Comprehensive End-Stage Renal Disease Care (CEC) Model

Performance Year 2 Annual Evaluation Report

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Glossary of Terms

Acronym	Definition
ACH	Acute Care Hospital
ACO	Accountable Care Organization
ACSC	Ambulatory Care Sensitive Condition
AHRQ	Agency for Healthcare Research and Quality
AIM	ACO Investment Model
A-APM	Advanced Alternative Payment Model
AV	Arteriovenous
BETOS	Berenson-Eggers Type of Services
BMI	Body Mass Index
CATI	Computer-Assisted Telephone Interviews
CBSA	Core-Based Statistical Area
CC	Condition Category
CCLF	CMS Claims and Claim Line Feed
CCN	CMS Certification Number
CCS	Clinical Classifications Software
CCW	Chronic Conditions Data Warehouse
CDC	Centers for Dialysis Care
CEC	Comprehensive End-Stage Renal Disease (ESRD) Care
CHF	Congestive Heart Failure
CKD	Chronic Kidney Disease
CME	Common Medicare Environment
CMMI	Center for Medicare & Medicaid Innovation
CMS	Centers for Medicare & Medicaid Services
CNU	Care Navigation Unit
COPD	Chronic Obstructive Pulmonary Disease
CROWNWeb	Consolidated Renal Operations in a Web-enabled Network
CY	calendar year
DCI	Dialysis Clinic, Inc.
DiD	difference-in-differences
E&M	Evaluation and Management
ED	emergency department
EDIE	emergency department information exchange
EHR	electronic health records
ESCO	ESRD Seamless Care Organization
ESRD	end-stage renal disease
FAI	Financial Alignment Initiative
FFS	fee-for-service
GEM	General Equivalence Mappings
HbA1c	hemoglobin A1c test
HCC	hierarchical condition category
HCPCS	Healthcare Common Procedure Coding System
HMO	health maintenance organization
HRQOL	health-related quality of life
HRSA	Health Resources and Services Administration

Acronym	Definition
IAH	Independence at Home
ICC	intra-cluster correlation coefficients
ICD-10	International Classification of Disease, 10th Revision
ICD-9	International Classification of Disease, 9th Revision
ICH CAHPS	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems
IRB	Institutional Review Board
IT	information technology
KDQOL [KDQOL-36]	Kidney Disease Quality of Life [Kidney Disease Quality of Life Short Form 36]
LDL	low-density lipoprotein
LDO	large dialysis organization
MA	Medicare Advantage
MACRA	Medicare Access and CHIP Reauthorization Act
MBSF	Master Beneficiary Summary File
MCS	Mental Component Summary
MDM	Mahalanobis distance matching
MDS	Long Term Care Minimum Data Set
MIPS	Merit-Based Incentive Payment System
MME	morphine milligram equivalent
MMRF	Minneapolis Medical Research Foundation
MTM	medication therapy management
NGACO	Next Generation ACO
NKC	Northwest Kidney Centers
non-LDO	non-large dialysis organization or small dialysis organization
NPI	National Provider Identifier
NQF	National Quality Forum
OLS	ordinary least squares
ONS	oral nutritional supplements
OPTN	Organ Procurement and Transplantation Network
OREC	original reason for entitlement code
P4P	pay-for-performance
PAC	post-acute care
PBPM	per beneficiary per month
PCP	primary care provider
PCS	Physical Component Summary
PPS	Prospective Payment System
PQI	Prevention Quality Indicator
PSM	propensity score matching
PY1	performance year one (October 1, 2015 through December 31, 2016)
PY2	performance year two (January 1, 2017 to December 31, 2017)
QIP	Quality Incentive Program
QQ	quantile-quantile
RAND	Research and Development Corporation
REMIS	Renal Management Information System
SDO	small dialysis organization
SF-12	Short Form 12 (for the KDQOL survey)
SHR	standardized hospitalization ratio

Acronym	Definition
SMD	standardized mean difference
SMR	standardized mortality ratio
SNF	skilled nursing facility
SRR	standardized readmission ratio
SRTR	Scientific Registry of Transplant Recipients
SSP	Shared Savings Program
TIN	Taxpayer Identification Number
TQS	total quality score
US	United States
USRDS	US Renal Data System
VRDC	Virtual Research Data Center

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.

In 2016, fewer than 1% of the fee-for-service (FFS) Medicare beneficiary population had ESRD, yet they accounted for about 7% of FFS Medicare spending.[3] Beneficiaries with ESRD have more and longer hospitalizations than other beneficiaries and their readmission rates are 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 Advanced Alternative Payment Model (A-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, partner to form ESRD Seamless Care Organizations (ESCOs). ESCOs are specialty-oriented Accountable Care Organizations (ACOs) that assume financial responsibility for the quality of care and Medicare Part A and Part B spending of their aligned beneficiaries. The ESCOs participating in the model are separated into two waves, differentiated by the date on which they joined the CEC Model. Wave 1 includes ESCOs that joined the model on October 1, 2015; Wave 2 includes ESCOs that joined the model on January 1, 2017. The model runs five years.

This second annual report provides findings on the impact of the CEC Model during the first two performance years: October 1, 2015 through December 31, 2016 (PY1) and January 1, 2017 through December 31, 2017 (PY2). It combines findings from quantitative and qualitative research to address a core set of questions. For instance, data from interviews with ESCOs and facilities addressed the questions of why organizations chose to participate and how they implemented the model, including perceived successes and challenges. This second annual report focuses on Wave 2 ESCO interviews, while the first annual report presents findings for Wave 1 ESCO interviews.[4] Quantitative research complements the qualitative data by addressing how participation in the CEC Model for both Wave 1 and Wave 2 ESCOs affected dialysis care, coordination of care beyond

[3] United States Renal Data System, 2018 Annual Data Report: Volume 2 – ESRD in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2018.

[4] For findings from the Wave 1 ESCO site visits, please see the first annual report (https://innovation.cms.gov/Files/reports/cec-annrpt-py1.pdf).

dialysis, hospitalizations and emergency department (ED) visits, and Medicare spending across the continuum of care.

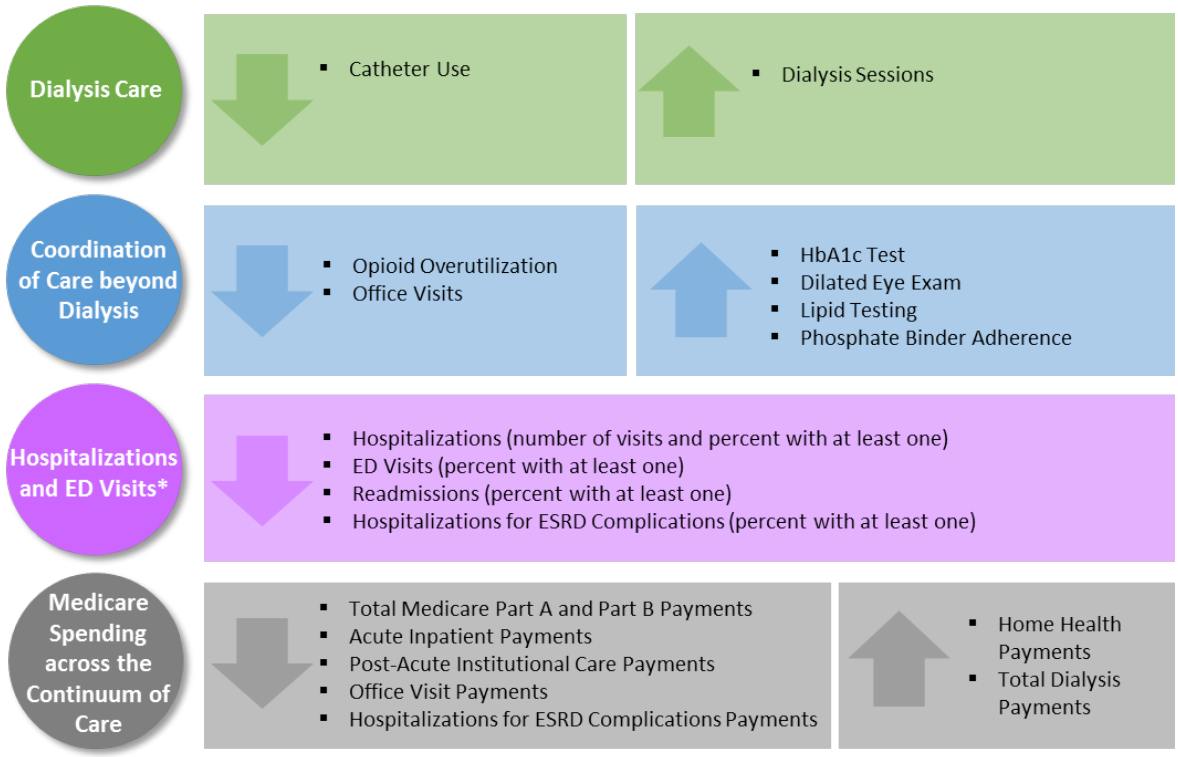
B. Overview of Findings

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 inpatient and outpatient settings. The second performance year saw a major expansion of the CEC Model. In January 2017, 24 new ESCOs joined the 13 original ESCOs that began operations in October 2015. Nationally, 12% of dialysis facilities are now participating in the model.

Overall, the CEC Model showed promising results over the first two years, with improvements on some quality and health care utilization measures as well as a decrease in total spending (see **Exhibit ES-1** for a summary of the evaluation findings). The CEC Model resulted in a $68 million reduction in spending over the first two performance years. However, after accounting for the $114.3 million in shared savings that ESCOs received across PY1 and PY2, Medicare experienced aggregate net losses of $46.1 million ($p \leq 0.10$). At the same time, beneficiary-reported quality of life remained largely unchanged. Results from the first two performance years suggest that the reduction in Medicare payments for CEC beneficiaries has primarily been generated through a reduction in hospitalizations. The percent of beneficiaries with at least one ED visit or readmission also decreased. Additionally, ESCOs reported various interventions to improve adherence to dialysis. These resulted in an increase in the number of dialysis treatments and dialysis spending, but a decrease in spending for hospitalizations associated with dialysis complications.

There is also evidence that, for beneficiaries with ESRD, the CEC Model performed better than primary care-based ACOs. We saw meaningful improvements in spending and utilization outcomes under the CEC Model, whereas primary care-based ACOs showed no evidence of improved outcomes or reduced spending for beneficiaries with ESRD. This suggests that beneficiaries with ESRD fare better in the specialized CEC Model than in primary care-based ACOs.

Exhibit ES-1. Summary of Evaluation Findings*



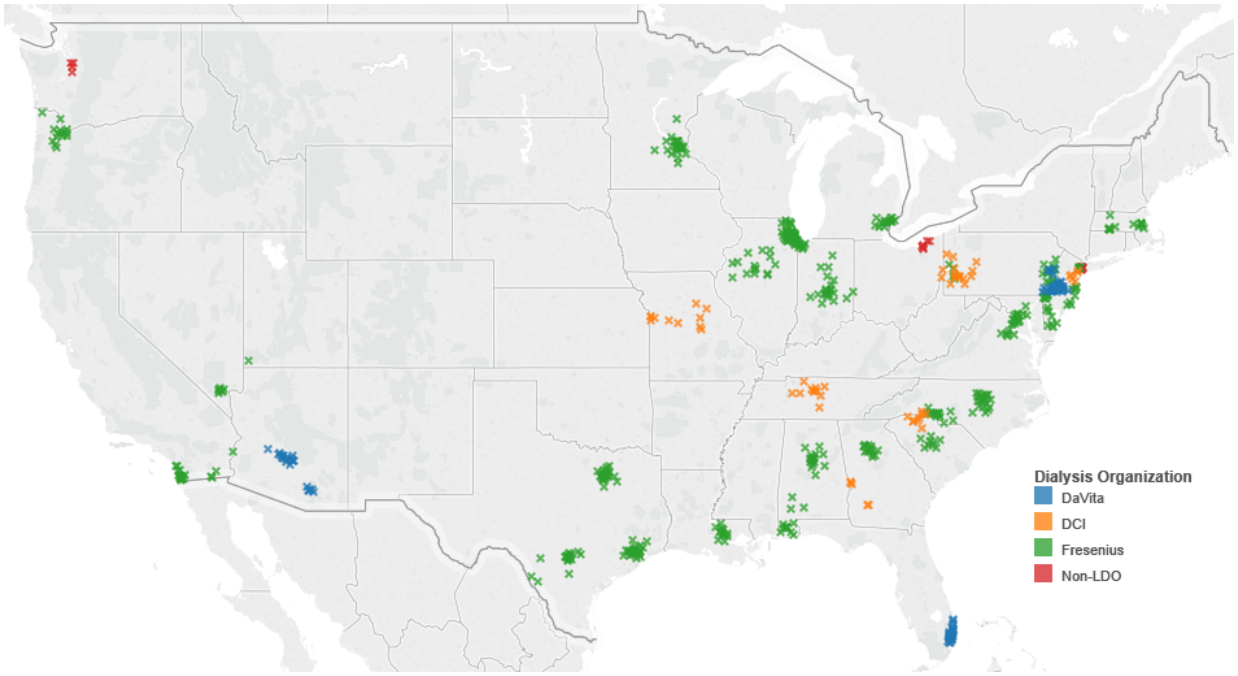
***Shows statistically significant evaluation impacts for all ESCOS across PY1 and PY2**

Notes: ⬇ boxes indicate measures with a statistically significant decrease; ⬆ boxes indicate measures with a statistically significant increase. Each impact estimate is based on a difference-in-differences (DiD) analysis, and reflects the difference in the regression-adjusted average outcome for beneficiaries in CEC facilities for the first two performance years with baseline relative to the same difference over time for beneficiaries in matched comparison facilities. Significance identified with p-values ≤ 0.10. *We evaluated the impact of the CEC Model on the odds of experiencing at least one event in a given month and the number of events per month on the following outcomes: hospitalizations, ED visits, and readmissions. For all other measures under this domain we only explored the impact of the CEC Model on the odds of experiencing at least one event in a given month.

1. Who Participates in the CEC Model?

Thirty-seven ESCOs, representing three large dialysis organizations (LDOs) (DaVita, Fresenius, and Dialysis Clinic, Inc. [DCI]) and four small dialysis organizations or non-LDOs (Rogosin Institute, Atlantic Dialysis, Centers for Dialysis Care [CDC], and Northwest Kidney Centers [NKC]), joined the CEC Model as of January 2017. Of these 37 ESCOs, 13 joined the CEC Model on October 1, 2015 as Wave 1 ESCOs, while the remaining 24 ESCOs joined the CEC Model as Wave 2 ESCOs on January 1, 2017. Collectively, these ESCOs had 685 dialysis facilities and were spread across 27 states and Washington, D.C. **Exhibit ES-2** shows the location of participating facilities.

Exhibit ES-2. Location of CEC Dialysis Facilities



Source: CEC Model participation data extracted from Salesforce on 01/03/2018.

Dialysis Organization Representation. The 37 ESCOs are diverse along several important dimensions, including geographic region, ownership, and size. While both LDOs and non-LDOs are represented in the model, Fresenius was the dominant participant, making up 72% of ESCO facilities. DaVita was the next largest group, representing 16% of ESCO facilities. ESCOs covered a wide range of markets in terms of Medicare Part A and Part B payments per beneficiary per month (PBPM), with no apparent selection into high-cost markets. However, ESCOs tended to operate in larger urban markets, likely reflecting the requirement to have at least 350 patients with ESRD. In particular, ESCOs were located in many of the largest population centers in the United States (US), with the average CEC Core-Based Statistical Area (CBSA) having a population three and a half times larger than the average non-CEC CBSA.

2. Why Did Wave 2 ESCOs Join the CEC Model and How Did They Prepare?

Reasons for Joining the CEC Model. Wave 2 ESCOs joined the model because of its potential to improve patient care, increase efficiency, and reduce costs, as well as to build upon strong existing relationships between dialysis providers and nephrologists and to develop or strengthen relationships with other partners such as hospitals, hospice/palliative care providers, and vascular surgery practices. The success and experience of Wave 1 ESCOs and the influence of the Medicare Access and CHIP Reauthorization Act (MACRA) also encouraged participation. Because the CEC Model was deemed an A-APM, participating nephrologists could exempt themselves from reporting requirement and payment adjustments under MACRA's Merit-based Incentive Payment System (MIPS). Wave 2 ESCOs joined the model for reasons that were similar to the Wave 1 ESCOs.[5] However, Wave 2 ESCOs were less likely to cite the desire to

[5] Only detailed findings from the Wave 2 ESCO site visits are included in this annual report. For findings from the Wave 1 ESCO site visits, please see the first annual report (https://innovation.cms.gov/Files/reports/cec-annrpt-py1.pdf).

influence future payment models and more likely to cite the success of Wave 1 ESCOs and MACRA as reasons for joining the model.

New or Enhanced Partnerships. All dialysis organizations and their associated ESCOs established formal financial risk-sharing partnerships with nephrologists, as required for participation in the CEC Model. Similar to Wave 1 ESCOs in PY1, some Wave 2 ESCOs created additional risk-sharing partnerships with other providers such as vascular access centers, as well as non-risk sharing partnerships with a wide range of organizations such as hospitals, additional nephrologists and vascular surgeons, skilled nursing facilities (SNFs), information technology (IT) service providers, pharmacies, and hospice and palliative care organizations. On average, non-LDOs partnered with a more diverse set of organizations and had more partnerships compared to the LDOs. This may be because the non-LDOs were exclusively local nonprofit organizations that had existing community partnerships and continued outreach to form new partnerships.

Preparations for the Model. During our interviews with Wave 1 ESCOs in PY1, we learned that dialysis organizations invested in two major areas: new staff and IT to support care coordination and care redesign efforts. Likewise, all Wave 2 ESCOs hired new staff, particularly care coordinators. Care coordinators serve multiple functions, including coordinating non-dialysis care, facilitating care transitions, following up with patients and staff to avoid potential care oversights, discussing social issues with patients (e.g., insurance and homelessness), and providing encouragement to patients. Some ESCOs hired other types of staff, including data analysts, administrative assistants, admissions nurses, and palliative care staff. Wave 2 ESCOs also made IT investments, including new equipment, electronic health records (EHR) upgrades, software updates, and notification systems to alert nephrologists and the dialysis facility when patients present to the ED.

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 representatives discussed the use of patient engagement waivers (i.e., transportation, oral nutritional supplements [ONS], and patient IT) and did not mention other program waivers (i.e., pay-for-performance [P4P], ESCO remuneration, ESCO IT, and care coordination). Of the patient engagement waivers, the transportation waiver was used most frequently by both Wave 2 ESCOs in PY2 and Wave 1 ESCOs in PY1.

3. How Did Wave 2 ESCOs Change Care Delivery to Meet CEC Model Goals?

Care Redesign Strategies. Wave 2 participants in the CEC Model implemented three general strategies to improve patient care:

- **Increased Access to Dialysis Care.** ESCOs used strategies such as extending facility hours, increasing dialysis capacity at facilities, and improving flexibility around rescheduling treatments to help increase patients' access to dialysis care and reduce missed dialysis treatments.
- **Enhanced Coordination of Non-Dialysis Care.** ESCOs developed risk stratification models to identify patients vulnerable to hospitalizations and directed increased effort into managing their care. Care management efforts included medication reconciliation,

referrals to specialists, and coordination with non-dialysis providers. A few ESCOs also established partnerships with hospice and palliative care organizations.

- **Improved Patient-Centered Care and Communication.** ESCOs made changes to their patient and family education strategies to improve patient-centered care and communication. These strategies included informing patients of the role and goals of the ESCO, preparing chronic kidney disease (CKD) patients for dialysis treatment, or providing patients with contact information to triage their concerns and deter unnecessary hospitalizations.

Implementation Challenges. ESCOs experienced several challenges in implementing the model. Some of the most frequently noted challenges pertained to model design. For example, respondents commented on significant upfront costs associated with starting an ESCO, ESCOs' inability to engage outside providers to collaborate with the model's goals, concerns about the lack of patient accountability built into the model, and burdensome program rules and regulations. Other challenges frequently cited by respondents were resource-related or operational in nature including limited availability and lack of reliable transportation services for beneficiaries and the time lag in receiving data from CMS.

4. What Were Beneficiaries' Perceptions of the CEC Model?

Most beneficiaries participating in focus groups were unaware or only minimally aware of the CEC Model. But when shown the letter they received from CMS a few beneficiaries did recall the letter. While they may not have been aware of the ESCO as a formal entity, they were aware of at least some of its activities, particularly the new care coordinator role. When participants were given information about the CEC Model, they perceived that the model sounded useful. However, focus group participants thought the model would be more beneficial to patients with less experience managing their dialysis care.

5. What Was the Association between Alignment in the CEC Model and Beneficiary Quality of Life?

We found little evidence of change in beneficiary quality of life during PY2 as reported in the Kidney Disease Quality of Life (KDQOL-36) survey.[6] Compared to similar ESRD beneficiaries not participating the model, CEC beneficiaries were slightly less likely to be bothered by their symptoms of kidney disease or report limitations due to their physical health. Although statistically significant, the differences between were small in magnitude and judged to not be clinically meaningful. The CEC and similar ESRD beneficiaries not participating the model did not differ in terms of the overall burden of kidney disease in their life or their reported mental health. The ESCOs' focus on saving costs did not have the unintended consequence of decreasing quality of life.

6. What Were the Impacts of the CEC Model?

Overall, during the first two performance years, the CEC Model resulted in improvements in delivery and quality of dialysis care and reductions in acute care utilization and Medicare

[6] We also conducted a quality of life survey in PY1. The PY1 survey results are included in the first annual report (https://innovation.cms.gov/Files/reports/cec-annrpt-py1.pdf).

spending. **Exhibit ES-3** summarizes the estimated impacts over the first two performance years of the model on dialysis care, coordination of care beyond dialysis, hospitalizations and ED visits, and Medicare spending across the continuum of care. Unless otherwise noted, all CEC effects are reported as impact estimates relative to similar Medicare beneficiaries with ESRD not participating in the model, and as percent changes relative to the pre-CEC period.

Exhibit ES-3. Summary of Difference-in-Differences (DiD) Impact Estimates, All ESCOs PY1+PY2

Measure		CEC		Comparison		Difference-in-Differences Estimate			
		Pre-CEC	Post-CEC	Pre-CEC	Post-CEC	DiD	90% Lower CI	90% Upper CI	Percent Change[7]
Dialysis Care	Fistula Use (percent of beneficiaries in a given month who had a fistula and had at least 90 days dialysis)	64.6%	64.5%	64.2%	64.8%	-0.64	-1.5	0.19	-0.99%
	Catheter Use (percent of beneficiaries in a given month who had a catheter for 90 days or longer)	9.3%	9.4%	11.4%	12.2%	-0.78***‡	-1.3	-0.28	-8.3%
	Hemodialysis (percent with at least one)	92.1%	91.2%	91.5%	90.3%	0.42	-0.52	1.4	0.45%
	Peritoneal Dialysis (percent with at least one)	6.4%	6.6%	6.9%	7.4%	-0.28	-1.3	0.69	-4.4%
	Home Hemodialysis (percent with at least one)	1.5%	1.7%	1.4%	1.4%	0.25	-0.17	0.68	17.0%
	Home Dialysis (percent with at least one)	8.1%	8.3%	8.1%	8.0%	0.24	-0.15	0.63	2.9%
	Emergency Dialysis (percent with at least one)	1.8%	1.8%	1.9%	2.0%	-0.01	-0.14	0.11	-0.71%
	Gap in Dialysis (percent)	8.7%	8.5%	9.2%	9.2%	-0.20‡	-0.52	0.12	-2.3%
	Number of Outpatient Dialysis Sessions per 1,000 Beneficiaries per Month	12,254	12,319	12,263	12,257	71.3***	34.4	108.2	0.58%
	Percent of Beneficiaries Rating Kidney Doctors at the Highest Level	56.6%	58.0%	58.9%	60.0%	0.27	-1.5	2.0	0.47%
	Percent of Beneficiaries Rating Dialysis Center Staff at the Highest Level	57.4%	58.7%	59.7%	61.1%	0.00	-1.9	1.9	-0.01%
	Percent of Beneficiaries Rating Dialysis Center at the Highest Level	62.3%	64.1%	64.8%	66.1%	0.57	-1.4	2.5	0.92%
	Percent of Beneficiaries Seen within 15 Minutes of Appointment Time	38.0%	40.2%	39.4%	41.6%	-0.12	-2.2	1.9	-0.31%
	Percent of Beneficiaries Receiving Explanation of Transplant Ineligibility	68.8%	68.8%	69.4%	70.1%	-0.68	-2.8	1.4	-0.99%
	Percent of Beneficiaries Rating Nephrologists' Communication and Caring at the Highest Level	65.9%	67.0%	66.3%	67.2%	0.28	-1.1	1.6	0.43%
	Percent of Beneficiaries Rating Quality of Dialysis Center Care and Operations at the Highest Level	59.5%	60.3%	60.5%	61.6%	-0.38	-1.5	0.78	-0.63%
	Percent of Beneficiaries Receiving Information from Dialysis Center Staff/ Doctor	77.8%	78.0%	79.0%	79.2%	-0.01	-0.89	0.87	-0.01%

[7] Percent change is defined as the DiD estimate divided by the margins predicted pre-CEC mean for facilities participating in the CEC Model.

Measure		CEC		Comparison		Difference-in-Differences Estimate			
		Pre-CEC	Post-CEC	Pre-CEC	Post-CEC	DiD	90% Lower CI	90% Upper CI	Percent Change[7]
Coordination of Care beyond Dialysis	Percent of Beneficiaries Receiving Flu Vaccinations^	40.3%	40.0%	40.8%	39.7%	0.84	-1.8	3.5	2.1%
	Percent of Diabetic Beneficiaries Receiving at Least One Dilated Eye Exam in a Given Year	40.0%	41.6%	40.7%	41.0%	1.4**	0.38	2.4	3.5%
	Percent of Beneficiaries Receiving at Least One Low-Density Lipoprotein (LDL) Cholesterol Test in a Given Year	55.2%	57.9%	56.0%	50.1%	8.5***	6.5	10.5	15.4%
	Percent of Beneficiaries Receiving at Least One Hemoglobin A1c (HbA1c) Test in a Given Year	75.8%	76.3%	77.5%	74.0%	4.0***	2.6	5.5	5.3%
	Percent of Beneficiaries Receiving Hospice Services in a Given Month	0.88%	0.78%	0.86%	0.75%	0.01	-0.05	0.07	1.1%
	Number of Evaluation and Management (E&M) Office Visits per 1,000 Beneficiaries per Month	2,471	2,446	2,433	2,464	-56.5**	-102.4	-10.6	-2.3%
	Percent of Beneficiaries with Greater than 50 mg Average Morphine Milligram Equivalent (MME) in a Given Month	6.0%	5.4%	6.0%	5.8%	-0.38*	-0.73	-0.04	-6.4%
	Percent of Beneficiaries with Greater than 80% of Days Covered for Phosphate Binder Prescription in a Given Month	34.3%	36.3%	34.4%	35.1%	1.2***	0.53	2.0	3.6%
	Percent of Beneficiaries with at Least One Contraindicated Medication Prescription Fill in a Given Month	3.5%	3.8%	3.4%	3.7%	-0.02	-0.28	0.23	-0.66%
	Percent of Beneficiaries Starting Dialysis with No Prior Nephrology Care	25.4%	23.5%	28.5%	26.4%	0.16	-2.4	2.7	0.62%
Hospitalizations and Emergency Department Visits	Number of Hospitalizations per 1,000 Beneficiaries per Month	126.6	123.1	128.6	130.1	-5.0***	-7.9	-2.1	-4.0%
	Number of ED Visits per 1,000 Beneficiaries per Month	137.7	144.0	142.1	152.3	-3.9	-7.9	0.22	-2.8%
	Number of Readmissions per 1,000 Beneficiaries per Month	347.9	340.5	349.7	348.9	-6.2	-15.1	2.8	-1.8%
	Percent of Beneficiaries with at Least One Hospitalization in a Given Month	11.2%	10.9%	11.4%	11.5%	-0.47***	-0.71	-0.23	-4.2%
	Percent of Beneficiaries with at Least One ED Visit in a Given Month	10.9%	11.3%	11.2%	11.9%	-0.29*	-0.54	-0.05	-2.7%

Measure		CEC		Comparison		Difference-in-Differences Estimate			
		Pre-CEC	Post-CEC	Pre-CEC	Post-CEC	DiD	90% Lower CI	90% Upper CI	Percent Change[7]
Hospitalizations and Emergency Department Visits (cont'd)	Percent of Beneficiaries with at Least One Readmission within 30-days of an Index Hospitalization Stay in a Given Month	29.5%	28.8%	29.5%	29.5%	-0.71*	-1.4	-0.03	-2.4%
	Percent of Beneficiaries with at Least One Observational Stay in a Given Month	2.3%	2.5%	2.3%	2.5%	0.02	-0.10	0.13	0.74%
	Percent of Beneficiaries with at Least One ED Visit within 30-days of an Acute Hospitalization in a Given Month	19.9%	20.3%	20.3%	21.0%	-0.31	-0.01	0.24	-1.6%
	Average Inpatient Length of Stay (in days)	6.2	6.1	6.3	6.2	0.01	-0.09	0.10	0.12%
	Percent of Beneficiaries with at Least One Hospitalization for Vascular Access Complications in a Given Month	0.58%	0.61%	0.63%	0.66%	0.003	-0.04	0.04	0.50%
	Percent of Beneficiaries with at Least One Hospitalization for ESRD Complications in a Given Month	1.8%	1.8%	1.8%	1.9%	-0.11**	-0.19	-0.04	-6.4%
	Percent of Beneficiaries with at Least One Admission for Diabetes Short-Term Complications in a Given Month	0.12%	0.10%	0.14%	0.10%	0.01	-0.01	0.03	9.3%
	Percent of Beneficiaries with at Least One Admission for Diabetes Long-Term Complications in a Given Month	0.77%	0.66%	0.77%	0.68%	-0.01	-0.06	0.04	-1.9%
	Percent of Beneficiaries with at Least One Admission for Asthma or Chronic Obstructive Pulmonary Disease (COPD) in Older Adults in a Given Month	0.68%	0.78%	0.70%	0.74%	0.06	-0.02	0.14	9.0%
	Percent of Beneficiaries with at Least One Admission for Congestive Heart Failure (CHF) in a Given Month	1.5%	1.6%	1.6%	1.8%	-0.08	-0.16	0.01	-5.3%
Medicare Spending across the Continuum of Care	Total Part A and Part B PBPM	$6,315	$6,199	$6,317	$6,315	-$114**	-$188	-$40	-1.8%
	Acute Inpatient PBPM	$1,634	$1,636	$1,669	$1,739	$-68***	-$105	-$31	-4.1%
	Readmissions PBPM	$563	$567	$573	$607	-$29**	-$53	-$6	-5.2%
	Home Health PBPM	$178	$175	$173	$161	$10**	$2	$18	5.5%
	Hospice PBPM	$24	$21	$23	$20	$0.00	-$2	$2	0.01%
	Institutional Post-Acute Care PBPM	$572	$521	$541	$549	-$59***	-$89	-$30	-10.4%
	Hospital Outpatient PBPM	$368	$385	$401	$422	-$4‡	-$15	$7	-1.2%
	Total Part B PBPM	$4,034	$3,963	$4,036	$3,974	-$9	-$37	$19	-0.22%

Measure		CEC		Comparison		Difference-in-Differences Estimate			
		Pre-CEC	Post-CEC	Pre-CEC	Post-CEC	DiD	90% Lower CI	90% Upper CI	Percent Change[7]
Medicare Spending across the Continuum of Care (cont'd)	Office Visits PBPM	$310	$306	$300	$306	-$11***	-$17	-$4	-3.5%
	Total Dialysis PBPM	$2,595	$2,591	$2,599	$2,580	$15***	$8	$22	0.59%
	Hospitalizations for ESRD Complications PBPM	$149	$163	$148	$171	-$10**	-$17	-$2	-6.5%
	Part B Drug PBPM	$25	$33	$23	$30	$0.72	-$2	$4	2.9%
Unintended Consequences	Total Part D Drug Cost PBPM	$820	$1,119	$836	$1,123	$12‡	-$9	$34	1.5%

Notes: A DiD design was used to estimate the differential change in outcomes for beneficiaries receiving care from CEC dialysis facilities between the baseline and the intervention periods relative to a comparison group of beneficiaries aligned to matched dialysis facilities that were not participating in CEC. Estimates include both waves from October 2015 - December 2017, and are the combined cumulative impact of CEC, accounting for different lengths of exposure to the model. About 33% of facilities have nine quarters of CEC participation (October 2015 to December 2017); the remaining 67% participated in CEC from January 2017 to December 2017 (four quarters). 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 the intervention period with baseline relative to the same difference over time for beneficiaries in matched comparison facilities. Significance of the DiD impact estimate is indicated next to each outcome where * implies significance at the 10% level, ** at the 5% level, and *** at the 1% level assuming a two-tailed test. ‡ Data from the baseline period showed intervention and matched comparison facilities were not on parallel trends for this outcome, which is required for an unbiased impact estimate.

Dialysis Care. We expected the CEC Model to incentivize better vascular access practices and improve adherence to dialysis that could in turn reduce hospitalization rates. Vascular access related bacteremia, caused by infected catheter sites, can require hospitalization. The successful creation of arteriovenous (AV) fistulas and AV grafts can reduce risk. Care coordination by the ESCOs may include referrals to vascular surgeons to increase the rate of fistula placements. Contrary to expectations, CEC beneficiaries showed a small but not statistically significant decrease of 1% in the use of fistulas. However, consistent with expectations, use of catheters for more than 90 days showed a statistically significant decrease of 8%.[8] There are also early signs that ESCOs' reported increased efforts to promote dialysis adherence were successful, as CEC beneficiaries increased their dialysis sessions by 1%.

There was no evidence of changes in patient-reported quality of dialysis care among CEC dialysis facilities. We did not expect to see changes in these measures since dialysis facilities already have financial incentives to score highly on these outcomes through the ESRD QIP,[9] and these results confirm the CEC Model has not resulted in lower dialysis quality.

Coordination of Care beyond Dialysis. Because ESCOs are accountable for all of a beneficiary's Medicare Parts A and B costs, providers have the incentive to invest in preventive services and chronic disease management activities beyond their standard dialysis care. Also, ESCOs may offer patients with ESRD more education about hospice and end-of-life care, for instance, through their partnerships with palliative care organizations. We found that CEC beneficiaries experienced a statistically significant increase in preventive health care services such as hemoglobin A1c (HbA1c) testing, low-density lipoprotein (LDL) cholesterol testing, and dilated eye exams. CEC reduced the likelihood of a beneficiary with ESRD overusing opioid prescriptions by 6% and improved adherence to phosphate binder use by 4%. CEC beneficiaries also had 2% fewer evaluation and management (E&M) office visits. This may suggest participating nephrologists are addressing primary care needs in addition to dialysis care. CEC had no statistically significant impact on hospice use.

Hospitalizations and ED Visits. By introducing incentives for reducing total cost of care, the CEC Model was expected to reduce acute hospitalization admissions, readmissions, and ED use. CEC beneficiaries experienced statistically significant reductions in hospitalizations. Specifically, CEC reduced the likelihood of at least one hospitalization by 4% and the number of hospital visits by 4% in the first two years of the model. CEC beneficiaries were also 3% less likely to visit the ED and 2% less likely to be readmitted to the hospital although these declines were not statistically significant. Wave 1 ESCOs saw a statistically significant reduction of 3% in the number of ED visits in PY2. Additionally, CEC beneficiaries were 6% less likely to be hospitalized for ESRD complications.

Mortality. Ideally, the care redesign changes reported by ESCOs would decrease mortality as a byproduct of preventing hospitalizations. However, there is a potential risk that ESCOs may discourage complicated patients from continuing dialysis as an unintended consequence of having full financial responsibility for their Parts A and B spending. We compared the

[8] There are three types of vascular access for hemodialysis: fistulas, grafts, and catheters.

[9] See https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/index.html

standardized mortality ratio (SMR) between ESCOs and comparison facilities and found no differences.

Medicare Spending across the Continuum of Care. ESCOs were able to reduce costs mainly through a reduction in spending on hospitalizations, although the overall impact on payments was modest. Average total Medicare Part A and Part B standardized payments, our measure of overall Medicare spending, decreased from the baseline to PY2 for both the CEC and comparison group beneficiaries. The decrease was greater for the CEC group, resulting in a 2% relative reduction ($114 PBPM) for CEC beneficiaries, about 2.4% for Wave 1 ESCOs and 0.5% for Wave 2 ESCOs. Overall, the CEC Model resulted in a reduction in spending of $68 million over the first two performance years.[10] Spending decreased by $25 million in PY1 and by $43 million in PY2. The $18 million additional spending decline from PY1 to PY2 is due to larger reductions in spending for Wave 1 ESCOs in PY2 relative to PY1 (from $25 million to $36.5 million) and the additional $6.5 million reduction in spending achieved by Wave 2 ESCOs in PY2. After accounting for the $114.3 million in shared savings ($194 PBPM) that ESCOs received across PY1 and PY2, Medicare experienced aggregate net losses of $46.1 million ($78 PBPM, $p \leq 0.10$).

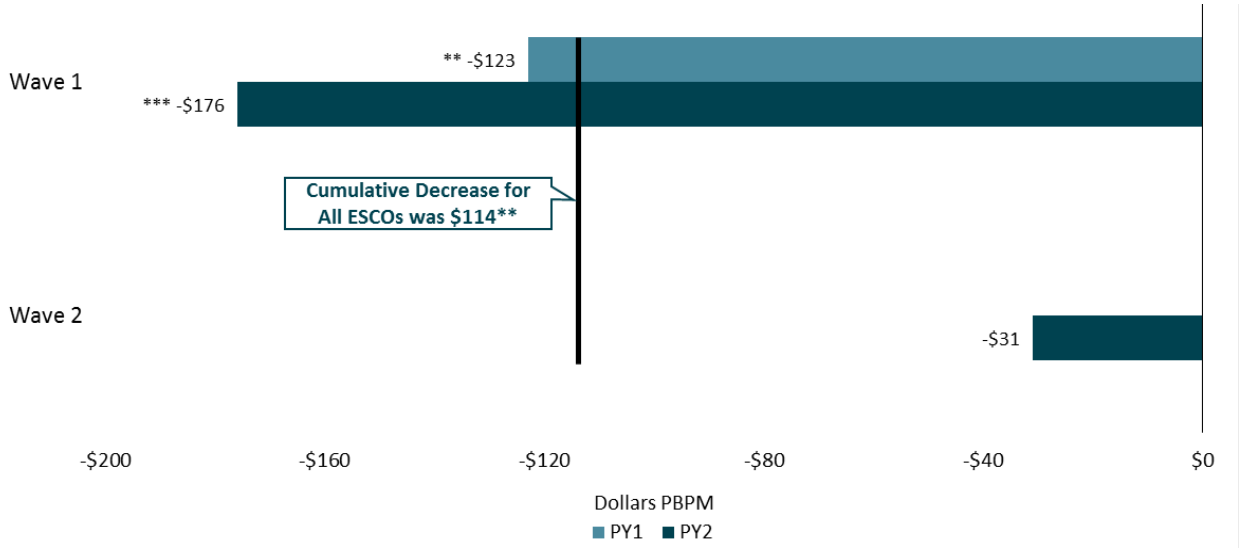
Waves 1 and 2 also experienced different results in PBPM costs (See **Exhibit ES-4** for a comparison of Wave 1 and Wave 2 estimated spending reductions). While the average reduction in spending for all ESCOs was $114 PBPM, estimates were smaller and not statistically significant for Wave 2 ESCOs ($31 PBPM in their first performance year versus $123 PBPM for Wave 1 ESCOs in their first performance year). Notably, Wave 1 ESCOs reduced spending more during their second performance year to $176 PBPM.

Medicare spending for CEC beneficiaries declined in all Part A settings. Medicare spending declined for acute inpatient stays (4%), readmissions (5%), and institutional post-acute care (10%). Spending on some Medicare Part B services also declined; spending for office visits showed a statistically significant decrease of 4% for CEC beneficiaries. Improved adherence likely led to the observed 1% increase in payments for dialysis treatments and the 7% decreased spending on hospitalizations for ESRD complications. Home health spending also increased for CEC beneficiaries by 6%.

The smaller decline in Medicare spending in Wave 2's first performance year may be due to differences in Wave 2 facilities. Whereas Wave 1 ESCO facilities had higher Medicare spending, and higher standardized hospitalization and readmission rates than non-CEC facilities, those joining in Wave 2 had lower spending and lower standardized hospitalization and readmission rates than non-CEC facilities. This suggests that the facilities in Wave 2 ESCOs may have had less room to improve on their pre-CEC performance. Additionally, Wave 1 and Wave 2 had very different "lead-in" periods. Delays in the start date for Wave 1 may have allowed greater preparation time, and may have contributed to differences in outcomes across the two waves. Finally, Wave 1 ESCOs may contain more motivated participants that were willing to be early adopters, while at least some Wave 2 participants may have been motivated more strongly by gaining exemption from MIPS requirements than by enthusiasm for the model.

[10] These estimates do not account for payments between ESCOs and CMS resulting from PY1+PY2 reconciliation.

Exhibit ES-4. Impact of CEC on Total Part A and Part B Standardized Medicare Payments PBPM



Notes: PY1 covers October 2015 - December 2016, PY2 covers January 2017 - December 2017. All ESCOs estimates include both waves from October 2015 - December 2017. The estimate of All ESCOs is the combined cumulative impact of CEC, accounting for different lengths of exposure to the model. About 33% of facilities have nine quarters of CEC participation (October 2015 to December 2017); the remaining 67% participated in CEC from January 2017 to December 2017 (four quarters). A weighted average of the performance years by wave may not exactly equal the All ESCO result because the All ESCO and the wave-performance year specific estimates were generated by separate regression models. 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 the intervention period with baseline relative to the same difference over time for beneficiaries in matched comparison facilities. Significance of the DiD impact estimate is indicated next to each outcome bar plot where * implies significance at the 10% level, ** at the 5% level, and *** at the 1% level assuming a two-tailed test.

7. What Were the Differences in Performance between the CEC and Primary Care-Based ACO Models?

We found key differences in performance between primary care-based ACO models[11] and the CEC Model relative to a FFS comparison group for the six key outcomes that were evaluated: total Part A and Part B Medicare payments, ED visits, hospitalizations, fistula use, catheter use, and readmissions. Specifically, FFS beneficiaries with ESRD who became aligned to CEC experienced statistically significant relative reductions in Medicare payments, hospitalizations, and ED visits during the first year after alignment.[12] However, FFS beneficiaries with ESRD who were newly aligned to a primary care-based ACO experienced no statistically significant impacts.

8. Were There Unintended Consequences of the CEC Model?

While the CEC Model is intended to create incentives for care that is more efficient and/or higher quality, it is also important to monitor for potential adverse, unintended consequences.

[11] Primary care-based ACOs evaluated include Medicare Shared Savings Program (SSP), Pioneer ACO Model, and Next Generation ACO Model (NGACO).

[12] Readmissions failed the parallel trend test for the newly aligned CEC beneficiaries with a p-value just slightly below 0.10. A falsification test, using a pseudo intervention period during the baseline period, yielded insignificant results, suggesting parallel trends of the newly aligned CEC beneficiary readmission rate compared to the matched FFS comparison group despite the below 0.10 p-value of trends test coefficient.

We examined if the model inadvertently shifted spending to parts of the Medicare program for which the ESCOs are not accountable (Part D prescription drug benefit); resulted in implicit or explicit selection of more favorable patients, or reduced referral of patients for transplantation.

There is no evidence that the CEC Model had an impact on these outcomes. First, there was no impact on Part D drug costs. Second, there was no evidence that physicians changed their referral patterns due to the CEC Model (such as assigning sicker dialysis patients to non-CEC rather than CEC facilities in an effort to lower ESCO costs). Finally, there was no evidence that participation in CEC impacted referrals to the transplant waiting list.

C. Discussion

Overall, the first two years of experience under the CEC Model appear promising, with lower spending, improvements in some utilization measures, and no obvious indicators of unintended or adverse consequences. Part A and B Medicare payments declined by over $100 PBPM representing a decrease in spending of nearly 2%. The spending reductions were most evident in Medicare Part A with significant reductions in acute inpatient, readmission, and institutional post-acute care categories. Reductions in utilization paralleled the spending reductions, with significant declines in the likelihood of hospitalizations, readmissions, and ED visits. The number of dialysis treatments and spending on dialysis increased, which could be a consequence of fewer missed treatments, while hospitalizations for and spending on dialysis complications declined. Significant reductions in catheter as vascular access were also observed, suggesting overall improvements in the quality of dialysis care.

Utilization and spending results reinforce the qualitative findings that are based on dialysis facility site visits and corporate interviews. Improving coordination of care across institutional settings was cited as a key objective by the ESCOs, backed by new investments such as care coordination staff and IT. Reducing hospitalizations and readmissions was a particular area of emphasis. Similarly, the observed increase in the number of dialysis treatments and dialysis payments may reflect a decrease in skipped outpatient treatments, either directly or indirectly (due to less time in hospital), which was another key emphasis cited by the ESCOs. Many ESCOs sought to improve communications with local EDs in order to divert patients with conditions such as fluid overload from the inpatient setting. This improved communication was sometimes coupled with enhanced provision of standby dialysis slots to facilitate rescheduled or extra treatments in such cases. Overall, many of the care redesign strategies were enhancements or more formal extensions of processes in existence prior to the implementation of the CEC Model. Many ESCOs felt that building partnerships with hospice and palliative care providers was important, but was an area where their efforts had lagged behind other initiatives. More generally, engagement with non-participating providers and the inability to provide patient incentives were seen as limitations to the model, and may have limited the reductions in spending that were achieved.

The dialysis-dependent ESRD population may be a particularly appropriate population for the development of a specialty-oriented ACO as hemodialysis patients have regular contact with the specialty care institution (three times weekly) and the nephrologist (three to four times monthly). Home dialysis patients have less frequent, but still regular, contact. Therefore, positive outcomes for the CEC Model might not be directly generalizable to populations with other chronic

illnesses such as diabetes, HIV, or congestive heart failure. Nonetheless, the CEC experience could still provide lessons about the potential benefits of specialty providers increasing their responsibilities in an ACO context, whether that ACO is entirely comprised of a population with a particular chronic condition or only represents a defined subpopulation within a primary care-based ACO.

In addition to the CEC Model's positive results relative to similar beneficiaries in FFS Medicare, it is also notable that the CEC Model had superior results relative to primary care-based ACOs. Beneficiaries with ESRD in primary care-based ACOs appear to have experienced no statistically significant impacts relative to the FFS comparison group, suggesting that beneficiaries with ESRD may fare better in the specialized CEC Model than being mixed into a primary care-based ACO population. Given the regular and frequent contact with both the dialysis facility and the nephrologist, as well as the clinical complexity of the ESRD population, a specialty-oriented care model like CEC may be more appropriate and effective for this subset of patients than a more general primary care-based ACO model.

The findings presented in this report have several limitations. First, the 37 ESCOs are not representative of the population of Medicare providers, limiting our ability to generalize the results presented here to all Medicare providers or FFS with ESRD beneficiaries. However, the addition of new participants in PY2 increased the representation of markets participating in CEC. Second, although the analysis employed 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 CEC and comparison facilities and their patients. There may also be unobservable characteristics such as motivation to participate in an A-APM that we cannot sufficiently control for with secondary data.

Future annual reports will build on these analyses in several ways. First, with increased sample sizes and more time under the model, we will be able to do more in-depth analyses of how results may vary across particular participant types, markets, and beneficiary sub-populations. In particular, we will compare the performance of participants from LDOs and non-LDOs and investigate the experience of subpopulations who may be more vulnerable to declines in quality of care. Second, we will analyze variation in ESCO performance and draw from both qualitative and quantitative analyses to identify factors that contributed to the success of individual ESCOs or LDOs in achieving the CEC objectives. Third, with increased participation of Medicare beneficiaries with ESRD in two-sided risk ACOs, we will be able to limit our comparison of CEC and primary care-based ACO beneficiaries to participants in two-sided risk models. Finally, we will evaluate the impact of CEC on Medicaid-only services, which include primarily long-term care and home- and community-based services.

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 promotes comprehensive and coordinated care and improved 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 (PPS) and the ESRD Quality Incentive Program (QIP).[13]

The Lewin Group, Inc. (Lewin), along with its partners, the University of Michigan's Kidney Epidemiology and Cost Center, General Dynamics Information Technology, and ICF International, 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 quality of care, health outcomes, utilization, and spending of Medicare beneficiaries with ESRD.

This is the second of four annual reports and covers the 37 ESCOs operating in the first two performance years of the model from October 1, 2015 through December 31, 2017. Of these 37 ESCOs, 13 (Wave 1) joined at the start of performance year one (PY1) of the model on October 1, 2015 and 24 new ESCOs (Wave 2) joined the CEC Model on January 1, 2017, at the start of PY2.

A. Research Questions Addressed in the Second Annual Report

The second 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**.

[13] See the CEC Model Performance Year 1 Annual Evaluation Report (https://innovation.cms.gov/Files/reports/cec-annrpt-py1.pdf) and the CEC Model website (https://innovation.cms.gov/initiatives/comprehensive-ESRD-care/) for additional information on the CEC Model.

Exhibit 1. CEC Evaluation Logic Model (Abbreviated Version)

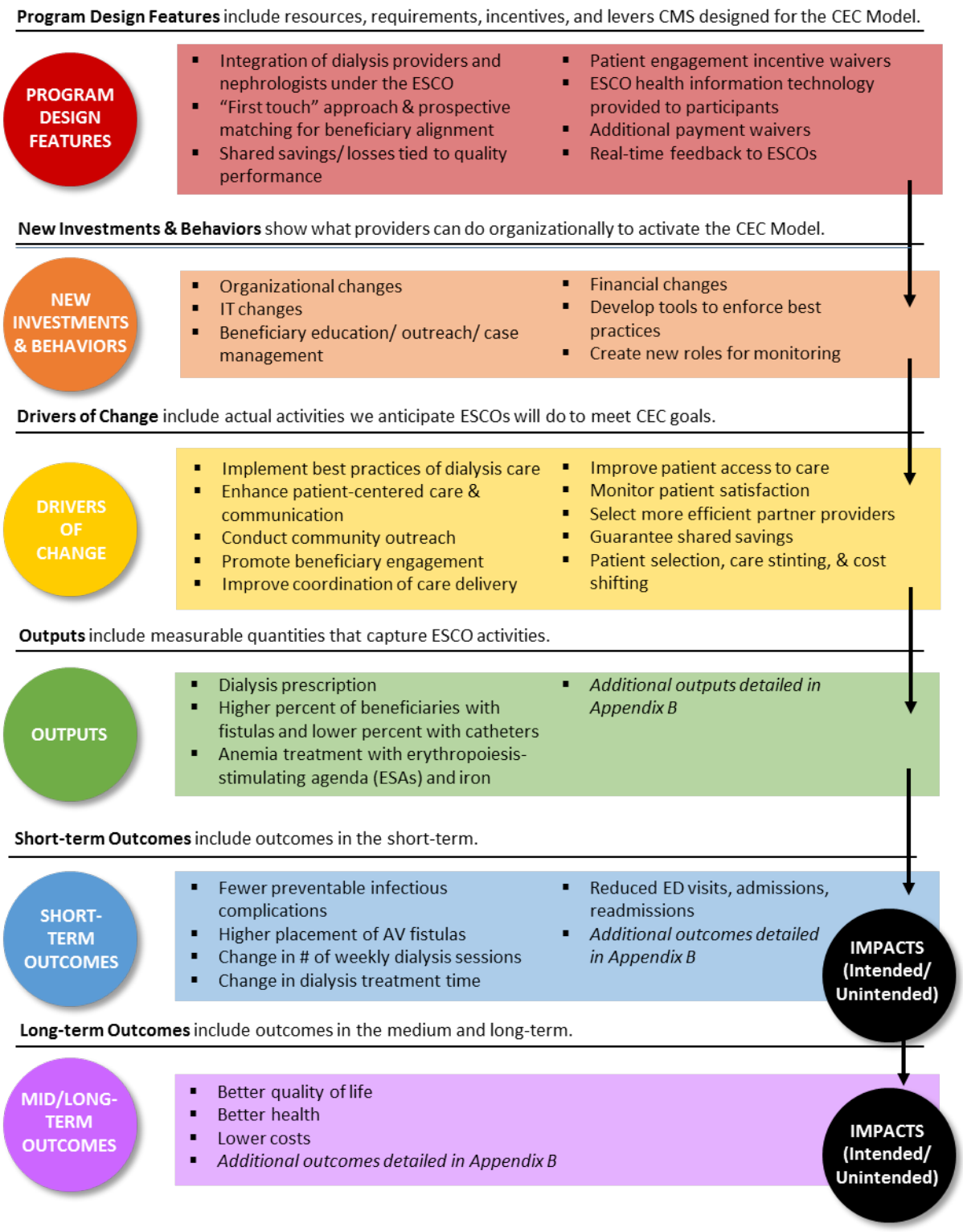


Exhibit 1 and Appendix B provide the conceptual framework that describes our understanding of the resources participants bring to the CEC Model, the design features and incentives that are

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, spending 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 compared them to non-CEC participants and markets. We developed market profiles using data from the Provider of Service, Dialysis Facility Compare, Area Health Resource Files, and other secondary data. We also compared CEC-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. Why Did Wave 2 ESCOs Join the CEC Model and How Did They Prepare?

We assessed Wave 2 ESCOs' goals for joining the CEC Model and their readiness to implement changes.[14] Data from site visits and interviews with ESCO representatives were used to investigate the decision-making process and motivations as to why certain providers chose to participate in the model. We provide information about the types of partnerships (risk-sharing and non-risk-sharing) dialysis organizations made to form and operate their ESCOs, the information technology (IT) and staff investments made by ESCOs, and use of program waivers. Finally, we summarize ESCO owners' perceptions of financial and risk arrangements.

3. How Did Wave 2 ESCOs Change Care Delivery to Meet CEC Model Goals?

We explored ESCOs' strategies for reducing costs, improving quality, and coordinating care. These strategies included increasing patient access to dialysis care, enhancing the coordination of care, and improving patient-centered care and communication. We used data from application materials, site visits, and calls with ESCOs to identify the most common approaches for care redesign, detailed why they were chosen, and assessed how they were implemented during PY2, calling attention to commonalities and differences in approaches across ESCOs. In addition to providing information on common care redesign strategies, our data allowed us to recognize challenges across ESCOs and unique innovations among participating 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 [PCPs], specialists) most willing and able to deliver efficient, high quality care to a dialysis population; enhanced information flows among all partners (through health IT and

[14] Only detailed findings from the Wave 2 ESCO site visits are included in this annual report. For findings from the Wave 1 ESCO site visits, please see the first annual report (https://innovation.cms.gov/Files/reports/cec-annrpt-py1.pdf).

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 Were Beneficiaries' Perceptions of the CEC Model?

We gauged beneficiaries' perceptions of the CEC Model during focus groups with patients with ESRD who received 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 Was the Association between Alignment in the CEC Model and Beneficiary Quality of Life?

We used data from the Kidney Disease Quality of Life (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-36 instrument is designed to collect data on 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 the Impacts of the CEC Model?

We evaluated the impact of the CEC Model on dialysis care, coordination of non-dialysis care, inpatient and outpatient utilization outcomes such as hospitalizations and emergency department (ED) visits, and the rate of Medicare spending per beneficiary per month (PBPM) across the continuum of care during the first two performance years of the model.

First, we explored indicators related to the delivery of dialysis care. Because dialysis facilities and nephrologists are the main points of care for Medicare beneficiaries with ERSD, it is natural to consider the delivery and clinical quality of dialysis-related care that is centered in the facility and how the model affected it. This involved assessing the model's impact on dialysis treatment modality and location, patients' adherence to dialysis treatment, and patients' experience with dialysis care. Multiple evidence-based clinical metrics were used to assess the model's impact on the care delivered by dialysis facilities and nephrologists (e.g., establishment of vascular access with low rates of vascular access complications, number of outpatient dialysis sessions, percent of beneficiaries missing dialysis sessions, or percent of beneficiaries with unscheduled emergency dialysis sessions). Additionally, we used the In-Center Hemodialysis Consumer Assessment of Healthcare Providers (ICH CAHPS®) survey to assess the impact of the CEC Model on patients' self-reported experiences with dialysis care and to capture potential unintended consequences of the program.

Second, we looked at measures associated with the coordination of care beyond dialysis such as appropriate preventive health care, disease management, and end-of-life care. These measures included flu vaccinations and diabetes-related testing (e.g., hemoglobin A1c [HbA1c] tests and dilated eye exams), phosphate binder adherence for disease management, and hospice use for end-of-life care, given the high mortality rate in the ESRD population and the fact that several ESCOs focused specifically on hospice referral. In this second annual report we include additional measures that evaluated the potential impact of the CEC Model on the quality of care associated

with diseases that often accompany ESRD (e.g., diabetes, chronic obstructive pulmonary disease [COPD], asthma, congestive heart failure [CHF]).

Third, we examined changes in utilization of distinct inpatient and outpatient services received by patients with ESRD related to hospitalizations and ED visits. Given that reducing hospitalizations has been identified as an area for needed improvement in ESRD care and was the primary focus of most ESCOs, we were especially interested in this outcome. Because patients with ESRD often have co-occurring conditions and CEC is intended to help providers focus on the continuum of care, we also looked at the hospital admissions related to common comorbidities such as diabetes and heart disease.

Finally, because ESCOs are expected to redesign care and adopt cost savings strategies, this second annual report examines changes in the costs of care, using Medicare standardized payments for total Part A and Part B services and payments by type of services.[15] Beginning in this report, there is additional analysis that targeted payments for claims specifically associated with hospitalizations for ESRD complications. All analyses accounted for different risk levels of beneficiaries by matching on key demographic, clinical, and utilization characteristics.

7. What Were the Differences in Performance between the CEC and Primary Care-Based ACO Models?

We evaluated whether ESCOs were better able to provide care for Medicare beneficiaries with ESRD than primary care-based ACOs by exploring whether beneficiaries with ESRD who became aligned to CEC had better outcomes than those who became aligned to a primary care-based ACO. The results illustrate a relative performance of the care models to a FFS baseline.

8. Were There Unintended Consequences of the CEC Model?

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, changing referral patterns and transplant strategies, or substituting inferior or inappropriate services could result in worse quality of care and quality of life for beneficiaries. 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.

To assess whether the CEC Model had unintended consequences for CEC beneficiaries, we examined the impact of the CEC Model on Part D drug costs and wait listing for transplantations. We also used Medicare claims data to assess referral patterns for dialysis to explore whether nephrologists were selectively referring healthier patients to ESCO facilities.

[15] 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.

II. Who Participates in the CEC Model?

For PY1, through a rigorous application process, CMMI selected 13 ESCOs (i.e., Wave 1) that included 235 participating dialysis facilities in the CEC Model. In PY2, 24 additional ESCOs (i.e., Wave 2) joined CEC and existing ESCOs enrolled more facilities to the CEC Model for a total of 37 participating ESCOs that included 685 dialysis facilities.

Participation in the CEC Model is voluntary and includes requirements based on market area and minimum number of Medicare beneficiaries treated at each ESCO. Each ESCO must be located in a specific single market, restricted to no more than three Medicare Core-Based Statistical Areas (CBSAs)[16] and any rural dialysis facilities in counties that are contiguous to one of the Medicare CBSAs or separated from one of these CBSAs by no more than two rural counties. ESCOs are also required to have a minimum of 350 beneficiaries over the course of the performance year. These program rules led to differences between CEC and non-CEC facilities and the markets in which they reside.

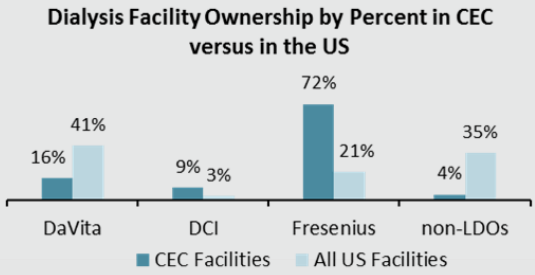
[16] Medicare CBSAs are Metropolitan CBSAs, with each CBSA Division separated, from the Office of Management and Budget CBSA definition.

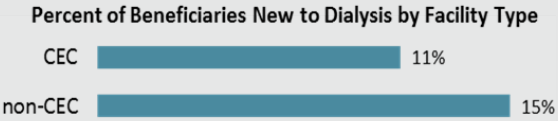
A. Key Findings

Baseline Differences in Facility and Market Characteristics between CEC and Non-CEC Facilities. CEC and non-CEC facilities and markets differed along a number of facility, beneficiary, and population characteristics.

Key Findings:

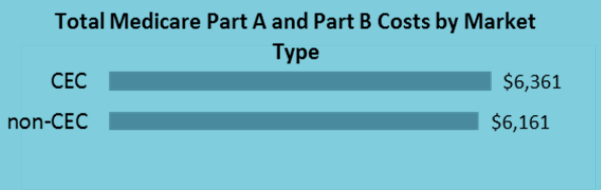
- CEC facilities included a disproportionally high number of Fresenius facilities
- CEC facilities had more dialysis stations, more patients, and a lower standardized readmission ratio (SRR) than non-CEC facilities
- CEC facilities had fewer patients new to dialysis than non-CEC facilities





- Wave 1 CEC facilities in had slightly more dialysis stations and Medicare beneficiaries than Wave 2 CEC facilities

- CEC markets (Medicare CBSAs), on average, were larger and more racially diverse and had higher median income than non-CEC markets
- Compared to non-CEC markets, CEC markets had beneficiaries with ESRD with higher total Medicare Part A and Part B standardized payments
- CEC markets in Wave 1 were larger and more racially diverse than Wave 2 CEC markets



B. Methods

CEC facilities were identified through participation data collected through Salesforce, a software tool maintained by CMS to track model participants. We constructed a dialysis facility dataset that included facility-level characteristics from the 2015 Dialysis Facility Compare database and a summary of 2012-2014 Medicare claims as well as market-level characteristics from 2014 based on the Area Health Resource Files, Census American Community Survey, and a summary of 2012-2014 Medicare claims. We aggregated county-level characteristics to the Medicare CBSA level by weighting individual county observations by population. CEC markets were defined as those Medicare CBSAs that had at least one CEC facility, while non-CEC CBSAs were those without CEC facilities.

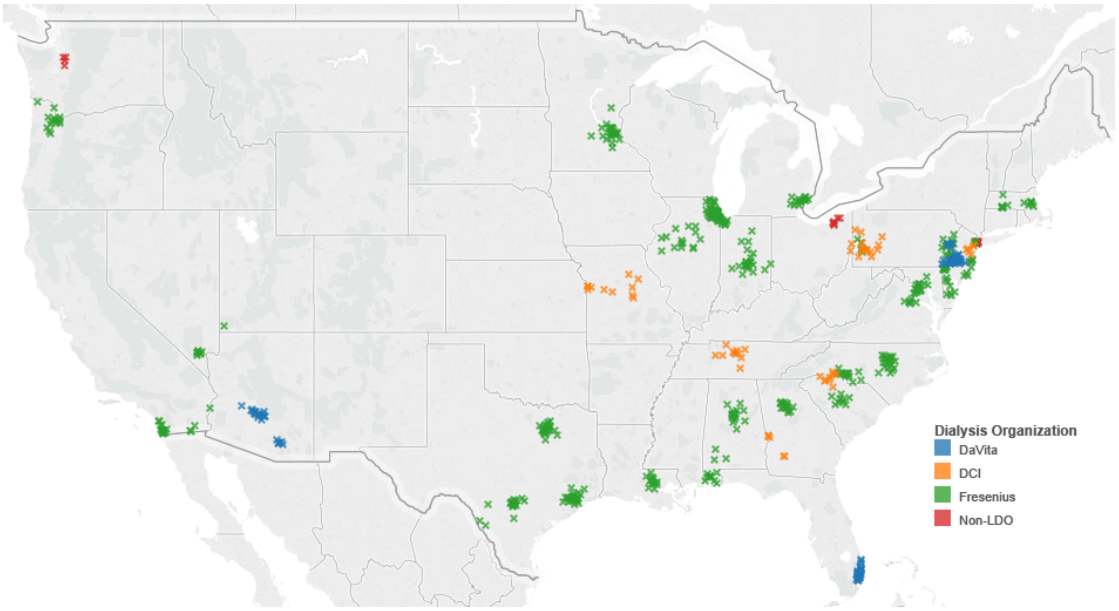
C. Results

The discussion below details findings based on the comparison of facility- and market-level characteristics between CEC and non-CEC facilities and between markets with CEC participants versus markets without CEC participants. CEC and non-CEC facilities and markets differed along a number of characteristics.

1. What Are the Characteristics of CEC Facilities?

The 37 ESCOs participating in the CEC Model represent three large dialysis organizations (LDOs): DaVita, Fresenius, and Dialysis Clinic, Inc. (DCI), and four small dialysis organizations or non-LDOs: Rogosin, Centers for Dialysis Care (CDC), Northwest Kidney Centers (NKC), and Atlantic. Collectively, ESCOs included 685 dialysis facilities across 27 states and Washington, D.C. **Exhibit 2** provides a visualization of the location of participating facilities.

Exhibit 2. Location of CEC Dialysis Facilities



Source: CEC Model participation data extracted from Salesforce on 01/03/2018.

CEC facilities represented about 12% of all dialysis facilities nationally in PY2. **Exhibit 3** compares the characteristics observed in 2014, before the start of the model, for PY1 and PY2 CEC facilities and non-CEC facilities. CEC facilities associated with DaVita, DCI, and Fresenius represented 16%, 9%, and 72% of all CEC facilities, respectively. Combined, non-LDOs (CDC, Rogosin, NKC, and Atlantic) represented the remaining 3%. DaVita, DCI, Fresenius, and non-LDOs represented 41%, 3%, 21%, and 35% of non-CEC facilities, respectively. The distribution by dialysis organization varied across the two waves, mainly due to the fact that Wave 2 had no DaVita ESCOs.

On average, ESCOs had 18.5 facilities each, ranging from two to 72 facilities per ESCO. LDO ESCOs were much larger than non-LDO ESCOs with 20.2 dialysis facilities on average versus 4.8 dialysis facilities. Compared to non-CEC facilities, CEC facilities had, on average, two more dialysis stations and treated around nine more Medicare beneficiaries. More CEC facilities offered a late dialysis shift (i.e., the facility is open after 5pm). A smaller proportion of CEC facilities offered peritoneal dialysis services (47% versus 61%). Standardized rates for hospitalization and readmission were very similar (within one percentage point) between CEC and non-CEC facilities. Standardized rates for mortality were seven percentage points lower across CEC facilities on average. CEC facilities had fewer patients new to dialysis. Several other characteristics were similar on average between CEC and non-CEC facilities including: profit status, vascular access rates for catheter and fistula, Medicare payments PBPM, and percent of patients with no prior nephrology care. These comparisons were similar across ESCO waves with the exception that Wave 1 facilities had a slightly higher average number of dialysis stations and more Medicare beneficiaries relative to Wave 2 facilities. Additionally, Fresenius facilities represented a lower share of Wave 1 facilities (56%) than Wave 2 facilities (86%).

Exhibit 3. Characteristics of CEC Facilities and Non-CEC Facilities in 2014[17,18]

Characteristics	Wave 1 CEC Facilities (N=311) Mean	Wave 2 CEC Facilities (N=374) Mean	All CEC Facilities (N=685) Mean	Non-CEC Facilities (N=4,814) Mean
For-Profit Facility	90%	90%	90%	88%
Chain-Owned Facility	91%	90%	90%	88%
Number of Dialysis Stations	20.6	18.9	19.7	17.3
Late Shift (facility is open after 5pm)	18%	25%	22%	17%
Peritoneal Service Offered	46%	49%	47%	61%
Medicare Beneficiary Count	75.0	63.7	68.9	60.6
Hemodialysis Beneficiary Count	70.7	59.5	64.6	55.8
Peritoneal Dialysis Beneficiary Count	6.0	6.0	6.0	6.6
Percent of Patients on Hemodialysis	94%	94%	94%	91%
Percent of Patients on Peritoneal Dialysis	8%	9%	8%	12%

[17] Data were not available for select characteristics for up to 40 of the 685 CEC facilities. Reported mean and distribution are based on all non-missing values.

[18] Dialysis facilities that joined the CEC Model in PY3 (January 2018) and dialysis facilities without beneficiaries aligned in calendar year 2014 using the first touch method are excluded. Data were not available for select characteristics for up to 334 of the 4,835 non-CEC facilities. Reported mean and distribution are based on all non-missing values.

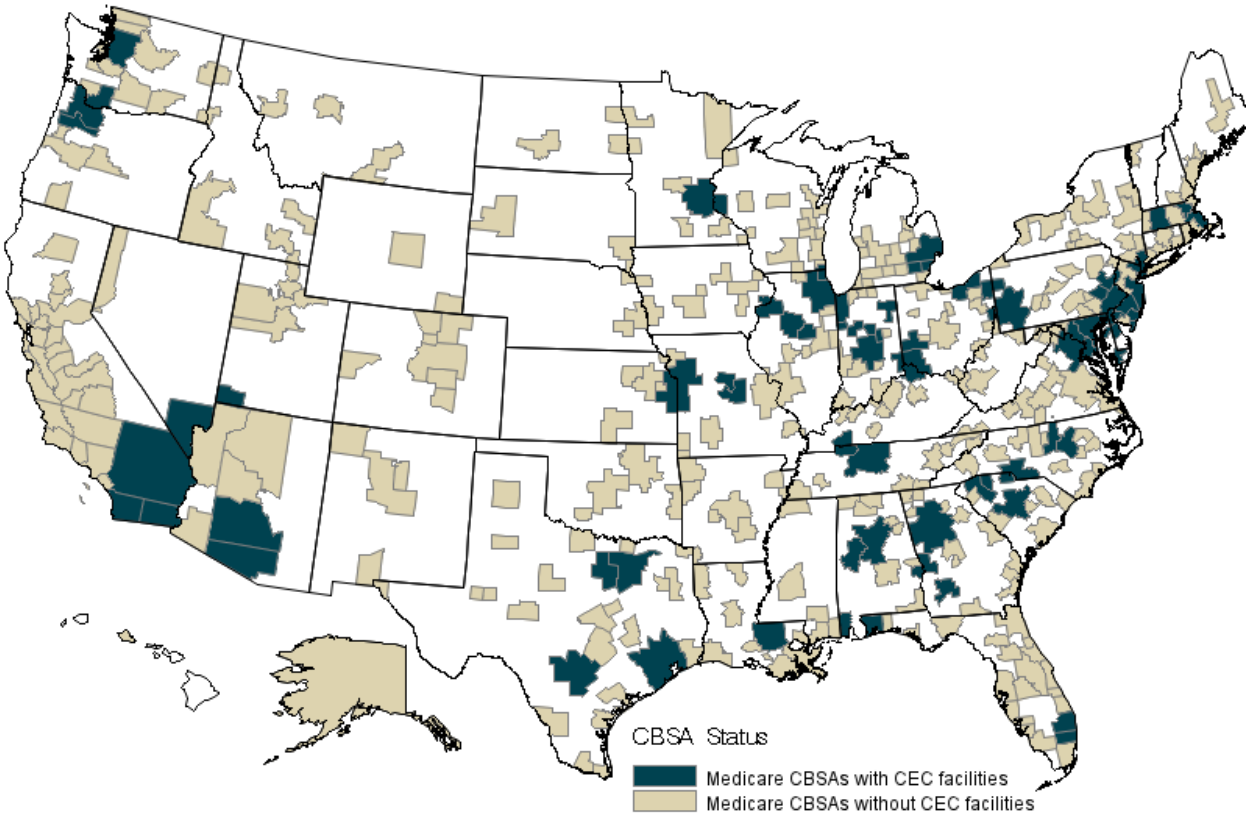
Characteristics	Wave 1 CEC Facilities (N=311) Mean	Wave 2 CEC Facilities (N=374) Mean	All CEC Facilities (N=685) Mean	Non-CEC Facilities (N=4,814) Mean
Percent of Patients with Vascular Catheter	10%	9%	10%	11%
Percent of Patients with Arteriovenous Fistula	61%	62%	62%	63%
Standardized Hospitalization Ratio	1.02	0.96	0.99	0.99
Standardized Readmission Ratio	0.99	0.93	0.96	0.97
Standardized Mortality Ratio	0.94	0.95	0.95	1.02
Total Part A and Part B Standardized Payments PBPM	$6,643	$6,484	$6,557	$6,588
Facility CBSA Total Part A and Part B PBPM Ratio	1.00	1.04	1.02	1.04
DaVita Indicator	34%	0%	16%	41%
DCI Indicator	9%	9%	9%	3%
Fresenius Indicator	56%	86%	72%	21%
Percent of Patients New to Dialysis	11%	11%	11%	15%
Percent of Patients with No Prior Nephrology Care	46%	43%	45%	45%

Source: Lewin analysis of the 2014 Area Health Resource Files, Dialysis Facility Compare data from 2014, CEC Model participation data extracted from Salesforce on 01/03/2018, and Medicare claims between 2012 and 2014.

2. What Are the Characteristics of CEC Markets?

We examined whether the CBSAs where CEC dialysis facilities were located were typical or atypical of other CBSAs not containing CEC facilities across the United States (US). In 2014, 384 of the 389 Medicare CBSAs had at least one dialysis facility. CEC facilities were located in 96 Medicare CBSAs, as illustrated by the map in **Exhibit 4**.

Exhibit 4. Medicare CBSAs with CEC Facilities



Source: Dialysis Facility Compare data from 2014 and CEC Model participation data extracted from Salesforce on 01/03/2018.

Markets with CEC facilities or "CEC CBSAs" differed from those without CEC facilities or non-CEC CBSAs in some dimensions, including population size, median income, racial and ethnic demographics, and types of providers. **Exhibit 5** compares the market characteristics of CBSAs with and without CEC facilities. CEC CBSAs included many of the largest population centers in the US. The average CEC CBSA had a population four times larger than the average non-CEC CBSA. Median income was higher in CEC CBSAs, and they had a higher proportion of Black and Hispanic residents. CEC CBSAs tended to have a higher rate of specialists per 10,000 residents but lower access to skilled nursing facility (SNF) beds per 10,000 residents relative to non-CEC CBSAs. CEC CBSAs also had fewer dialysis facilities per 10,000 residents even though these CBSAs had a similar prevalence of ESRD. Compared to non-CEC CBSAs, CEC markets had beneficiaries with ESRD who had higher total Medicare Part A and Part B standardized payments.

Within CEC markets, Medicare CBSAs with Wave 1 facilities had on average a larger population, fewer SNF beds, a larger Hispanic population, and a lower rate of specialists per 10,000 residents than those with Wave 2 facilities. Wave 1 CBSAs also had beneficiaries with ESRD who had higher total Medicare Part A and Part B standardized payments. Wave 1 CBSAs also had fewer dialysis facilities per 10,000 residents even though these CBSAs had a similar prevalence of ESRD.

Exhibit 5. Characteristics of Markets with and without CEC Facilities in 2014

Characteristics	Wave 1 CEC Medicare CBSAs (N=24) Mean	Wave 2 CEC Medicare CBSAs (N=43) Mean	All CEC Medicare CBSAs (N=65) Mean	All Non-CEC Medicare CBSAs (N=319) Mean
CBSA Population	2,520,421	1,685,564	1,827,984	453,477
Median Household Income	$ 54,003	$ 55,118	$ 54,347	$ 48,653
Percent White	53%	66%	63%	72%
Percent Black	14%	16%	15%	10%
Percent Hispanic	23%	10%	14%	12%
Percent 65 & Older	14%	15%	13%	14%
PCPs per 10,000	7.1	8.1	7.6	7.4
Specialists per 10,000	9.9	12.7	11.2	8.2
SNF Beds Per 10,000	43.7	55.4	51.5	56.2
Percent Dual Eligible	3%	3%	3%	3%
Hospitals with Kidney Transplant Services per 10,000	0.005	0.008	0.007	0.005
Percent with No High School Diploma	17%	13%	14%	14%
Average Total Medicare Part A and Part B Payments	$6,470	$6,296	$6,340	$6,185
Percent ESRD	0.13%	0.13%	0.13%	0.13%
Percent of ESRD with Medicare & Medicaid	52%	48%	49%	49%
Dialysis Facilities	56.9	44.7	46.5	14.2
Dialysis Facilities per 10,000	0.26	0.34	0.31	0.42

Source: Lewin analysis of the 2014 Area Health Resource Files, Dialysis Facility Compare data from 2014, CEC Model participation data extracted from Salesforce on 01/03/2018, and Medicare claims between 2012 and 2014.

D. Discussion

Over the time period covered in this report, the CEC Model expanded to include 24 new ESCOs (Wave 2) in addition to the 13 original ESCOs that joined in Wave 1. Fresenius, an LDO, dominated participation in the model in Wave 2. Wave 1 and Wave 2 facilities had similar characteristics, although relative share of facilities under each LDO varied from Wave 1 to Wave 2. Additionally, the Medicare CBSAs represented by Wave 1 and Wave 2 facilities differed slightly in terms of population and access to SNFs.

Overall, CEC facilities accounted for 12% of dialysis facilities nationally. Participating facilities were different than non-participating facilities in that they tended to be somewhat larger in terms of number of dialysis stations and number of Medicare beneficiaries treated, but were similar on other key standardized outcome-related measures. The markets served by ESCOs tended to be larger than those without an ESCO. The addition of new participants in PY2 increased the representation of markets participating in CEC.

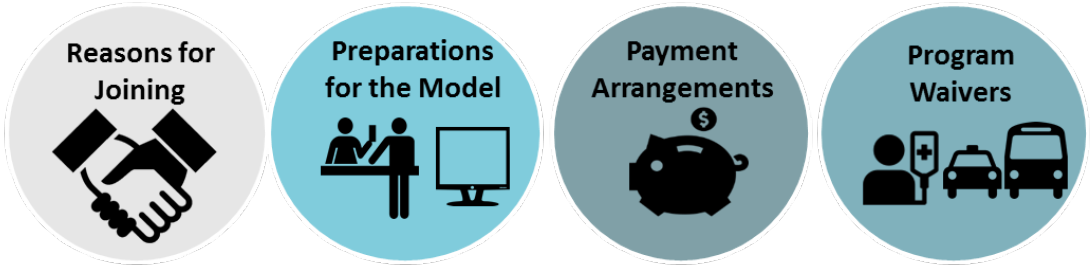
III. Why Did Wave 2 ESCOs Join the CEC Model and How Did They Prepare?

At the start of PY2, 24 new ESCOs (Wave 2) joined the 13 existing Wave 1 ESCOs under the CEC Model. During PY1, we conducted site visits with the initial set of ESCOs to collect information regarding participants' rationale for joining the model and preparations for the model (these site visits were reported in the first annual report[19]). In an effort to understand the factors that encouraged dialysis organizations and nephrologists to establish ESCOs later in the model, we conducted site visits at a sample of Wave 2 ESCOs. This chapter reports on Wave 2 participants' decisions to enter the model, perceptions of the payment and risk arrangements under the model, and model investments and waiver use. Similarities and differences in Wave 2 and Wave 1 ESCO participants' motivations and preparations are noted.

[19] For findings from the Wave 1 ESCO site visits, please see the first annual report (https://innovation.cms.gov/Files/reports/cec-annrpt-py1.pdf).

A. Key Findings

Entry Decisions and Preparation for the CEC Model. During site visits with Wave 2 CEC participants, we asked program participants about the following topics:



Key Findings:

Reasons for Joining

- Opportunity to improve patient care, increase efficiency, and reduce costs
- Strong existing relationships with partner organizations/ nephrologists
- Success of Wave 1 ESCOs
- ESCO qualification as an Advanced Alternative Payment Model (A-APM) under the Medicare Access and CHIP Reauthorization Act (MACRA)

Preparations for the Model

- Key investments were made in two major areas:
  - Hiring new staff, particularly care managers
  - Information technology (IT)

Payment Arrangements

- Nephrologist owners were most familiar with shared savings
- Nephrologists were optimistic or had mixed opinions about achieving shared savings, depending on organization affiliation

Program Waivers

- The waivers discussed by respondents were patient engagement incentive waivers (i.e., transportation, oral nutritional supplements, patient IT)
  - The transportation waiver was used most frequently

B. Methods

The site visits occurred between September 5, 2017 and December 14, 2017. A sample of 11 of the 24 Wave 2 ESCOs were visited, with two to three facilities visited per ESCO, for a total of 26 dialysis facility site visits. In addition, corporate-level interviews were conducted with staff members at each Wave 2 dialysis organization that did not participate in PY1 of the CEC Model: Atlantic, CDC, and NKC. A total of 82 individual or small group interviews were conducted

across the site visits, with one to six individuals participating in each interview. Interviews were recorded and transcribed; transcripts were coded and analyzed using ATLAS.ti qualitative data analysis software. **Appendix C** provides additional detail on the criteria used to select facilities, the interview protocols used for the site visits, and how the site visit data were analyzed.

C. Results

1. Why Did Wave 2 ESCOs Join the Model?

Wave 2 ESCOs reported a number of reasons for joining the CEC Model, several of which were also cited by Wave 1 ESCOs during PY1. For example, representatives from all ESCOs described that improving patient care was a major driver in the decision to join the CEC Model. Additionally, at nearly every ESCO, representatives highlighted the desire to lower cost and improve efficiency as motivation to join the model. Representatives from all of the dialysis organizations also described existing resources or relationships with partners and nephrologists as factors that influenced their decision to participate.

What was new for the Wave 2 ESCOs was CMS's decision to allow ESCO owners to qualify for participation in an Advanced Alternative Payment Model (A-APM) under the Medicare Access and CHIP Reauthorization Act (MACRA). MACRA took effect after the Wave 1 ESCOs joined the model and, therefore, was not identified as a factor initially. This opportunity increased nephrologists' willingness to accept a risk-sharing ownership role. Representatives from all ESCOs with two-sided risk cited qualification as an A-APM as a major motivator in joining the CEC Model, whereas only one one-sided risk ESCO described A-APM qualification as a factor. In addition, representatives at two of the three DCI ESCOs and all of the non-LDO ESCOs mentioned the experience and success of the Wave 1 ESCOs in the model as a reason for joining.

Less frequently cited factors included the desire to shape future renal payment models; changes in program rules from PY1 that made the model more enticing (e.g., ESCO geography requirements changed and non-LDOs can now choose two-sided risk, thereby increasing eligible shared savings and qualifying as an A-APM under MACRA); previous experience with integrated care; alignment of the CEC Model with their organizational mission; and the ability to gain experience with performance-based payment models.

2. What New or Enhanced Partnerships Did Wave 2 ESCOs Develop?

All Wave 2 ESCOs established risk-sharing partnerships with nephrologists, as required for participation in the CEC Model, but some ESCOs also included other organizations in their risk-sharing arrangements (as did some Wave 1 ESCOs in PY1). These organizations included vascular access centers and behavioral health organizations. In addition to risk-sharing arrangements, ESCOs reported a number of non-risk-sharing partnerships that included hospitals, additional nephrologists and vascular surgeons, SNFs, IT service providers, pharmacies, and hospice and palliative care organizations.

Fresenius and DCI ESCOs cited non-risk-sharing partnerships with local hospitals, and one Fresenius and one DCI ESCO each referenced relationships with vascular surgery practices. All Fresenius ESCOs used MemberMatch, a third-party software package that enables ESCOs to identify when patients register at a hospital. Since both parties (i.e., the ESCO and the hospital) must sign up for this program to work, Fresenius respondents described MemberMatch as a

reason for improving their partnerships with local hospitals. DCI respondents spoke about their positive relationships with local hospitals that pre-dated the ESCO, although they reported greater collaboration with these hospitals after the ESCO was established. The Fresenius ESCO that developed a relationship with a vascular access center did so to coordinate fistula creation and provide patients and their families with education and counseling about fistula use.

While Fresenius and DCI ESCOs reported some partnerships with outside organizations, non-LDO ESCOs reported greater variety in the types of partnerships they developed. In contrast to non-risk-sharing relationships with vascular surgeons that respondents described at LDO site visits, all non-LDOs formed risk-sharing partnerships with vascular surgeons through the ESCO. Among the non-LDOs, all of their relationships with the ESCO-owner vascular surgeons preceded the CEC Model. Representatives from two non-LDOs noted they partnered with vascular surgeons with the intent of improving patient access to vascular care.

Two non-LDOs referred to non-risk-sharing partnerships with organizations that provided hospice and palliative care. One of these ESCOs partnered with a local hospice and palliative care organization to educate ESCO staff, increase patient access to these services, and develop new strategies for communicating with patients and families. A second non-LDO leveraged an existing relationship with a local hospice and palliative care organization to educate patients about the breadth of services these organizations can provide (as described in **Section IV.C.1.c.**).

Two non-LDOs established partnerships with data analysis organizations to assist in managing and analyzing the CEC Model data (**Section IV.C.3.e.**). Two non-LDOs also established non-risk-sharing arrangements with pharmacy organizations to help with medication therapy management (MTM). One non-LDO established a risk-sharing relationship with a local mental health services provider to educate facility staff about effective de-escalation strategies in situations that may arise with more challenging patients, which provided staff with a greater sense of workplace security (**Section IV.C.1.c.**).

3. How Did Wave 2 ESCOs Prepare for the CEC Model?

In an effort to make their ESCOs successful, representatives reported investments in the areas of staffing and IT. Investment areas were fairly similar across Fresenius, DCI, and non-LDOs.

a. Staff Investments

As was the case with all Wave 1 ESCOs, representatives from all Wave 2 ESCOs reported hiring new staff. New Fresenius ESCO staff included Care Navigation Unit (CNU) care coordinators (e.g., nurses, support staff) to manage and coordinate the CEC Model for their facilities. Care coordinators served multiple functions including coordinating non-dialysis care, facilitating care transitions, following up with patients and staff to avoid potential care oversights, discussing social issues with patients (e.g., insurance and homelessness), and providing encouragement to patients. CNU staff typically worked remotely from the dialysis facilities, but some facilities indicated that they received periodic visits from local CNU nurses. DCI representatives reported adding additional in-facility staff who served in a similar care coordination role.

Two non-LDOs hired data analysts and care coordinators; one also hired an administrative assistant to facilitate ESCO operations. A representative of one non-LDO reported that the

largest financial investment for the ESCO was hiring new employees. Another representative from a non-LDO cited costs associated with establishing a palliative care service in the organization and with the hiring of a care coordinator and admissions nurse. In addition, this non-LDO invested in behavioral health training for its employees (**Section IV.C.1.c.**).

> *"Out of all the costs, the salaries are the top thing. […] We've got the care managers. We've got the half time nurse. And we're going to be adding an administrative assistant, and will probably add a data analyst."*

b. Information Technology Investments

Investments in IT were reported by representatives from Fresenius and non-LDO ESCOs. These included new equipment, electronic health records (EHR), and other software updates. Representatives from the Wave 2 DCI ESCOs did not report any ESCO-level IT investments. Fresenius respondents described investing in MemberMatch (**Section III.C.2.**) and in EHR upgrades to assist in care transitions and the secure communication of patient information to other providers (e.g., hospitals). Representatives from one Fresenius ESCO reported investing in a telehealth platform that assisted with coordinating transportation for patients and improved the management of urgent patient care needs.

Respondents from one non-LDO ESCO referred to acquisition of software systems that enhanced data collection, improved analytic capabilities (i.e., tracking/trending data, billing, creating reports), and sent text message alerts when patients presented to the ED. Another non-LDO ESCO invested in data software for secure text messaging for patient alerts. Representatives of the third non-LDO ESCO reported investments aimed at developing teleconferencing platforms for home patients and for video conferencing with pharmacists.

Representatives from several ESCOs also cited resources spent on changes to their EHRs, including addition of new data fields to capture information on quality of care (e.g., vaccinations), details to assess high-risk patients (e.g., presence of a catheter, number of skipped treatments, hospital admissions, and readmissions), and information on other medical conditions (e.g., diabetes).

> *"We've smoothed out our pass-offs, and then we've also put in follow-up visits as part of the EHR. It's part of our infrastructure in our EHR that we invested and built ourselves, so that when patients are out of the hospital there's much more detailed information that gets transitioned to the dialysis unit."*

4. What Were Wave 2 Owner Nephrologists' Perceptions of ESCO Financial Arrangements, Risk Arrangements, and Anticipated Shared Savings?

Nephrologist owners had limited familiarity with the CEC Model's financial incentives beyond shared savings, and they had mixed reactions to risk-sharing arrangements.

a. Financial Arrangements

The nephrologist owners we interviewed expressed relatively little familiarity with the ESCOs' financial arrangements beyond shared savings. The nephrologists at one non-LDO were the only nephrologists we interviewed who were aware of the pay-for-performance (P4P) program.

However, these nephrologists reported that the P4P program had proven to be complicated and that they were still working to understand it. Virtually no nephrologist owners claimed awareness of the option to distribute care coordination payments to nephrologists. One nephrologist, who was aware of the care coordination payments, described it as too administratively burdensome to use.

b. Risk Arrangements

In general, Fresenius-affiliated nephrologists were neutral to slightly positive in their attitude toward the individual financial risk component of the CEC Model. In comparison, DCI-affiliated nephrologists seemed slightly more risk-averse, although a few respondents reported that a two-sided risk arrangement was a small risk to take if they could in return participate in an A-APM and avoid the Merit-Based Incentive Payment System (MIPS).

Nephrologists affiliated with non-LDO ESCOs were mixed in their opinions about risk-sharing arrangements. Two of these ESCOs selected a one-sided risk track, and nephrologists at both ESCOs reported this decision was made because they were uncertain about their ability to drive improvements in patient costs. One ESCO respondent explained that the organization started with low-intensity care redesign interventions and the anticipated yield was relatively low, while a respondent at the other ESCO felt that the organization had historically adopted many best practices and that it would be difficult to drive costs even lower.

c. Anticipated Shared Savings

When asked about the likelihood and magnitude of potential shared savings, nephrologists' responses generally varied by affiliated dialysis organization. Fresenius-affiliated nephrologists were hopeful that they could achieve shared savings, although they were generally uncertain as to the amount. DCI-affiliated nephrologists expressed uncertainty about achieving shared savings. Some reported an awareness of the shared savings achieved by DCI ESCOs in PY1, while others expressed indifference to shared savings because they expected savings to be negligible.

Among non-LDOs, nephrologists at one ESCO expected shared savings because they perceived that, although the ESCO had made relatively few investments, it had still been effective at reducing hospitalizations. Nephrologists at the other two non-LDOs reported they expected to recoup their investment but significant shared savings might be difficult to achieve due to the cost of the programs undertaken for the model. Additionally, non-LDO corporate representatives were also uncertain they would achieve shared savings.

> *"We can expect, if things continue, a modest shared savings, which would translate to a modest amount of increased income for our practice."*
>
> *"I think we'll probably break even on our expenses. […] It takes about four years to really get with this [model], we're still learning. We haven't reaped the rewards that everybody's putting into it yet. So if we do get to that point in the first year, I think that's good. […] I think in subsequent years of all the work will start to bear some significant fruit."*

5. What Waivers Did Wave 2 ESCOs Use?

The only program waivers[20] discussed by respondents were the patient engagement incentive waivers (i.e., transportation, oral nutritional supplements [ONS], and patient IT), while the other program waivers (i.e., P4P, ESCO remuneration, ESCO IT, and care coordination) were not discussed by respondents. Of all the waivers, the transportation waiver was used most frequently.

a. Transportation Waiver

During PY1, both Fresenius and DCI Wave 1 ESCOs reported use of the transportation waiver. During PY2, only Fresenius ESCOs reported using this waiver, but waiver use varied among facilities. Some Fresenius respondents claimed use of the transportation waiver and commented that the waiver was helpful for their patients. Several respondents suggested the waiver could be improved by allowing its use for transportation between any licensed medical providers instead of limiting it to specific providers. Multiple respondents reported that the $500 annual limit per beneficiary was a barrier. They suggested that transportation funds would be more helpful if they were allocated to a general account, since some patients reach the cap quickly while others do not use funds at all. This was true particularly for facilities in rural locations. A minority of respondents did not use the waiver because transportation was not a significant barrier in their location or they used the waiver on only one occasion.

Respondents from DCI ESCOs reported they were not using waivers because DCI corporate had not yet rolled out the waivers for Wave 2 ESCOs. Respondents from two non-LDOs mentioned they are not using the transportation waiver because they perceive the waiver is unnecessary. Specifically, respondents described a recent Department of Health and Human Services Office of Inspector General final rule[21] that they believe permits dialysis organizations to provide local transportation to patients without violating federal law. This rule provides protection to providers from anti-kickback criminal penalties for providing free or discounted local transportation services to Federal health care program (e.g., Medicare) beneficiaries. In order for the protection to apply, the conditions under which the transportation is provided must meet certain criteria outlined in the rule.

b. Oral Nutritional Supplements Waiver

While Fresenius's Wave 1 ESCOs used the ONS waiver in PY1, respondents from Fresenius explained that the ONS waiver was not used among Wave 2 ESCOs because its efficacy was being reviewed at the corporate level. DCI respondents also indicated they did not use the ONS waiver. Respondents from both DCI and Fresenius thought patients would benefit from the waiver but reported using other sources to fund use of nutritional supplements.

Respondents from one non-LDO stated that they were using the ONS waiver but had already been providing supplements prior to the waiver. One respondent mentioned that they were not able to give the supplements to non-ESCO patients and that they were required to take ESCO

[20] See **Appendix A** for a full list of CEC Program Waivers.

[21] Department of Health and Human Services. Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements. Federal Register Vol. 81, No. 235, December 7, 2017. Available from https://www.gpo.gov/fdsys/pkg/FR-2016-12-07/pdf/2016-28297.pdf.

patients off the supplements when their albumin had reached a certain level, which was a change from their pre-ESCO practices. Representatives from another non-LDO reported they did not need to use the ONS waiver because they had other nutritional resources.

c. Patient Information Technology Waiver

The majority of Wave 2 ESCO respondents were not aware of the patient IT waiver, and several respondents asked questions of the site visit team regarding the definition of the waiver and what it covered. Use of the patient IT waiver among Wave 1 ESCOs was also limited; only Rogosin indicated use of this waiver in PY1.

D. Discussion

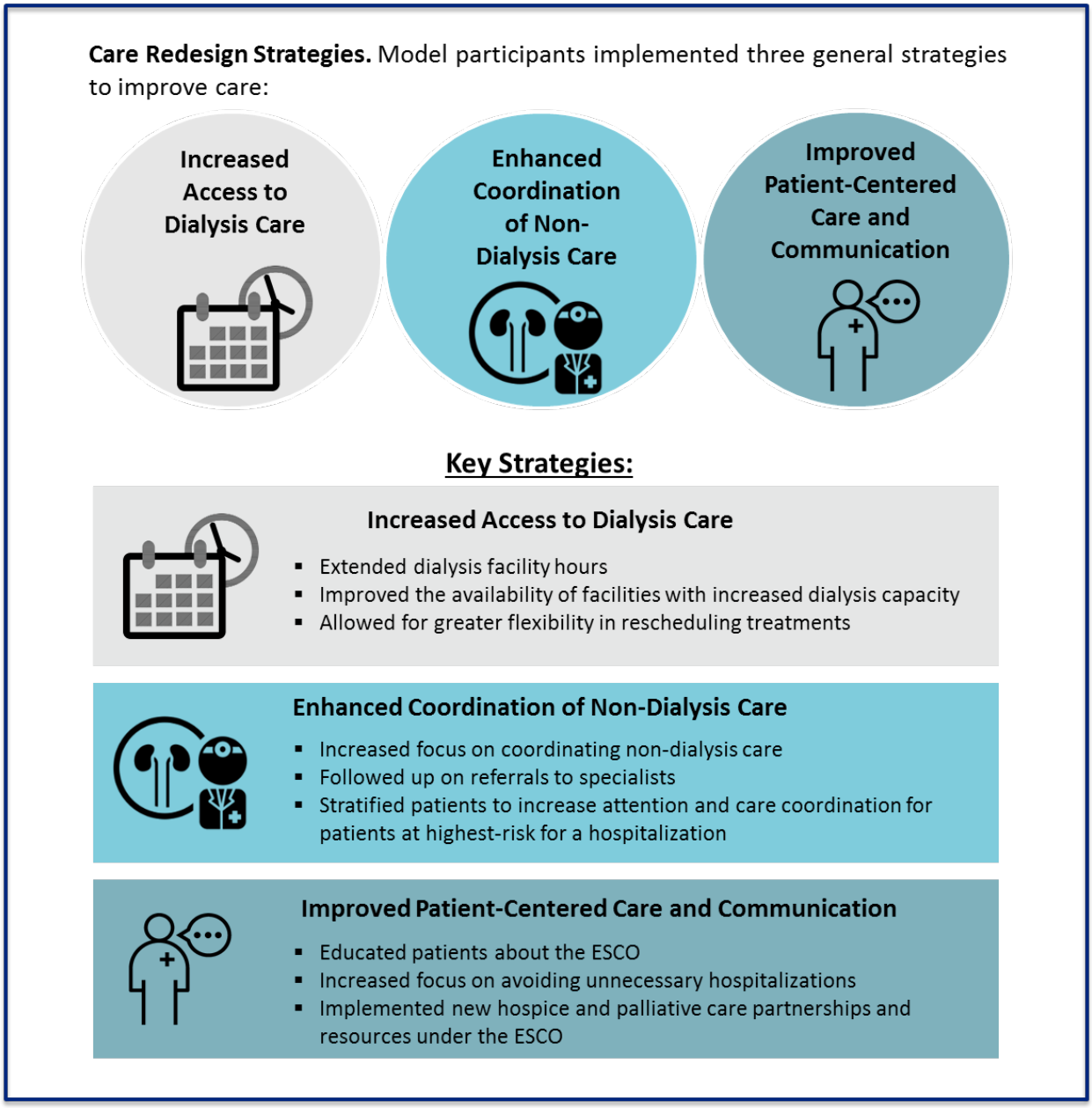
While the CEC's quality and cost goals were consistent with organizational missions, the driving factor influencing participation was provider willingness to take on risk. Attaining status as an A-APM under MACRA provided additional motivation to nephrologists to participate in Wave 2, which may have contributed to differences in performance across the waves. Before each performance year, ESCOs may seek CMS approval for including additional providers as ESCO participants, and shifting attitudes towards value-based payment might enhance more providers' interest in the model going forward. Additionally, while Wave 2 ESCOs had less time to prepare for the model than Wave 1 ESCOs (due to the delayed start of the model for Wave 1), they made similar investments that focused on hiring new staff and investments in IT.

In future years, we will follow-up with nephrologist owners about their perception of the risk arrangements after more time in the model and research changes in investments, partnerships, and waiver use over time.

IV. How Did Wave 2 ESCOs Change Care Delivery to Meet CEC Model Goals?

The CEC Model focuses on improving quality of care and health outcomes, and reducing unnecessary healthcare utilization and spending, through the coordination of care. ESCOs are encouraged to implement patient-centered approaches to care redesign that promote comprehensive and coordinated care delivery and improve access to services. Using data from application materials, site visits, and calls with ESCOs, we explored Wave 2 ESCOs' strategies to improve patient care. In this chapter, we identify the most common approaches for care redesign, calling attention to commonalities and differences in approaches across ESCOs, and summarize implementation experiences during PY2. We also present information collected during site visits pertaining to Wave 2 ESCO participants' access to and use of quality-related data and the role these data had in care redesign.

A. Key Findings



B. Methods

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

C. Results

1. How Did Wave 2 ESCOs Change Care?

ESCO representatives described a variety of strategies to improve patient care, including increased access to dialysis care, enhanced coordination of non-dialysis care, and improved patient-centered care and communication.

a. Increased Access to Dialysis Care

Added Dialysis Capacity

Organizations adopted different strategies to increase the availability of dialysis chairs to improve their ability to reschedule missed treatments or arrange treatments for patients with urgent need of dialysis (e.g., patients in the ED for whom a hospital admission could be prevented). Fresenius ESCOs incorporated facilities with "backup capacity" such as extended operating hours or additional dialysis units for rescheduled or ED-diverted patients. One Fresenius ESCO also kept a chair vacant overnight at a "nocturnal" facility. As a result of the CEC Model, Fresenius has also made it easier for patients to reschedule treatments at other Fresenius facilities if their home facility is full.

DCI respondents described increased flexibility of facility scheduling to allow for longer or extra treatments, to permit patients to schedule treatments during a different shift, and to quickly schedule new treatments at a nearby facility with available capacity. Representatives from non-LDOs described no changes in dialysis capacity since implementation of the CEC Model, but two of these ESCOs initiated a process to track daily capacity at each facility in order to assist with rescheduling treatments and assigning new patients to facilities.

> *"We have the opportunity with the [ESCO] to get that patient [in the ED] to a safety net facility. […] We have safety net facilities that are available with third and fourth shift opportunities to get them in that same day."*

Rescheduling Patients Who Miss Dialysis Treatment

Representatives from all 11 ESCOs spoke about contacting patients to reschedule dialysis if they missed treatment. Each ESCO facility reported rescheduling patients who missed treatment prior to the CEC Model; however, representatives from some ESCOs said the CEC Model added extra support and emphasis to this task. Several nephrologists shared that the ESCO has made facility staff more willing to reschedule patients and accept additional patients from the hospital (i.e., ED diversion or post-discharge) or other facilities.

In some of the Fresenius ESCOs, remote support from the CNU was an added resource that clinic staff used to reschedule patients, find open dialysis chairs, arrange transportation, and do more intensive reviews to identify reasons why patients missed dialysis. However, representatives from one Fresenius ESCO said they tried using the CNU to reschedule patients, but they discontinued using the CNU for rescheduling because they found greater success when the calls to patients came from clinic staff.

Representatives from two DCI ESCOs described more focus and consistency in following up with patients who missed dialysis and getting them rescheduled as a result of the CEC Model. Respondents from one facility described a shift in expectations for patients; since the start of the ESCO there has been greater emphasis on ensuring patients attend their dialysis treatments and call in if they need to reschedule. One DCI ESCO reported no change in rescheduling patients as a result of the ESCO.

Representatives from the non-LDOs reported few changes in rescheduling patients as a result of the ESCO; however, respondents from one non-LDO described an increased emphasis with the ESCO to both determine underlying causes of missed treatments and get patients to reschedule.

> *"Since we are here three shifts [5am to 9:30pm], we have an opportunity here. If one of our first shift patients calls and says, 'I can't get there,' we can hopefully identify the needs and arrange for them to come in [for] the third shift. I think that is one of the more significant benefits of this program. […] Things are now fixable where in the past we would just say, 'Well, you be very cautious with your fluids and be cautious with high potassium containing foods and we'll see you in 48 hours.' This is clearly better."*
>
> *"There was a period of time when we had patients call to say when they're coming or not coming [to dialysis]. […] Missed treatments skyrocketed at that point. We said there's something very wrong, patients should not be calling us to tell us if they're coming; the expectation is they're coming. […] We started to change the culture […] calling patients when they've missed a treatment."*

b. Enhanced Coordination of Non-Dialysis Care

Reducing Emergency Department Visits and Avoidable Hospital Admissions

Representatives from all ESCOs engaged in various strategies to reduce ED visits and prevent unnecessary hospitalizations. Representatives from a few ESCOs described educating ED staff about the CEC Model and attempted to form ESCO-ED partnerships. This strategy had mixed success, and no sites reported establishing any risk-sharing partnerships with EDs. Representatives from one ESCO shared that a local teaching hospital would not collaborate with the ESCO to divert patients with ESRD requiring dialysis from the ED to ESCO facilities. They speculated this was because the hospital wanted their residents to gain experience with patients with ESRD; therefore, they did not want to send patients back to the facility. Representatives from a few ESCOs also shared that hospitals/EDs affiliated with other dialysis companies posed a challenge in forming ESCO-ED partnerships.

The majority of ESCOs relied on notifications from ED staff or electronic notification systems (e.g., MemberMatch, Patient Ping, and Emergency Department Information Exchange [EDIE]) to let the ESCO know when an ESCO patient was admitted to the ED (**Section III.C.3.b.**). The availability and quality of health information exchange notification systems varied by state. For example, EDIE was created by the State of Washington to allow providers (including ESCOs) to be informed when their patients present to any ED in the state; NKC was the only ESCO with access to the program. When ESCO staff received such notifications, an ESCO nephrologist or staff member would contact the ED to try to divert the patient back to a dialysis facility; if the patient could not be diverted, they shared patient records with the ED.

Coordinating Non-Dialysis Care

All CEC Model participants highlighted the importance of coordinating non-dialysis care. As conveyed by Wave 1 ESCO interviewees in PY1, respondents at every Wave 2 ESCO reported making appointments for patients with specialists such as cardiologists, psychiatrists, pulmonologists, podiatrists, and physical therapists. At a number of ESCOs, respondents noted that since joining the ESCO there was greater focus on ensuring staff followed up on referrals and made any necessary appointments.

Care coordination roles established in all ESCOs served to ensure that facility staff received the necessary support to monitor and coordinate patients' dialysis, as well as non-dialysis, care. In addition to coordinating non-dialysis appointments, care coordinators scheduled transportation to appointments and followed up to ensure patients attended appointments. At some Fresenius ESCOs, staff used the CNU to make appointments and assist patients with coordinating non-dialysis care.

One non-LDO created a new "patient navigator" position for which they hired non-clinician individuals with personal or family dialysis experience. This individual was responsible for talking with patients, listening to their concerns, and relaying their concerns to appropriate facility staff. Representatives explained that patients saw these patient navigators as more of a peer (e.g., rather than as a clinician) and generally appeared to feel more comfortable opening up to them. If patient navigators identified barriers to care in their conversations with patients, they would bring that information to the appropriate team member (e.g., nephrologist, nurse, social worker, or dietician) and work with the team to remove that barrier.

> *"Patient navigators, who are not nurses, who are not doctors, who are simply folks to talk to […]can find out so much about the patient that physicians or nurses were not able to."*
>
> *"We're seeing the ESCO care coordinators as just another [interdisciplinary] team member. They are an extender. [Care coordinators] have a place at the table now and what we are trying to instill is a culture where [the care team members] are mutually contacting each other as needed."*

Obtaining Medical Records

Some respondents reported having access to patient records from hospitals and other providers or the ability to request and receive the records easily. However, other respondents referred to significant difficulty in obtaining medical records from all providers and even more difficulty in getting patients to provide this information. Many facilities reported that their method of obtaining medical records has not changed since joining the ESCO.

In general, most Fresenius respondents claimed that the ESCO had not improved data sharing with other providers and they had not instituted any new processes for obtaining medical records since the ESCO began. These respondents described that some hospitals provided electronic access to records while some did not and they reported that PCPs typically did not respond to requests for patient records. A few Fresenius ESCO respondents stated that the CNU assisted in getting medical records. Some Fresenius ESCOs recently adopted Transition of Care forms that help nephrologists coordinate care and reconcile discharge information. In these ESCOs, nephrologists are required to complete the Transition of Care form within 30 days of a hospital discharge but aim for completing the form within seven days of the discharge. The form requires nephrologists to do medication reconciliation and complete a discharge summary in order to better understand why patients were hospitalized and to prevent future hospitalizations.

Respondents from a few DCI ESCOs reported access to some hospital records. They explained they could access discharge summaries, but they were rarely available on time. Representatives at other DCI ESCOs faced challenges in obtaining electronic access. They mentioned that hospitals appeared reluctant to provide access because they were affiliated with a competing

dialysis organization. Other respondents noted hospitals were reluctant to provide access due to privacy laws.

Respondents from one non-LDO reported that EHRs have improved the timeliness with which they could obtain discharge summaries, but the timeliness varied by hospital. Staff from another non-LDO stated that they were working to integrate their records with the statewide health information exchange that would allow for information to be shared across multiple provider types. Respondents from another non-LDO reported electronic notifications when a patient enters an ED through a statewide system. Some hospital systems also provide notifications when a patient is admitted or discharged through this system. Representatives from this ESCO also explained that the ability to receive medical records varied from hospital to hospital and that it was challenging to get direct access to hospital data systems for their care managers.

Representatives from a few ESCOs claimed that it was particularly challenging to obtain information, especially patient discharge summaries, from Department of Veterans Affairs hospitals. Furthermore, one respondent reported that the Veterans Affairs hospital required patients to start dialysis with a catheter in the hospital (e.g., rather than placing a fistula in advance and starting scheduled dialysis on an outpatient basis).

> *"To this day, our biggest challenge remains transitions of care."*
>
> *"Some of them we are very good with but there are other hospitals where we struggle to get papers from. Once they're discharged, they won't talk to us. No one is responsible once the person is discharged. The paperwork is gone. It's hard to track someone down."*

Identifying and Focusing on High-Risk Patients

Similar to Wave 1 ESCOs in PY1, all Wave 2 ESCOs reported using risk stratification strategies to identify patients at high-risk of hospitalization. ESCOs held meetings among providers, leadership, and staff to discuss high-risk patients identified using risk-stratified lists generated by computer algorithms and clinical criteria like comorbidities, missed treatments, and previous hospitalizations. Risk stratification meetings existed, in some form, prior to the implementation of the CEC Model in all ESCOs interviewed. Fresenius, DCI, and one non-LDO used computer algorithms to generate lists of high-risk patients. These computer-generated lists were new for both DCI and Fresenius ESCOs but existed pre-ESCO for the non-LDO. Two non-LDOs did not use a computer-generated list of high-risk patients but instead used data on hospitalizations, missed treatments, and lab results to identify patients who were likely at a higher risk for adverse events.

> *"[Flagging a patient as high-risk] prompts more attention on monitoring and, if need be, informing the physician and talking with the staff that are not part of the ESCO process [about] what we need to be looking at for this patient."*

Medication Therapy Management

All ESCOs reported performing MTM, including medication reconciliation, prior to joining the CEC Model. However, several respondents described adopting new MTM practices since starting the ESCO. Respondents from all ESCOs reported reconciling patient medications at least once monthly. Virtually all ESCOs claimed that they also aimed to do so after each

hospitalization, although there was variability in how consistently different ESCOs performed these post-hospitalization reconciliations.

Frequency of and Staff Participation in Medication Reviews

Among Fresenius ESCOs, the CNU was identified as a key resource for ensuring that medication reconciliation was performed consistently. One Fresenius ESCO respondent noted that nephrologists should perform medication reconciliation within seven to 14 days of hospital discharge and the CNU would do that task if the nephrologist did not. Respondents reported that Fresenius nephrologists are now required to conduct medication reconciliation as part of the post-hospitalization Transition of Care form. This form is new for the Fresenius ESCOs and several non-nephrologist respondents stated that medication reconciliation was performed more quickly as a result.

DCI respondents described that routine medication reconciliation was performed on a monthly basis, but this was most important following hospitalization. Nephrologists and nurse practitioners typically performed these reconciliations. Respondents reported that there were plans for DCI-employed pharmacists to perform intensive medication reviews with CEC beneficiaries (as reported in the first annual report[22]) on a semiannual basis but these reviews had not yet started for the DCI ESCOs that began in PY2.

All non-LDOs utilized employed or affiliated pharmacists to assist with MTM. One non-LDO worked with pharmacists that the organization had directly employed for many years. The two other non-LDOs partnered with affiliated pharmacies to help ESCO patients with MTM. At one of these ESCOs, pharmacists began conducting twice-annual intensive medication reviews with CEC beneficiaries; ESCO representatives reported that they hoped to eventually extend this practice to all patients. Representatives from the other non-LDO explained that their partnered pharmacy service will conduct home visits (if permitted by the patient) and will arrange for home deliveries of patient medications.

Data Sources for MTM

During ESCO site visits, respondents described different data (and potentially complementary) approaches to reconciling patient medications: asking patients to report medication changes, referencing printed medication lists (e.g., from a physician office visit or hospitalization), and examining bottles of medications that patients report they are taking. Respondents consistently agreed that medication bottles were more accurate data sources than the medication lists provided to patients in hospital discharge paperwork, but the degree to which respondents relied on each of these data sources varied substantially across ESCOs. There were no consistent trends within Fresenius, DCI, or non-LDO ESCO groups in this regard.

Errors on Hospital Medication Lists

Incorrect medication lists were identified as a major source of problems during medication reconciliation. When asked to estimate the proportion of patients with errors on their medication lists after hospital discharge, respondents at a majority of ESCOs described that more than 50%

[22] For findings from the Wave 1 ESCO site visits, please see the first annual report (https://innovation.cms.gov/Files/reports/cec-annrpt-py1.pdf).

of their patients would have such medication discrepancies; some respondents estimated that 70% or more of patients would have significant medication problems after discharge. Only three ESCOs reported that medication errors were present on hospital discharge summaries for fewer than 50% of patients.

> *"We have trouble in this clinic doing the medication reconciliation for various reasons. Not getting the records, the patients not understanding what they're taking. You go through the list and they say, yeah, yeah, yeah, I'm taking it and the next day, they tell you they're not taking it. So, we're never quite sure if the list is correct. Bringing the meds in, we've started doing that. […] Some of them do, some of them don't."*
>
> *"Ninety percent [of patients have medication errors on hospital discharge summaries]. It is unbelievable. We send them records – the minute we know they're in the hospital, we send [the hospital] the updated medication list – but they don't update [the data on] their end. When that discharge list comes out, it's not even remotely close."*

c. Improved Patient-Centered Care and Communication

Early and Ongoing Patient and Caregiver Education

Representatives from all ESCOs agreed that patient education was important, but they also noted only minor changes to education under the CEC Model. The only consistent change across all ESCOs was new content about ESCO structure and new ESCO resources.

Respondents from DCI ESCOs often cited the organization's use of the Reach Kidney Care program, an education program designed to prepare patients with Chronic Kidney Disease (CKD) for dialysis, as crucial in getting permanent access placed, avoiding early complications, and reducing costs. Although the Reach program is offered to all patients not yet on dialysis, respondents at all DCI ESCOs underscored the role this program played in improving outcomes and quality of care once patients transition to dialysis. Additionally, two DCI ESCOs reported focusing education efforts on MTM and avoiding unnecessary ED visits. DCI ESCOs otherwise had relatively little change in patient education.

One non-LDO cited a stronger emphasis on encouraging patients to call the dialysis facility before going to an ED; no other significant education changes were reported by non-LDOs.

> *"Now, I think we're getting a better, a clearer picture of where the patient is in terms of where we can start with the education. Something that I assumed they already knew, or they've heard numerous times, they really haven't heard."*
>
> *"If we are looking at your hospitalization, we are more interested to know what happened in the hospital and how do we keep you from going back in and what steps are we, together, going to take to prevent the next hospitalization."*

Hospice and Palliative Care

Many ESCOs reported limited use of hospice and palliative care services, with some exceptions. Social workers were identified at most ESCOs as the primary staff members tasked with advanced care planning and end-of-life discussions with patients and their families; at other ESCOs, respondents reported that nephrologists or PCPs have these conversations. There was also significant variation in the willingness of nephrologists to discuss these topics with patients,

due to their personal beliefs or level of comfort with the topic. Some respondents explained that nephrologists may be reluctant to initiate end-of-life conversations because they view their role as one of prolonging life; some respondents also called attention to a lack of training among some nephrologists in end-of-life care.

While many ESCOs did not make changes related to hospice or palliative care services, many respondents expressed a desire for improved hospice and palliative care resources. A few ESCOs established, strengthened, or formalized partnerships with hospice and palliative care organizations, which included staff training, patient education on palliative care services, and "lobby days" during which hospice and palliative care organizations visit dialysis facilities and provide information to patients. One ESCO was piloting a mobile palliative care team that meets patients at various locations (at the dialysis facility, at home, at another physician office, or elsewhere) to provide symptom management and support.

> *"If we are going to create a culture shift then we can't only be taking patients who are actively dying because everybody else who sees our team come in and only see dying people then they are going to associate us with dying… [A patient with high health care utilization in the last six months] would be a great person to be involved in. What is happening? Is there any extra support that we can offer? Any symptom management that we can offer that maybe hasn't been tried yet to get them stable?"*

Staff Training and Education

Staff training and education typically focused on ESCO-related activities, communication, partners, and other miscellaneous topics. Training was administered over the phone, by video, in-person, via online webinars, and through handouts and presentations sent via email.

Staff Training and Education on the ESCO

Fresenius respondents described multiple areas of staff training and education including: the ESCO, the CNU, and how to identify ESCO patients. Some Fresenius respondents and one DCI respondent reported the ESCO changed their organizational culture with regard to patient care. Having initially thought the program would increase their workload, respondents claimed that the ESCO encouraged interdisciplinary work and innovative thinking. Many Fresenius ESCO respondents explained that training was received through daily huddles and weekly, biweekly, and monthly meetings. Some of these trainings were developed by Fresenius corporate entities. DCI respondents reported similar training modules with specific trainings on MTM, hospitalizations, depression screenings, and preventing ED visits.

Respondents from Fresenius and DCI said that training on the overall CEC Model could be improved. While there were positive comments made on education and training, several Fresenius and DCI respondents mentioned that education on the ESCO was insufficient and that the program was not introduced to staff properly. There was confusion about roles and responsibilities. A few Fresenius respondents were unsure how the CEC Model affected their work. Respondents indicated they needed more information on resources available through the ESCO, as they just recently learned about the resources offered by the CNU. Some respondents reported they had no knowledge of the resources offered by the CNU and had never spoken to anyone at the CNU call center. Others thought the CNU added redundant work because they required the center to follow up on missed treatment issues that the dialysis facility was already

processing. Respondents from one facility indicated they were receiving calls from the CNU at one point, and then the calls stopped abruptly. Conversely, respondents at other facilities recognized the CNU as helpful and central to the coordination practices of their facilities.

Respondents from one non-LDO stated that trainings helped them learn how to triage patients' non-emergent concerns instead of sending patients to the hospital. They also claimed that their training in reducing bloodstream infections improved outcomes for their patients. Some of these trainings were in place before officially rolling out the ESCO. Several respondents from DCI indicated that they had noticed no change in training or education since the ESCO began. Some respondents reported that they did not have time to attend all the trainings they learned about through email, while others referred to high staff turnover that led to some staff being currently untrained.

Other Staff Training Topics

Other trainings were administered at DCI and non-LDO ESCOs and included topics such as palliative care, data systems, mental health, trauma, and handwashing.

> *"Here's a brand-new program, and we're going to tell you this much about it, and you're supposed to do this much work. It was very hard to know where our focus should be […] Where I still see our biggest breakdown is the clinic direct patient care staff do not quite understand their role and how they [fit in with the ESCO]."*
>
> *"Our initial meetings were more about numbers and not so much of the plan. And then this last meeting we brought in the nurse managers, dieticians, and social workers, and the plan was reintroduced. […] You could see the lightbulbs kicking on and understanding how their team needed to help the care coordinators to do things. And we've seen a lot of headway in just the last month or so from having that meeting."*

2. Did the CEC Model Change Collection or Use of Quality-Oriented Data for Wave 2 ESCOs?

Respondents from most Wave 2 ESCOs described some level of change in the utilization-related quality data (e.g., hospitalizations, readmissions, and ED visits) they reviewed as a result of the CEC Model. This is in contrast to Wave 1 ESCO interviewees in PY1, most of whom did not report at the time of our site visits changes in the quality data they track for dialysis care.

Respondents from Fresenius Wave 2 ESCOs offered a range of opinions with regard to whether and how the CEC Model impacted their quality processes. For example, some Fresenius respondents explained there were no changes. Other Fresenius respondents said they were doing the same quality process but thought the ESCO brought a greater focus on quality and has helped them to be better about closing the loop and following up when there are issues. Some Fresenius respondents expressed concerns about the added bureaucracy to patient care plans, such as the ESCO requiring more meetings with corporate or other staff outside of the facility to discuss patient care plans, and whether the quality data would show improvements in patient health and cost. Other respondents said the ESCO has increased nephrologist engagement. For example, Fresenius respondents in several ESCOs described additional reports and portals that Fresenius corporate made available to participating nephrologists and ESCO staff that drills the outcome data down to different levels for comparison across sites (e.g., ESCO, facility, and nephrologist). Other changes described by Fresenius respondents included changes to the EHR so it captures more information, and some additional coordination with hospitals such as the use of

MemberMatch software and direct access to EHRs of some hospital systems (**Section III.C.3.b.**).

Respondents from DCI ESCOs described increased communication and awareness about quality data as a result of the ESCO. One respondent explained the usefulness of the claims data and how it has allowed them to understand where the patients' costs are, As a result, they are better able to focus on ways in which they can improve patient care and quality of life. Some respondents also claimed that the ESCO has increased staff communication and that they have more check-ins with other members of the care team to focus on quality.

Respondents from the non-LDOs made changes to their EHRs to capture ESCO data. They also reported working with in-house and outside data analytics resources in order to utilize the CMS Claims and Claim Line Feed (CCLF) data so they can determine where to focus their interventions (**Section IV.C.3.e.**).

> *"[The ESCO] has not obviously [influenced our approach to quality improvement]; we do all of the routine stuff. We do the meetings with the clinic manager and the director of operations. We have our monthly meetings and we talk about everything including depression, compliance, and nutrition. We've been doing that for years and years. I can't tell you any specific thing where ESCO has changed what we've been doing."*
>
> *"The ESCO has allowed us to compare our units against each other and with each other, and we can kind of share amongst everyone in the practice, the data, and try to improve everybody and standardize everybody in the way that we go look at care in a more organized fashion. So that's the nice thing about the ESCO, they just introduced a transparency dashboard that looks at the quality measures of each unit and of each physician and we're able to corral outliers and try to help understand what the issues are at different units and try to improve everybody's numbers."*

3. What Early Implementation Challenges Did Wave 2 ESCOs Face?

During interviews with Wave 1 ESCOs in PY1, respondents reported several challenges in implementing the CEC Model, including difficulties with the beneficiary attribution mechanism and regulations that restrict delivery of care by non-nephrology providers. In contrast, Wave 2 ESCOs cited challenges related to transportation, engaging outside providers, lack of patient responsibility, complicated program rules, the lag in receiving program data, and the up-front costs associated with starting an ESCO.

a. Transportation

Representatives from all ESCOs identified transportation as a challenge on some level, especially in terms of availability and reliability of transportation services, patient wait times, use of higher-cost ambulances, and restrictions in the transportation waiver (e.g., annual cap per person, cannot be used for transportation to non-ESCO providers). While transportation issues are not unique to ESCO patients, transportation was a major discussion topic in all ESCO site visits.

Representatives from two ESCOs reported that some ambulance companies refused to transport Medicare dialysis patients due to recent lawsuits that claimed these companies were billing CMS for services provided to ineligible patients. Representatives from one ESCO discussed the overuse of ambulances by their patients due to PCPs or other doctors who will authorize non-emergency ambulatory transportation without verifying that it is necessary. Representatives from another

ESCO discussed changes in state Medicaid plans that stopped providing transportation for patients, which impacted adherence since patients can no longer afford to get to dialysis three times a week.

b. Engaging Non-Owner Providers

Representatives from the majority of the ESCOs described challenges in encouraging non-owner providers, especially PCPs and emergency physicians, to collaborate toward the model's goals (e.g., nephrologists providing primary care, efforts to reduce unnecessary hospitalizations) since these providers' incentives are often misaligned with those of the CEC Model. Several ESCO representatives also described issues in communication where different practices and specialties often do not talk to one another. These barriers to clear communication can cause confusion around proper medication use and other medical direction since patients often receive different advice depending on the specialist they are seeing.

Representatives from a few ESCOs also expressed frustration that specialists (e.g., podiatrists, ophthalmologists) were unable to evaluate patients in the dialysis facility. They reported that it is often challenging to get patients to follow up with other appointments, and it would be easier to coordinate this care if it occurred in the dialysis facility. A lack of appropriate exam space was also identified as a barrier to having specialists see patients at the dialysis facility.

Representatives from a few ESCOs reported challenges associated with coordinating care of CEC beneficiaries under the care of nephrologists not participating in the model. For example, nephrologists not participating in CEC had less incentive to participate in ESCO activities led by the CEC dialysis facility or parent organization, or – conversely – non-participating nephrologists were not informed of or were excluded from certain CEC-related activities (e.g., case management discussions) because they were not part of the ESCO. Some ESCO representatives expressed concern about the consequences of these challenges on the quality of care received by such patients.

c. Patient Responsibility

Representatives from some ESCOs described challenges in improving outcomes and lowering cost when patients are not actively engaged in their care. Some nephrologists expressed a need for a waiver to be able to incentivize patient engagement, monetarily or otherwise, to change behaviors and increase patient accountability.

> *"The thing that is notoriously missing from all of these efforts are ways to get the patients engaged by carrot or by stick. There is none of that. Until that is in place, this thing will never be. Maybe that would be a good area to explore, but there are no consequences for no patient participation."*

d. Program Rules

ESCO representatives expressed frustration with several CEC Model rules and concerns around quality measures. For instance, representatives from a few ESCOs questioned the mandate to conduct smoking cessation and depression screenings even when patients refuse, which can strain relationships with patients. Respondents from several ESCOs were also discontented about patient surveys making up 20% of their ESCO quality score due to survey results being largely out of their control. They described patient surveys as unpredictable because it can be hard to

know if patients will give an unfavorable review just because they had a recent disagreement with a staff member or were unhappy that day. Some respondents also expressed concerns about low response rates due to the large number of non-English speaking patients in their facility. Others also voiced concern about using all of the facility's patients, including non-ESCO patients, in the ESRD QIP scores.

> *"Stop the surveys. Stop them. The patients are just so burnt out. […] There are times when patients are dishonest about their feelings. They just put check, check, and check. I can't tell you how many times we get surveys back and we're like, 'Did you really say this? Did you really put this?' They were like, 'Oh no, I'm trying to appease you and give you back your paper with your pen.'"*

e. Data Lag

Representatives from several ESCOs expressed frustration with the time lag in receiving data from CMS because it is important for evaluating their performance. They expressed difficulty in managing the raw CCLF data files,[23] especially for ESCOs without large data analytics resources. Non-LDO representatives also reported needing to make large investments or establish contracts with outside data analytics organizations to overcome this challenge.

> *"CMMI should have developed the data analytics rather than dumping this undifferentiated, incomprehensible pile of data and asking every facility to do it themselves. It is a huge waste of time and resources. […If CMMI is] sharing in half the savings, that's the investment they should have made. They should have had a data analytic tool available at the claims level. Their dashboard is quite nice, but it doesn't get you to the claims level."*

f. Costs Associated with Starting an ESCO

Representatives from the non-LDOs described the large up-front costs to start an ESCO as a challenge and a potential barrier for other non-LDOs to participate in the model. For example, respondents from one non-LDO described costs associated with limited liability company set-up fees, legal paperwork, and associated expenses for staff to work on these initiatives. Representatives from another non-LDO referenced legal costs associated with creating the ESCO as a barrier to non-LDO participation. LDOs may have made similar investments at the corporate level, which would not have been reported by ESCO respondents.

> *"Keep in mind our relative size. It's costly to start up a legal entity. So certainly no shortage of legal costs just to get the ESCO functioning."*

4. How Did Wave 2 ESCOs Use the Learning System?

Members of several ESCO leadership teams reported participating in the CEC Learning System webinars with some frequency, while the participation level among facility staff tended to be much lower. Many respondents cited the times at which webinars were scheduled, the length of the webinars, and the low relevance of some content as primary reasons for not taking a more

[23] The monthly CCLF files are provided from CMS to active Shared Savings Programs, such as ESCOs in the CEC Model, to assist ESCOs with their care coordination. The files include claims for the ESCO's aligned CEC beneficiaries.

active role in the webinars. Respondents suggested lessons learned and best practices from Wave 1 ESCOs, nutrition, improving patient compliance, and improving patient quality of life as topics that they would like to see at future webinars. Most respondents appeared to have some knowledge of the Learning System webinars, even if they did not participate in them, but there appeared to be very little awareness of the CEC Dashboard compiled by CMS, which shows ESCO-level data on quality, cost, and utilization for each quarter. Among respondents familiar with the CEC Dashboard, there were mixed reports about the utility and the intuitiveness of the dashboard.

D. Discussion

Qualitative findings based on site visits and corporate interviews identified the objectives set in place by Wave 2 ESCOs and the strategies used to achieve program goals, revealing a number of similarities between Wave 1 and Wave 2 ESCOs as well as some differences among the Wave 2 ESCOs. Improving access to dialysis care has been a goal of both Wave 1 and Wave 2 ESCOs. Wave 2 LDOs more commonly reported improving access to dialysis through added capacity (i.e., extended hours or extra shifts), whereas the non-LDOs focused more on improved tracking of daily capacity at facilities to assist with rescheduling. Improving coordination of care across institutional settings has also been a key objective of both Wave 1 and Wave 2 ESCOs, promoting investments in staff, specifically care coordination staff, and IT, which were reported by all Wave 2 ESCOs. As with Wave 1 ESCOs, another key goal among Wave 2 ESCOs was reducing hospitalizations and re-admissions, including decreasing skipped outpatient treatments and improving communications with the ED in order to divert patients with certain conditions from the inpatient setting. Improved communication was sometimes used by Wave 2 ESCOs, in addition to adding standby dialysis slots by LDOs, to facilitate rescheduled or extra treatments in such cases. Many of the care redesign strategies noted by Wave 2 ESCOs were not new investments, but were enhancements or more formal extensions of processes in existence prior to the implementation of the CEC Model.

Many Wave 2 ESCOs noted the importance of partnerships with hospice and palliative care providers, but partnership efforts in this area were not as strong as those in other initiatives for most Wave 2 ESCOs, with the exception of one ESCO that is piloting a mobile palliative care team. Other perceived general limitations to the model included engagement with non-participating providers and the inability to provide patient incentives. Non-LDO ESCO representatives in particular called attention to financial challenges, including costs associated with ESCO start up as well as the need to invest in data analytic capabilities.

In future site visits, we will inquire about changes to ESCO investments and care redesign strategies, as well as perceived model impacts. We will also ask participants about particular strategies and investments they believe had the greatest effect on model outcomes.

V. What Were Beneficiaries' Perceptions of the CEC Model?

We conducted an initial round of focus groups at new organizations with Wave 2 ESCOs to assess how beneficiaries perceived being served by an ESCO, and to determine if beneficiaries noticed changes in the quality and delivery of their care since their facility joined the CEC Model.[24]

A. Key Findings

Beneficiaries' Perceptions of the CEC Model. We conducted focus groups with CEC beneficiaries to assess:

Key Findings:

Awareness of CEC Model

- In general, focus group participants were unaware of the CEC Model
- After receiving information about the CEC Model in the focus group, a few said they were previously aware of the materials

Benefits of ESCO

- Most of the focus group participants who saw the ESCO as a potential benefit were generally newer to dialysis
  - Focus group participants with multiple years of dialysis experience tended to see less of a benefit with the ESCO

Role of Dialysis Staff

- In two of the ESCOs, new staff positions focused on improving care coordination and patient education
  - Focus group participants were not aware of these new roles

[24] For findings from the Wave 1 ESCO focus groups, please see the first annual report (https://innovation.cms.gov/Files/reports/cec-annrpt-py1.pdf).

B. Methods

Beneficiary focus groups were conducted in the three new non-LDO ESCOs during the site visits that occurred from October 26, 2017 to December 14, 2017. No focus groups were held at Wave 2 Fresenius or DCI ESCOs in PY2 because focus groups were already conducted at two Wave 1 Fresenius and two Wave 1 DCI ESCOs in PY1. Although only one focus group was conducted at each selected ESCO, participants may have been from any of that ESCO's participating facilities.

A total of 14 beneficiaries participated in the three non-LDO focus groups. Each focus group session lasted approximately 90 minutes. The focus group selection criteria, analysis, structure, and discussion guide are described in **Appendix D**.

C. Results

As was the case with Wave 1 focus group participants, the majority of participants in the focus groups held at Wave 2 ESCOs were unaware of the CEC Model and did not see the potential benefit of having their facility participate in an ESCO.

1. What Did Beneficiaries Know about the CEC Model?

Most focus group participants did not appear to be aware of the CEC Model or of any changes in their care since the start of the model. When asked about the quality of care and services provided by their facility, almost no participant responses differentiated between CEC-related care and care unrelated to CEC. When participants reviewed the ESCO-specific education materials that were provided by their dialysis facility, many participants indicated no prior awareness of the materials.

2. What Did Beneficiaries Perceive as the Strengths of Their ESCO?

Few of the participants perceived the CEC Model as a service that would improve their care. While some participants did note strengths associated with their facility (e.g., satisfaction with their care, receipt of useful information from facility social workers and dieticians, flexibility in rescheduling appointments), they were likely strengths that existed in their facility prior to the model because participants reported no changes in the quality or type of care they received from their dialysis facilities.

Upon review of the ESCO-related educational materials, most participants expressed confusion about the purpose of the ESCO and the services it offered. Participants with multiple years of dialysis experience generally saw little need for the ESCO because they were already engaged in managing and coordinating their own care and they doubted the ability of dialysis facility staff to improve upon the care coordination they were able to provide themselves. Most participants did not think their care would change under the ESCO; however, some participants were suspicious of the ESCO's goals and worried the CEC Model had been introduced to reduce the services they received.

Although most focus group participants did not see much utility in the CEC Model, participants in one focus group expressed more enthusiasm for the model relative to the other two focus groups. Most of the beneficiaries participating in that focus group were on dialysis for fewer

years, on average. The relative inexperience of these dialysis patients may have informed how they viewed the ESCO as they had less basis for comparison.

> *"[The ESCO is] a good idea because sometimes you need changes in your medication...Or there's something that you're going through that you may need your doctor to know. They can do you the favor of contacting the doctor and saying listen, your patient has been going through this. So, it is a good idea."*
>
> *"I saw [the ESCO letter and thought] they must want information to know what they could get rid of, what they could trim, to save money, and that's why they were asking us about our care."*

3. What Were the Changes Beneficiaries Perceived as a Result of Their Facility's Participation in the ESCO?

Overall, few participants knew about the CEC Model, even after they were prompted with the ESCO education materials. Participants did not attribute any specific programs or actions from their dialysis facility to the model.

D. Discussion

Focus groups with patients in Wave 2 ESCOs revealed limited patient knowledge of the CEC Model. After receiving information, patients tended to agree that the idea of an ESCO sounded useful, especially to patients who were newer to dialysis. These findings were consistent with what we had heard from Year 1 focus groups with patients from Wave 1 ESCOs. Overall, patients were generally satisfied with their dialysis care and did not report any changes in the quality or type of care they received from their facilities. This suggests that future efforts under the CEC Model may benefit from greater emphasis on patient education and engagement to distinguish the activities of the CEC Model from usual care.

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

The CEC Model incentivizes ESCOs to maintain and improve quality by requiring that performance thresholds be met. In PY2, ESCOs were only eligible for shared savings if they also achieved a set of quality standards.[25] Shared savings/losses also depend on an ESCO's total quality score (TQS).[26] The broader accountability for both quality outcomes and costs also further incentivizes ESCOs to improve these measures using patient-centered approaches (for example, enhanced communication and education). While KDQOL is no longer included in the TQS for PY2, we continued to monitor it because in a patient-centered care model, quality of life is a key outcome. We also assessed health-related quality of life (HRQOL) to ensure there were no unintended adverse consequences of CEC's incentives to achieve costs savings.

This section presents findings on the association between participation in the CEC Model and HRQOL during PY2.[27] The analysis used survey data collected using the KDQOL-36 questionnaire from both CEC participants and a matched comparison group of beneficiaries.[28] Our analysis assessed whether CEC beneficiaries were experiencing better quality of life relative to what would be expected had they not been aligned to a participating ESCO.

A. Key Findings

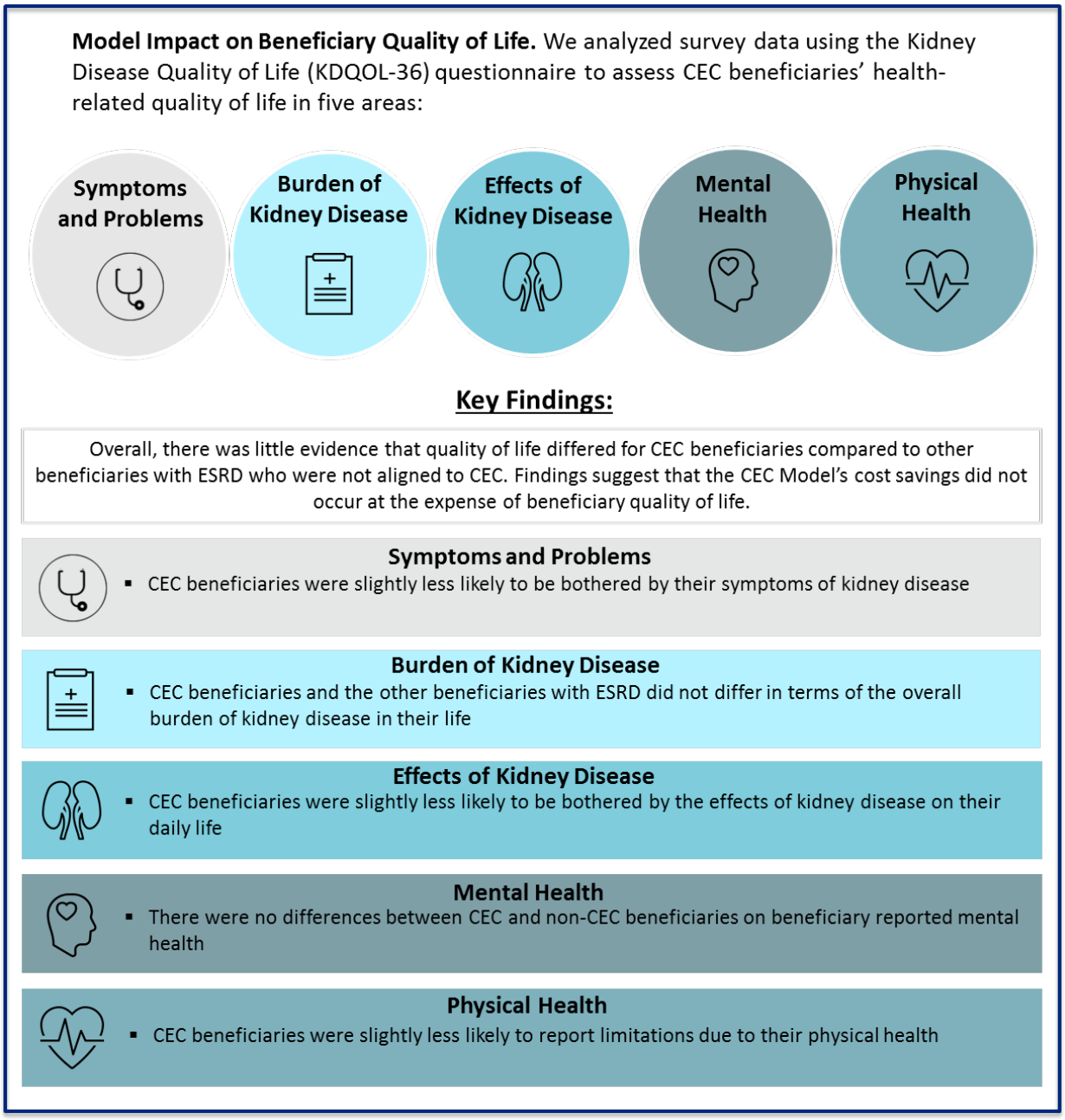
Overall, there was little evidence that quality of life differed for CEC beneficiaries compared to other beneficiaries with ESRD who were not aligned to CEC. Beneficiaries in the CEC Model had higher HRQOL scores in the areas of the effects of kidney disease, symptoms and problems, and physical quality of life, but these differences were small in magnitude.

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

[26] 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.

[27] We also conducted a quality of life survey in PY1. The PY1 survey results are included in the first annual report (https://innovation.cms.gov/Files/reports/cec-annrpt-py1.pdf).

[28] 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.).



B. Methods

The KDQOL-36 is a validated 36-item survey that has been administered to thousands of patients since 2002.[29,30,31] The KDQOL-36 survey consists of the Short Form 12 (SF-12) generic core of

[29] 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.

[30] 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.

health-related 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 composite scores according to established methods:[32] Physical Component Summary (PCS), Mental Component Summary (MCS), Burden of Kidney Disease, Symptoms and Problems, and Effects of Kidney Disease. Each composite score is calculated such that a higher value represents better quality of life. Individual questions included in each composite score are shown in **Appendix E**, **Exhibits E-4** and **E-5**.

The association between participation in the CEC Model and quality of life was estimated for CEC beneficiaries, relative to the matched comparison group of beneficiaries with ESRD, using multivariable regression methods. Because there was no pre-CEC data collected, a cross-sectional study design was used. The 17,198 CEC beneficiaries who were sampled for the KDQOL survey were aligned to a CEC facility by the end of March 2017 and were surveyed from May through the end of August 2017. We were able to match 14,663 (85%) of these aligned beneficiaries to comparison group beneficiaries who met CEC enrollment criteria but were not aligned to an ESCO. Of the 14,663 potential comparators, a matched sample of 10,500 beneficiaries were surveyed from September through November 2017. **Appendix E** describes in detail the survey administration, and the methods for selecting beneficiaries in the comparison group and for estimating regression models.

For the KDQOL-36 survey, the response rate among CEC beneficiaries was about 41% (7,012 of 17,198 responded), and lower for the comparison group at 36% (3,779 of 10,500 responded). Response rates stratified by select characteristics (e.g., demographics) are available in **Exhibit E-6** 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. Based on standards used in the literature a greater than five-point difference/change is typically considered clinically meaningful whereas smaller differences/changes might not be considered clinically meaningful, even if they are statistically significant. For example, for the KDQOL-36 measures that range from 0-100, a five-point difference essentially represents a five percentage point increase in the fraction of the maximum possible points that were attained. A one-half standard deviation difference/change has also been noted as being clinically meaningful, but literature in this area cautions against adopting one value given that this may vary across different types of patient populations.[33]

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[31] Peipert et al. Psychometric properties of the Kidney Disease Quality of Life 36-item short-form survey (KDQOL-36) in the United States. *Am. J. Kidney Dis.* 2018; 71(4): 461-468.

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

[33] 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.

Exhibits 6a and **6b** show the distribution of select characteristics across CEC and comparison group respondents. CEC beneficiaries who responded to the survey were slightly older and more likely to be White relative to the entire CEC group who were sent the survey (i.e., all respondents and non-respondents). Similarly, the comparison group respondents were older and more likely to be White than the entire comparison group who were surveyed (i.e., all respondents and non-respondents). The impact of these differences on the results were minimized by using sample-balancing weights to match the distribution by age, sex, and race/ethnicity for the total surveyed and respondent groups (see **Appendix E, Exhibits E-7** and **E-8**). Finally, respondents across the CEC and matched comparison groups exhibited similar distributions for sex and similar average hierarchical condition category (HCC) scores. However, CEC respondents were more likely to be younger than 65 and included a greater percent of Black beneficiaries relative to comparison respondents.

Exhibits 6a and 6b. Characteristics by Respondent Group

Characteristics		CEC Beneficiaries				Matched Comparison Beneficiaries			
		All Surveyed		Respondents		All Surveyed		Respondents	
		N	%	N	%	N	%	N	%
Age	<65	8,795	51.1	3,292	46.9	5,127	48.8	1,475	39.0
	65 to 85	7,401	43.0	3,270	46.6	4,707	44.8	2,004	53.0
	85 +	989	5.8	442	6.3	665	6.3	299	7.9
Sex	Female	9,557	55.6	3,912	55.8	5,791	55.2	2,064	54.6
	Male	7,628	44.4	3,092	44.1	4,708	44.8	1,714	45.4
Race/Ethnicity	Black	7,764	45.1	2,964	42.3	4,717	44.9	1,385	36.6
	White	6,988	40.6	3,165	45.1	4,438	42.3	1,969	52.1
	Hispanic	1,079	6.3	370	5.3	559	5.3	164	4.3
	Other	1,354	7.9	505	7.2	785	7.5	260	6.9

	CEC Beneficiaries				Matched Comparison Beneficiaries			
	All Surveyed		Respondents		All Surveyed		Respondents	
	N	Mean	N	Mean	N	Mean	N	Mean
HCC Score	16,170	2.9	6,604	2.8	9,932	2.9	3,592	2.9

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

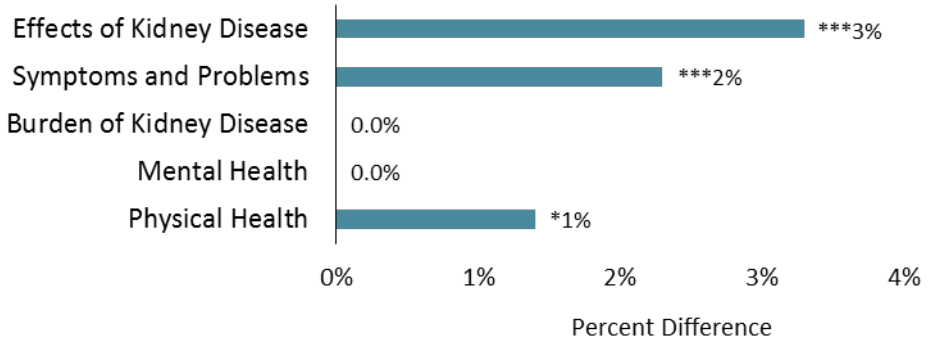
C. Results

Exhibit 7 summarizes the empirical association between participation in the CEC Model and quality of life, as measured by KQDOL-36 composite scores. The analysis showed that, within PY2 of the CEC Model, there were no clinically meaningful differences in HRQOL between participants in the CEC Model and the comparison group. CEC beneficiaries had on average 3% higher scores on self-reported effects of kidney disease on quality of life, 2% higher scores on symptoms and problems, and 1% higher self-reported physical quality of life relative to the

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.

comparison group. While statistically significant ($p \leq 0.01$), these differences were small and not likely to be clinically significant.[34] **Exhibit E-10** in **Appendix E** displays the regression results for all covariates included in the models, including clinical conditions.

Exhibit 7. Associations between Beneficiary Participation in the CEC Model and Health-Related Quality of Life (HRQOL)



Notes: Values show the percent difference in scores between CEC beneficiaries and the comparison group. Significance of the CEC estimated association is indicated next to each outcome bar plot where * implies significance at the 10% level, ** at the 5% level, and *** at the 1% level assuming a two-tailed test.

D. Discussion

The results suggest that beneficiaries in the CEC Model on average had slightly higher HRQOL scores relative to the comparison group in the areas of the effects of kidney disease, symptoms and problems, and physical quality of life. This finding is consistent with ESCOs' reported efforts to enhance patient-centered approaches including improved communication, education, and access to care. This finding also suggests that the CEC Model did not negatively affect patient quality of life, a concern for models like CEC that are focused on saving costs.

There are a few limitations to consider when interpreting the survey results. To begin, response rates were generally low in both groups and, consequently, may not be representative of the population of CEC aligned beneficiaries or the general ESRD population. In addition, this study uses cross-sectional differences in risk-adjusted scores to infer associations with the CEC Model; since survey results prior to the CEC Model were unavailable we were unable to assess changes over time before and after implementation of the model. The strength of these results, therefore, is dependent on how well the comparison group represents what would have happened absent the CEC Model. Additionally, 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.

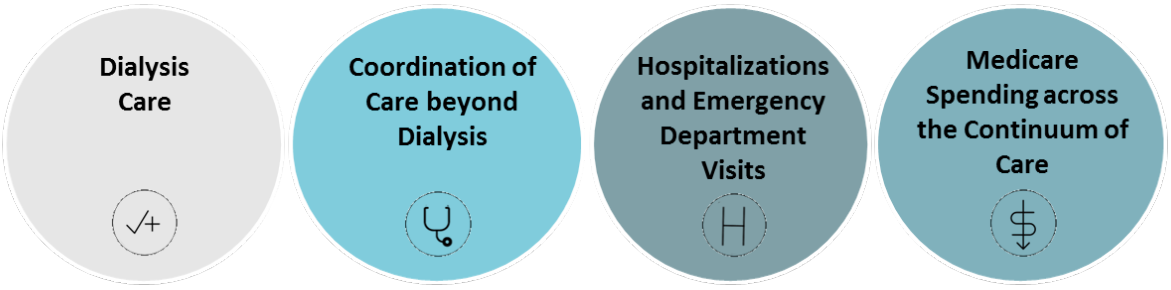
[34] The mean PCS is 34.2 so a 0.46 increase is equivalent to a 1.4% increase relative to the mean in the sample (note: calculating manually will appear to be 1.3% due to loss of significant digits). See **Exhibit E-9** in **Appendix E**.

VII. What Were the Impacts of the CEC Model?

This section presents quantitative findings of the impact of the CEC Model on dialysis care, coordination of care beyond dialysis, hospitalizations and ED visits, and Medicare spending over the first two performance years.

A. Key Findings

CEC Model Impacts. We examined the impacts of the CEC Model for beneficiaries, relative to a comparison group, in the following areas:



Key Findings:

Dialysis Care

- Overall, vascular access placements and dialysis treatment adherence improved modestly for CEC beneficiaries but there was no evidence of improve or declines with their experience with care
  - Catheter use improved as it declined (by 8%) among CEC beneficiaries
  - The number of dialysis sessions per month increased (by 0.6%) among CEC beneficiaries
  - There were no changes in patient satisfaction with care

Coordination of Care beyond Dialysis

- There is some evidence that the CEC Model improved coordination of care beyond dialysis
  - Although CEC beneficiaries had fewer physician office visits, the CEC Model increased the use of preventive care (e.g., cholesterol tests and labs)
  - The CEC Model had a favorable impact on medication management, with 6% fewer CEC beneficiaries overutilizing opioid prescriptions and 4% more adherent to phosphate binder medication; no impact was estimated on the use of medications that could be contraindicated for beneficiaries with ESRD

Hospitalizations and Emergency Department Visits

- Utilization of hospital and ED services declined under the CEC Model
  - The percent of CEC beneficiaries who had at least one hospitalization, ED visit, or readmission in a given month declined by 4%, 3%, and 2%, respectively
  - The CEC Model reduced the likelihood of a hospitalization due to ESRD complications (by 6%), but it had no impact on hospitalizations for vascular access complications

Medicare Spending across the Continuum of Care

- Total Medicare Part A and Part B payments for CEC beneficiaries declined by about 2%, suggesting aggregate reductions in spending of $68 million during the first two performance years
  - Aggregate spending reductions were accomplished by decreases in spending for acute inpatient service (by 4%), institutional post-acute care (by 10%), readmissions (by 5%), hospitalizations for ESRD complications (by 6%), and office visits (by 3%)
  - Payments increased for dialysis services (by 0.6%) and home health (by 6%)

B. Methods

Our evaluation used a difference-in-differences (DiD) approach to estimate impacts of the CEC Model on key outcomes depicted in **Exhibit 8**, relative to the comparison group. DiD is a statistical method that quantifies the impact of the model by comparing changes in risk-adjusted outcomes for CEC beneficiaries, before and after implementation of the CEC Model, to changes in outcomes for similar beneficiaries in the comparison group, before and after CEC implementation. This approach controls for beneficiary-, market-, and facility-level differences between the CEC and comparison populations. It also minimizes biases from time-invariant differences between the CEC and comparison populations and controls for secular trends. The comparison group consisted of beneficiaries from non-participating dialysis facilities matched to CEC facilities based on key market and facility characteristics as well as the sociodemographic and clinical composition of beneficiaries served.

The DiD analysis used Medicare Part A and Part B enrollment and claims data from January 2014 to December 2017 in combination with other program, provider, and market data sources. We estimated two DiD models, one estimated the cumulative impact of the CEC Model for all 37 ESCOs and one that estimated wave- and performance year-specific effects for the original 13 ESCOs (Wave 1) and the additional 24 ESCOs (Wave 2).

We divided the period of analysis into pre-CEC, transition, and post-CEC periods for each of the waves of the ESCO facilities. The pre-CEC period for facilities that joined CEC in October 2015 ran from January 2014 through March 2015, and was followed by a six-month transition period from April 2015 through September 2015 to account for the delayed start of the model. The pre-CEC period for facilities that joined CEC in January 2017 ran from January 2014 through June 2016 and was followed by a six-month transition period from July 2016 through December 2016. The last intervention quarter for all waves concluded in December 2017. Due to the different intervention start times and multiple groups of Wave 1 facilities, Wave 1 ESCOs contribute nearly two times as many intervention quarters as Wave 2 ESCOs to the aggregate CEC Model DiD impact estimate. See **Appendix F** for a description of the DiD methodology including data sources, outcomes definitions, methods for identifying comparison populations and any applied exclusion criteria, and statistical models. **Appendix G** discusses the evaluation's statistical power to detect impacts.

Exhibit 8. CEC Model Evaluation Difference-in-Differences Measures

Category	Evaluation Measure
Dialysis Care	▪ Vascular access • Fistula use: percent of adult patients in a given month who had a fistula and had 90 days or longer of dialysis • Catheter use: percent of adult patients in a given month who had a catheter for 90 days or longer. ▪ 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 receiving home dialysis in a given month ▪ Percent of beneficiaries with at least one unscheduled or emergency dialysis session in a given month ▪ Percent of beneficiaries with a gap in dialysis defined as having fewer than 12 dialysis sessions in a given month without an observable reason ▪ Number of outpatient dialysis sessions per 1,000 beneficiaries per month ▪ Patients' experience with care (ICH CAHPS Survey) • Rating of kidney doctors (global ratings)^ • Rating of dialysis center staff (global ratings)^ • Rating of dialysis center (global ratings)^ • Beneficiary was seen within 15 minutes of appointment time (individual survey item) • Beneficiary received an explanation for why they were not eligible for a kidney transplant (individual survey item) • Nephrologists' communication and caring (composite score)^ • Quality of dialysis center care and operations (composite score)^ • Providing information to patients (composite score)^
Coordination of Care beyond Dialysis	▪ Preventive care indicators (percent of beneficiaries) • Flu vaccinations • Dilated eye exam (diabetic beneficiaries) • Low-density lipoprotein (LDL) cholesterol testing • HbA1c testing ▪ Percent of beneficiaries receiving hospice services in a given month ▪ Number of evaluation and management (E&M) office visits per 1,000 beneficiaries per month ▪ Medication management indicators (percent of beneficiaries) • Indicator of opioid overutilization, average daily morphine milligram equivalent (MME) dose greater than 50 mg in a given month • Indicator of phosphate binder adherence, proportion of days covered by phosphate binder over 80% in a given month • Indicator of contraindicated medication prescription fill in a given month ▪ Percent of beneficiaries starting dialysis with no prior nephrology care – beneficiary had no previous nephrology care

Category	Evaluation Measure
Hospitalizations and Emergency Department Visits	▪ Percent of beneficiaries with at least one hospitalization in a given month ▪ Percent of beneficiaries with at least one ED visit in a given month ▪ Percent of beneficiaries with at least one readmission in a given month ▪ Number of hospitalizations per 1,000 beneficiaries per month ▪ Number of ED visits per 1,000 beneficiaries per month ▪ Number of readmissions per 1,000 beneficiaries per 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 in a given month ▪ Average acute hospital inpatient length of stay, in days ▪ Percent of beneficiaries with at least one hospitalization for vascular access complications in a given month ▪ Percent of beneficiaries with at least one hospitalization for ESRD complications (i.e., volume depletion, hyperpotassemia, fluid overload, heart failure, and pulmonary edema) in a given month ▪ Standardized readmission ratio (National Quality Forum [NQF] #2496) ▪ Standardized hospitalization ratio (NQF#1463) ▪ Standardized mortality ratio (NQF#0369)^ ▪ Percent of beneficiaries with at least one admission for Ambulatory Care Sensitive Conditions (ACSC) in a given month • Admissions for diabetes short-term complications (NQF#0272) • Admissions for diabetes long-term complications (NQF#0274) • Admissions for asthma or Chronic Obstructive Pulmonary Disease (COPD) in older adults (NQF#0275) • Admissions for Congestive Heart Failure (CHF) (NQF#0277)
Medicare Spending across the Continuum of Care	▪ Average Part A and Part B Medicare standardized payments PBPM ▪ Average standardized payments PBPM for the following services: inpatient, readmissions, institutional post-acute care (PAC), home health, hospice, outpatient, office visits, total Part B, dialysis care, hospitalizations for ESRD complications, and Part B drug[35]

Notes: Medicare payments were standardized to remove the effects of Medicare's geographic wage, teaching, and other payment adjustments. (^) Denotes measures included in the total 16 measures in the CEC Model Quality Measures Set.

ICH CAHPS Instrument and Measures. The ICH CAHPS survey was developed through a collaboration between CMS and the Agency for Healthcare Research and Quality and was designed to measure adult hemodialysis patients' experience with in-center hemodialysis care from Medicare-certified dialysis facilities.[36] We used this survey to assess the impact of CEC on the quality of dialysis care. We also use the survey to explore potential unintended consequences of the model, such as ESCOs investing only in quality measures included in the model and/or reducing quality of care on other dimensions not captured in the CEC quality set. To this end, we selected eight ICH CAHPS measures (**Exhibit 8**): three global rating measures (rating of kidney doctors, dialysis center staff, and dialysis center); three composite measures currently used in the CEC Model Quality Measures Set (nephrologists' communication and caring, quality of dialysis center care and operations, and providing information to patients); and two additional measures based on individual survey responses that address other components of quality (beneficiary was

[35] Medicare Part A and B payment categories include all beneficiary months and are not conditioned to whether a beneficiary received that specific service, hence payments can be zero in a given beneficiary month.

[36] In-Center Hemodialysis CAHPS Survey, official website (https://ichcahps.org/).

seen within 15 minutes of appointment time and beneficiary received an explanation for why they were not eligible for a kidney transplant). The calculation of the global and composite measures uses the same methods CMS uses for the publicly reported ICH CAHPS measures published on Dialysis Facility Compare.[37] Individual questions are shown in **Appendix H**, **Exhibits H-2** and **H-3**.

For each measure, we used a DiD approach to estimate the change from the pre-CEC to the post-CEC periods of the percent of beneficiaries reporting quality in the "top box" category (i.e., what would best demonstrate improvement)[38] among beneficiaries receiving care from CEC facilities relative to beneficiaries receiving care from facilities in the comparison group. Among 632 matched pairs of CEC and comparison group facilities, 448 (71%) had sufficient[39] ICH CAHPS survey responses for inclusion in the analysis. Surveys collected between the ICH CAHPS' fall 2014 and fall 2017 waves were included in the analysis. **Appendix H** describes the data, study population, and DiD analytic methods in detail.

C. Results

This section presents results from the DiD models for outcomes related to dialysis care, coordination of non-dialysis care, hospitalizations and ED visits, and Medicare spending. The final sample consisted of 73,094 CEC and 60,464 comparison beneficiaries. The analytic sample included all the eligible and aligned monthly beneficiary observations between January 2014 and December 2017. CEC and comparison beneficiaries were similar. For both groups, 40% were female, slightly over 40% were White, and approximately 40% were Black. Both CEC and comparison beneficiaries averaged 63 years in age and had been on dialysis for an average of over 40 months. More than 90% of both groups used hemodialysis (see **Appendix F**, **Exhibit F-14**).

DiD impact estimates are reported as the change in the value of the outcome measure, relative to the comparison group, and also in terms of the percent change of the outcome measures, relative to the pre-CEC period. We report the statistical significance of all results. We present estimates for all ESCOs and each wave, cumulatively and by performance year. Detailed results, pre-CEC and post-CEC descriptive statistics, and sample sizes are located in **Appendix F**, **Exhibits F-18** through **F-29**.

1. What Was the Impact of CEC on Dialysis Care?

Dialysis facilities and nephrologists are the focal point of care within an ESCO. Hence, we examined the delivery and quality of dialysis-related care. Multiple evidence-based clinical metrics are available to assess delivery of better care by dialysis facilities and nephrologists. Measures capture vascular access, treatment adherence, and patients' experience with care. We highlighted these measures in the logic model as dialysis best practices under the sections for

[37] https://www.medicare.gov/dialysisfacilitycompare/#about/dialysisfacility-info

[38] "Top box" is a label used in ICH CAHPS research to describe the most positive responses. For example, responses categorized as top box include responses of 9 or 10 on a scale of 0 (worst) to 10 (best) on the Global Ratings Measures and responses of Always or Yes on the Composite Scores and individual survey items.

[39] To ensure beneficiary confidentiality, the ICH CAHPS data received for this analysis had already applied rules suppressing facility results when there were 10 or fewer respondents in a given period.

new behaviors and investments/drivers of change, as well as outputs, and ultimately patient outcomes (see **Appendix B**).

At present, there is an established P4P program, the ESRD QIP, which provides financial incentives for all dialysis programs, regardless of CEC participation, to improve many of these measures. Likewise, public quality reporting under the Dialysis Facility Compare initiative also applies to all facilities and may provide indirect incentives (e.g., through influencing patient choice of facility) to maintain or improve quality. Therefore, we did not anticipate that the CEC Model would result in dramatic changes in these measures, with the possible exception of a shift in vascular access initiation. Overall, our analyses revealed that vascular access placements and dialysis treatment adherence improved modestly for CEC beneficiaries but there was no evidence of an improvement or a decline in their experience with care.

a. Dialysis Treatment Modality and Adherence

There were modest improvements in dialysis treatment adherence but no evidence that the CEC Model affected treatment modality or location. The vast majority of US dialysis patients receive three weekly, in-center hemodialysis treatments with a typical duration of three to four hours. This practice pattern is driven partially by payment policy (payment for more than three weekly treatments requires clinical justification) and shift scheduling. The percent of patients treated with home therapies is relatively low in the US, although home therapies may provide the flexibility to help individual patients maintain their lifestyle and some research has shown that home hemodialysis patients report a higher quality of life relative to patients receiving in-center hemodialysis.[40] The global payment that is made under the CEC Model gives ESCOs an incentive to innovate in terms of dialysis frequency, location of treatment, and modality if such changes resulted in better patient outcomes or lower costs elsewhere in the system (e.g., reduced hospitalizations). We identified modality, treatment location, and frequency directly from claims.

We found no evidence that the CEC Model impacted the modality or the location of dialysis treatment. The change in the modality of treatment pre and post-CEC was very modest and not statistically significant (see **Appendix F**, **Exhibits F-18** (All ESCOs), **F-19** (Wave 1), and **F-20** (Wave 2)).

ESCOs reported various strategies to increase patients' adherence to dialysis treatment and to minimize the occurrence of dialysis treatment in emergency rooms when an outpatient dialysis session was a viable alternative. These strategies included:

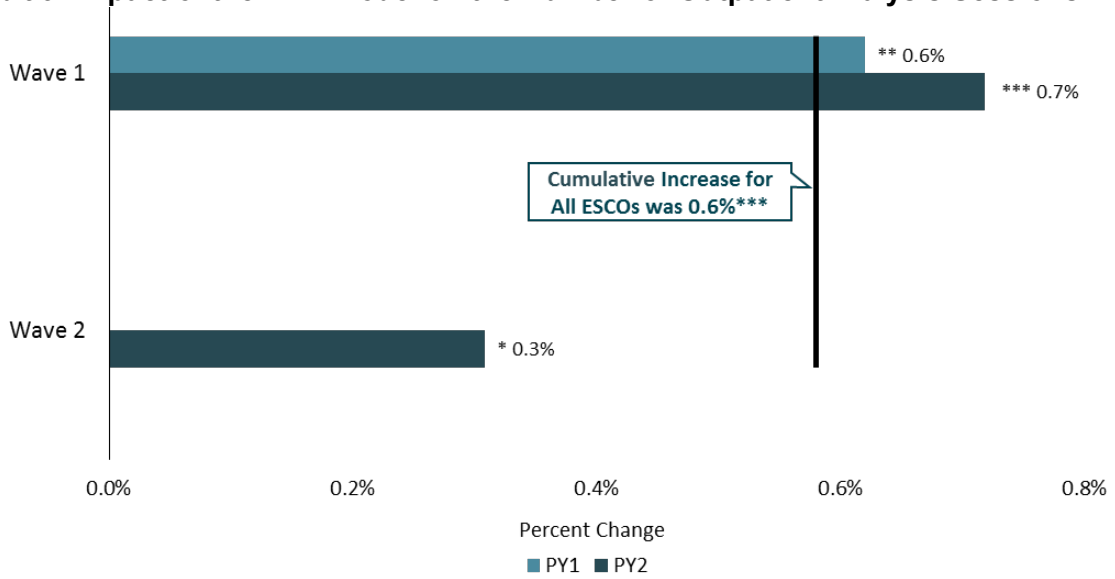
- increasing the number of treatment slots available at one or more CEC facilities to accommodate the need to provide extra treatments or reschedule missed treatments;
- building relationships with area EDs to help divert patients back to outpatient dialysis; and
- proactively communicating with patients who missed treatments.

To assess the success of these strategies, we evaluated whether the model impacted the frequency of dialysis sessions, the frequency of gaps in dialysis, and the use of emergency

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

dialysis sessions. We found modest evidence that supports improvement in these measures. Overall outpatient dialysis sessions increased by 0.6% ($p \leq 0.01$). Results were mainly driven by Wave 1 CEC beneficiaries, who saw an increase of 0.6% ($p \leq 0.05$) in PY1 and of 0.7% ($p \leq 0.01$) in PY2 (see **Exhibit 9**). The corresponding increase for Wave 2 CEC beneficiaries was 0.3% ($p \leq 0.10$). Each of these changes represents the differential trend between the CEC and comparison group before and after the CEC Model. There are a few potential reasons for the different results across waves. It is possible that the stronger results for Wave 1 are the consequence of the greater lead-in time between initial application and the model start. Wave 1 ESCOs may also have been more motivated to participate in the model and therefore expended greater effort into quality improvement. The 0.6% increase in outpatient dialysis sessions translates into an increase of 71 outpatient sessions per 1,000 beneficiaries per month for CEC beneficiaries[41] (see **Appendix Exhibit F-18**). We found there were no statistically significant impacts on the percent of beneficiaries who experienced a gap in dialysis. See **Appendix F** for detailed results: **Exhibit F-18** (All ESCOs), **Exhibit F-19** (Wave 1), and **Exhibit F-20** (Wave 2).[42] Overall, the results are consistent with the expectation that the CEC Model would create incentives to avoid or reschedule missed treatments in the outpatient setting.

Exhibit 9. Impact of the CEC Model on the Number of Outpatient Dialysis Sessions PBPM



Notes: Performance year one (PY1) covers October 2015 - December 2016, PY2 covers January 2017 - December 2017. All ESCOs estimates include both waves from October 2015 - December 2017. The estimate of All ESCOs is the combined cumulative impact of CEC, accounting for different lengths of exposure to the model. About 33% of facilities have nine quarters of CEC participation (October 2015 to December 2017); the remaining 67% participated in CEC from January 2017 to December 2017 (four quarters). A weighted average of the performance years by wave may not exactly equal the All ESCO result because the All ESCO and the wave-PY specific estimates were generated by separate regression models. 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 the intervention period with baseline relative to the same difference over time for beneficiaries in matched comparison facilities. Significance of the DiD impact estimate is indicated next to each

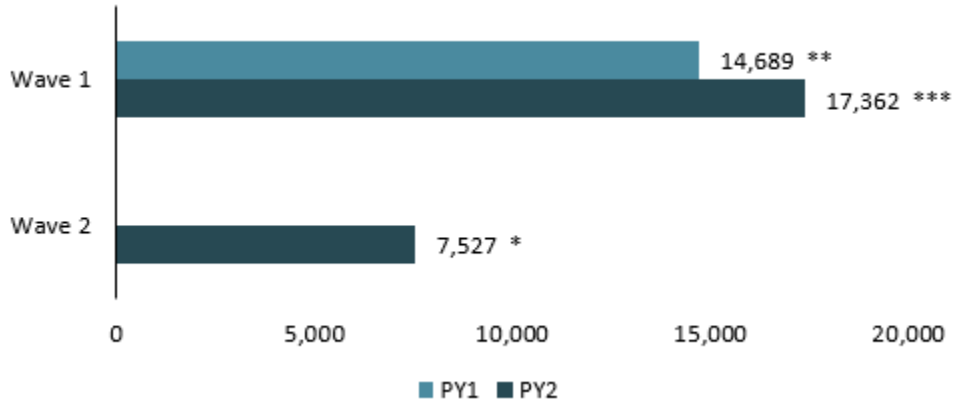
[41] DiD values are estimated at the PBPM level and transformed post estimation to per 1,000 beneficiaries per month values. Since the per 1,000 beneficiaries per month values are linear transformations of the PBPM DiD estimates, the percent change values are identical for both levels.

[42] The denominator excluded patients who may have fewer dialysis sessions due to the following reasons: dialysis started in the month, beneficiary died in the month, kidney transplant in the month, resumption of dialysis in the month following a failed transplant, or inpatient admission in the month.

outcome bar plot where * implies significance at the 10% level, ** at the 5% level, and *** at the 1% level assuming a two-tailed test.

In aggregate, the CEC Model increased the number of outpatient dialysis sessions by about 14,700 and 25,000 total additional dialysis sessions in PY1 and PY2, respectively (**Exhibit 10**). The increase from PY1 to PY2 was driven by the larger impact Wave 1 ESCOs had in PY2 relative to PY1 (from 14, 689 to 17,732) and the additional 7,527 dialysis sessions added by Wave 2 in PY2.

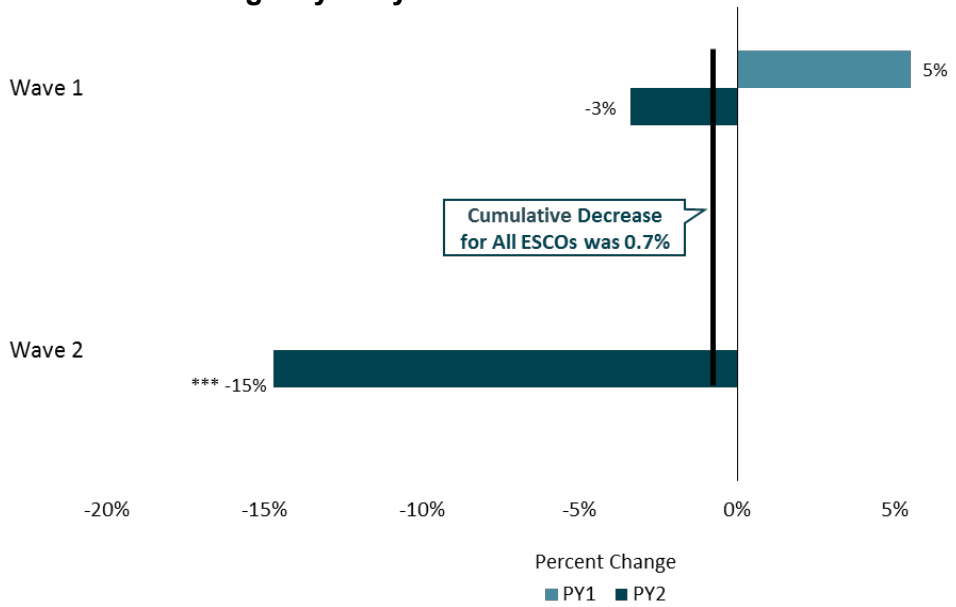
Exhibit 10. Impact of the CEC Model on the Aggregate Number of Outpatient Dialysis Sessions



Notes: Significance of the DiD impact estimate is indicated next to each outcome bar plot where * implies significance at the 10% level, ** at the 5% level, and *** at the 1% level assuming a two-tailed test. Aggregate estimates are based on the estimated total number of aligned intervention member months for the 685 CEC facilities participating in the CEC Model.

Overall, emergency dialysis sessions, i.e., dialysis sessions identified in claims that are unscheduled and occur in a non-dialysis facility setting, were unaffected by the CEC Model, as shown in in **Exhibit 11**. However, for Wave 2 ESCOs, the percent of beneficiaries with at least one emergency dialysis session decreased by 0.27 percentage points ($p \leq 0.01$) relative to the comparison group, which translates into a 15% reduction, relative to the pre-CEC period. Although not statistically significant, the trend of lower emergency dialysis rates in PY2 relative to PY1 for Wave 1 facilities is encouraging. See **Appendix F** for detailed results: **Exhibit F-18** (All ESCOs), **Exhibit F-19** (Wave 1), and **Exhibit F-20** (Wave 2).

Exhibit 11. Impact of the CEC Model on the Percent of Beneficiaries with at Least One Emergency Dialysis Session in a Given Month



Notes: PY1 covers October 2015 - December 2016, PY2 covers January 2017 - December 2017. All ESCOs estimates include both waves from October 2015 - December 2017. The estimate of All ESCOs is the combined cumulative impact of CEC, accounting for different lengths of exposure to the model. About 33% of facilities have nine quarters of CEC participation (October 2015 to December 2017); the remaining 67% participated in CEC from January 2017 to December 2017 (four quarters). A weighted average of the performance years by wave may not exactly equal the All ESCO result because the All ESCO and the wave-PY specific estimates were generated by separate regression models. 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 the intervention period with baseline relative to the same difference over time for beneficiaries in matched comparison facilities. Significance of the DiD impact estimate is indicated next to each outcome bar plot where * implies significance at the 10% level, ** at the 5% level, and *** at the 1% level assuming a two-tailed test.

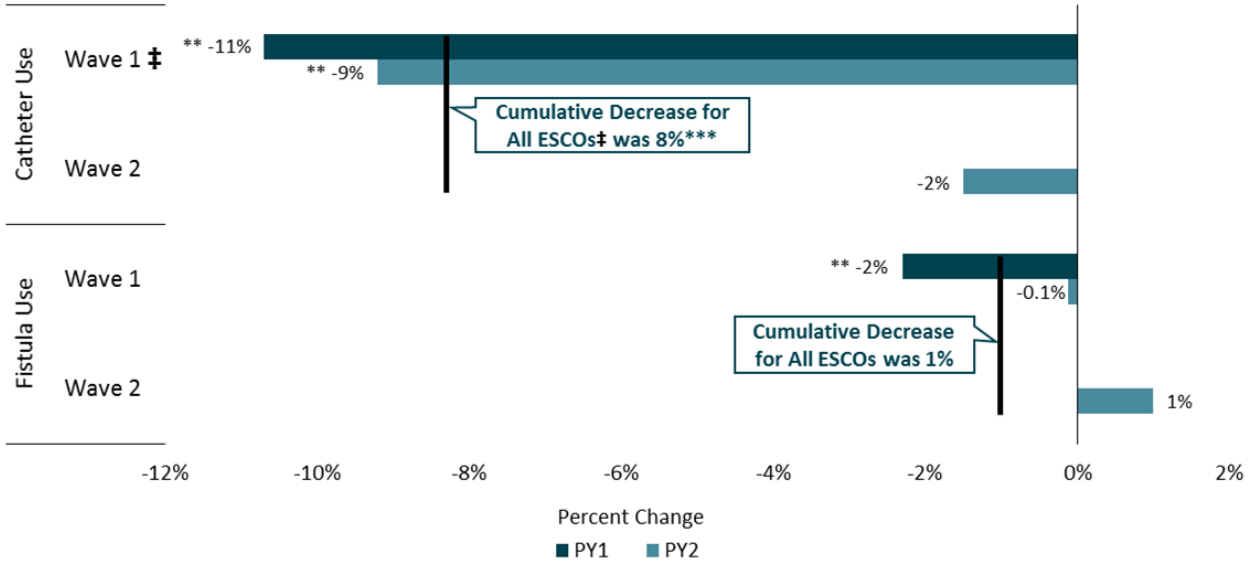
b. Vascular Access Type

There is a relatively high frequency of infections and infection-related hospitalizations in chronic dialysis patients with tunneled catheters as a means of vascular access. Hence, we anticipate that ESCOs may focus additional resources on prevention of these infections through successful creation of arteriovenous (AV) fistula and AV graft. The effect of the model on vascular access patterns was ambiguous, with an improvement (decline) in catheter rates in ESCOs relative to the comparison group, but a worsening (decline) in fistula rates in ESCOs relative to the comparison group. However, the magnitude of the relative change in catheter use was much larger than the change in fistula use, suggesting that overall vascular access patterns became more favorable in ESCOs. A number of ESCOs indicated that partnerships, formal or informal, with vascular surgeons were an important part of their strategy to reduce vascular access complications.[43] Furthermore, the opportunities for coordination of care through the ESCO may allow for improved vascular access results. We anticipate improvements in vascular access placement, with reduced rates of tunneled catheter use and increased rates of permanent AV access (AV fistula and AV graft) over the course of the CEC Model.

[43] Tunneled catheters are tubes surgically placed under the skin and underlying tissues (tunneled) into a large vein, usually in a patient's neck or chest, to allow access to the patient's bloodstream for dialysis treatments.

The results, presented in **Exhibit 12**, show that catheter use among CEC beneficiaries significantly declined relative to the comparison group. The percent of CEC beneficiaries who used catheters as a means of vascular access for 90 days or more remained constant from the pre-CEC to the post-CEC period, while it increased for the comparison group. As a result of the CEC Model, the percent of CEC beneficiaries who used catheters in a given month decreased by 0.78 percentage points ($p \leq 0.01$), relative to the comparison group, an 8% reduction relative to the pre-CEC period.[44] This result was driven by Wave 1 ESCOs, with no statistically significant change among Wave 2 ESCOs. There was no statistically significant relative cumulative impact on fistula use (see **Appendix F**, **Exhibits F-18** (All ESCOs), **F-19** (Wave 1), and **F-20** (Wave 2)).

Exhibit 12. Impact of the CEC Model on the Percent of Beneficiaries by Vascular Access Type in a Given Month



Notes: PY1 covers October 2015 - December 2016, PY2 covers January 2017 - December 2017. All ESCOs estimates include both waves from October 2015 - December 2017. The estimate of All ESCOs is the combined cumulative impact of CEC, accounting for different lengths of exposure to the model. About 33% of facilities have nine quarters of CEC participation (October 2015 to December 2017); the remaining 67% participated in CEC from January 2017 to December 2017 (four quarters). A weighted average of the performance years by wave may not exactly equal the All ESCO result because the All ESCO and the wave-PY specific estimates were generated by separate regression models. 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 the intervention period with baseline relative to the same difference over time for beneficiaries in matched comparison facilities. Estimate label values are rounded to the nearest whole number, therefore bar lengths may differ despite showing the same rounded label value. Significance of the DiD impact estimate is indicated next to each outcome bar plot where * implies significance at the 10% level, ** at the 5% level, and *** at the 1% level assuming a two-tailed test. ‡ Data from the baseline period showed intervention and matched comparison facilities were not on parallel trends for this outcome, which is required for an unbiased impact estimate.

c. CEC Patients' Experience with Dialysis Care

Overall, there was no evidence of improvement in patients' experience of care as measured by the ICH CAHPS survey measures. However, there is also no evidence of any decrease in quality of dialysis care as captured by the survey. Although reduced quality is a potential concern in any

[44] Catheter did not pass statistical testing of the parallel trends assumption. However, visual inspection of the trend graph which compared trends between the treatment (CEC) and comparison group yielded no obvious differences. Additionally, the trend coefficient although significant, equals 0.00046.

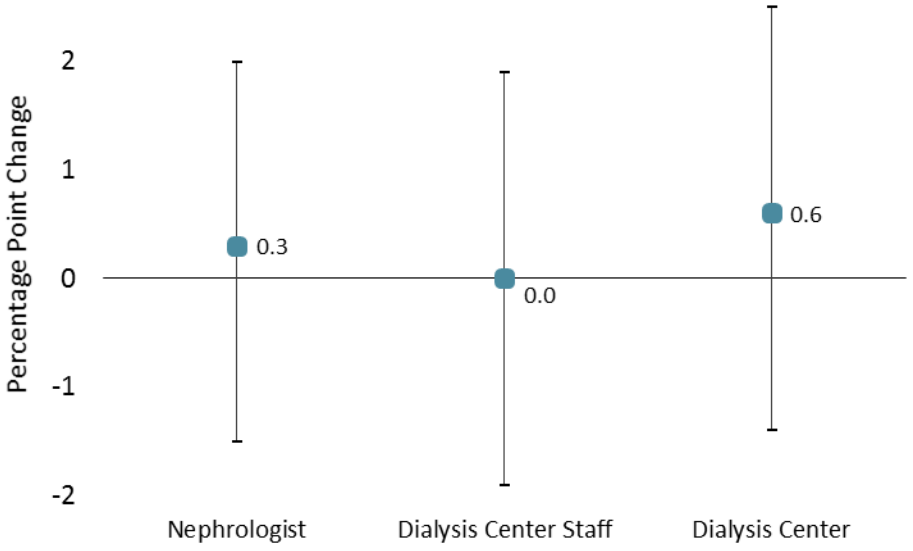
model intended to drive down total cost of care in a vulnerable population, we did not anticipate such an effect given the existing P4P and quality reporting initiatives applying to all dialysis facilities.

Specifically, the CEC Model did not have statistically significant impacts on the percent of beneficiaries who reported the highest level of satisfaction with care (i.e., top-box level) across the ICH CAHPS measures examined. The eight ICH CAHPS measures evaluated included three global ratings measures (**Exhibit 13**), two individual survey items (**Exhibit 14**), and three composite score measures (**Exhibit 15**). We provide additional descriptive statistics for each measure by wave and performance year in **Appendix H**.

On average, the ICH CAHPS responses observed for both the CEC facilities and comparison facilities were similar to national averages across all response levels (i.e., top, middle, and bottom). The post-CEC comparison facility values were similar to the national averages whereas the post-CEC values in CEC facilities were slightly lower. **Exhibit H-4** in **Appendix H** presents the 2017 national average for the global ICH CAHPS ratings and composite scores, for purposes of comparison.

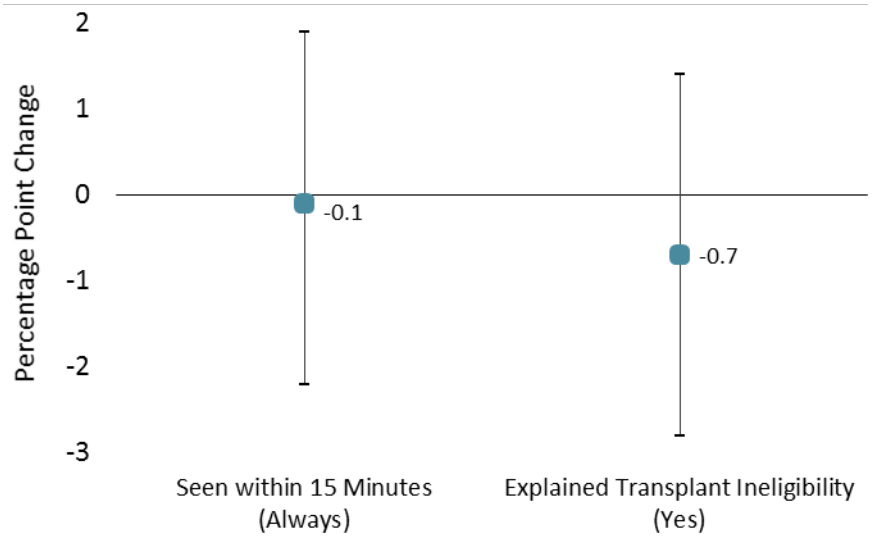
Survey response rates may affect our interpretation of these results. The response rates for CEC and comparison facilities were 41% and 36%, respectively. Consequently, we cannot assess if the observed results are representative of the larger proportion of beneficiaries who did not respond.

Exhibit 13. Impact of CEC on ICH CAHPS Global Ratings Measures
Percent of Beneficiaries Reporting Highest Level of Satisfaction



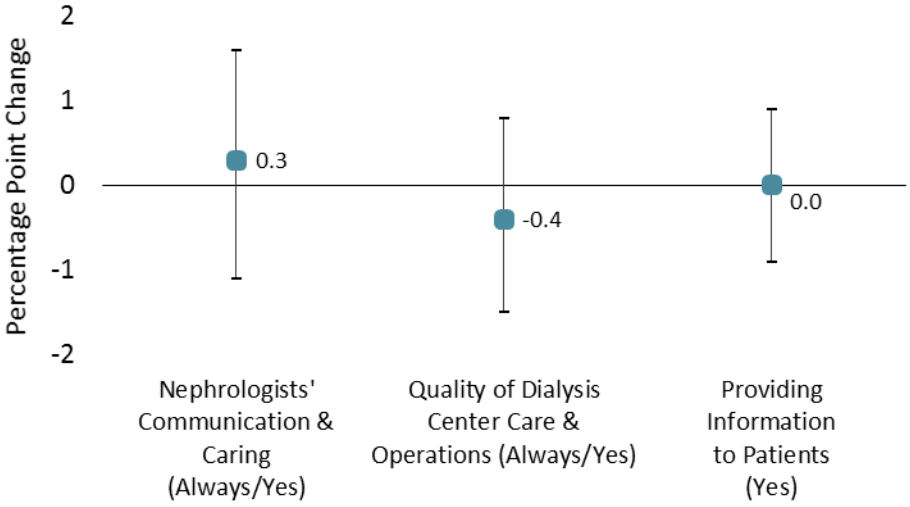
Notes: This analysis included results from the fall 2014 through the fall 2017 ICH CAHPS surveys, which encompass the pre-period, PY1, and PY2. Plotted values are the DiD estimates and 90% confidence intervals. The responses categorized as top box include responses of 9 or 10 on a scale of 0 (worst) to 10 (best). Individual questions are available in **Appendix H**.

Exhibit 14. Impact of CEC on ICH CAHPS Individual Survey Items
Percent of Beneficiaries Reporting Highest Level of Satisfaction



Notes: This analysis included results from the fall 2014 through the fall 2017 ICH CAHPS surveys, which encompass the pre-period, PY1, and PY2. Plotted values are the DiD estimates and 90% confidence intervals. Individual questions are available in **Appendix H**.

Exhibit 15. Impact of CEC on ICH CAHPS Composite Score Measures
Percent of Beneficiaries Reporting Highest Level of Satisfaction



Notes: This analysis included results from the fall 2014 through the fall 2017 ICH CAHPS surveys, which encompass the pre-period, PY1, and PY2. Plotted values are the DiD estimates and 90% confidence intervals. Individual questions are available in **Appendix H**.

2. What Was the Impact of CEC on the Coordination of Care beyond Dialysis?

Because ESCOs are accountable for all of a beneficiary's Medicare Parts A and B costs, providers have the incentive to invest in preventive services and chronic disease management activities beyond their standard dialysis care. ESCOs reported various efforts to coordinate non-dialysis care for aligned beneficiaries, such as promoting preventive health, chronic disease management, and the use of other services such as hospice. We evaluated whether the CEC

Model increased the use of preventive health services, such as lab tests and immunizations, care correlated with chronic disease management, such as evaluation and management (E&M) office visits and selected medication management outcomes, and hospice referral.

ESCOs can also reduce spending by providing additional care in the later stages of CKD to improve outcomes once dialysis starts. Adverse outcomes after the start of dialysis are associated with unplanned dialysis starts or inadequate preparation for dialysis.[45] Several ESCOs indicated that they were attempting to improve pre-dialysis care for this reason. To assess the extent ESCOs focused on improving pre-dialysis care, we investigated the impact of the model on the percent of beneficiaries who receive nephrology care before the start of dialysis.[46]

Overall, we found some evidence that the CEC Model improved coordination of care beyond dialysis.

a. Preventive Care

Overall, the CEC Model increased the use of preventive care screening tests and labs as shown in **Exhibit 16**. These included testing for HbA1c,[47] low-density lipoprotein (LDL) cholesterol control, and dilated eye exams for beneficiaries with ESRD that are diabetic. These measures are important to consider because of the high rate of comorbidity of diabetes and heart disease in the ESRD population. In addition, dilated eye exams for diabetic beneficiaries is one of the quality measures that determine ESCOs total quality performance for shared savings calculations.[48]

While there was an increase in all three preventive care measures across all ESCOs, estimates were primarily driven by Wave 1 ESCOs with positive impacts in two of the three measures in PY1 and in all three measures in PY2. Wave 2 ESCOs' only statistically significant estimate was for HbA1c testing. See additional results in **Appendix F**, **Exhibits F-21** (All ESCOs), **F-22** (Wave 1), and **F-23** (Wave 2). There was no statistically significant impact of CEC on the rate of flu vaccinations among CEC beneficiaries among Wave 1 ESCOs (see **Appendix F**, **Exhibit F-22**).[49]

[45] Molnar, Amber O. et al. "Risk Factors for Unplanned and Crash Dialysis Starts: A Protocol for a Systematic Review and Meta-Analysis." Systematic Reviews 5 (2016): 117. PMC. Web. 18 Sept. 2018.

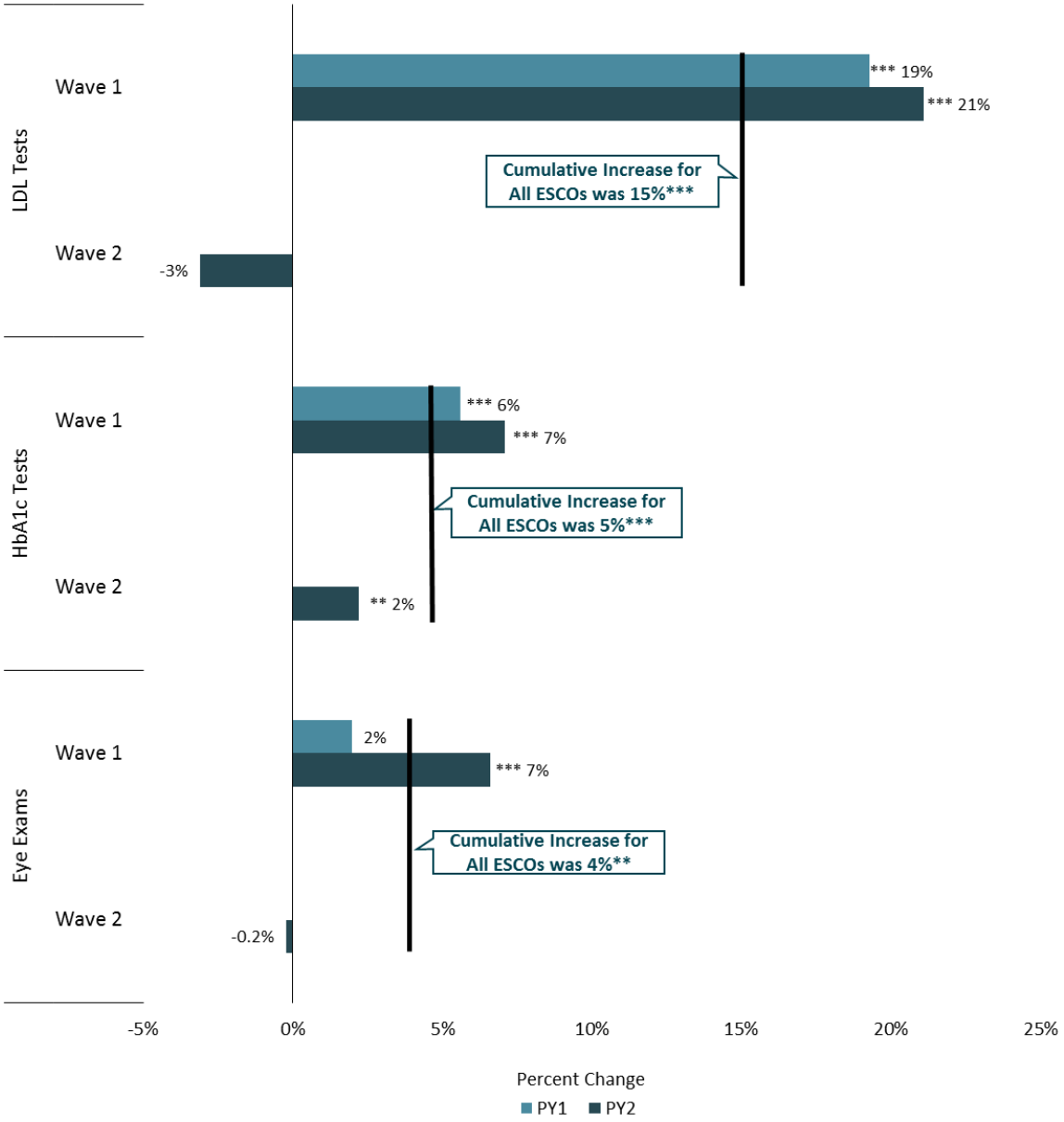
[46] A beneficiary was considered to have no prior dialysis care if their first vascular access type was not a graft or fistula and if they did not have select services such as treatment by a nephrologist, kidney dietician, or receive erythropoietin.

[47] According the to the 2017 USRD Report HbA1c testing has been decreasing over time and may reflect an increasing awareness of the limitations of HbA1c as an indicator of average glycemia in diabetic patients with ESRD.

[48] See https://innovation.cms.gov/initiatives/comprehensive-esrd-care/ for the full CEC quality performance set.

[49] The flu season is defined as October through March. Based on the data used for this analysis a full flu season for late starting Wave 1 facilities and Wave 2 ESCOs was not available. As a result, the flu estimate only represents Wave 1 facilities that started in October 2015 (Wave 1.1). 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 the intervention period with baseline relative to the same difference over time for beneficiaries in matched comparison facilities.

Exhibit 16. Impact of the CEC Model on the Percent of Beneficiaries Receiving at Least One Test for a Given Preventive Measure in a Given Year



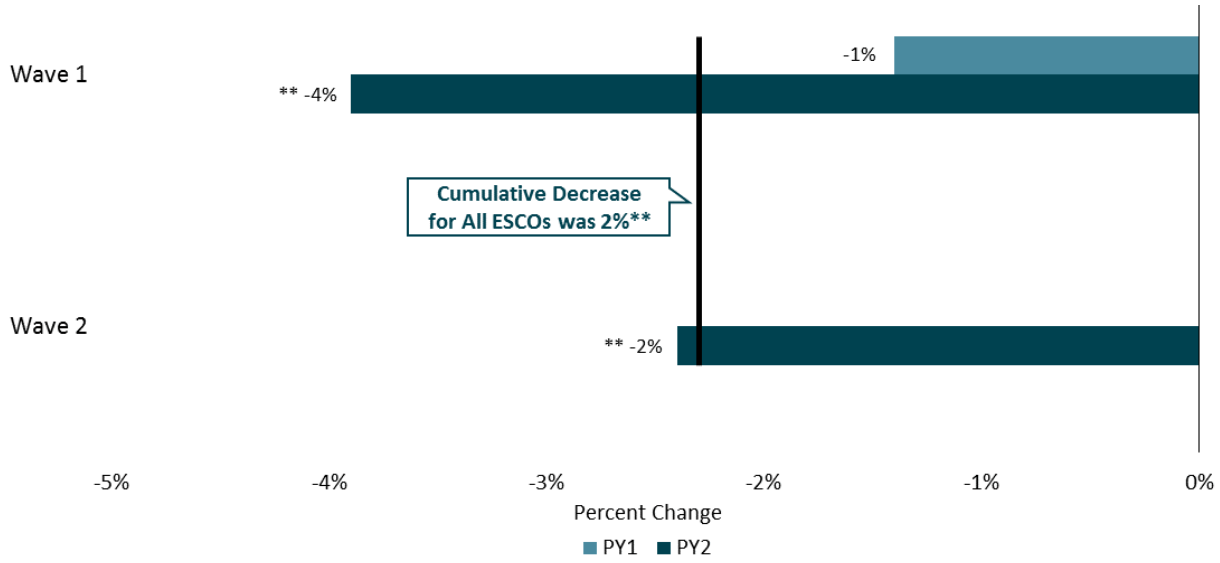
Notes: Preventive care measures are evaluated at the yearly level. PY1 is defined as 2016 and PY2 is defined as 2017. All ESCOs estimates include both waves from 2016 through 2017. The estimate of All ESCOs is the combined cumulative impact of CEC, accounting for different lengths of exposure to the model. About 33% of facilities have nine quarters of CEC participation (October 2015 to December 2017); the remaining 67% participated in CEC from January 2017 to December 2017 (four quarters). A weighted average of the performance years by wave may not exactly equal the All ESCO result because the All ESCO and the wave-performance year specific estimates were generated by separate regression models. 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 the intervention period with baseline relative to the same difference over time for beneficiaries in matched comparison facilities. Estimate label values are rounded to the nearest whole number, therefore bar lengths may differ despite showing the same rounded label value. Significance of the DiD impact estimate is indicated next to each outcome bar plot where * implies significance at the 10% level, ** at the 5% level, and *** at the 1% level assuming a two-tailed test.

b. Evaluation and Management Office Visits

Under the CEC Model we observed a significant decline in E&M office visits (**Exhibit 17**). Specifically, compared to the pre-CEC period, office visits declined by 2% ($p \leq 0.05$). This reduction translates into 57 fewer office visits per 1,000 beneficiaries per month. There were statistically significant declines for both waves in PY2, with a larger impact for Wave 1 of 96 visits per 1,000 beneficiaries per month versus 59 visits per 1,000 beneficiaries per month for Wave 2.

The interpretation of this finding is unclear, as we expected to see an increase in office visits due to ESCOs' incentives to enhance identification and management of comorbidities. One potential explanation is that the CEC Model allows participating nephrologists to address more primary care needs in addition to dialysis care, which would reduce the need for additional E&M visits from primary care doctors. Future evaluation work will disentangle changes in primary and specialty care office visits by specialty. See **Appendix F** for detailed results: **Exhibit F-21** (All ESCOs), **Exhibit F-22** (Wave 1), and **Exhibit F-23** (Wave 2).

Exhibit 17. Impact of the CEC Model on the Number of Office Visits PBPM



Notes: PY1 covers October 2015 - December 2016, PY2 covers January 2017 - December 2017. All ESCOs estimates include both waves from October 2015 - December 2017. The estimate of All ESCOs is the combined cumulative impact of CEC, accounting for different lengths of exposure to the model. About 33% of facilities have nine quarters of CEC participation (October 2015 to December 2017); the remaining 67% participated in CEC from January 2017 to December 2017 (four quarters). A weighted average of the performance years by wave may not exactly equal the All ESCO result because the All ESCO and the wave-performance year specific estimates were generated by separate regression models. 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 the intervention period with baseline relative to the same difference over time for beneficiaries in matched comparison facilities. Estimate label values are rounded to the nearest whole number, therefore bar lengths may differ despite showing the same rounded label value. Significance of the DiD impact estimate is indicated next to each outcome bar plot where * implies significance at the 10% level, ** at the 5% level, and *** at the 1% level assuming a two-tailed test.

c. Hospice Referral

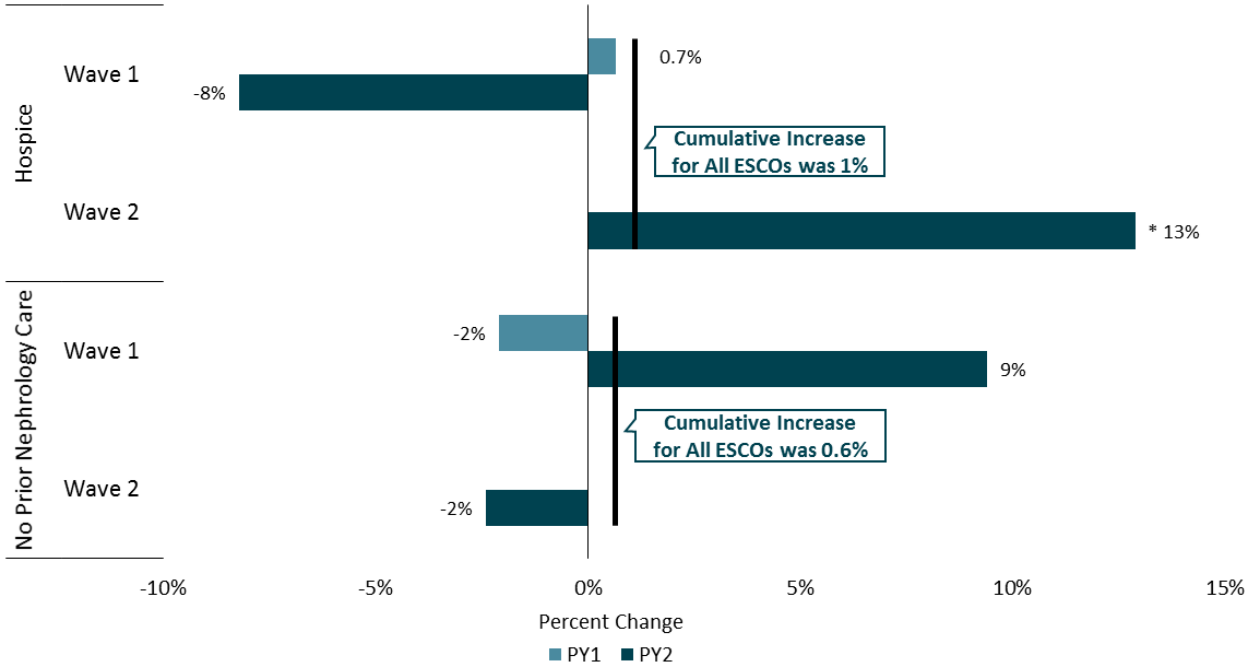
Although some ESCOs reported offering more education about hospice and end-of-life care through their partnerships with palliative care organizations, there was no indication that CEC

affected hospice use (**Exhibit 18**). Data on hospice use can exhibit considerable variation: for example, Wave 2 ESCOs had a 13% increase ($p \leq 0.10$) in the percent of CEC beneficiaries who received hospice care in a given month. The Wave 2 result was driven by a relative decline in hospice use in the comparison group, but the rates in both the CEC and comparison group remained small and differences were likely not clinically meaningful.

d. Prior Nephrology Care

We expected the model to increase pre-dialysis care, however, there were no statistically significant changes in the percent of beneficiaries who started dialysis with no prior nephrology care. Future evaluation work will continue to investigate changes in beneficiaries who receive nephrology care prior to starting dialysis and differences in this outcome by ownership type (profit vs. not-for-profit). See **Appendix F** for detailed results: **Exhibits F-21** (All ESCOs), **Exhibit F-22** (Wave 1), and **Exhibit F-23** (Wave 2).

Exhibit 18. Impact of the CEC Model on the Percent of Beneficiaries Receiving at Least One Hospice Service and Percent of Beneficiaries with No Prior Nephrology Care in a Given Month



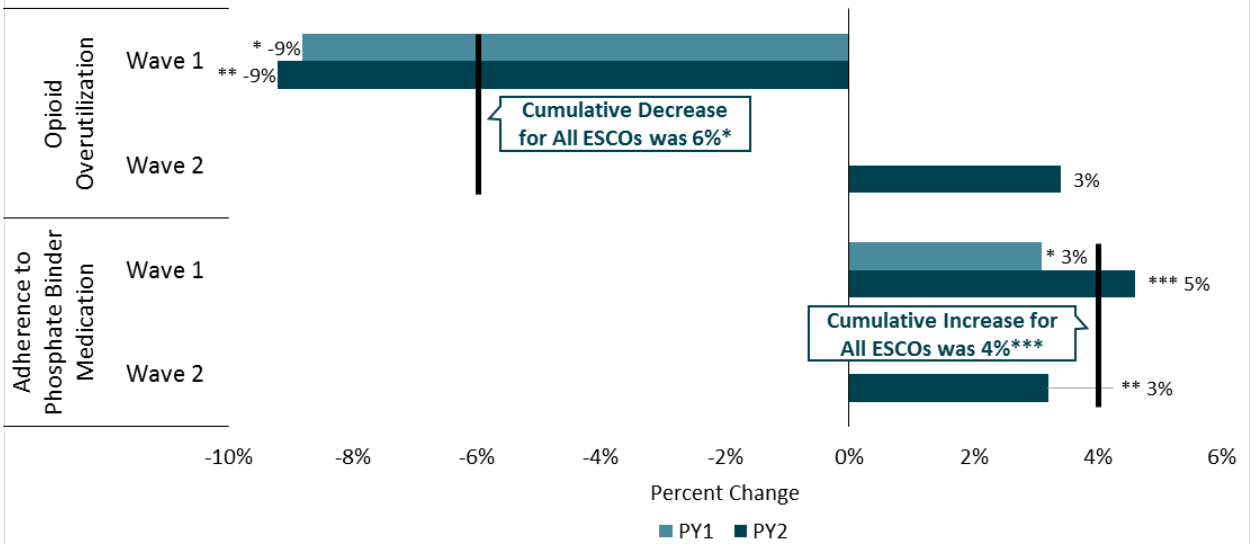
Notes: PY1 covers October 2015 - December 2016, PY2 covers January 2017 - December 2017. All ESCOs estimates include both waves from October 2015 - December 2017. The estimate of All ESCOs is the combined cumulative impact of CEC, accounting for different lengths of exposure to the model. About 33% of facilities have nine quarters of CEC participation (October 2015 to December 2017); the remaining 67% participated in CEC from January 2017 to December 2017 (four quarters). A weighted average of the performance years by wave may not exactly equal the All ESCO result because the All ESCO and the wave-performance year specific estimates were generated by separate regression models. 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 the intervention period with baseline relative to the same difference over time for beneficiaries in matched comparison facilities. Estimate label values are rounded to the nearest whole number, therefore bar lengths may differ despite showing the same rounded label value. Significance of the DiD impact estimate is indicated next to each outcome bar plot where * implies significance at the 10% level, ** at the 5% level, and *** at the 1% level assuming a two-tailed test.

e. Medication Management

Several ESCOs adopted new medication reconciliation practices in order to reduce the incidence of complications that require urgent care from an ED and can potentially result in a hospitalization. Therefore, we expected improved medication management. We evaluated the impact of medication reconciliation on reducing opioid overuse and use of contraindicated medications, and improving phosphate binder adherence. These three measures were restricted to beneficiary months where the beneficiary with ESRD had Medicare Part D coverage, which was approximately 83% of the sample.

The CEC Model had a statistically significant, favorable impact on opioid overuse and phosphate binder adherence (**Exhibit 19**). We measured opioid overuse as the percent of beneficiaries who had an average daily morphine milligram equivalent (MME) greater than 50 milligrams: overuse declined by 6% ($p \leq 0.10$), relative to the pre-CEC period. Both Wave 1 and Wave 2 CEC beneficiaries showed improved adherence to phosphate binders, which can prevent toxic build-ups in patients with ESRD between dialysis sessions. Overall, all ESCOs' phosphate binder adherence rates increased by 4% ($p \leq 0.01$), relative to the pre-CEC period. Wave 1 CEC beneficiaries showed improved phosphate binder adherence from PY1 to PY2, as the rate of beneficiaries with at least 80% of their days covered in a month increased from 3% ($p \leq 0.10$) in PY1 to 5% ($p \leq 0.01$) in PY2.

Exhibit 19. Impact of the CEC Model on the Percent of Beneficiaries Overutilizing Opioids and Adhering to Phosphate Binder Medication in a Given Month



Notes: PY1 covers October 2015 - December 2016, PY2 covers January 2017 - December 2017. All ESCOs estimates include both waves from October 2015 - December 2017. The estimate of All ESCOs is the combined cumulative impact of CEC, accounting for different lengths of exposure to the model. About 33% of facilities have nine quarters of CEC participation (October 2015 to December 2017); the remaining 67% participated in CEC from January 2017 to December 2017 (four quarters). A weighted average of the performance years by wave may not exactly equal the All ESCO result because the All ESCO and the wave-performance year specific estimates were generated by separate regression models. 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 the intervention period with baseline relative to the same difference over time for beneficiaries in matched comparison facilities. Estimate label values are rounded to the nearest whole number, therefore bar lengths may differ despite showing the same rounded label value. Significance of the DiD impact estimate is indicated next to each

outcome bar plot where * implies significance at the 10% level, ** at the 5% level, and *** at the 1% level assuming a two-tailed test.

Finally, we evaluated whether there was an impact of the CEC Model on the use of medications that could be contraindicated for beneficiaries with ESRD, such as Nitroprusside, which is associated with reduced nitroprusside metabolite and eventually toxicity.[50] There were no statistically significant impacts of CEC Model on contraindicated medication use (see **Appendix F**, **Exhibits F-21** (All ESCOs), **F-22** (Wave 1), and **F-23** (Wave 2)).

3. What Was the Impact of CEC on Hospitalizations and Emergency Department Visits?

The CEC Model involves incentives, through the shared savings model, for better coordination across the continuum of care in order to reduce expensive inpatient utilization. Hospital admissions and readmissions are a major burden for patients with ESRD, who on average are admitted to the hospital nearly twice a year.[51] Inpatient treatment also accounted for about 33% of total Medicare expenditures for beneficiaries with ESRD.[52] All ESCOs described efforts to reduce ED visits and hospitalizations through improved risk stratification and post discharge coordination with local hospitals. We assessed the impact of CEC on these key utilization outcomes and overall, our findings suggest that CEC beneficiaries were less likely to be hospitalized and had fewer hospitalizations relative to the comparison group. CEC beneficiaries were also less likely to have an ED visit or readmission, though the number of ED visits and readmissions did not decrease significantly relative to the comparison group. Reductions in these key measures were driven by Wave 1 ESCOs and increased over time, suggesting that with more experience in the model all ESCOs may be able to achieve meaningful effects on utilization.

a. Overall Hospitalizations, ED Visits, and Readmissions

Exhibit 20 presents the impact estimates of the CEC Model on the number of hospitalizations, ED visits, and readmissions PBPM. Consistent with the ESCOs' reported strategies to reduce hospitalizations, we found statistically significant net declines across PY1 and PY2 in the number of hospitalizations, relative to the comparison group. Specifically, the number of hospitalizations declined by 4% PBPM ($p \leq 0.01$), relative to the pre-CEC period. This impact estimate translates into a decrease of five hospitalizations per 1,000 beneficiaries per month, in CEC relative to the comparison group. This result is exclusively due to Wave 1 ESCOs, which experienced a 4% PBPM ($p \leq 0.05$) reduction in hospitalizations in PY1 and a 5% PBPM ($p \leq 0.01$) reduction in PY2, relative to the Wave 1 pre-CEC period. Overall there was no significant change in the number of ED visits. However, Wave 1 ESCOs saw a 3% PBPM ($p \leq 0.05$) reduction in the number of ED visits in PY1, relative to the Wave 1 pre-CEC period. This result translates into seven fewer ED visits per 1,000 beneficiaries per month, in CEC

[50] A complete list of contraindicated medications is provided in **Appendix F**, **Exhibit F-3**.

[51] United States Renal Data System, 2017 Annual Data Report: Volume 2 (Chapter 4) – ESRD in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2017. https://www.usrds.org/2017/view/v2_04.aspx

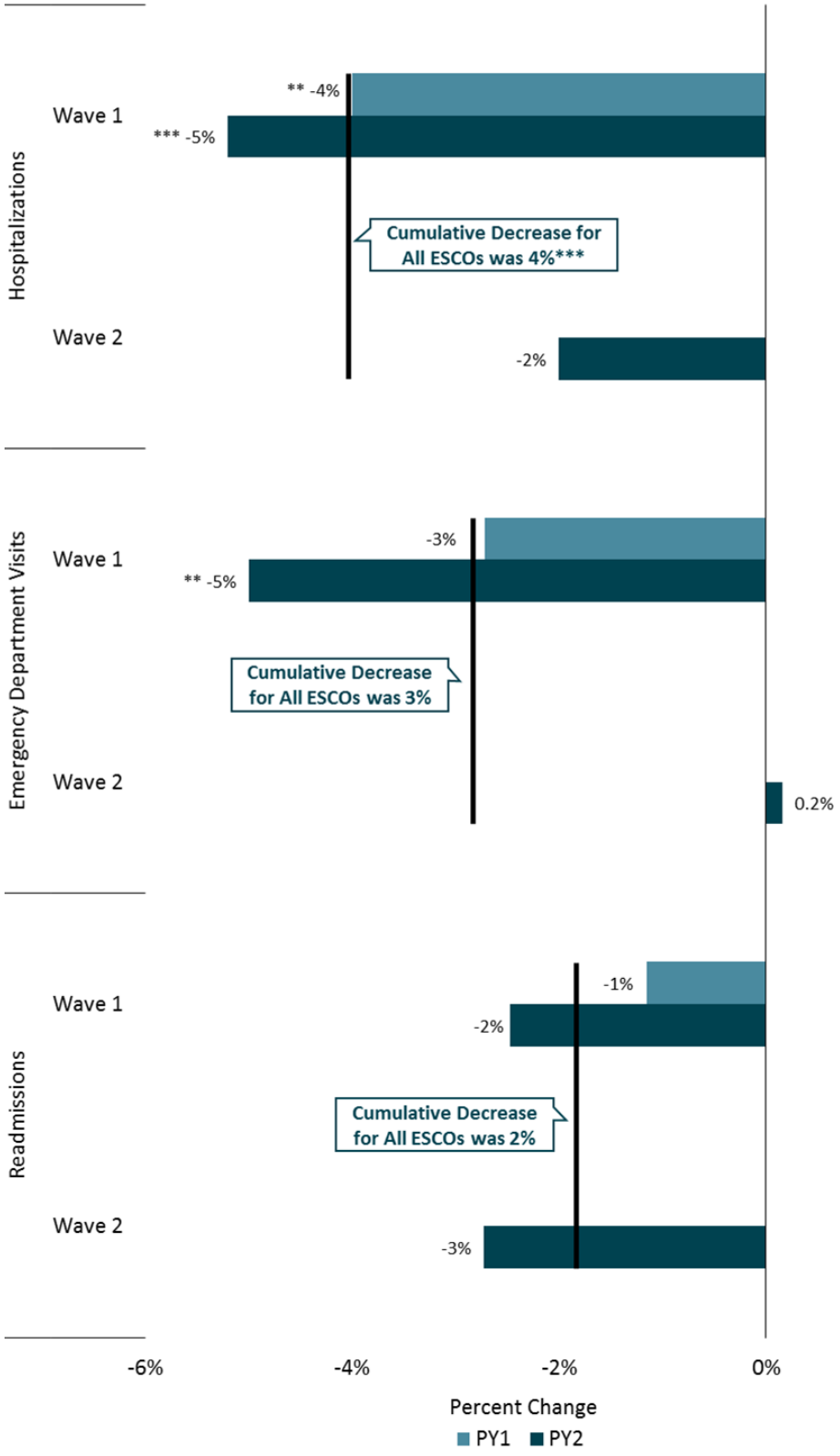
[52] United States Renal Data System, 2017 Annual Data Report: Volume 2 (Chapter 4) – ESRD in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2017. https://www.usrds.org/2017/view/v2_04.aspx

relative to the comparison group. While there were trends toward fewer readmissions, these results were not statistically significant.[53] See additional results in **Appendix F**, **Exhibit F-24** (All ESCOs), **Exhibit F-25** (Wave 1), and **Exhibit F-26** (Wave 2).

We also evaluated whether CEC beneficiaries were more or less likely to experience at least one hospitalization, ED visit, or readmission in a given month. Results are shown in **Appendix F**, **Exhibit F-24** (All ESCOs), **Exhibit F-25** (Wave 1), and **Exhibit F-26** (Wave 2). For all three measures, we found statistically significant cumulative reductions in the occurrence of these events in CEC beneficiaries relative to the comparison group across PY1 and PY2. The percent of CEC beneficiaries who experienced at least one hospitalization within a given months decreased by 4% ($p \leq 0.01$) relative to pre-CEC period. Additionally, the percent of CEC beneficiaries who experienced at least one ED visit declined by 3% ($p \leq 0.10$) and the percent that were readmitted to the hospital within a 30-day period declined by 2% ($p \leq 0.10$), relative to the pre-CEC period.

[53] The distribution of the number of occurrences (e.g., number of ED visits PBPM) may have high variance due to outlier observations, which can increase standard error estimates and make it more difficult to identify statistical significance.

Exhibit 20. Impact of the CEC Model on the Number of Hospitalizations, ED Visits, and Readmissions PBPM

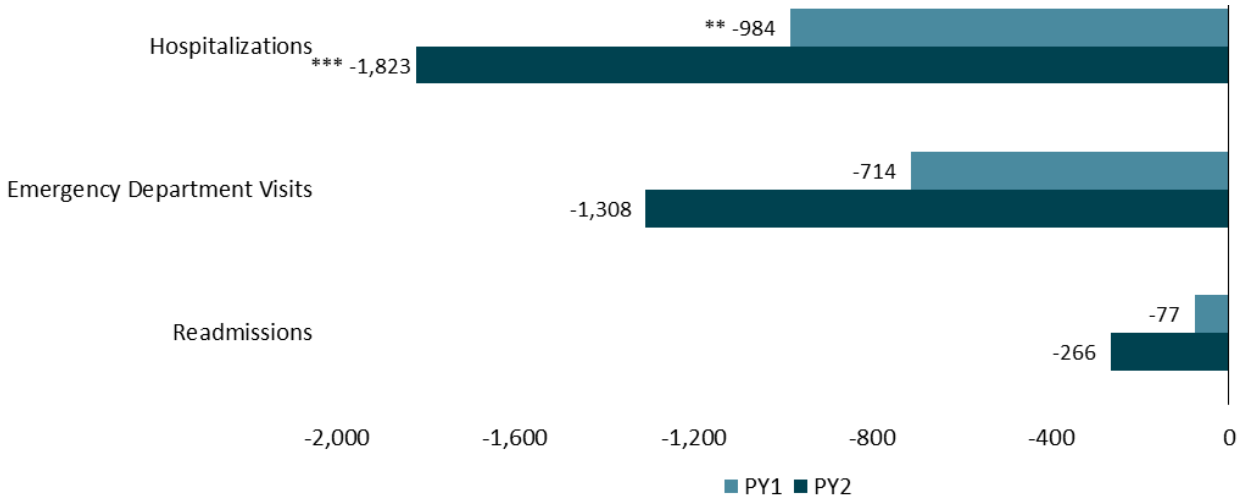


Notes: PY1 covers October 2015 - December 2016, PY2 covers January 2017 - December 2017. All ESCOs estimates include both waves from October 2015 - December 2017. The estimate of All ESCOs is the combined cumulative impact of CEC, accounting for different lengths of exposure to the model. About 33% of facilities have nine quarters of CEC participation (October 2015 to December 2017); the remaining 67% participated in CEC from January 2017 to December 2017 (four quarters). A weighted average of the performance years by wave may not exactly equal the All ESCO result because the All ESCO and the wave-performance year specific estimates were generated by separate regression models. 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 the intervention period with baseline relative to the same difference over time for beneficiaries in matched comparison facilities. Estimate label values are rounded to the nearest whole number, therefore bar lengths may differ despite showing the same rounded label value. Significance of the DiD impact estimate is indicated next to each outcome bar plot where * implies significance at the 10% level, ** at the 5% level, and *** at the 1% level assuming a two-tailed test.

Overall, these findings suggest that CEC beneficiaries were less likely to be hospitalized and had fewer hospitalizations relative to the comparison group. CEC beneficiaries were also less likely to have an ED visit or readmission, though the number of ED visits and readmissions did not decrease significantly relative to the comparison group. Reductions in these key measures were driven by Wave 1 ESCOs and increased over time, suggesting that with more experience in the model all ESCOs may be able to achieve meaningful effects on utilization.

Exhibit 21 shows the impact of CEC on the aggregate number of hospital admissions and ED visits by performance year. The statistically significant impact of the CEC Model on the number of hospitalizations translates into approximately 1,000 fewer admissions in PY1 and 1,800 fewer admissions in PY2.[54]

Exhibit 21. Impact of the CEC Model on the Aggregate Number of Hospitalizations, Emergency Department Visits, and Readmissions by PY

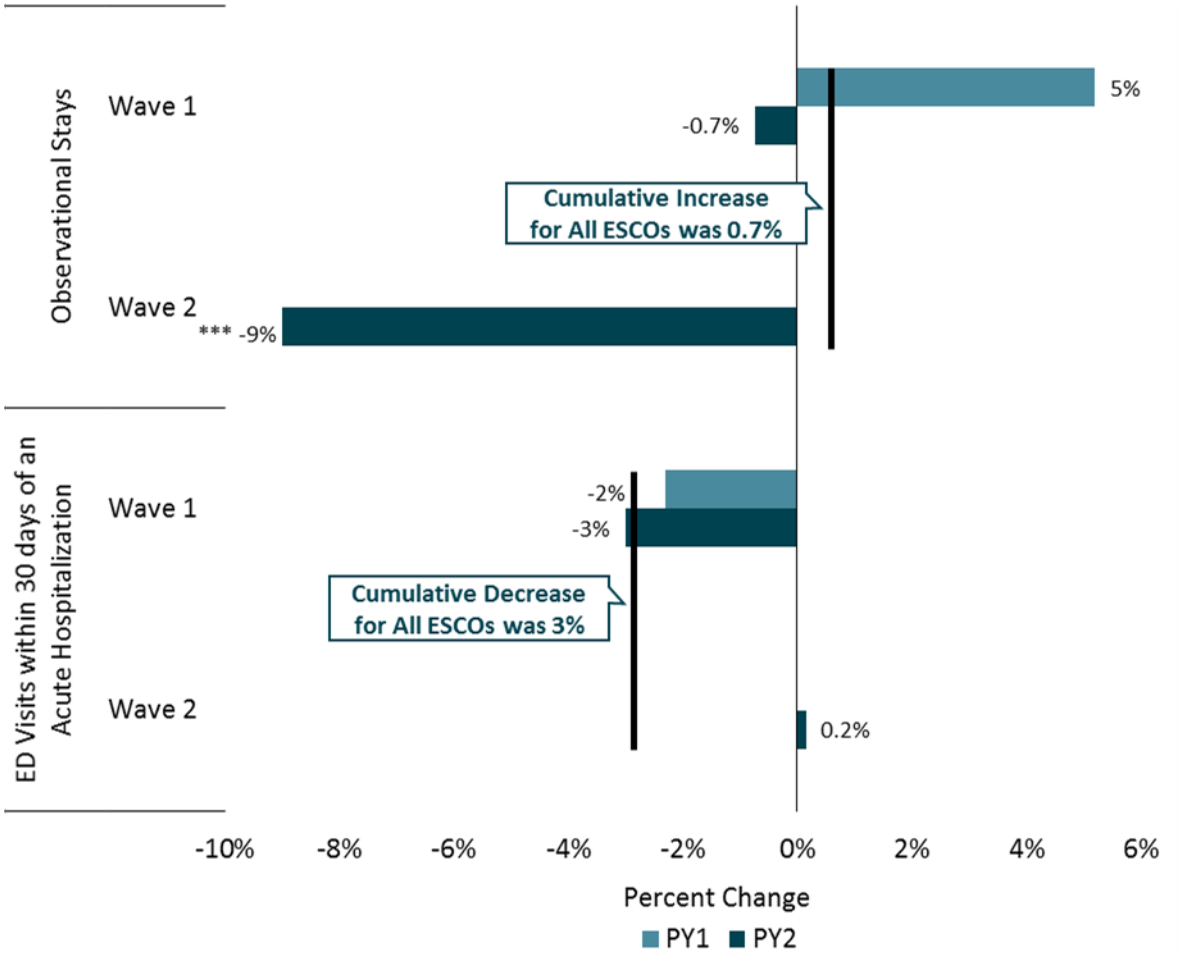


Notes: Significance of the DiD impact estimate is indicated next to each outcome bar plot where * implies significance at the 10% level, ** at the 5% level, and *** at the 1% level assuming a two-tailed test. Aggregate estimates are based on the estimated total number of aligned intervention member months for the 685 CEC facilities participating in the CEC Model. Readmission member months are adjusted for claims lag as well as the ratio of readmission observations to hospitalization observations to mimic the conditional relationship between these two outcomes.

[54] Aggregate estimates are based on the number of aligned performance period CEC member months and the PBPM DiD estimate for each outcome. For example, aggregate PY1 reduced number of hospitalizations equals 193,022 member months multiplied by -0.0051 PBPM hospitalizations which equals approximately 984 fewer estimated hospitalizations in PY1.

We also examined whether the rate of observational stays and ED visits within 30 days of an acute hospitalization changed for CEC beneficiaries. As shown in **Exhibit 22**, although no overall cumulative impact was detected in observational stays, an impact was detected among Wave 2 ESCOs. Specifically, Wave 2 ESCO beneficiaries were less likely to experience an observational stay in a given month by 9% ($p \leq 0.01$), relative to the Wave 2 pre-CEC period. The model did not significantly impact ED visits within 30 days of an acute hospitalization. Results are shown in **Appendix F**, **Exhibit F-24** (All ESCOs), **Exhibit F-25** (Wave 1), and **Exhibit F-26** (Wave 2).

Exhibit 22. Impact of the CEC Model on the Percent of Beneficiaries with at Least One Observational Stay and at Least One ED Visit within 30 days of an Acute Hospitalization in a Given Month



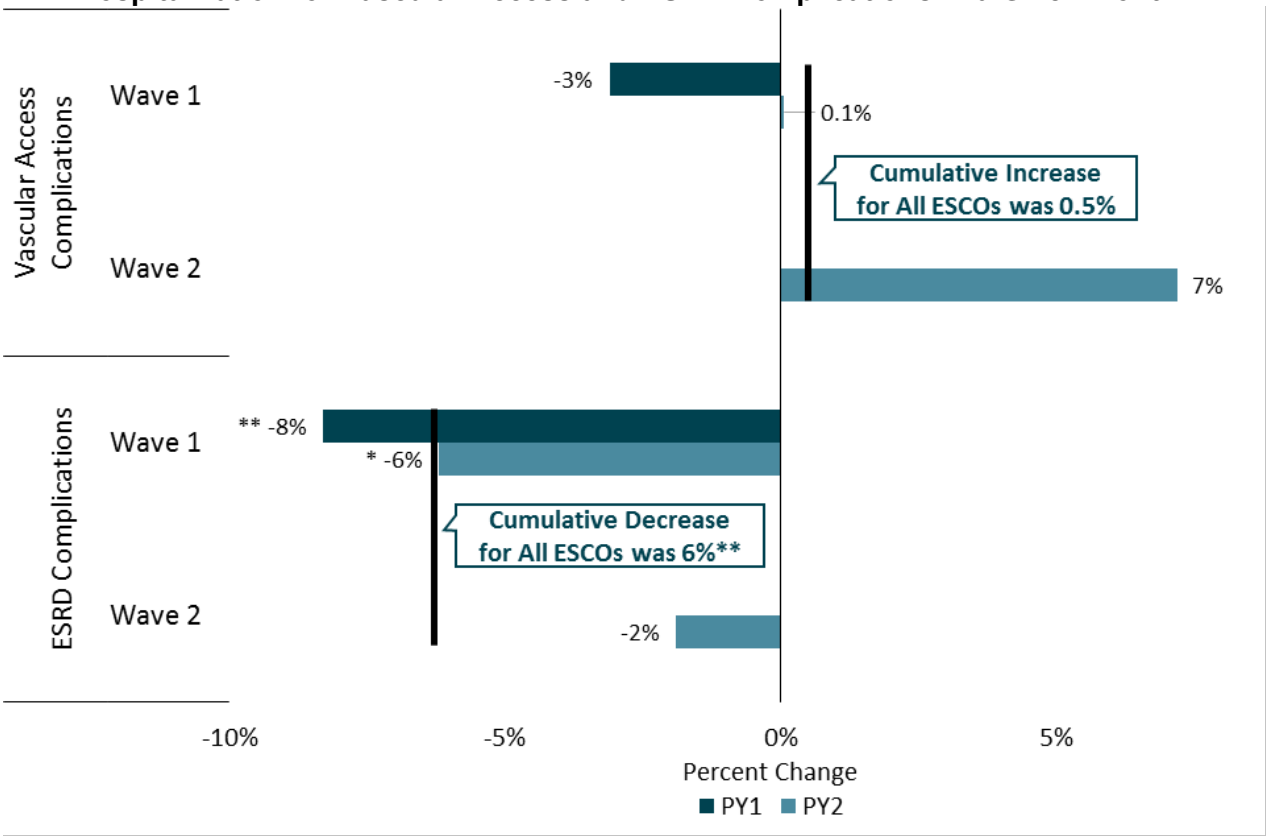
Notes: PY1 covers October 2015 - December 2016, PY2 covers January 2017 - December 2017. All ESCOs estimates include both waves from October 2015 - December 2017. The estimate of All ESCOs is the combined cumulative impact of CEC, accounting for different lengths of exposure to the model. About 33% of facilities have nine quarters of CEC participation (October 2015 to December 2017); the remaining 67% participated in CEC from January 2017 to December 2017 (four quarters). A weighted average of the performance years by wave may not exactly equal the All ESCO result because the All ESCO and the wave-performance year specific estimates were generated by separate regression models. 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 the intervention period with baseline relative to the same difference over time for beneficiaries in matched comparison facilities. Estimate label values are rounded to the nearest whole number, therefore bar lengths may differ despite showing the same rounded label value. Significance of the DiD impact estimate is indicated next to each outcome bar plot where * implies significance at the 10% level, ** at the 5% level, and *** at the 1% level

assuming a two-tailed test. Readmission drops the last quarter of intervention data to account for a lag in claims to prevent an underestimation due to a lack of claims maturity.

b. Hospitalizations for ESRD-related Adverse Events

The CEC Model incentivizes ESCOs to reduce hospital admissions associated with poor dialysis care including hospitalizations for vascular access and ESRD complications. **Exhibit 23** presents the results for hospitalizations for vascular access complications and ESRD complications such as volume depletion, fluid overload, and pulmonary edema.[55] As expected, CEC beneficiaries were 6% ($p \leq 0.05$) less likely to experience a hospitalization for ESRD complications in a given month, relative to the pre-CEC period. This result was exclusively due to Wave 1 ESCOs. There was no statistically significant impact on hospitalizations for vascular access complications overall or by wave over the first two performance years (see **Appendix F**, **Exhibits F-24** (All ESCOs), **F-25** (Wave 1), and **F-26** (Wave 2)).

Exhibit 23. Impact of the CEC Model on the Percent of Beneficiaries with at Least One Hospitalization for Vascular Access and ESRD Complications in a Given Month



Notes: PY1 covers October 2015 - December 2016, PY2 covers January 2017 - December 2017. All ESCOs estimates include both waves from October 2015 - December 2017. The estimate of All ESCOs is the combined cumulative impact of CEC, accounting for different lengths of exposure to the model. About 33% of facilities have nine quarters of CEC participation (October 2015 to December 2017); the remaining 67% participated in CEC from January 2017 to December 2017 (four quarters). A weighted average of the performance years by wave may not exactly equal the All ESCO result because the All ESCO and the wave-performance year specific estimates were generated by separate regression models. 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 the intervention period with baseline relative to the same difference over time for beneficiaries in matched comparison facilities. Estimate label values are rounded to the nearest whole number, therefore

[55] The set of diagnoses codes that define each type of complication can be found in **Appendix J**.

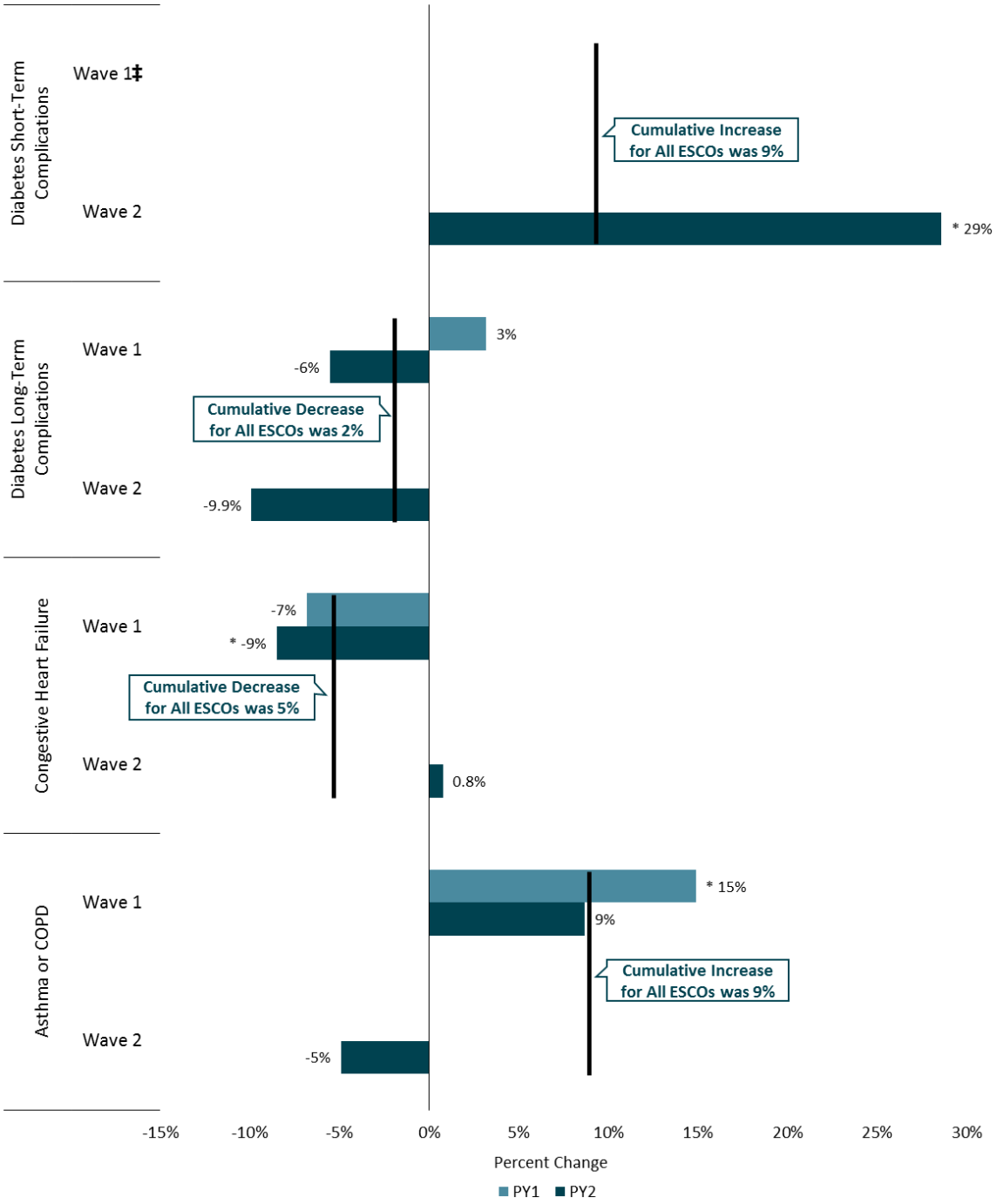
bar lengths may differ despite showing the same rounded label value. Significance of the DiD impact estimate is indicated next to each outcome bar plot where * implies significance at the 10% level, ** at the 5% level, and *** at the 1% level assuming a two-tailed test.

c. Hospitalizations for Ambulatory Care Sensitive Conditions

Under the CEC Model, ESCOs have an incentive to invest in prevention and management of chronic diseases to avoid complications that can lead to hospitalizations. To assess ESCOs' success in avoiding preventable hospitalizations, we investigated changes in the percent of beneficiaries with at least one hospitalization in a 30-day period for a list of Ambulatory Care Sensitive Conditions (ACSC) defined by Agency for Healthcare Research and Quality.[56] The results for ACSC hospitalizations for diabetes short-term or long-term complications, CHF, and asthma or COPD are shown in **Exhibit 24**. None of the measures achieved statistically significant cumulative effects across all ESCOs, but we found statistically significant effects for Wave 1. Specifically, Wave 1 ESCOs showed statistically significant declines in the likelihood of admissions for CHF of 9% ($p \leq 0.10$) in PY2 and increases in the likelihood of admissions for asthma or COPD of 15% ($p \leq 0.10$) in PY1, relative to the pre-CEC period (see **Appendix F**, **Exhibits F-24** (All ESCOs), **F-25** (Wave 1), and **F-26** (Wave2)).

[56] https://www.ahrq.gov/downloads/pub/ahrqqi/pqiguide.pdf

Exhibit 24. Impact of the CEC Model on the Percent of Beneficiaries with at Least One Admission for Ambulatory Care Sensitive Conditions (ACSC) in a 30-day Period



Notes: PY1 covers October 2015 - December 2016, PY2 covers January 2017 - December 2017. All ESCOs estimates include both waves from October 2015 - December 2017. The estimate of All ESCOs is the combined cumulative impact of CEC, accounting for different lengths of exposure to the model. About 33% of facilities have nine quarters of CEC participation (October 2015 to December 2017); the remaining 67% participated in CEC from January 2017 to December 2017 (four quarters). A weighted average of the performance years by wave may not exactly equal the All ESCO result because the All ESCO and the wave-performance year specific estimates were generated by separate regression models. 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 the intervention period with baseline relative to the same difference over time for beneficiaries in matched comparison facilities. Estimate label values are rounded to the nearest whole number, therefore bar lengths may

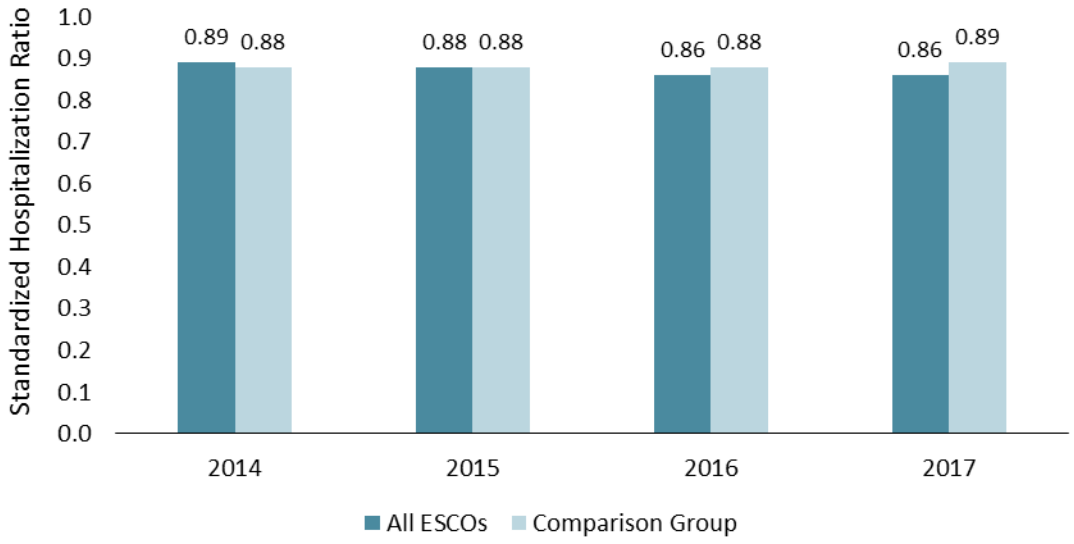
differ despite showing the same rounded label value. Significance of the DiD impact estimate is indicated next to each outcome bar plot where * implies significance at the 10% level, ** at the 5% level, and *** at the 1% level assuming a two-tailed test. Wave 1 admissions for short-term complications fails the parallel trends test. ‡ DiD results are not shown because data from the baseline period showed intervention and matched comparison beneficiaries were not on parallel trends for this outcome, which is required for an unbiased estimate.

d. Standardized Hospitalization, 30-day Readmission, and Mortality Ratios

Standardized measures are useful for examining whether ESCO-specific adverse event rates (i.e., hospitalizations, 30-day readmissions, and mortality) are similar to event rates for the comparison group (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.

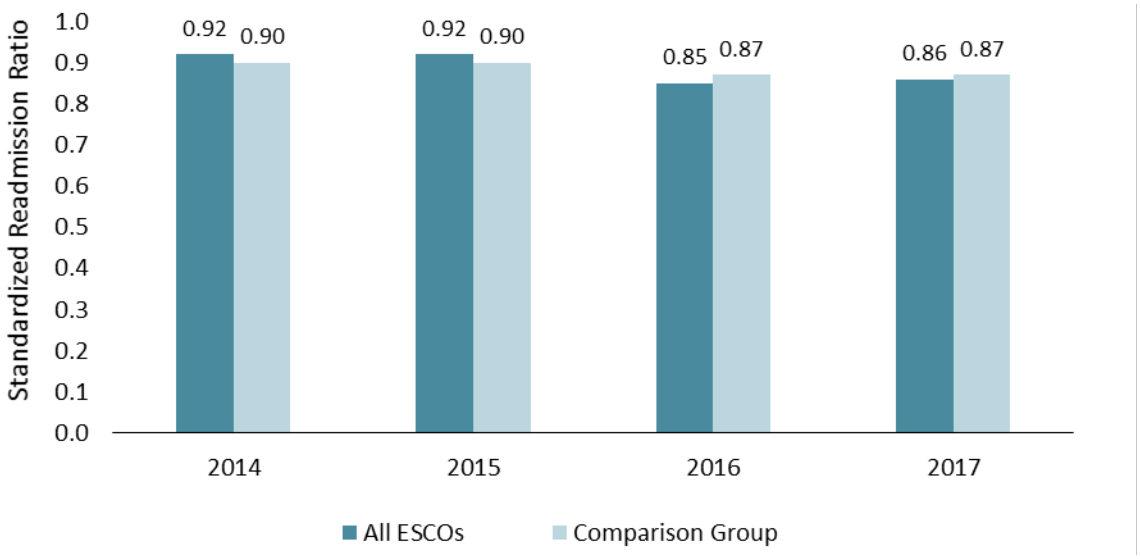
Beginning in 2014, hospitalization rates, as measured by the standardized hospitalization ratio (SHR), improved relative to the comparison group, with the greatest differences between the comparison group and the all ESCO group in calendar year 2016 and 2017. The chart in **Exhibit 25** presents the SHR for all ESCOs and the comparison group in each year starting in 2014 through 2017.

Exhibit 25. Standardized Hospitalization Ratio for All ESCOs and Comparison Group, 2014-2017



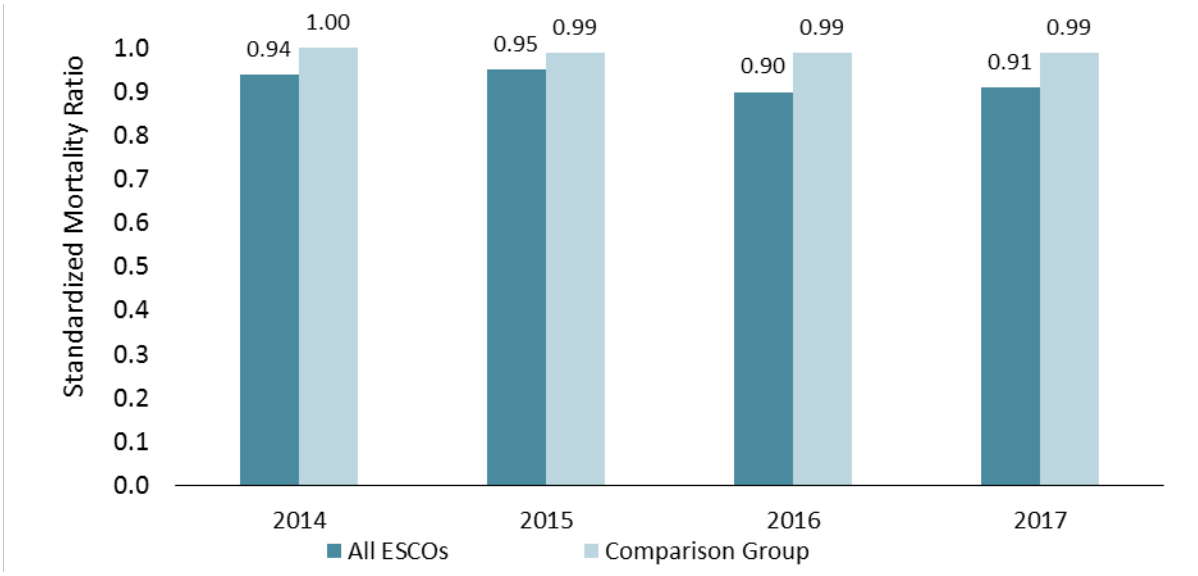
Patterns for the standardized readmission ratio (SRR) were generally similar to those observed for the SHR. Both the ESCOs and the comparison group showed improvement over time. The all ESCO SRR exhibited the greatest reduction relative to the comparison group in 2016. The chart in **Exhibit 26** presents the SRR for all ESCOs and the comparison group for each year starting in 2014 through 2017.

Exhibit 26. Standardized Readmission Ratio for All ESCOs and Comparison Group, 2014-2017



Mortality is a primary health outcome and therefore is an important performance measure for assessing quality of care under any health care delivery model. In the CEC context, the standardized mortality ratio (SMR) provides additional assurance that the CEC Model is not adversely impacting patient survival. The chart in **Exhibit 27** presents the SMR for all ESCOs and the comparison group for each year starting in 2014 through 2017. Overall, the mortality trends observed suggest stable SMR for the comparison group over the most recent four years. The combined ESCO group had somewhat lower SMR over the same period, with a trend toward declining mortality that is most pronounced in 2016 and 2017. These trends suggest a possible effect of the CEC Model on mortality, although results should be interpreted with caution as some of the CEC results in 2016 are for Wave 2 ESCOs and reflect those organizations' baseline performance rather than a CEC effect. Even when interpreted conservatively, these trends provide assurance that the observed reductions in hospitalization rates described above and other potential changes in care motivated by the CEC Model incentives have not adversely impacted patient mortality.

Exhibit 27. Standardized Mortality Ratio for All ESCOs and Comparison Group, 2014-2017



Calculation and interpretation of the standardized measures is subject to some limitations, including ambiguity in determining whether observed changes over time are due to changes in risk-adjusted expected events, observed events, or both. For a detailed description of the standardized measures, as well as of the limitations in the measures, see **Appendix J**.

4. What Was the Impact of CEC on Medicare Spending across the Continuum of Care?

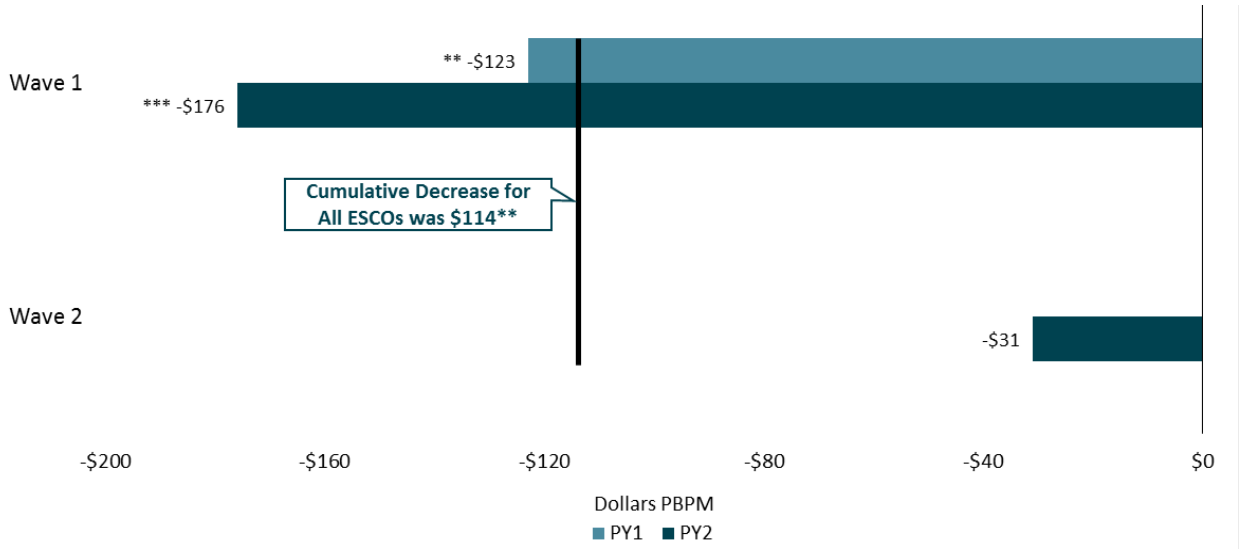
The impacts of the CEC Model on Medicare payments across the continuum of care are consistent with the changes in utilization described above. Medicare payments for outpatient dialysis sessions increased slightly, while Medicare payments for hospitalizations and readmissions went down. In general, Wave 1 ESCOs had more significant and consistent impacts on payments compared to Wave 2 ESCOs. In aggregate, these changes combined to reduce Medicare Part A and B spending.

Overall, the total Medicare Part A and Part B standardized payments, a measure of overall Medicare spending decreased for CEC beneficiaries, while showing no change in the comparison group (**Exhibit 28**). This resulted in a statistically significant reduction in spending of $114 PBPM ($p \leq 0.05$) for CEC beneficiaries relative to the comparison group, which represents about 2% of the average PBPM Medicare Part A and Part B payments for CEC beneficiaries at baseline.

Exhibit 28. Average Risk-Adjusted Total Medicare Part A and Part B Payments PBPM for CEC and Comparison Beneficiaries

This result was primarily driven by Wave 1 ESCOs, which reduced spending by $123 PBPM in PY1 ($p \leq 0.05$) and $176 PBPM in PY2 ($p \leq 0.01$), representing a 2.4% decrease. Wave 2 ESCOs decreased payments by only $31 PBPM in PY2, a 0.5% reduction, and the estimate did not achieve statistical significance (**Exhibit 29**). While Wave 1 ESCOs had more exposure to the CEC Model than Wave 2 ESCOs (eight[57] versus four quarters), the difference in impacts is not likely due to differences in their length of CEC participation since Wave 1 ESCOs lowered spending in both their first and second performance years (see **Appendix F**, **Exhibits F-27** (All ESCOs), **Exhibit F-28** (Wave 1), and **Exhibit F-29** (Wave 2)).

Exhibit 29. Impact of CEC on Total Part A and Part B Standardized Medicare Payments PBPM



Notes: PY1 covers October 2015 - December 2016, PY2 covers January 2017 - December 2017. All ESCOs estimates include both waves from October 2015 - December 2017. The estimate of All ESCOs is the combined cumulative impact of CEC,

[57] Eight Wave 1 quarters is the weighted average of intervention quarters among Wave 1 facilities with nine and four quarters of participation.

accounting for different lengths of exposure to the model. About 33% of facilities have nine quarters of CEC participation (October 2015 to December 2017); the remaining 67% participated in CEC from January 2017 to December 2017 (four quarters). A weighted average of the performance years by wave may not exactly equal the All ESCO result because the All ESCO and the wave-performance year specific estimates were generated by separate regression models. 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 the intervention period with baseline relative to the same difference over time for beneficiaries in matched comparison facilities. Significance of the DiD impact estimate is indicated next to each outcome bar plot where * implies significance at the 10% level, ** at the 5% level, and *** at the 1% level assuming a two-tailed test.

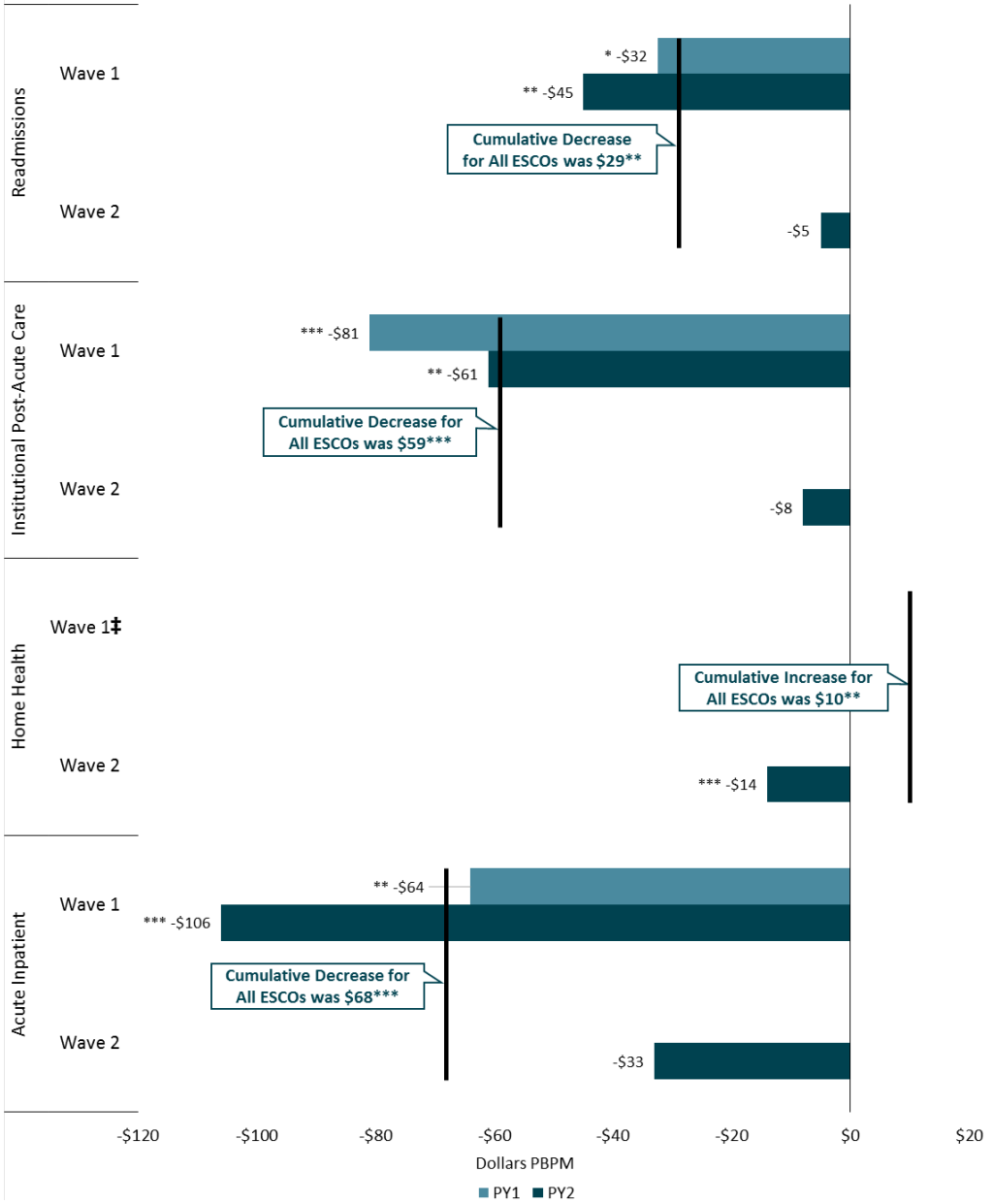
The main drivers of decreases in Medicare spending under the CEC Model were reductions in spending on hospitalizations and services that regularly accompany hospitalizations (e.g., readmissions, institutional post-acute care [PAC]). See **Exhibit 30**. Specifically, relative to the comparison group, spending declined for acute inpatient stays ($68 PBPM, $p \leq 0.01$), readmissions ($29 PBPM, $p \leq 0.05$), and institutional PAC ($59 PBPM, $p \leq 0.01$).[58] These declines in spending are consistent with our finding that CEC beneficiaries were less likely to be hospitalized or readmitted, and had fewer hospitalizations relative to the comparison group (**Exhibit 20**). Spending also declined for hospitalizations for ESRD complications ($10 PBPM, $p \leq 0.05$), in line with the fact that CEC beneficiaries were less likely to experience a hospitalization for ESRD complications (**Exhibit 23**). Wave 1 ESCOs consistently achieved larger reductions in spending compared to Wave 2 ESCOs, even during their first performance period, and their spending reductions were greater in PY2 relative to PY1.

Spending for home health services, which are often provided to safely transition patients home after an acute or post-acute institutional stay, increased by $10 PBPM ($p \leq 0.05$), with increases for Wave 1 ESCOs and decreases for Wave 2 ESCOs, relative to the comparison group. Home health use could increase despite fewer hospitalizations if beneficiaries are substituting institutional PAC for home health care. The fact that we observed a reduction in spending on PAC supports this hypothesis. Additionally, home health services are not always associated with a hospital stay,[59] so we may observe higher home health use if beneficiaries are referred to other covered home health services like teaching and training activities by skilled nursing personnel. Future evaluation work will disentangle home health use with and without a preceding inpatient stay.

[58] Institutional post-acute care (PAC), includes payments from inpatient rehabilitation facilities (IRF), SNFs, and long-term care hospitals. Individual analysis of these payments groups identified that spending reductions in institutional PAC was primarily driven by long-term care hospital Medicare payment reductions.

[59] In 2014, 68% of home health episodes were not preceded by a hospital stay. http://www.medpac.gov/docs/default-source/reports/mar17_medpac_ch9.pdf

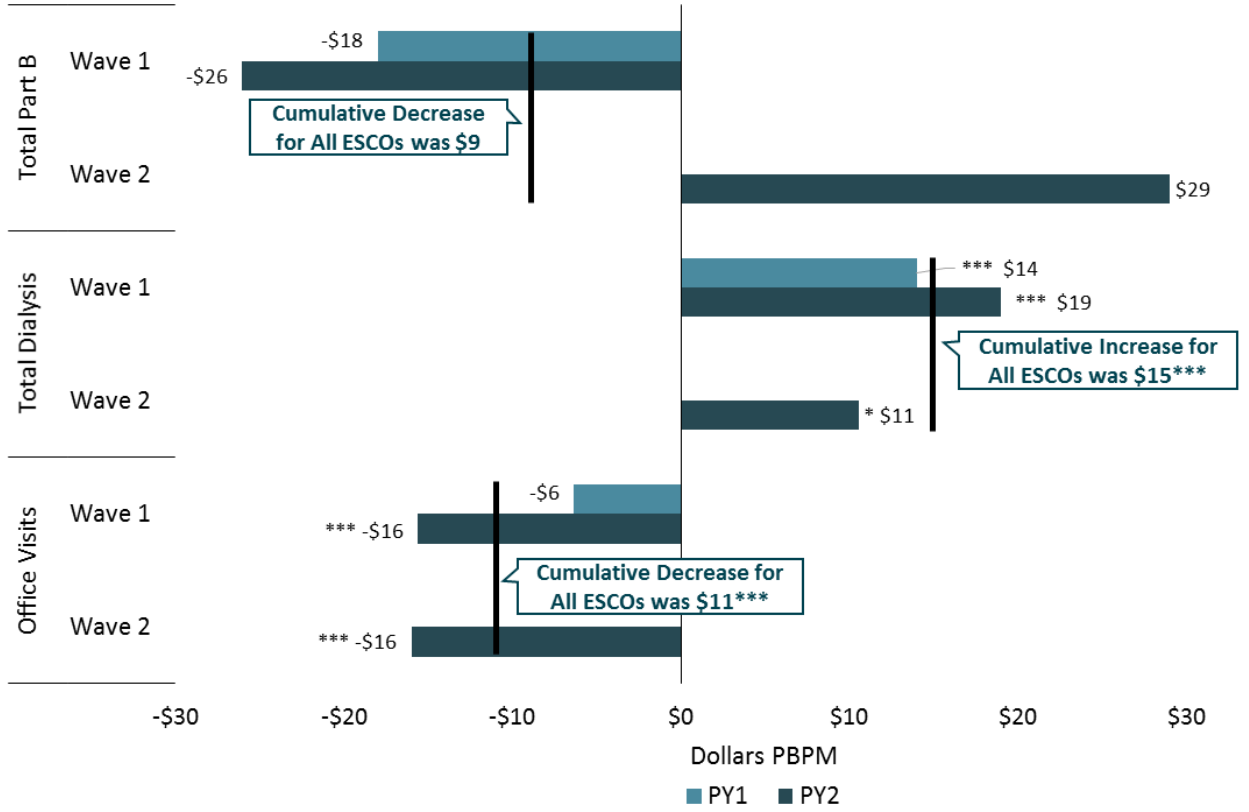
Exhibit 30. Impact of CEC on Readmissions, Institutional Post-Acute Care, Home Health, and Acute Inpatient Payments PBPM



Notes: PY1 covers October 2015 - December 2016, PY2 covers January 2017 - December 2017. All ESCOs estimates include both waves from October 2015 - December 2017. The estimate of All ESCOs is the combined cumulative impact of CEC, accounting for different lengths of exposure to the model. About 33% of facilities have nine quarters of CEC participation (October 2015 to December 2017); the remaining 67% participated in CEC from January 2017 to December 2017 (four quarters). A weighted average of the performance years by wave may not exactly equal the All ESCO result because the All ESCO and the wave-performance year specific estimates were generated by separate regression models. 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 the intervention period with baseline relative to the same difference over time for beneficiaries in matched comparison facilities. DiD impact estimate is indicated next to each outcome bar plot where * implies significance at the 10% level, ** at the 5% level, and *** at the 1% level assuming a two-tailed test. Readmission are included in the overall acute inpatient spending and we exclude the last quarter of intervention data to account for a lag in claims to prevent underestimation. ‡ DiD results are not shown because data from the baseline period showed intervention and matched comparison beneficiaries were not on parallel trends for this outcome, which is required for an unbiased estimate.

There were also statistically significant impacts in spending for certain Part B services (**Exhibit 31**). Driven by Wave 1, all ESCOs' dialysis payments increased by $15 PBPM ($p \leq 0.01$), relative to the comparison group. Given that the bundled payment rate per session is fixed (aside from case-mix adjustments), this increase could be driven by an increase in outpatient treatments. Such an increase could reflect ESCO efforts to avoid or reschedule missed treatments, to obtain authorization for treatments beyond three weekly in order to prevent hospitalizations (e.g., for fluid overload), or simply because, to the extent that ESCOs reduce inpatient days, more outpatient treatments can be delivered. Fewer physician office visits for CEC beneficiaries (**Exhibit 17**) translated into relative declines for both Wave 1 and Wave 2 ESCOs' payments for office visits, a reduction of $11 PBPM ($p \leq 0.01$). Again, Wave 1 ESCOs achieved larger declines in spending compared to Wave 2 ESCOs. No statistically significant impacts were estimated for other Part B services such as hospital outpatient and Part B drugs (see **Appendix F**, **Exhibits F-27** (All ESCOs), **F-28** (Wave 1), and **F-29** (Wave 2)).

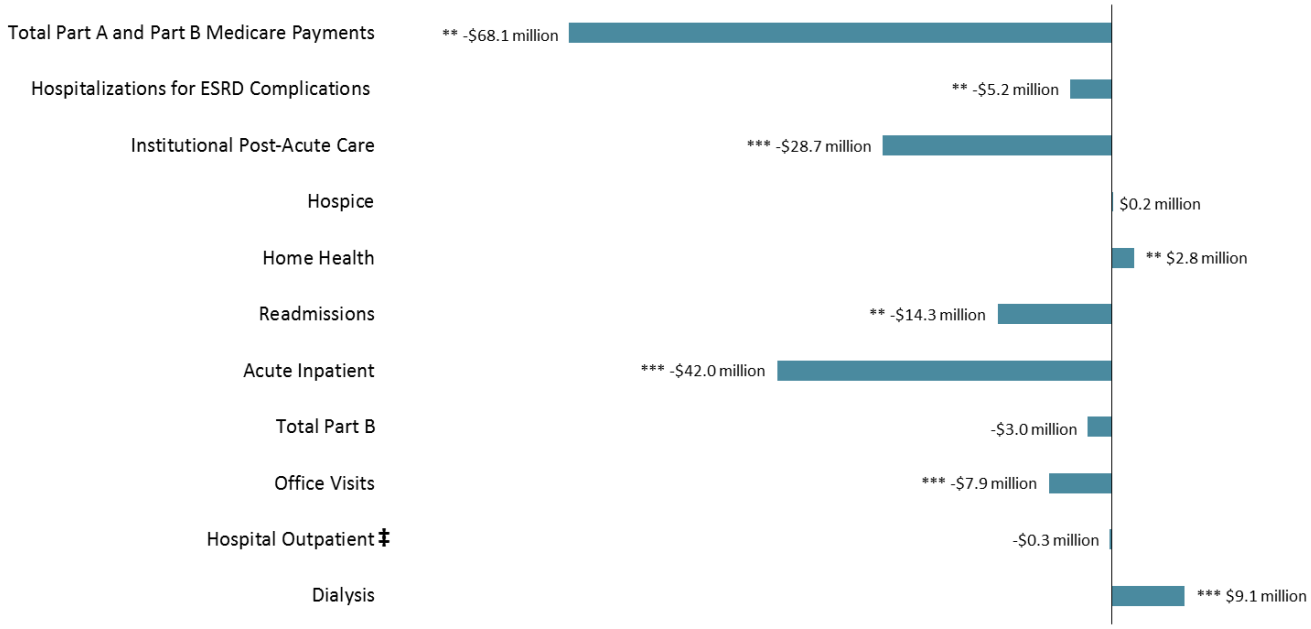
Exhibit 31. Impact of CEC on Total Part B, Total Dialysis, and Office Visit Payments PBPM



Notes: PY1 covers October 2015 - December 2016, PY2 covers January 2017 - December 2017. All ESCOs estimates include both waves from October 2015 - December 2017. The estimate of All ESCOs is the combined cumulative impact of CEC, accounting for different lengths of exposure to the model. About 33% of facilities have nine quarters of CEC participation (October 2015 to December 2017); the remaining 67% participated in CEC from January 2017 to December 2017 (four quarters). A weighted average of the performance years by wave may not exactly equal the All ESCO result because the All ESCO and the wave-performance year specific estimates were generated by separate regression models. 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 the intervention period with baseline relative to the same difference over time for beneficiaries in matched comparison facilities. Estimate label values are rounded to the nearest whole number, therefore bar lengths may differ despite showing the same rounded label value. Significance of the DiD impact estimate is indicated next to each outcome bar plot where * implies significance at the 10% level, ** at the 5% level, and *** at the 1% level assuming a two-tailed test.

The impact of the CEC Model on total Part A and Part B payments translates into an aggregate reduction in spending of approximately $68 million over the first two performance years: $25 million in PY1 and $43 million in PY2 (**Exhibit 32**).[60] A key contributor to the decline in total spending was an aggregate reduction in spending for acute inpatient services ($42 million).

Exhibit 32. Aggregate Estimates of Reductions in Medicare Spending by Service Setting



Notes: Significance of the DiD impact estimate is indicated next to each outcome bar plot where * implies significance at the 10% level, ** at the 5% level, and *** at the 1% level assuming a two-tailed test. Reductions in spending are based on the estimated total number of intervention member months for the 685 CEC facilities participating in the CEC Model. DiD impact estimates are adjusted to non-standardized values using the average ratio total standardized and non-standardized payments. Readmission and hospitalizations for ESRD complications expenditures are included in the overall acute inpatient spending. ‡ Data from the baseline period showed intervention and matched comparison facilities were not on parallel trends for this outcome, which is required for an unbiased impact estimate

In addition to the DiD estimates, we estimated the net change in spending for Medicare as a result of the CEC Model by taking into account the shared savings payments to ESCOs. After accounting for the $114.3 million in shared savings ($194 PBPM) that ESCOs received across PY1 and PY2, Medicare experienced aggregate net losses of $46.1 million ($78 PBPM, $p \leq 0.10$).[61] Wave 1 ESCOs received $247 PBPM in shared savings payments, while Wave 2 ESCOs received much less, $91 PBPM.

5. What Was the Impact of CEC on Medicare Beneficiary 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 (race, sex), basis of Medicare eligibility, dual Medicaid status, and their time on dialysis (six months or less versus over six months) (results reported in **Appendix F, Exhibit F-30**). To this end, we estimated

[60] These estimates do not account for payments between ESCOs and CMS resulting from PY1+PY2 reconciliation.

[61] In addition to the DiD estimates, we estimated the probability of observing changes in spending for Medicare as a result of the CEC model. The findings and methods used to calculate these probabilities are outlined in **Appendix I**.

stratified DiD models with the specification described in **subsection D of Appendix F**. The decomposition provides insights to the subpopulations that may be influencing the respective DiD results.

For most groups, the stratified results are consistent with those observed for total Part A and Part B Medicare payments, hospitalizations, ED visits, catheter use, and readmissions in the full CEC population. However, the stratified results show that average impacts mask differences across subgroups. For example, the largest reductions in total PBPM Part A and Part B spending by demographic group was found among Medicare beneficiaries with ESRD who were White ($181 PBPM, $p \leq 0.01$), who were male ($145 PBPM, $p \leq 0.01$), who entered Medicare due to ESRD and disability ($187 PBPM, $p \leq 0.01$), or who were fully Medicaid eligible ($129 PBPM, $p \leq 0.10$). Additionally, beneficiaries with ESRD with greater than six months of dialysis experienced significant declines in spending ($110 PBPM, $p \leq 0.05$). Significant decreases in 30-day readmissions were also observed for beneficiaries who were categorized as White or Other race (non-White/non-Black), had full Medicare and Medicaid coverage, and had more than six months of dialysis. While the subgroup analyses were exploratory, it will be useful to determine the extent to which these patterns continue to hold consistent over time, and use further analyses or site visits to build an understanding of their causes and consequences.

D. Discussion

Overall, the early experience under the CEC Model appears promising, with improvements in delivery and quality of dialysis care and reductions in acute care utilization and Medicare spending. First, consistent with ESCOs' strategies to improve dialysis-related care and coordination of care beyond dialysis, the CEC Model generated improvements in terms of vascular access, adherence to dialysis treatment, and preventive health measures. Second, reductions in utilization provided further evidence of efforts to reduce acute care, with statistically significant declines in hospitalizations and ED visits. Finally, CEC resulted in Medicare spending reductions across the continuum of care but overall net losses. Specifically, the impact analyses found reductions of over $100 PBPM for total Part A and Part B Medicare payments, representing a decrease of nearly 2%. Wave 1 ESCOs reduced spending by about 2.4%, while for Wave 2 ESCOs reductions in spending were lower, at 0.5%. After accounting for the shared savings received by ESCOs, Medicare experienced aggregate net losses of $46.1 million over the first two performance years. Given that the Wave 2 ESCOs only had one year of program experience, next year's annual report will examine whether an additional year yields continued or larger declines in spending for ESCOs. The spending reductions were most evident in Medicare Part A, with significant reductions in acute inpatient, readmission, and institutional PAC categories. Dialysis spending also rose while spending for dialysis complications declined, which correlates with qualitative findings that ESCOs increased dialysis access in order to increase adherence and avoid complications.

CEC Model impacts varied across waves. Wave 1 ESCOs tended to have larger impacts on clinical and economic outcomes than did Wave 2 ESCOs, when comparing each wave's first year of operation. Additionally, Wave 1 ESCOs generally had larger impacts in their second year of operation than in their first year. These differences could reflect several factors. It is possible that, in the absence of MACRA, Wave 1 ESCO participants were more strongly motivated to join the program than Wave 2 ESCO participants. In addition, because of delays with model

start, Wave 1 ESCOs may have had more lead time to prepare for CEC and develop their care coordination services.

Future analyses will be able to determine the extent to which Wave 1 ESCOs can maintain or further build upon their early results, whether Wave 2 ESCOs can close the performance gap relative to Wave 1 ESCOs, and whether Wave 2 ESCOs also follow the pattern of increasing impact with time in the program.

VIII. What Were the Differences in Performance between the CEC and Primary Care-Based ACO Models?

The overall goals and financial incentives of the CEC Model are similar to those of primary care-based ACOs. In both models, participants assume financial responsibility for the quality of care and Medicare Part A and Part B spending of their aligned beneficiaries. Despite these shared characteristics, there are important differences between the two models. One of the primary differences is that participants in the CEC Model (ESCOs) only provide care to Medicare beneficiaries with ESRD, while ACOs serve the general Medicare population. Additionally, ESCOs are built around dialysis centers and nephrologists, while traditional ACOs are built around PCPs. This allows ESCOs to have more frequent interactions with their aligned population, as dialysis patients typically visit the clinic three times a week for three- to four-hour sessions. Finally, the programmatic rules for primary care-based ACOs differ from those of CEC, one example being the level of risk participating providers in each model are required to undertake.

This section presents findings from our analysis of whether CEC provided better results for beneficiaries with ESRD than primary care-based ACOs. We compared six key outcomes (Medicare payments, hospitalizations, readmissions, ED visits, and vascular access type) before and after alignment to each of these models relative to a matched comparison group.

A. Key Findings

We found key differences in performance between CEC and ACO care models. Differences are measured relative to a comparison group of beneficiaries with ESRD receiving care in traditional Medicare FFS and are described below:

CEC Model versus Primary Care-Based ACOs. We examined outcomes for Medicare beneficiaries with ESRD a year before and a year after alignment to CEC or a primary care-based ACO. Both groups were compared to beneficiaries with ESRD in traditional fee-for-service (FFS) Medicare in terms of:

Key Findings:

Overall, results suggest that beneficiaries with ESRD may fare better in a specialty-oriented ACO model like CEC rather than in a primary care-based ACO model.

Quality of Care

- There was no evidence that the CEC Model or primary care-based ACOs impacted use of catheters or fistulas for beneficiaries with ESRD

Inpatient/Outpatient Care Utilization

- Beneficiaries with ESRD newly aligned to CEC had 5% fewer hospitalizations and ED visits during the first year of alignment
- No changes were estimated for beneficiaries with ESRD newly aligned to a primary care-based ACO

Medicare Spending

- Medicare spending decreased by $110 per beneficiary per month (PBPM) in the first year of alignment for beneficiaries with ESRD who were aligned to CEC
- No impacts were estimated on Medicare payments for newly aligned ACO beneficiaries with ESRD

B. Methods

We used a DiD approach to evaluate whether CEC performed better than primary care-based ACOs. The DiD approach compared the experiences of beneficiaries with ESRD over time, before and after they transitioned into either CEC or a primary care-based ACO, relative to beneficiaries with ESRD who remained in Medicare FFS. Specifically, we compared outcomes across three groups of beneficiaries. We created two intervention groups consisting of beneficiaries with ESRD

who became aligned to a participating CEC or alternatively participating ACO provider, and were in usual FFS prior to alignment. The ACO intervention group included beneficiaries with ESRD enrolled in various ACO programs including Pioneer, Shared Savings Program (SSP) Tracks 1, 2, and 3, and Next Generation ACO (NGACO). Ideally, the analysis would not include SSP Track 1, because it is not an ACO model with a two-sided risk arrangement, like most ESCOs in CEC. However, SSP Track 1 ACO programs were included in the analysis to increase statistical power. The comparison group consisted of CEC eligible matched beneficiaries (see **Appendix K** for a description of the methods used to construct matched comparison beneficiaries) who continued to receive services under the usual FFS.

Due to the high mortality rate in the ESRD population, the intervention and comparison groups may become unbalanced over time. Beneficiaries with better odds of survival will increase their share in the analytic sample as we extend the observation period. To help mitigate this potential bias, we shortened the observation period to the year before and year after alignment to either CEC or a primary care-based ACO. **Exhibit 33** describes the comparison and intervention groups.

Exhibit 33. Intervention and Comparison Groups of the DiD Model

Group	Pre Intervention Period
Intervention Group 1 (ACO)	CEC eligible beneficiaries who received services under usual Medicare FFS, became aligned to a primary care-based ACO, and met the following criteria: ▪ Were eligible during the month preceding the alignment start date ▪ Were eligible during the month following alignment
Intervention Group 2 (CEC)	CEC eligible beneficiaries who received services under usual Medicare FFS, became aligned to CEC, and met the following criteria: ▪ Were eligible during the month preceding the alignment start date ▪ Were eligible during the month following alignment
Matched Comparison Group	Matched CEC eligible beneficiaries who received services under usual Medicare FFS, did not become aligned to either model, and who met the following criteria: ▪ Were eligible during the month preceding one of the four potential alignment dates ▪ Were eligible during the month following one of the four potential alignment dates

The intervention sample included beneficiaries who became newly aligned to an ACO or CEC in 2015[62] or later. Alignment changes happened at multiple points throughout this period, which spanned different starting dates for the ACO programs and CEC's ESCO waves included in the analysis (see **Exhibit 34**). We identified intervention and comparison groups for four potential alignment dates beginning in the year CEC started: January 2015, October 2015, January 2016, and January 2017. These include alignment dates where we were able to identify transitions from usual FFS to CEC at the two start dates of the model[63] (October 2015 and January 2017) and alignment dates for usual FFS to primary care-based ACOs transitions (January 2016, January 2016, and January 2017).

[62] Chosen because CEC launched in October 2015.

[63] While beneficiaries with ESRD can become aligned to the CEC Model at any month if they start receiving dialysis services from a CEC facility, these transitions were excluded from the analysis in order to minimize transitions associated with a change in facility of care.

Exhibit 34. ACO and CEC Timeline

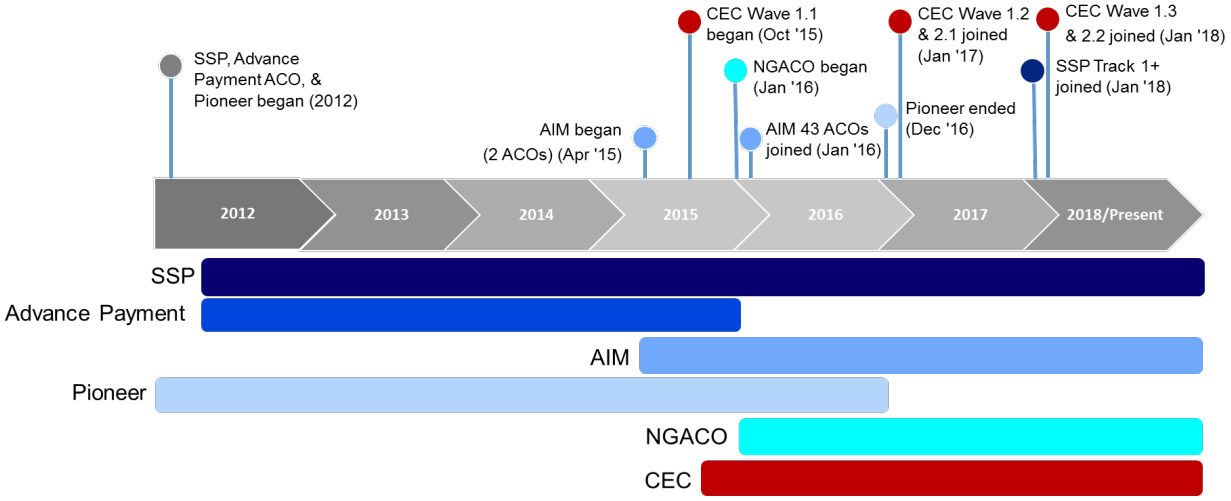
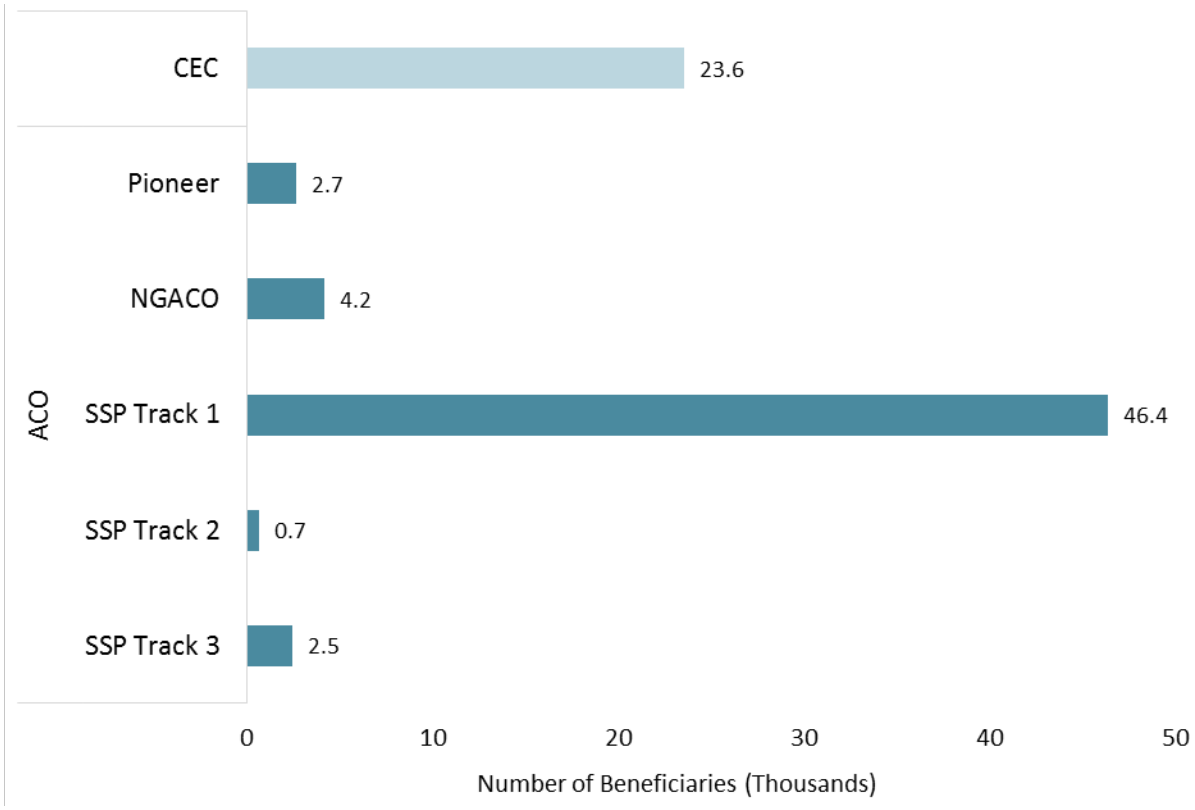


Exhibit 35 shows the number of beneficiaries with ESRD included in each group used in the analysis.

Exhibit 35. Number of Beneficiaries (in Thousands) with ESRD in CEC and Primary Care-based ACO Intervention Groups



The analytic sample consisted of 23,583 CEC and 56,454 ACO newly aligned beneficiaries, and 80,037 matched comparison beneficiaries. We estimated the impact of CEC and ACO care models using a risk-adjusted DiD model that included the same beneficiary, facility, and market

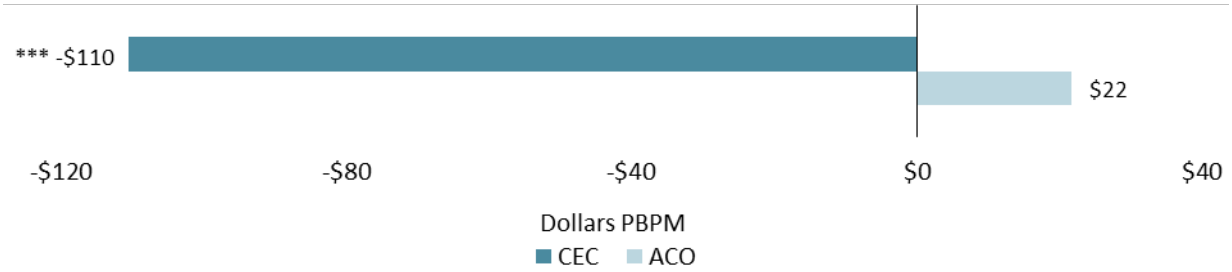
characteristic controls used in the main DiD analysis. We estimated the DiD impact of CEC relative to FFS and the DiD impact of primary care-based ACOs relative to FFS, and compared the respective results. This approach controlled for beneficiary-, market-, and facility-level differences between the intervention and comparison populations, minimized biases from time-invariant differences between the intervention and comparison populations, and controlled for secular trends. The matching methods, DiD model specifications, and power calculations used are described in **Appendix K**.

C. Results

This section presents results from the DiD models for the six key outcomes: Medicare payments, hospitalizations, readmissions, ED visits, and vascular access type (e.g., fistula and catheter). Results are presented for both the primary care-based ACO and CEC intervention groups. We found key differences in performance between CEC and primary care-based ACO care models, with only the CEC Model resulting in a reduction in Medicare spending, hospitalizations, and ED visits.

Exhibit 36 shows that the CEC Model had a greater impact on total Medicare Part A and Part B payments than did the primary care-based ACO models. Relative to a matched comparison group, Medicare spending decreased by $110 PBPM (2%, $p \leq 0.01$) in the first year of alignment for beneficiaries with ESRD who were aligned to CEC. On the other hand, there were no statistically significant changes in Medicare spending for beneficiaries with ESRD who were aligned to a primary care-based ACO in the first year of alignment (see **Appendix K, Exhibit K-10**).

Exhibit 36. CEC and Primary Care-based ACO Impacts on Total Medicare Part A and Part B Payments PBPM

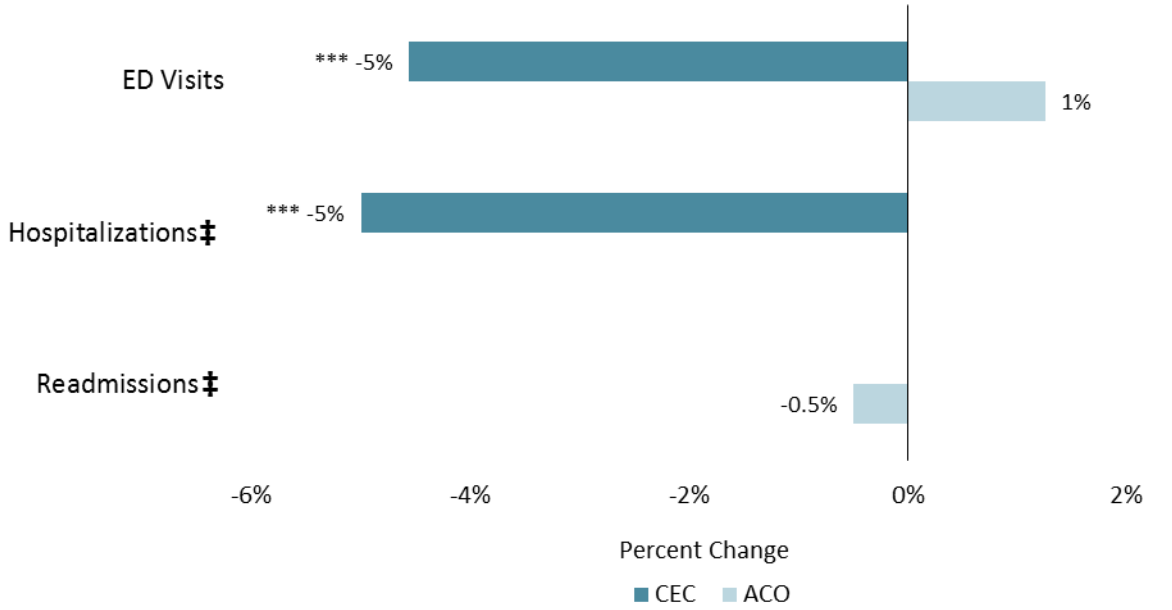


Notes: Each impact estimate is based on retrospective cohort study that evaluated changes in outcomes for up to 12 months before and after following alignment into CEC or a primary care-based ACO model relative to matched comparison groups of beneficiaries who did not transition from Medicare FFS. ***$p \leq 0.01$, **$p \leq 0.05$, *$p \leq 0.1$. See **Appendix K** for detailed results.

The reduction in spending observed in newly aligned CEC beneficiaries was driven by a reduction in the number of ED visits and hospitalizations (**Exhibit 37**). Specifically, in their first year of alignment, CEC beneficiaries experienced statistically significant reductions in the number of ED visits (5%, $p \leq 0.01$) and hospitalizations (5%, $p \leq 0.01$) relative to the pre intervention period. These results translate into six fewer ED visits per 1,000 beneficiaries per month and 10 fewer hospitalizations per 1,000 beneficiaries per month among the CEC population. Primary care-based ACO beneficiaries, however, did not experience a significant change in the number of ED visits or hospitalizations after they were aligned to an ACO. Additionally, models evaluating the percent of newly aligned beneficiaries who experienced at

least one hospitalization, ED visit, or readmission are presented in **Appendix K, Exhibits K-9** and **K-10**. Results show that newly aligned CEC beneficiaries experienced statistically significant reductions in the likelihood of having ED visits and hospitalizations during the first year of alignment, which decreased by 6% ($p \leq 0.01$) and 5% ($p \leq 0.01$) relative to the pre intervention period, respectively.

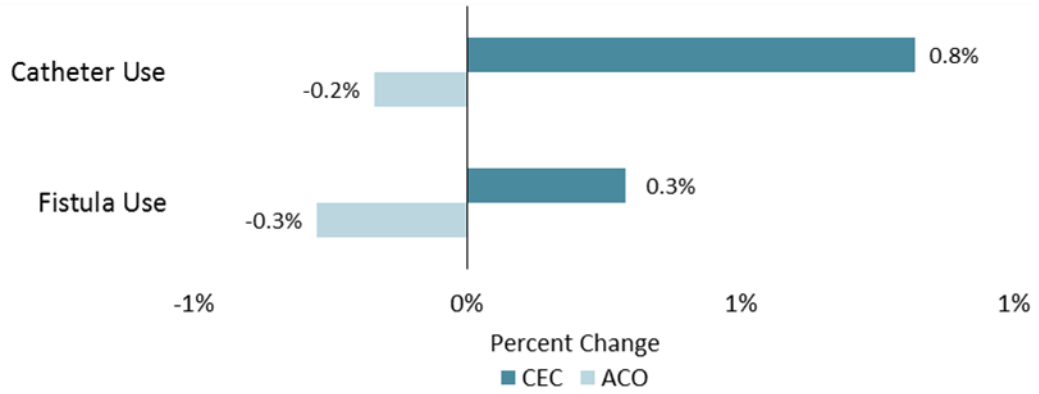
Exhibit 37. CEC and Primary Care-based ACO Impacts on the Number of ED Visits, Hospitalizations, and Readmissions PBPM



Notes: Each impact estimate is based on retrospective cohort study that evaluated changes in outcomes for up to 12 months before and after following alignment into CEC or a primary care-based ACO model relative to matched comparison groups of beneficiaries who did not transition from Medicare FFS. Estimate label values are rounded to the nearest whole number, therefore bar lengths may differ despite showing the same rounded label value. ***$p \leq 0.01$, **$p \leq 0.05$, *$p \leq 0.1$. ‡ DiD results are not shown when data from the baseline period showed intervention and matched comparison beneficiaries were not on parallel trends for this outcome, which is required for an unbiased estimate. See **Appendix K** for additional results.

Finally, **Exhibit 38** presents the results on quality measures for vascular access. No statistically significant impacts were estimated for either newly aligned CEC or ACO beneficiaries on catheter or fistula use in their first year of alignment.

Exhibit 38. CEC and Primary Care-based ACO Impacts on Vascular Access PBPM



Notes: Each impact estimate is based on retrospective cohort study that evaluated changes in outcomes for up to 12 months before and after following alignment into CEC or an ACO care model relative to matched comparison groups of beneficiaries who did not transition from Medicare FFS. ***p≤0.01, **p≤0.05, *p≤0.1. None of the outcomes show statistically significant results. See **Appendix K** for additional results.

D. Discussion

Results suggest that beneficiaries with ESRD may fare better in a specialty-oriented ACO model like CEC rather than in a primary care-based ACO model. This may be because a specialty-oriented care model is more effective for the ESRD population given their regular contact with both the dialysis facility and the nephrologist. It is important to continue to measure differences in outcomes as CEC and ACOs continue to expand.

Our current analysis cannot conclusively rule out that the risk structure is driving the difference in results because the majority of the analytic sample of the ACOs had one-sided risk, whereas, the majority of the ESCOs had two-sided risk arrangements. We will update the analysis as more data become available from two-sided risk ACOs in the future.

IX. Did the CEC Model Have Unintended Consequences?

An important component of the evaluation of the CEC Model is identifying potential unintended consequences that may result from the incentives created by the CEC Model. In this section, we explore if the CEC Model affected cost-shifting, patient selection, and referrals to transplants.

Part D Cost-Shifting. Medicare Part D drug costs are not included in the total cost of care calculations for determining ESCO shared savings and losses. As a consequence, ESCOs may not consider Part D drug costs in care redesign and may not be aware of the impact such changes have on drug costs. Medication reconciliation, which is one of the key strategies reported by several ESCOs, could result in fewer prescriptions and lower costs. However, the reduction in hospitalizations among CEC beneficiaries and the enhanced focus on managing chronic conditions common in the ESRD population by CEC participants could lead to an increase in prescription drug utilization. This section evaluates the impact of the CEC Model on Part D PBPM total drug costs.[64]

Patient Selection. The CEC Model may incentivize CEC nephrologists to refer sicker patients to non-CEC facilities while keeping healthier patients at CEC facilities. The model, however, is designed to limit the ways in which CEC nephrologists may cherry-pick patients. The "first-touch" approach of the program limits physicians' ability to steer existing patients away from the ESCO. Furthermore, once patients' dialysis schedules are established at their chosen facility, it takes a significant amount of effort to get patients to switch facilities. One way that selection might occur is if nephrologists decide to steer patients that are new to dialysis to certain types of facilities depending on their expected risk. This section focuses on whether there is evidence that new dialysis patients in CEC facilities were healthier compared to new dialysis patients in matched comparison facilities.

Referrals to Transplant Services. Since beneficiaries are removed from the CEC Model if they receive a transplant, a decrease in referrals for transplants could indicate that CEC providers are delaying transplant referrals of patients with the intent of extending the time that relatively healthier patients are aligned to ESCOs. Keeping healthier patients aligned for longer periods could improve the ESCOs' overall numbers and increase their chance of meeting requirements to qualify for shared savings under the model. This section presents findings on the impact of the CEC Model on participation in the Organ Procurement and Transplantation Network (OPTN) waiting list during the first two performance years of CEC.

[64] Total Part D drug cost represents total cost of prescriptions including: ingredients costs, dispensing fee, sales tax, and vaccine administration fee (if applicable).

A. Key Findings

Unintended Consequences. We explored potential unintended consequences of the CEC Model such as:

Key Findings:

Medicare Part D Drug Costs

- There was no evidence that the CEC Model had an effect on Medicare Part D Drug costs

Patient Selection

- There was no evidence that physicians changed their referral patterns due to the CEC Model (such as assigning sicker dialysis patients to non-CEC rather than CEC facilities in an effort to lower ESCO costs)

Referrals to Transplant Services

- There was no evidence that participation in CEC impacted referrals to the transplant waiting list

B. Methods

We used several data sources and methods to assess unintended consequences of the CEC Model.

Medicare Part D Drug Costs. We used a DiD approach to estimate impacts of the CEC Model on Part D PBPM costs, relative to the comparison group. The DiD model for Part D PBPM drug costs followed the same specifications as the models described in **Section VII** and **Appendix F**.

Patient Selection. We used a facility-level general DiD framework to assess the impact of the CEC Model on patient selection by comparing the number of new dialysis patients with comorbid conditions in ESCO facilities before and after implementation of CEC, relative to this number in

comparison facilities before and after implementation of CEC.[65] We defined patients as new to dialysis if their first dialysis claim from January 2014 to December 2017 occurred within the first three months after their dialysis start date as reported in CMS Form 2728.[66] We used data from CMS Form 2728 to identify beneficiaries with multiple comorbid conditions at the start of dialysis or in the 10 years preceding the start of dialysis. Our sample includes 39,188 new dialysis patients. On average, new dialysis patients had 2.8 comorbid conditions, and almost half (49%) had at least three comorbidities.

Because taking on new dialysis patients can pose potential financial risk for dialysis facilities, we also considered the total number of new dialysis patients as an outcome in our analyses. We then analyzed the number of new dialysis patients who had at least three and four comorbid conditions. A challenge in this analysis was the small number of new dialysis beneficiaries with a certain number of comorbid conditions in a given facility.[67] See **Appendix L** for a detailed description of the sample, the distribution of outcomes, and DiD models.

Referrals to Transplant Services. We used a DiD approach to quantify the impact of the CEC Model by comparing the changes in waiting list participation between the baseline and intervention periods for the aligned CEC population and the comparison population. This approach attributes any change in waiting list participation to CEC by contrasting the experience of beneficiaries under age 70 aligned to ESCOs to the experience of beneficiaries under age 70 aligned to comparison facilities. We estimated two DiD models, one estimated the impact of the CEC Model for all 37 ESCOs and one that estimated the impact for each ESCO wave and performance year.[68] The DiD models are described in **Appendix L**.

The study population included all beneficiaries under the age of 70 who were aligned between 2014 and 2017 to either a CEC facility or a matched comparison facility. The methods used to select the comparison facilities are described in more detail in **Appendix F**. The study population included only beneficiaries under 70 because older patients are waitlisted for and receive transplants with much less frequency than younger patients.[69] The analysis was based on yearly Medicare claims and enrollment data along with information provided by the Scientific Registry of Transplant Recipients (SRTR).[70] The beneficiary's Medicare information was linked to the corresponding waiting list record in the SRTR database by the SRTR data administration team. The SRTR data system includes data on all donors, wait-listed candidates, and transplant recipients in the US, submitted by the members of OPTN.[71] The linkage indicated if the

[65] The methods used to select the comparison facilities are described in more detail in **Appendix F**.

[66] https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-Items/CMS008867.html

[67] Due to potential limitations in variation in the data for those with at least five comorbidities, we focus on those with at least three and four comorbidities. See **Exhibit L-1.**

[68] Wave 1 is comprised of the original 13 ESCOs that first entered the CEC Model in October 2015. Wave 2 is the additional 24 ESCOs that entered in 2017.

[69] Transplants in people aged 70 or greater occur with much less frequency than do transplants in younger patients. As a robustness check, the analysis described in this chapter was also performed. All results were robust to removing this age restriction and to using an age cutoff of 75.

[70] Since transplant wait listing is a rare event, a yearly dataset was used instead of a monthly dataset.

[71] The Health Resources and Services Administration (HRSA), U.S. Department of Health and Human Services provides oversight to the activities of the OPTN and SRTR.

beneficiary identified in the Medicare database was in the SRTR database and the time period the beneficiary was active on any of the organ waiting lists.[72]

In a given calendar year, a beneficiary in the study population was identified as active in the waiting list if the beneficiary was active on the OPTN waiting list at some time during the year, and the beneficiary was waiting for either a kidney or a kidney and pancreas transplant. A beneficiary who received a donation from a living donor was considered active on the OPTN waiting list during the year that the donation occurred.

C. Results

Our analyses found no conclusive evidence of cost-shifting, adverse selection, or a reduction in transplant waiting list participation under the CEC Model.

1. Is There Evidence of Cost-Shifting to Medicare Part D?

There was no statistically significant difference in the rate of change in Part D PBPM drug costs from baseline to intervention between the CEC and comparison groups (**Exhibit 39**).[73]

Exhibit 39. Impact of the CEC Model on Part D Drug Cost PBPM

Measure		CEC		Comparison		DiD Estimate			
		Pre-CEC	Post-CEC	Pre-CEC	Post-CEC	DiD	90% Lower CI	90% Upper CI	Percent Change
Total Part D Drug Cost	All ESCOs	$820	$1,119	$836	$1,123	$12‡	-$9	$34	1.5%
	Wave 1 PY1	$819	$1,078	$835	$1,091	$2‡	-$26	$31	0.30%
	Wave 1 PY2	$819	$1,174	$835	$1,165	$26‡	-$5	$56	3.2%
	Wave 2 PY2	$899	$1,163	$915	$1,165	$15‡	-$11	$40	1.6%

Notes: PY1 covers October 2015 - December 2016, PY2 covers January 2017 - December 2017. All ESCOs estimates include both waves from October 2015 - December 2017. The estimate of All ESCOs is the combined cumulative impact of CEC, accounting for different lengths of exposure to the model. About 33% of facilities have nine quarters of CEC participation (October 2015 to December 2017); the remaining 67% participated in CEC from January 2017 to December 2017 (four quarters). A weighted average of the performance years by wave may not exactly equal the All ESCO result because the All ESCO and by-wave performance year estimates ware generated by regression models estimated separately for all ESCOs or by wave. 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 the intervention period with baseline relative to

[72] The data reported here have been supplied by the Minneapolis Medical Research Foundation (MMRF) as the contractor for the SRTR. The interpretation and reporting of these data are the responsibility of the authors and in no way should be seen as an official policy of or interpretation by the SRTR or the U.S. Government. This study was submitted to and subsequently approved by the Western Institutional Review Board (IRB). The IRB determined that the study met the criteria for an exemption and additionally granted a Waiver of HIPAA authorization.

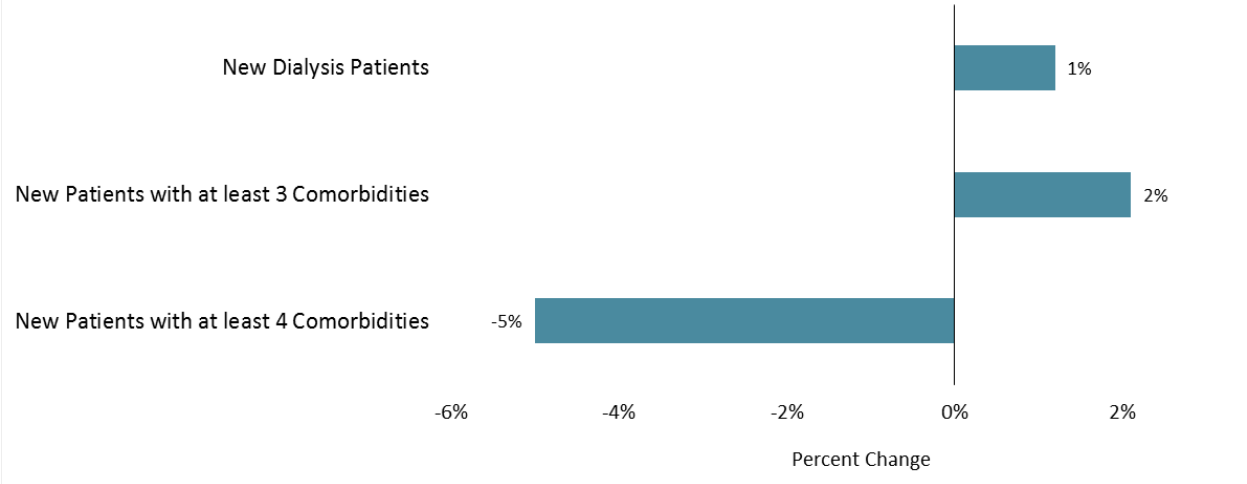
[73] Since Total Part D Drug cost did not pass statistical testing of the parallel trends assumption, we also inspected the trends graph which compared trends between the CEC beneficiaries and the comparison group and observed no evident differences. Additionally, the coefficient on the difference in trends at baseline, although significant, equaled: -1.92 (all ESCOs); -1.78 (Wave 1) and -2.06 (Wave 2).

the same difference over time for beneficiaries in matched comparison facilities. Significance of the DiD impact estimate is indicated next to each outcome bar plot where * implies significance at the 10% level, ** at the 5% level, and *** at the 1% level assuming a two-tailed test. Readmission are included in the overall acute inpatient spending. ‡ Data from the baseline period showed intervention and matched comparison facilities were not on parallel trends for this outcome, which is required for an unbiased impact estimate. Total Part D represents total cost of prescriptions including: ingredients costs, dispensing fee, sales tax, and vaccine administration fee (if applicable).

2. Is There Evidence of Adverse Selection within CEC Facilities?

Overall, we did not find consistent evidence that CEC facilities treated healthier new dialysis patients compared to matched comparison non-CEC facilities. Results are presented in **Exhibit 40**. Relative to non-CEC facilities, CEC facilities had 1% more new dialysis patients. In assessing the number of comorbidities that patients had, we found that CEC facilities had 2% more new patients with at least three comorbidities, and 5% fewer patients with at least four comorbidities. None of these estimates were statistically significant. We will continue to monitor for adverse selection as more facilities join the model and sample sizes increase.

Exhibit 40. Impact of the CEC Model on the Number of New Dialysis Patients with Comorbidities



Notes: Significance of the DiD impact estimate is indicated next to each outcome bar plot where * implies significance at the 10% level, ** at the 5% level, and *** at the 1% level assuming a two-tailed test. Regression controls for the number of new dialysis patients (with the exception of the New Dialysis Patients outcome), number of dialysis stations at each facility in each quarter, beneficiary count, whether or not the facility offers a late shift, for-profit status, indicators for LDO, rural/urban indicators, region dummies and market characteristics (percent of population that has ESRD, median family income, dual population, MA percent, ACO percent, and PCPs per 10,000).

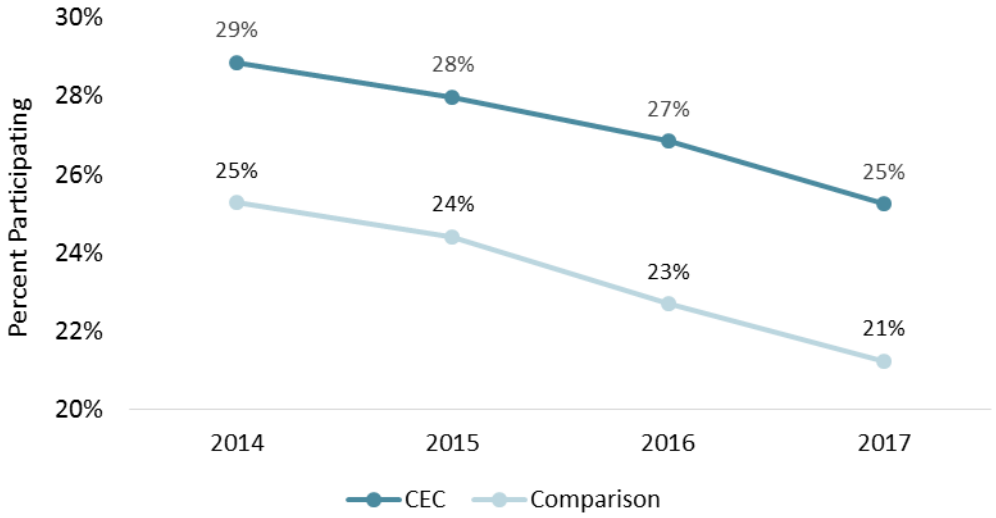
3. What Was the CEC Model's Impact on Transplant Waiting List Participation?

Exhibit 41 summarizes the yearly transplant waiting list participation by CEC participation status. The raw year-over-year change in waiting list participation was very similar between the CEC and non-CEC groups.[74] The average waiting list participation for CEC facilities was 29% in 2014 and 25% in 2017. Waiting list participation in the CEC facilities was consistently higher than that in comparison facilities, which had an average of 25% in 2014 and 21% in 2017. The decreasing trend in both groups was consistent with what was observed in the larger population

[74] These numbers may be impacted by changes in the kidney allocation system which took effect in December 2014. These changes impact both comparison and participating facilities.

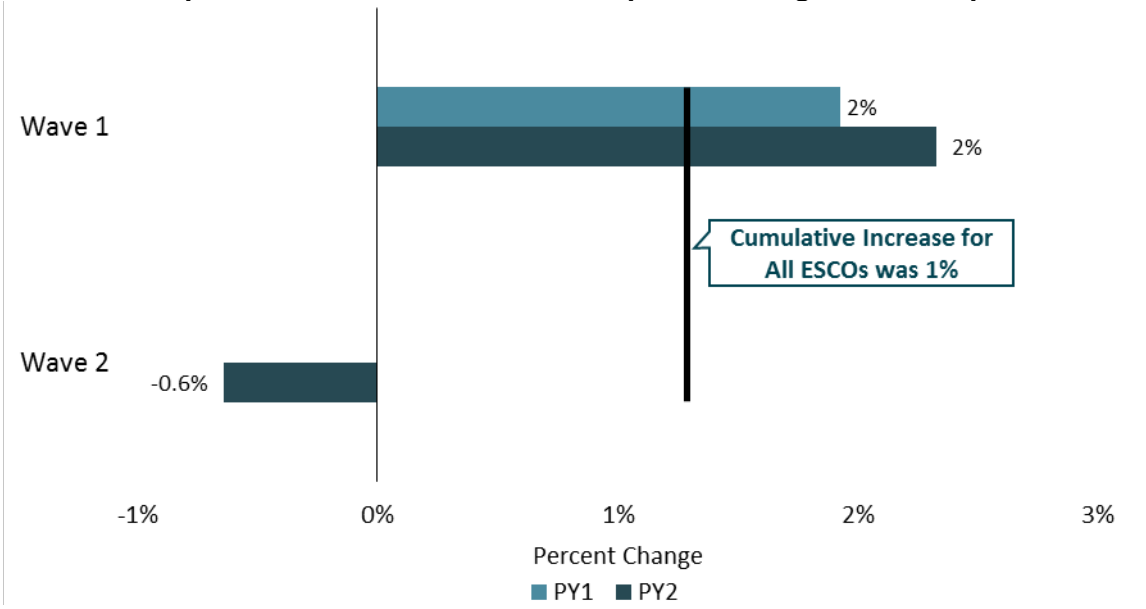
of beneficiaries who were active on the transplant waiting list. Specifically, we observed a decrease in the overall number of entries added to the waiting list and an increase in the number of entries removed from the waiting list in recent years (**Appendix L, Exhibit L-3**).

Exhibit 41. Transplant Waiting List Participation by CEC Participation Status



The findings from the DiD analysis are summarized in **Exhibit 42** (see also **Appendix L, Exhibit L-6**). The transplant waiting list participation decreased from the baseline to intervention for both CEC and comparison group beneficiaries, but slightly more so in Wave 1 PY1 and less so for each wave in PY2, resulting in negative DiD estimates for Wave 1 PY1 and positive DiD estimates for both waves in PY2. However, the DiD estimates were not statistically significant in either the analysis for the overall impact or the analysis separating ESCO waves by performance year. Therefore, we conclude that there is no evidence that CEC changed the waiting list participation in the first two performance years.

Exhibit 42. Impact of the CEC Model on Transplant Waiting List Participation PBPM



Notes: Estimate label values are rounded to the nearest whole number, therefore bar lengths may differ despite showing the same rounded label value. Significance of the DiD impact estimate is indicated next to each outcome bar plot where * implies significance at the 10% level, ** at the 5% level, and *** at the 1% level assuming a two-tailed test. None of these estimates are statistically significant.

D. Discussion

In a model such as CEC that encourages lower spending, it is important to search for potential unintended consequences that may negatively affect beneficiary care. The analysis did not yield conclusive evidence of the unintended consequences of cost-shifting to Medicare Part D, adverse selection, or a reduction in transplant waiting list participation under the CEC Model. There was no statistically significant difference in the change in Medicare Part D drug costs from baseline to intervention between the CEC and comparison groups. In this preliminary descriptive analysis, we found that CEC facilities did not have a statistically significant difference in the number of new dialysis patients or new patients with at least three or four comorbid conditions. Finally, transplant waitlist participation has been declining over time for both CEC and comparison beneficiaries, and there is no evidence that CEC changed transplant waiting list participation.

There are several important limitations in our analysis. The first limitation is the potential error in identifying a patient that is new to dialysis. We lack historical claims on about half of the beneficiaries who are eligible for Medicare due to ESRD because they were not Medicare beneficiaries prior to their ESRD diagnosis, and, as a result, there may be misidentification of patients who were new to dialysis. Further, we may have selected a healthier population because we required beneficiaries survive to their third month of dialysis before we counted them as a new dialysis patient in our analysis. Another limitation of the analysis is that we did not account for facilities within the same physician referral network. The waiting list participation analysis is limited by the frequency with which the transplant waiting list is updated. When the health status of a beneficiary changes or the beneficiary receives a kidney in another country there is typically a delay in when the waitlist entry is updated. Therefore, the dates of waitlist participation are approximate.

X. 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 for the total cost of care of their aligned beneficiaries. The time period covered by this report saw a major expansion of the CEC Model with the addition of 24 new ESCOs (Wave 2) to the 13 original ESCOs (Wave 1) that began operations in October 2015. Fresenius was particularly active in developing new ESCOs. Nationally, 12% of dialysis facilities were participating in the model in PY2. Participating facilities tended to be somewhat larger than non-participating facilities, and the markets served by ESCOs tended to be larger than those without an ESCO. CEC attaining status as an A-APM under MACRA motivated nephrologists' willingness to bear risk to participate in the new ESCOs and may ultimately contribute to both differences in performance across the waves and the potential to recruit new participants. Among participants, providers often cited alignment with CEC quality and cost goals as a motivation for participating. Shifting attitudes towards value-based payment might also enhance more providers' interest in the model going forward.

Overall, the first two years of experience under the CEC Model appear promising, with lower spending, improvements in some quality and utilization measures, and no obvious indicators of unintended adverse consequences. Declines in spending of nearly 2% were observed for total Part A and Part B Medicare payments. Spending reductions were most evident in Medicare Part A, with significant reductions in acute inpatient, readmission, and institutional PAC categories. Reductions in utilization paralleled the spending reductions, with significant declines in hospitalizations, readmissions, and ED visits. They were also consistent with ESCOs' reported efforts to avoid ED visits and hospitalizations through risk stratification, care coordination, and improved adherence to dialysis treatments. ESCOs specifically described strategies to decrease skipped dialysis treatments by improving communications with the ED and adding standby dialysis slots in order to divert patients from the inpatient setting for conditions that could be addressed through dialysis. The number of dialysis treatments and spending on dialysis increased while spending for hospitalizations for ESRD complications declined, which provides further evidence of fewer missed treatments. ESCOs also improved the quality of dialysis care, as seen in reductions in catheter placements, and improved some aspects of care beyond dialysis as demonstrated in higher rates of preventive health services.

Most results were driven by Wave 1 ESCOs, with few statistically significant changes for Wave 2 ESCOs. Differences in characteristics of the facilities by wave provide a possible explanation for the smaller spending reductions in Wave 2's first performance year. Whereas facilities in Wave 1 ESCOs had higher Medicare spending and higher standardized hospitalization and readmission rates than non-CEC facilities, those joining in Wave 2 actually had lower spending and lower standardized hospitalization and readmission rates than non-CEC facilities. This suggests that the facilities in Wave 2 ESCOs may have had less room to improve on their pre-CEC performance. Additionally, it is possible that, compared to Wave 2 ESCOs, Wave 1 ESCOs were more strongly motivated to join the CEC Model since they joined before it was deemed an A-APM under MACRA. Finally, because of delays with the initial model start, Wave 1 ESCOs may have had more lead time to develop their strategies and capabilities. Future analyses will be able to determine the extent to which Wave 1 ESCOs can maintain or further build upon their

early results, whether Wave 2 ESCOs can close the performance gap relative to Wave 1 ESCOs, and whether Wave 2 ESCOs also follow the pattern of increasing impact with time in the model.

In addition to the CEC Model's positive results relative to a matched FFS comparison group, it is also notable that the CEC Model had positive results relative to primary care-based ACOs, suggesting that beneficiaries with ESRD may fare better in the specialized CEC Model than in primary care-based ACOs. Given the structure of ESRD care as well as the clinical complexity of the ESRD population, a specialty-oriented care model like CEC may be more effective than a more generally-oriented ACO model. The dialysis-dependent ESRD population may be a particularly appropriate focus for development of a specialty-oriented ACO, as hemodialysis patients have regular contact with the specialty care institution (three times weekly) and the nephrologist (three to four times monthly). Home dialysis patients have less frequent, but still regular, contact with dialysis providers. Therefore, positive outcomes for the CEC Model might not be directly generalizable to populations with other chronic illnesses such as diabetes, HIV, or CHF.

Given the incentives for efficiency that are central to shared-savings models like the CEC Model and the vulnerable population served by CEC, it is important to monitor for unintended consequences. So far, we found no evidence of adverse outcomes such as reductions in quality of life, increased mortality, and the diversion of sicker patients away from the ESCO, or delayed transplant referrals to retain relatively healthier patients aligned to ESCO.

Findings presented in this report have several limitations. First, the 37 ESCOs are not representative of the population of Medicare providers, limiting our ability to generalize the results presented here. However, the addition of new participants in PY2 increased the representation of markets participating in CEC. 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 CEC and comparison facilities and their patients. Third, the analyses in this report are risk-adjusted to account for differences in provider and market characteristics, as well as patient mix that is measurable with claims data. As with all regression models, it is possible that we did not control for all characteristics that may affect the outcomes such as the motivation to participate in a voluntary payment model.

Future annual reports will build on these analyses in several ways. First, with increased sample sizes, as well as extended exposure under the model, we will be able to do more in-depth analyses of particular participant types, market effects, and beneficiary sub-populations. In particular, we will compare the performance of participants from LDOs and non-LDOs, compare performance across LDOs, and investigate the experience of subpopulations who may be more vulnerable to declines in quality of care. Second, we will analyze variation in ESCO performance and draw from both qualitative and quantitative analyses to identify factors that contributed to the success of individual ESCOs or LDOs in achieving the CEC objectives. Third, with increased participation of Medicare beneficiaries with ESRD in two-sided risk ACOs, we will be able to compare experiences between CEC, and primary care-based ACO beneficiaries, limiting the analysis to two-sided risk ACOs. Finally, we will evaluate the impact of CEC on Medicaid-only services, which include primarily long-term care and home- and community-based services.