a full set of patient, facility, and market risk adjusters that are included in the DiD specification. Results of the parallel trend test are presented in **Exhibit F-13**. All measures, except imaging and Part B drugs spending PBPM, pass the parallel trends test with p-values greater than 0.10.

Results. Exhibit F-13 shows the DiD estimates of all outcomes considered in this report. Additionally, **Exhibit F-14** presents the DiD estimates for stratified models.

Exhibit F-13. Impact of the CEC Model on all Measures, PY1

Measures		Number of Observations		CEC		Comparison		Difference-in-Differences Estimate				
		CEC	Compari-son	Pre-CEC Mean	PY1 Mean	Pre-CEC Mean	PY1 Mean	DiD	90% Lower CI	90% Upper CI	Parallel Test	Percent Change
Expenditures ($) PBPM by type of service (Standardized allowed charges)	Total Part A and Part B	455,996	405,835	$7,486	$7,365	$7,618	$7,655	-$159 **	-$291	-$26	0.18	-2.12%
	Acute Inpatient	455,996	405,835	$1,601	$1,628	$1,663	$1,793	-$102 ***	-$163	-$42	0.31	-6.40%
	Readmission	430,930	383,854	$310	$319	$332	$366	-$24	-$50	$2	0.31	-7.78%
	Home Health	455,996	405,835	$189	$180	$168	$166	-$6	-$14	$2	0.40	-3.38%
	Hospice	455,996	405,835	$18	$15	$16	$14	-$1	-$4	$3	0.28	-3.60%
	Post-Acute Institutional Care	455,996	405,835	$561	$544	$605	$647	-$59 **	-$107	-$12	0.72	-10.56%
	Hospital Outpatient	455,996	405,835	$460	$457	$501	$490	$8	-$10	$27	0.92	1.84%
	Office Visits	455,996	405,835	$369	$377	$374	$396	-$13 *	-$24	-$2	0.32	-3.58%
	Other Part B	455,996	405,835	$838	$699	$887	$762	-$14	-$77	$49	0.30	-1.68%
	Total Dialysis	455,996	405,835	$3,328	$3,335	$3,311	$3,305	$12 *	$1	$23	0.43	0.36%
	Imaging ~	455,996	405,835	$108	$101	$112	$106	-$1	-$4	$2	0.00	-1.08%
	Part B Drug ~	455,996	405,835	$36	$31	$42	$37	$0	-$6	$7	0.06	0.96%
Utilization	Hospitalizations	436,121	385,910	10.80%	10.67%	11.08%	11.60%	-0.65 ***	-1.03	-0.26	0.14	-5.99%
	Readmissions	43,806	42,360	29.03%	29.04%	30.20%	30.97%	-0.76	-2.07	0.55	0.27	-2.61%
	Emergency Department (ED) Visits	455,996	405,835	10.97%	11.16%	11.10%	11.56%	-0.26	-0.61	0.09	0.19	-2.37%
	Observational Stays	455,996	405,835	2.54%	2.75%	2.37%	2.66%	-0.08	-0.24	0.08	0.74	-3.15%
	LOS	51,469	49,187	5.84	5.81	5.94	5.74	0.16 *	0.00	0.32	0.69	2.78%
	ED Visits Within 30 days of an Acute Hospitalization	455,996	405,835	2.40%	2.42%	2.53%	2.63%	-0.08	-0.25	0.08	0.32	-3.42%
	Hemodialysis	455,996	405,835	93.76%	93.03%	94.92%	94.13%	0.07	-0.57	0.72	0.87	0.08%
	Home Hemodialysis	428,133	381,063	1.98%	2.16%	1.53%	1.57%	0.14	-0.22	0.51	0.51	7.20%
	Peritoneal Dialysis	455,996	405,835	6.50%	7.12%	5.33%	5.98%	-0.04	-0.70	0.62	0.83	-0.54%
	Office Visits	455,996	405,835	0.85	0.87	0.89	0.93	-0.03 ***	-0.05	0.00	0.13	-2.94%

Measures		Number of Observations		CEC		Comparison		Difference-in-Differences Estimate				
		CEC	Compari-son	Pre-CEC Mean	PY1 Mean	Pre-CEC Mean	PY1 Mean	DiD	90% Lower CI	90% Upper CI	Parallel Test	Percent Change
Quality	Fistula	412,752	366,559	62.75%	63.45%	63.19%	63.08%	0.80	-0.22	1.82	0.98	1.28%
	Catheter	412,752	366,559	8.48%	8.84%	9.40%	10.49%	-0.72 *	-1.38	-0.05	0.16	-8.46%
	VA Complications	455,996	405,835	0.60%	0.60%	0.66%	0.76%	-0.09 **	-0.16	-0.02	0.22	-14.95%
	ESRD Complications	455,996	405,835	1.72%	1.67%	1.81%	1.96%	-0.21 ***	-0.35	-0.08	0.53	-12.41%
	Percent Starting Dialysis Without Prior ESRD-Nephrology Care	2,433	2,146	25.42%	23.22%	30.78%	28.08%	0.50	-4.61	5.61	0.17	1.97%
	Hospice	455,996	405,835	0.64%	0.53%	0.59%	0.49%	0.00	-0.10	0.10	0.17	-0.18%
	Flu Vaccinations	45,868	42,699	29.50%	38.60%	28.93%	38.34%	-0.32	-4.61	3.97	NA	-1.09%
Unintended Consequences	Total Part D Drug Cost	380,841	335,776	$826	$1,082	$858	$1,132	-$17	-$46	$11	0.11	-2.11%

Notes: PY1 covers the period from October 2015-December 2016. Each impact estimate is based on a DiD analysis, and reflects the difference in the regression-adjusted mean outcome for beneficiaries in CEC facilities for performance year one with pre-CEC relative to the same difference over time for beneficiaries in matched comparison facilities. CI = confidence interval. ***p<0.01, **p<0.05, *p<0.1. ~ indicates that the outcome did not pass the parallel trends test.

Exhibit F-14. Impact of the CEC Model on Core Six Measures – Stratified Categories, PY1

		Payments	Utilization	Quality			
		Standardized Total Part A and Part B	Hospitalizations	Readmissions	Emergency Department Visits	Fistula	Catheter
Race	White	-$38	-0.62*	-0.21	0.26	-0.11	-0.69
	Black	-$208**	-0.53*	-0.79	-0.48	2.00**	-0.92
	Other	-$346*	-1.03*	-3.76*	-0.87*	-0.55	-0.57
Sex	Male	-$174*	-0.60**	0.69	-0.36	0.68	-0.79*
	Female	-$143	-0.71**	-2.58**	-0.14	1.01	-0.65
Original Reason For Entitlement Code (OREC)	Age	$87	0.11	-0.71	0.34	0.82	-1.56**
	Disabled	-$233	-1.10	0.35	-0.11	2.11	-1.08**
	ESRD	-$131	-0.45**	-1.02	-0.20	0.73*	0.15
	ESRD and Disabled	-$350***	-1.19**	-1.95	-1.10**	0.27	-0.13
Dual Medicaid Medicare Status	Partial	-$239	-1.47**	-0.41	-0.36	-0.07	-0.80
	Full	-$278**	-1.11**	-2.24	-0.58	-0.74	-0.18
Months on Dialysis	≤ 6 months	$485*	-0.22	5.57**	0.77	2.82	-0.74
	> 6 months	-$213***	-0.67***	-1.73**	-0.34	0.74	-0.74

Notes: PY1 covers the period from October 2015-December 2016. Each impact estimate is based on a DiD analysis, and reflects the difference in the regression-adjusted mean outcome for beneficiaries in CEC facilities for PY1 with pre-CEC relative to the same difference over time for beneficiaries in matched comparison facilities. ***p<0.01, **p<0.05, *p<0.1. (*) Other race includes all non-White and non-Black beneficiaries with the majority of beneficiaries being Hispanic or Asian races. (+) for more details on OREC see https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c07.pdf.

Appendix G: Power Calculation Methodology

In this section we describe our power calculation methodology and our findings concerning the ability of our model to detect changes in allowed charges. Power calculations provide essential information for researchers to determine the smallest detectable difference, with a given sample size, in the average of the outcome variable between treatment and control groups. An equally important consideration in study designs is to control the type I error, which is the probability of falsely rejecting the null hypothesis when it is in fact true, or in other words claiming treatment efficacy when in fact it does not exist. We set an acceptable level of type I error to be 0.1, and compute power under this specification.

To compute power, we use a STATA user command called "clsampsi", developed by Batistatou et al. (2014).[22] The authors use a formula based on a non-central F distribution as described by Moser et al. (1989).[23]

$$\text{power} = \left[\frac{\delta}{\sqrt{\left[\frac{\sigma_t^2}{N_t}\left\{1+\left(\bar{m}+\frac{\sigma_{mt}^2}{\bar{m}}-1\right)\rho_t\right\}+\frac{\sigma_c^2}{N_c}\left\{1+\left(\bar{m}+\frac{\sigma_{mc}^2}{\bar{m}}-1\right)\rho_c\right\}\right]}} - z_\alpha\right] \qquad (1)$$

Here, δ denotes various effect sizes for potential predicted savings, ρ_t and ρ_c are intra-cluster correlation coefficients (ICC) (which measure how related the clustered observations are) for the treatment and control group, respectively. Clustered practices are standard in DiD designs.[24] Furthermore, we also consider how the fit of an estimation would impact power by adjusting the variance and ICC factors using an assumed R^2 of 0.3.[25] The term $\frac{\sigma_{mt,c}^2}{\bar{m}}$ corresponds to the variation in the size of clusters which has been shown by Guittet et al. (2006) to heavily influence power, when there is large variation.[26] Additionally, $\bar{m}$ refers to the average number of individuals per cluster. Finally, σ_t^2, N_t, σ_c^2, and N_c, are the variance outcome and the total sample size for each trial arm (t: treatment, c: control), respectively, and z_α is the one-tail z statistic. Combining these factors, we are able to generate two terms commonly referred to as the design effect (DE).

We calculate values of the factors discussed above for the outcome variable allowed charges using the matched beneficiary data. A key component of Equation (1) is the ICC, which depends on how observations are clustered. For each group we cluster observations by their aligned facility to identify individual beneficiary observations. Specifically, we cluster by aligned ESCO and comparison facilities identified in the matched sets which corresponds to 408 clusters units.

[22] Batistatou, E., Roberts, C., & Roberts, S. (2014). Sample size and power calculations for trials and quasi-experimental studies with clustering. *Stata J*, 14(1), 159-75.

[23] Moser, B. K., Stevens, G. R., & Watts, C. L. (1989). The two-sample t test versus Satterthwaite's approximate F test. Communications in Statistics-Theory and Methods, 18(11), 3963-3975.

[24] Bertrand, M., Duflo, E., Mullainathan, S., (2004). "How Much Should We Trust Differences-in-Differences Estimates?" *Quarterly Journal of Economics*, 119(1), pp. 249-75.

[25] The R^2 value provides an indication of how well the covariates of regression estimate the outcome of interest. Thus, the greater the value of R^2 the lower the necessary sample size needed to reach a desired level of power.

[26] Guittet, L., Ravaud, P., & Giraudeau, B. (2006). Planning a cluster randomized trial with unequal cluster sizes: practical issues involving continuous outcomes. *BMC medical research methodology*, 6(1), 1.

As a result, the power calculations do not take into consideration the repeated nature of the data, which would only improve power if all other calculations and assumptions were maintained.

For the first year evaluation of the CEC Model, the number of dialysis facilities and patients provides reasonable confidence that the analysis will detect modest impacts on Medicare service use and costs for all beneficiaries. Specifically, PY1 estimates of power using one-tailed tests at the 10% significance level and our estimated standard errors from the regression models imply that the evaluation has 80% power to detect impacts on standardized Medicare allowed charges of 3% or more.

Appendix H: Standardized Measures Methodology

The final section of the appendix defines the methodology used to create and evaluate standardized measures. Each measure is discussed individually with results summarized at the end of the section.

A. Standardized Measures

1. Data Sources

The CMS's CCW was the main data source for this annual report. We used Medicare claims data, beneficiary characteristics (e.g., demographics and enrollment), and CCW condition indicators.[27] This report includes CCW claims from January 1, 2012, through December 31, 2016 that were processed by March 31, 2017.[28] All CCW claims were final action claims and had a minimum of three months of run out.[29]

For the calculation of standardized measures, we used claims data from the CCW to identify hospitalization admission and discharge dates, primary diagnosis code for hospital admissions, and comprehensive listings of diagnosis codes across all institutional settings.

We also extracted patient data from Consolidated Renal Operations in a Web-enabled Network (CROWNWeb) to complete the patient history. For the first annual report, data were pulled from the January 2017 quarterly file (for data through December 2016) extracted from CROWNWeb.

Patient demographic and clinical information were extracted from the CMS ESRD Medical Evidence Report form (Form-2728). These data included, but were not limited to, primary cause of renal failure, cause of renal failure groupings, height, race, dry weight, physician name, dialysis type, and incident comorbidities.

The ESRD Death Notification form (Form-2746) provided data relating to primary causes of death for patients with ESRD.

The first service date was extracted from the Renal Management Information System (REMIS).

The Long-term Care MDS identified prior year nursing home status for adjustment to the models, respectively, for mortality and hospitalization. For the annual report, the complete MDS 2016 assessments were obtained in the May 4, 2017, upload from CMS.

[27] The CCW condition indicators are claims-based algorithms that identify beneficiaries with select clinical conditions (e.g., diabetes, hyperlipidemia, hypertension, etc.) https://www.ccwdata.org/web/guest/condition-categories.

[28] Kidney transplants are an exception, which also included claims that ended in 2011 to assess the kidney transplant exclusion criterion in 2012 (i.e., excluded in the 12 months following the month of a transplant).

[29] The analytic CCW claims files are based on final action claims. We used final action claims only to avoid internal data inconsistencies caused by use of original claims (e.g., we observed beneficiaries aligned based on original claims for whom we found no final action claims).

B. Methods

1. Monthly Patient Eligibility

Monthly eligibility criteria were incorporated into the standardized measures. Specifically, in the calculation of standardized hospitalization ratio (SHR) and standardized mortality ratio (SMR), if a patient is not eligible during the month, the time at risk and events that occur during the month (hospital admissions or deaths) are both excluded from the calculation. For standardized readmission ratio (SRR), hospital admissions that occur during an ineligible month are not counted as an index discharge, and the readmission associated with the ineligible index discharge is removed. However, if the readmission itself happens in an eligible month and it does not meet any of the exclusion criteria, then the readmission is kept as a new individual index discharge.

C. Standardized Hospitalization Ratio Methodology

This section reviews the techniques used to compute the SHR. First, we review patient assignment and development of measures used to compute the SHR. Then we describe the risk-adjusted model for the expected number of events during a given time period and the creation of the SHR measure.

1. Patient Assignment

Patient assignment to an ESCO begins after a patient has had ESRD for at least 90 days. A patient's time at risk is attributed to an ESCO after he/she has had ESRD for at least 90 days, and has been aligned in that ESCO for at least 60 days. If the patient had been treated in that ESCO for more than 60 days prior to January 1, 2012, that patient's time at risk is attributed to that ESCO as of January 1, 2012. If the patient had been treated for fewer than 60 days and aligned on January 1, 2012 to the ESCO, the patient's time at risk attributed to the ESCO facility would begin on day 61. Time at risk ends at the earliest occurrence of the following: three days prior to a transplant, date of death, end of ESCO alignment plus 60 days. As mentioned above, after we determine patient assignment, we exclude the ineligible time at risk and death events according to the monthly eligibility criteria.

Patient Exclusions:

- Beneficiaries with a missing ESRD Medical Evidence Form (Form-2728) in CROWNWeb
- Beneficiaries with a missing date of birth or sex

2. Ratio Calculation

a. Observed/Expected (O/E)

The SHR is calculated by dividing the observed total admissions (O) by the expected total admissions (E). It enables comparison of the ESCO's experience to the national average. A value of less than 1.0 indicates that the ESCO's total number of admissions was less than expected, based on national rates; whereas a value of greater than 1.0 indicates that the facility had total admissions higher than expected, based on national rates.

b. Observed Number of Hospital Admissions

O equals the observed number of hospital admissions among the patients assigned to this ESCO in the calendar year (CY). Admissions are counted at the discharge date. When applicable, admissions are bridged according to the discharge dates and admission dates. When there is one day between a discharge and admission, these events are bridged and a single admission is counted. If there is more than one day between two hospitalization events, then both events would be counted as hospital admissions.

c. Expected Number of Hospital Admissions

The expected number of hospital admissions among patients assigned to this ESCO in a CY equals *E*. The expected number of hospital admissions is calculated based on national rates for hospital admissions in the same year using a Cox model adjusting for patient age, sex, diabetes, duration of ESRD, nursing home status, patient comorbidities at incidence, body mass index (BMI) at incidence, and calendar year. Duration of ESRD is divided into six intervals with cut points at six months, one year, two years, three years, and five years; hospitalization rates are estimated separately within each interval. The baseline rate is assumed to be constant within each of these six intervals and are denoted as, $\alpha_1,\ldots,\alpha_6$.

For each patient, the time at risk in each ESRD interval is multiplied by the (adjusted) national admissions rate for that interval, and a sum over the intervals gives the expected number of admissions for each patient. Let *q* denote the number of patient characteristics being incorporated into the model, and note that these characteristics will include both main effect and interaction terms. Most covariates are fixed at entry for patients in the model, but some, such as nursing home status, can change over time. Let Z_{ijk} be the specific value of the *j*–th patient in the *i*–th ESRD within period *k*. The risk adjustment factor is given by

$$R_{ijk} = \exp(\beta^T Z_{ijk})$$

where β is the regression coefficient. Technical details for estimating β are provided below.

Let t_{ijk} represent the days at risk (until the current evaluation time) for patient j in ESCO i and in the kth interval with estimated rate α_k (defined in the first paragraph of this subsection). The corresponding expected number of hospital admissions in the kth interval for this patient j is calculated as

$$E_{ijk}=\alpha_k t_{ijk} R_{ijk}$$

It should be noted that t_{ijk} and hence can be 0 if patient *j* is never at risk during the *k*th interval. Summing the E_{ijk} over all six intervals and all *N* patients in a given ESCO gives the expected number of hospital admissions during follow-up at that ESCO. Details for variables included in the models may be found in ***Model Variables section***, below.

d. Risk-Adjusted Model for Computing Expected Number of Hospital Admissions

The calculation of expected hospital admissions is based on a two-stage model. In the first stage, the Cox model with piecewise-constant baseline rates stratified by facilities is used to estimate

regression parameters associated with $\hat{\beta}^T Z_{ij}$, e.g., the baseline hospitalization rate function for the *j*-th patient in the *i*-th facility is assumed as

$$\lambda_{ij}(t) = \lambda_0(t)\exp(\hat{\beta}^T Z_{ij}),$$

where Z_{ij} is a vector of adjustment covariates, β is the corresponding parameter, and $\lambda_{0i}(t)$ is the facility-specific baseline hospitalization rate function. This approach avoids complicated issues arising from, for example, interactions between patient characteristics and facility effects. In the second stage, the population baseline hospitalization rate function is computed through an unstratified Cox model using $\hat{\beta}^T Z_{ij}$ as an offset, i.e., the baseline hospitalization rate function for the *j*-th patient in the *i*-th facility is assumed as

$$\lambda_{ij}(t) = \lambda_0(t)\exp(\hat{\beta}^T Z_{ij}),$$

where $\lambda_0(t)$ is the common baseline hospitalization rate function. For computation purposes, we adopt piecewise constant baseline rates, i.e., the baseline rate is assumed to be a piecewise constant function with six intervals (91 days-6 months, 6 months-1 year, 1-2 years, 2-3 years, 3-5 years, or 5+ years duration of ESRD) and a separate level or rate in each interval.[30] We denote the estimated rates obtained at stage 2 as $\alpha_1,\ldots\alpha_6$.

D. Standardized Readmission Ratio Methodology

This section reviews the methods used to compute the SRR. First, we review patient assignment and development of measures used to compute the SRR. Then we describe the risk-adjusted model for the expected number of events during a given time period and the creation of the SRR measure.

1. Patient Assignment

The SRR measure for an ESCO is a measure of 30-day unplanned hospital readmission for dialysis patients discharged from any acute care hospital. The SRR is defined to be the ratio of the number of index discharges for Medicare-covered dialysis patients from acute care hospitals that resulted in an unplanned readmission to an acute care hospital within 30 days of discharge to the number of readmissions that would be expected (considering the discharging hospitals, patient characteristics and national norm for dialysis facilities). Note that in this document, "hospital" always refers to acute care hospital. Identification of an eligible *index hospital discharge* and a corresponding eligible readmission drives the SRR measure. When we consider eligibility of an event for SRR, monthly eligibility status in an ESCO determines the eligibility of an index discharge along with other criteria, as discussed in detail below.

The SRR was calculated from January 1, 2012 to December 31, 2016. For the annual SRR measures, the eligible indexed discharge date determines the year in which any corresponding readmission would be counted. For example, if an eligible hospitalization began in December 30, 2014, with a corresponding discharge date on January 4, 2015, the index discharge would be

[30] This specification was developed by Liu D, Kalbfleisch JD, Schaubel DE.Stat Biosci. 2014 May 1;6(1):19-37. Methods for Estimating Center Effects on Recurrent Events.

counted in 2015. If an index discharge occurred in December 2014 but the eligible readmission occurred in January 2015, this readmission would be counted in 2014.

Monthly eligibility status guides if a discharge is considered to be an indexed discharge. For example, if an admission occurs during an ineligible month but the corresponding discharge date occurs during an eligible month, then the index discharge is eligible, assuming other criteria are met. If a readmission occurs during an ineligible month but the index discharge occurs during an eligible month, the readmission will count against that eligible index discharge.

Index discharges are restricted to Medicare-covered hospitalizations for inpatient care at short-term acute care hospitals and critical access hospitals. Discharges from skilled nursing facilities (SNFs), Long Term Care Hospitals (LTCHs), rehabilitation hospitals, and Prospective Payment System (PPS)-exempt cancer hospitals – as well as those from separate dedicated units for hospice, rehabilitation and psychiatric care – are excluded. To be counted as an index discharge, the patient must be receiving dialysis treatment for ESRD at the time of discharge.

2. Patient Exclusions:

In addition to monthly eligibility requirements, the SRR denominator (index discharge) excludes hospitalizations:

- For patients who died during the hospitalization (*Rationale: There was no opportunity for readmission*);
- That are followed within 30 days by the patient's death (and no readmission);
- For patients who were discharged against medical advice (AMA) (*Rationale: Providers did not have the opportunity to deliver full care and prepare the patient for discharge*);
- That include a primary diagnosis of medical treatment of cancer, certain psychiatric conditions, or rehabilitation for prosthesis[31] (*Rationales: Admissions for medical treatment of cancer have a different mortality and readmission profile than the rest of the Medicare population, and outcomes for these admissions do not correlate well with outcomes for other admissions; patients admitted for psychiatric treatment are typically cared for in separate psychiatric or rehabilitation centers that are not comparable to short-term acute care hospitals; rehabilitation for prosthesis admissions are not typically to a short-term acute care hospital and are not for acute care*);
- That occur after a patient's 12th hospital admission in the time period *(Rationale: During the technical expert panel's review of the SRR measure, members were concerned that, especially for small facilities, allowing a patient at high risk of readmission (e.g., an HIV-positive patient) to contribute without limit to the denominator and numerator could unfairly skew that facility's measure. In response to this concern, hospitalizations following an individual patient's 12th discharge in the time period were excluded. Sensitivity analyses excluding this cap (representing 0.8% of 2012 hospital discharges) led to only small changes in the flagging rate for smaller facilities);*

[31] See http://www.hcup-us.ahrq.gov/toolssoftware/ccs/ccs.jsp for descriptions of the Agency for Healthcare Research and Quality (AHRQ) Clinical Classifications Software (CCS) used to identify these conditions.

- That took place at PPS-exempt cancer hospitals *(Rationale: These hospitals care for a unique population of patients that cannot reasonably be compared to patients admitted to other hospitals);*[32]
- That result in a transfer to another acute care facility *(Rationale: For patients who are transferred between one acute care hospital and another, the measure considers these multiple contiguous hospitalizations as a single acute episode of care, and readmission for transferred patients is attributed to the hospital that ultimately discharges the patient to a non-acute care setting).*

The event is defined as an unplanned readmission to an acute care hospital, with exclusions as stated above, within 30 days of the discharge date for the index hospitalization. Planned and unplanned readmissions are identified using Version 1.0 of the algorithm developed by the Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE) for the Hospital-Wide All-Cause Unplanned Readmission Measure that was endorsed in 2012 (National Quality Forum [NQF] #1789).[33] Hospitalizations are counted as events in the numerator if they met the definition of an unplanned readmission that (a) occurred within 30 days of a hospital discharge and (b) was not preceded by a "planned" readmission that also occurred within 30 days of discharge. A readmission is considered "planned" under two scenarios:[34]

1. The patient undergoes a procedure that is always considered planned (e.g., bone marrow transplant) or has a primary diagnosis that always indicates the hospitalization is planned (e.g., maintenance chemotherapy). These are identified using Clinical Classifications Software (CCS) groupers (see http://www.hcup-us.ahrq.gov/toolssoftware/ccs/ccs.jsp for descriptions of each Condition Category [CC]).
2. The patient undergoes a procedure that may be considered planned if it is not accompanied by an acute diagnosis. For example, a hospitalization involving a heart valve procedure accompanied by a primary diagnosis of diabetes would be considered planned, whereas a hospitalization involving a heart valve procedure accompanied by a primary diagnosis of acute myocardial infarction (AMI) would be considered unplanned. These are identified using a combination of CCS groupers and individual

[32] CMS 2016 All-Cause Hospital-Wide Measure Updates and Specifications Report: Hospital-Level 30-Day Risk Standardized Readmission Measure –Version 5.0, submitted by Yale New Haven Health Service Corporation/Center for Outcomes Research & Evaluation (YNHHSC/CORE), March 2016. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Hospital-Visits-after-Hospital-Outpatient-Surgery-Measure.pdf
In developing the SRR measure CMS wanted the Dialysis Facility SRR to align with the Hospital Wide Readmission (HWR) measure to the greatest extend possible. To that end the SRR adopted the exclusion criteria applied in the HWR measure by Yale Center for Outcomes Research, the measure developer.

[33] Hospital-Wide All-Cause Unplanned Readmission Measure Final Technical Report. Contract number: HHSM-500-2008-0025I/HHSM-500-T0001, Modification No. 000007. Prepared For: Centers for Medicare & Medicaid Services (CMS). July 2012. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html

[34] Report for the Standardized Readmission Ratio. Contract number: HHSM-500-2013-13017I. Prepared for Centers for Medicare & Medicaid Services (CMS). June 2014. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/MeasureMethodologyReportfortheProposedSRRMeasure.pdf

International Classification of Diseases (ICD) codes (ICD-9: before October 2015; ICD-10: after October 2015).

A planned admission itself can be an index discharge; however, it will never be considered a planned readmission.

3. Additional Patient Exclusions:

- Beneficiaries with a missing ESRD Medical Evidence Form (Form-2728) in CROWNWeb
- Beneficiaries with a missing date of birth or sex

4. Ratio Calculation

a. Observed/Expected

The SRR measure is useful for examining whether facility-specific readmission rates are in line with the national average across all dialysis facilities (adjusted for case mix). The SRR reflects the number of readmission events for patients in an ESCO, relative to the number of readmission events that would be expected based on overall national rates and the characteristics of the patients at that ESCO as well as the number of discharges. An ESCO that experienced readmissions at a rate higher than the national average will see its SRR larger than 1.0. In contrast, an ESCO experiencing readmissions at a rate lower than the national average will see its SRR smaller than 1.

b. Observed Number of Readmissions

Observed event: the actual number of readmission events over a specified time period. Please see the details above.

Expected event: the number of readmission events that would be expected if patients at the facility experienced readmission events at the national median rate for patients with similar characteristics.

To monitor readmission rates, let X_{ij} denote the observed outcome for the *j*-th discharge within the *i*-th facility. To compute SRR, *j* is sorted based on the time of discharge. Furthermore, X_{ij}=1 if the *j*-th discharge in ESCO *i* results in a readmission within 30 days, and X_{ij}=0 otherwise. The observed number of events (until the *t*-th observations) for the ESCO is given by

$$O_{it} = \sum_{j=1}^{t} X_{ij}$$

c. Expected Number of Readmissions

The expected number of events in one ESCO until the *t*-th discharge is computed as $\sum_{j=1}^{t} P_{ijM}$, where P_{ijM} represents the expected probability if the ESCO under investigation has the same

effects as the population average (benchmark: defined as the median facility effect across all dialysis facilities), e.g.

$$P_{ijM} = \frac{\exp(\gamma_M + \beta^T Z_{ij})}{1 + \exp(\gamma_M + \beta^T Z_{ij})}$$

with γ_M being the median population effect. The estimates for β and γ_M are calculated by fitting a logistic regression model. Regression adjustments include age, race, ethnicity, sex, duration of ESRD, diabetes as cause of ESRD, BMI at incidence, days hospitalized during index hospitalization, past-year comorbidities, high-risk diagnosis groups, and CY. Details for variables included in the models may be found in ***Model Variables section***, below.

5. Risk-Adjusted Model for Computing Expected Number of Readmissions

We consider a logistic model in which facilities are represented as fixed effects. This leads to a regression model of the form:

$$logit(P_{ij}) = \log\left(\frac{P_{ij}}{1-P_{ij}}\right) = \gamma_i + \beta^T Z_{ij}, \quad (1C)$$

where P_{ij} is the probability of readmission for the *j*-th discharge assigned to facility *i*, Z_{ijk} is a vector of adjustment covariates for this discharge and β are the corresponding coefficients. The parameter γ_i corresponds to the fixed facility effects in the sense that a large value of γ_i would indicate that the *i*-th facility performs more poorly.

E. Standardized Mortality Ratio Methodology

This section presents the methods used to compute the SMR. First, we review patient assignment and development of measures used to compute the SMR. Then we describe the risk-adjusted model for the expected number of events during a given time period and the creation of the SMR measure.

1. Patient Assignment

For SMR, patient time at risk determines the duration of time over which the death of a patient would be attributed to that particular ESCO, therefore counting as an observed event. Patient time at risk is attributed to an ESCO after he/she has had ESRD for at least 90 days, and has been aligned to that ESCO for at least 60 days.[35] If the patient had been treated in that ESCO for more than 60 days prior to January 1, 2012, that patient's time at risk would be attributed to that ESCO

[35] Since a patient's follow-up in the database can be incomplete during the first 90 days of ESRD therapy, we only include a patient's follow-up into the measure after that patient has received chronic renal replacement therapy for at least 90 days. This minimum 90-day period also assures that most patients are eligible for Medicare, either as their primary or secondary insurer. It also excludes from analysis patients who die or recover renal function during the first 90 days of ESRD. In order to exclude patients who only received temporary dialysis therapy, we assign patients to a facility only after they have been on dialysis there for the past 60 days. This 60-day period is used both for patients who started ESRD for the first time and for those who returned to dialysis after a transplant. For additional details see https://dialysisdata.org/sites/default/files/content/ESRD_Measures/nqf/SMR%20MIF.pdf

as of January 1, 2012. If the patient had been treated for fewer than 60 days and aligned on January 1, 2012, at the ESCO, the patient's time at risk attributed to the ESCO facility would begin on day 61. Time at risk ends at the earliest occurrence of the following: one day prior to a transplant, date of death, end of ESCO alignment plus 60 days.[36] As mentioned above, after we determine patient assignment, we exclude the ineligible time at risk and death events according to the monthly eligibility criteria.

Patient exclusions:

- Beneficiaries with a missing ESRD Medical Evidence Form (Form-2728) in CROWNWeb
- Beneficiaries with a missing date of birth or sex

2. Ratio Calculation

a. Observed/Expected

The SMR is useful for examining whether facility-specific mortality rates are in line with the national average across all dialysis facilities (adjusted for case mix) and provides additional assurance that the CEC Model is not adversely impacting patient survival. The annual SMR is the actual number of deaths divided by the expected number of deaths during the calendar year. An ESCO that experienced deaths at a rate higher than the national average will see its SMR larger than 1. In contrast, an ESCO experiencing deaths at a rate lower than the national average will see its SMR smaller than 1.

b. Observed Number of Deaths

O equals the observed number of deaths among the patients attributed to an ESCO during the calendar year. This count does not include deaths from street drugs or accidents unrelated to treatment. Cause of death data are obtained from the CMS ESRD Death Notification form (Form-2746). Deaths from street drugs or accidents unrelated to treatment vary by facility, with certain facilities (in particular, urban facilities that treated large numbers of male and young patients) reporting proportionally higher number of deaths from these causes when compared to other facilities.[37] Since these deaths are unlikely to have been due to treatment facility characteristics, we excluded them from the observed number of deaths calculations.

[36] This rule is used in the mortality (SMR), hospitalization (SHR), and transfusion (STrR) standardized outcome measures publically reported on DFC. It applies to both discharging dialysis and admitting facilities. Patient outcomes continue to be attributed to a dialysis facility for up to 60 days after the patient leaves that facility and, therefore, are not attributed to a patient's new facility until 60 days after their admission date. The rule attempts to acknowledge the delayed clinical consequences of dialysis facility care provided in the recent past (e.g., cumulative infection risk associated with specific VA use, cumulative risks of inadequate dialysis or fluid management).

[37] Turenne MN, Loos ME, Port FK, Emmert G, Hulbert-Shearon TE, Wolfe RA, Levine GN, Daugirdas JT, Agodoa LYC, Held PJ. The impact of deaths due to AIDS, accidents, and street drugs on standardized mortality ratios (SMRs) by facility. U.S. Renal Data System and University of Michigan, Ann Arbor. Poster presented at the American Society of Nephrology, New Orleans, LA, November 1996. Abstracts –J Am. Soc Nephrol 1996;7:1467.

c. Expected Number of Deaths

E equals the expected number of death events among the patients assigned to this ESCO during the calendar year. The expected number of deaths is calculated based on a Cox risk model, adjusting for patient age, race, ethnicity, sex, diabetes, duration of ESRD, nursing home status, patient comorbidities at incidence, patient BMI at incidence, and calendar year. The model also controls for age-adjusted population death rates by state and race, based on the U.S. population in 2012-2014.[38]

For mortality, the expected number of events is computed as

$$E_i(t) = \sum_{j=1}^{n_i} \int_0^t Y_{ij}(u) \exp\left(\hat{\beta}^T Z_{ij}\right) d\,\hat{\Lambda}_0\left(u;\hat{\beta}\right),$$

where $Y_{ij}(u)$ is the at risk indicator at time *u*, Z_{ij} is the covariate vector for the *j*-th patient in ESCO *i*, β is the estimated coefficients for adjustment variables and $\hat{\Lambda}_0\left(t;\hat{\beta}\right)$ is the estimated national average cumulative baseline hazard (benchmark is defined as the average facility effect across all dialysis facilities). Details for variables included in the models may be found in ***Model Variables section***, below.

3. Risk-Adjusted Model to Compute the Expected Mortality

The risk-adjusted model used to compute the expected number of deaths is discussed below.

Subscript *i* represents the facility and subscript *j* represents the individual patient-level values. Let *F* be the total number of facilities. The total number of patients is denoted by $n = \sum_{i=1}^{F} n_i$, where n_i is the number of subjects in facility *i*. Let T_{ij} represent the survival time and C_{ij} represent censoring time[39] (transplant; move out of facility; end of study period) for the *j*-th patient in facility *i*. Observation times are denoted by $X_{ij} = T_{ij} \wedge C_{ij}$, with at risk indicator $Y_{ij}(t) = I(X_{ij} \geq t)$, where $a \wedge b = \min(a, b)$ and $I(A)$ is an indicator function taking the value 1 when condition A holds and 0 otherwise. The observed death indicators are denoted by $\Delta_{ij} = I(T_{ij} \leq C_{ij})$, and the death counting process is defined as $N_{ij}(t) = \Delta_{ij} I(X_{ij} \leq t)$. The observed data consist of *n* independent vectors, $(X_{ij}, \Delta_{ij}, Z_{ij})$, where Z_{ij} is a vector of adjustment covariates.

The computation of E_{ij} (here, expected mortality for the *j*-th patient in the *i*-th facility) is done in a two-stage model. In the first stage, a Cox model stratified by dialysis facilities is used to estimate regression parameters associated with Z_{ij}, e.g., the hazard function for the *j*-th patient in the *i*-th facility is assumed as

$$\lambda_{ij}(t) = \lambda_0(t) \exp\left(\hat{\beta}^T Z_{ij}\right),$$

[38] Table 16, Health, United States, 2016 (http://www.cdc.gov/nchs/data/hus/2015/016.pdf).
[39] Censored at transplant; ineligibility/removal from ESCO; end of study period.

where β is the coefficients for adjustment variables and $\lambda_{0i}(t)$ is the facility-specific baseline hazard function. This approach avoids any problems that might arise with confounding between patient characteristics and facility effects.

In the second stage, the population-average cumulative baseline hazard is computed through a stratified Cox model (with no covariates) using $\hat{\beta}^T Z_{ij}$ as an offset, i.e., the hazard function for the *j*-th patient in the *i*-th facility is assumed as

$$\lambda_{ij}(t) = \lambda_0(t)\exp(\hat{\beta}^T Z_{ij}),$$

where β is the estimated coefficients for adjustment variables and $\lambda_0(t)$ is the common baseline hazard function. The corresponding estimated cumulative baseline hazard is

$$\hat{\Lambda}_0(t;\hat{\beta}) = \sum_{j=1}^{n_i} \int_0^t \frac{dN_{ij}(u)}{\sum_{j=1}^{n_i} Y_{ij}(u)\exp(\hat{\beta}^T Z_{ij})},$$

where β is estimated from stage 1, i.e., the stratified Cox model.

F. Model Variables: Adjustors and Data Sources for the Mortality, Readmission, and Hospitalization Risk-Adjustment Models

The following are details on the risk adjustors and data sources for the mortality, readmission, and hospitalization risk-adjustment models used to calculate the respective expected values. All three models use each covariate unless otherwise indicated.

- ***Age*:** Patient age is derived from the date of birth in the Master Beneficiary Summary File (MBSF).
- ***Race and ethnicity*:** Race and ethnicity are determined from CMS's Medical Evidence Report form (2728 form) at the time of ESRD incidence. Race and ethnicity (i.e., Hispanic versus non-Hispanic) are included as separate covariates. These two covariates are included only in the mortality model.
- ***Sex*:** Patient sex is obtained from the MBSF.
- ***Diabetes as cause of ESRD*:** Patient primary cause of ESRD is obtained from his/her CMS 2728 form. When cause of ESRD is missing, it is assumed diabetes is not the cause of ESRD.
- ***Years with ESRD*:** Each patient's length of time on dialysis is determined using the first service date from the REMIS database.
- ***Nursing home status*:** In the mortality and hospitalization models, the Nursing Home Minimum Dataset is used to determine if a patient was in a nursing home in the previous year.
- ***Comorbidities at incidence*:** Determined using a selection of comorbidities reported on the CMS-2728 form, namely alcohol dependence, atherosclerotic heart disease, cerebrovascular disease, chronic obstructive pulmonary disease, congestive heart failure, diabetes (includes currently on insulin, on oral medications, without

medications, and diabetic retinopathy), drug dependence, inability to ambulate, inability to transfer, malignant neoplasm, cancer, other cardiac disease, peripheral vascular disease, and tobacco use (current smoker). Each comorbidity is included as a separate covariate in the mortality and hospitalization models.

- ***BMI at incidence*:** Patient BMI is based on the height and weight provided on his/her CMS 2728 form. When height and/or weight are missing, a BMI is imputed for the patient based on the average BMI of all patients—specific to sex, race, diabetic status, and age at ESRD incidence.
- ***Calendar year***
- ***Population death rates*:** In the mortality model, age-adjusted population death rates (per 100,000) by state and race in 2012 to 2014 are obtained from the U.S. Centers for Disease Control National Center for Health Statistics.[40]
- ***Days hospitalized during index hospitalization*:** In the readmissions model, each hospitalization's length is determined by taking the difference between the date of admission and the date of discharge available on the inpatient claim. For patients who are transferred between one acute care hospital and another, the measure considers these multiple contiguous hospitalizations as a single acute episode of care, and the length is calculated by taking the difference between the date of admission for the first hospitalization and the date of discharge from the last hospitalization included.
- ***Past-year comorbidities (risk variables):*** In the readmissions model, all unique ICD diagnosis codes are identified for each patient reported on Medicare claims in the 365 days preceding (and inclusive of) the index discharge date. Note that SRR was developed to align with the risk adjustment approach of the CMS Hospital Wide All-Cause Readmission Measure. As part of this SRR includes risk adjustment for prevalent comorbidities (in the prior year) that are specifically associated with readmissions.[41] Five available claim types for codes are examined: inpatient, outpatient, SNF, hospice, and home health claims. These diagnosis codes are grouped by diagnosis area using CMS's HCCs.[42] The CCs used in the calculation of the readmissions model are:
    - CCs 177 and 178: Amputation status
    - CC 108: COPD
    - CC 79: Cardiorespiratory failure/shock
    - CC 46: Coagulation defects & other specified hematologic disorders
    - CCs 51 and 52: Drug and alcohol disorders

[40] Table 16, Health, United States, 2016 (http://www.cdc.gov/nchs/data/hus/2015/016.pdf)

[41] The SMR and SHR are the current production models in use. When they were originally developed they only included adjustment for a set of comorbidities at ESRD incidence. Note that the current SMR and SHR were updated in 2016 to include prevalent comorbidity adjustment however these measures are not in production and have not yet been implemented by CMS. They received final NQF endorsement in early 2017.

[42] Evaluation of the CMS-HCC Risk Adjustment Model Final Report, prepared by RTI International, March 2011 (https://www.cms.gov/Medicare/HealthPlans/MedicareAdvtgSpecRateStats/downloads/evaluation_risk_adj_model_2011.pdf)

- CCs 25 and26: End-stage liver disease
- CC 109: Fibrosis of lung or other chronic lung disorders
- CCs 67-69, 100, and 101: Hemiplegia, paraplegia, paralysis
- CC 158: Hip fracture/dislocation
- CC 174: Major organ transplant (excluding kidney)
- CC 7: Metastatic cancer/acute leukemia
- CC 44: Other hematological disorders
- CCs 6 and 111-113: Other infectious disease & pneumonias
- CCs 10-12: Other major cancers
- CC 32: Pancreatic disease
- CCs 54-56, 58, and 60: Psychiatric comorbidity
- CC 77: Respirator dependence/tracheostomy status
- CC 38: Rheumatoid arthritis & inflammatory connective tissue disease
- CC 74: Seizure disorders & convulsions
- CC 2: Septicemia/shock
- CCs 8 and 9: Severe cancer
- CCs 1 and 3-5: Severe infection
- CCs 148 and 149: Ulcers

- ***Discharged with High-Risk Condition*:** In the readmissions model, a high-risk diagnosis is defined as any diagnosis area (grouped by the Agency for Healthcare Research and Quality [AHRQ] CCS) that was rare in the population but had a 30-day readmission rate of at least 40%. Note that high-risk diagnosis groups related to cancer or mental health are not index discharges, and so such diagnoses are not included. The CCS areas identified as high-risk are:
  - CCS 5: HIV infection
  - CCS 6: Hepatitis
  - CCS 56: Cystic fibrosis
  - CCS 57: Immunity disorders
  - CCS 61: Sickle cell anemia
  - CCS 190: Fetal distress and abnormal forces of labor
  - CCS 151: Other liver diseases
  - CCS 182: Hemorrhage during pregnancy; abruptio placenta; placenta previa

- CCS 186: Diabetes or abnormal glucose tolerance complicating pregnancy; childbirth; or the puerperium
- CCS 210: Systemic lupus erythematosus and connective tissue disorders
- CCS 243: Poisoning by nonmedicinal substances

1. Standardized Measures Limitations

These measures utilize indirect standardization. While statistically appropriate for the data structure encountered with these outcomes, the resulting ambiguity in determining whether observed changes over time are due to changes in risk-adjusted expected events, observed events or both creates some difficulty. In addition, uncertainty about how these complex models, based on multiple years of data, adjust for the declining mortality and hospitalization relative to other risk adjusters is uncertain. Comparisons of standardized measures performance between the ESCOs and the comparison group within a given year can give a clearer picture, particularly when matching is used to select comparison groups.

In addition, the SRR has complex risk adjustment and exclusion components based on diagnoses derived from Medicare claims data. The predictive models that calculate the expected re-hospitalization values were developed using ICD-9 diagnosis coding system several years prior to implementation in the CEC Evaluation. On October 1, 2015, CMS mandated conversion to ICD-10 based diagnosis coding. Initial crosswalks were developed, based on CMS-recommended General Equivalence Mappings (GEM) reference databases for ICD-9 to ICD-10 conversion. These crosswalks have been implemented in the SRR reported publicly on DFC in 2016. Additional changes to the crosswalk are planned, based on the initial experience with the crosswalk, including an interim step of adding additional ICD-10 codes from the GEM ICD-10 to ICD-9 reference, as well as additional clinical review of the resulting crosswalk and coding results. Given the uncertainty inherent in conversion to a new coding tool, results for any measure dependent on complex claims-based risk adjustment should be interpreted with caution in the initial time period after implementation of the new tool. Such is the case for SRR, particularly for changes in SRR from 2014 through 2016, given that ICD-9 was used exclusively in 2014, both ICD-9 and ICD-10 systems were used for parts of 2015, and ICD-10 is being used as the sole coding instrument for 2016 data.

Exhibits H-1 to **H-3** display a summary of each standardized measure by year for all ESCOs and the comparison group.

Exhibit H-1. Standardized Hospitalization Ratio for All ESCOs and Comparison Group

ESCO	Statistic	Standardized Hospitalization Ratio (Admissions) Summary				
		2012	2013	2014	2015	2016
Comparison Group	Patient-years at risk	10507	11105	11355	11027	10383
	Observed number of hospital admissions	18555	18404	18291	18183	17394
	Expected number of hospital admissions	19390	19858	19860	19582	18334
	SHR	**0.96**	**0.93**	**0.92**	**0.93**	**0.95**
All ESCOs	Patient-years at risk	11584	12150	12486	12360	12313
	Observed number of hospital admissions	20179	20132	19222	19152	18689
	Expected number of hospital admissions	21120	21434	21475	21510	21300
	SHR	**0.96**	**0.94**	**0.90**	**0.89**	**0.88**

Exhibit H-2. Standardized Readmission Ratio for All ESCOs and Comparison Group

ESCO	Statistic	Standardized Readmission Ratio Summary				
		2012	2013	2014	2015	2016*
Comparison Group	Index discharges	19169	18264	18143	17899	17267
	Observed number of readmissions	6350	5804	5832	5711	5365
	Expected number of readmissions	6047	5539	6103	6047	5724
	SRR	**1.05**	**1.05**	**0.96**	**0.94**	**0.94**
All ESCOs	Index discharges	20495	19694	18648	18436	18243
	Observed number of readmissions	6754	6241	5720	5702	5264
	Expected number of readmissions	6470	5950	6216	6137	5989
	SRR	**1.04**	**1.05**	**0.92**	**0.93**	**0.88**

Exhibit H-3. Standardized Mortality Ratio for All ESCOs and Comparison Group

ESCO	Statistic	Standardized Mortality Ratio Summary				
		2012	2013	2014	2015	2016
Comparison Group	Patient years at risk	10507	11107	11357	11030	10386
	Observed number of deaths	1846	1791	1899	1837	1718
	Expected number of deaths	1822	1902	1947	1948	1846
	SMR	**1.01**	**0.94**	**0.98**	**0.94**	**0.93**
All ESCOs	Patient years at risk	11584	12152	12488	12362	12315
	Observed number of deaths	2013	1974	1986	2045	1993
	Expected number of deaths	2007	2075	2131	2155	2151
	SMR	**1.00**	**0.95**	**0.93**	**0.95**	**0.93**