

C H A P T E R

6

Outpatient dialysis services

R E C O M M E N D A T I O N

- 6** For calendar year 2021, the Congress should update the calendar year 2020 Medicare end-stage renal disease prospective payment system base rate by the amount determined under current law.

COMMISSIONER VOTES: YES 16 • NO 0 • NOT VOTING 0 • ABSENT 1

Outpatient dialysis services

Chapter summary

Outpatient dialysis services are used to treat the majority of individuals with end-stage renal disease (ESRD). In 2018, nearly 395,000 beneficiaries with ESRD on dialysis were covered under fee-for-service (FFS) Medicare and received dialysis from approximately 7,400 dialysis facilities. Since 2011, Medicare has paid for outpatient dialysis services based on a prospective payment system (PPS) bundle that includes certain dialysis drugs and ESRD-related clinical laboratory tests that were previously paid separately. In 2018, Medicare expenditures for outpatient dialysis services were \$12.7 billion, an 11 percent increase compared with 2017 expenditures. Nearly all of the growth in spending is due to payments for two drugs that qualified in 2018 for the ESRD PPS's transitional drug add-on payment adjustment (TDAPA). Without these TDAPA payments, dialysis spending would have increased at 0.5 percent, a rate similar to the growth seen between 2016 and 2017 (0.4 percent).

In this chapter

- Are Medicare payments adequate in 2020?
- How should Medicare payments change in 2021?
- Medicare's efforts to improve management of late-stage chronic kidney disease and end-stage renal disease
- Factors affecting the use of home dialysis

Assessment of payment adequacy

Our payment adequacy indicators for outpatient dialysis services are generally positive.

Beneficiaries' access to care—Measures of the capacity and supply of providers, beneficiaries' ability to obtain care, and changes in the volume of services suggest payments are adequate.

- ***Capacity and supply of providers***—Dialysis facilities appear to have the capacity to meet demand. Between 2017 and 2018, the number of dialysis treatment stations grew faster than the number of FFS dialysis beneficiaries.
- ***Volume of services***—Between 2017 and 2018, growth in the number of FFS dialysis beneficiaries matches growth in the total number of treatments. At the same time, dialysis drug use (including erythropoiesis-stimulating agents, which are used in anemia management) continued to decline, but at a slower rate than during the initial years of the ESRD PPS (2011 and 2012). The ESRD PPS created an incentive for providers to be more judicious about their provision of dialysis drugs that are included in the payment bundle.
- ***Marginal profit***—The 18 percent marginal profit in 2018 suggests that dialysis providers have a financial incentive to continue to serve Medicare beneficiaries.

Quality of care—Between 2013 and 2018, hospitalization rates declined, though the proportion of FFS dialysis beneficiaries using the emergency department increased. Rates of hospital readmission and mortality remained steady. Between 2013 and 2018, the share of beneficiaries using home dialysis, which is associated with better patient satisfaction, increased from 10 percent to 12 percent.

Providers' access to capital—Information from investment analysts suggests that access to capital for dialysis providers continues to be strong. The number of facilities, particularly for-profit facilities, continues to increase. Under the ESRD PPS, the two largest dialysis organizations have grown through acquisitions and mergers with midsized dialysis organizations.

Medicare payments and providers' costs—Our analysis of Medicare payments and costs is based on 2017 and 2018 claims and cost report data submitted to CMS by freestanding dialysis facilities, which provided 96 percent of all FFS dialysis treatments in 2018. During this period, cost per treatment increased by 7 percent, while Medicare payment per treatment increased by 11 percent. We estimate that the aggregate Medicare margin was 2.1 percent in 2018, and the 2020 Medicare margin is projected to be 2.4 percent.

How should payment rates change in 2021?

Under current law, the Medicare FFS base payment rate for dialysis services is projected to increase by 2.0 percent. Given that most of our indicators of payment adequacy are positive, the update recommendation is that for 2021, the Congress should update the ESRD PPS base rate by the amount determined under current law. ■

Dialysis treatment choices

Dialysis replaces the filtering function of the kidneys when they fail. The two types of dialysis—hemodialysis and peritoneal dialysis (PD)—remove waste products from the bloodstream differently. For each of these two dialysis types, patients may select various protocols.

Most dialysis patients travel to a treatment facility to undergo hemodialysis three times per week, although patients can also undergo hemodialysis at home.

Hemodialysis uses an artificial membrane encased in a dialyzer to filter the patient's blood. Because of recent clinical findings, there is increased interest in more frequent hemodialysis, administered five or more times per week while the patient sleeps, and short (two to three hours per treatment) daily dialysis administered during the day. Research also has increased interest in the use of "every-other-day" hemodialysis; reducing the two-day gap in thrice-weekly hemodialysis could be linked to improved outcomes. As of January 2020, the Agency for Healthcare Research and Quality has not issued its final report about the effects of more frequent or longer hemodialysis on end-stage renal disease patients' clinical outcomes and quality of life.

PD, the most common form of home dialysis, uses the lining of the abdomen (peritoneum) as a filter to clear wastes and extra fluid and is usually performed independently in the patient's home or workplace five to seven days a week. During treatments, a cleansing fluid (dialysate) is infused into the patient's abdomen through a catheter. This infusion process (an exchange) is done either manually (continuous ambulatory peritoneal dialysis) or using a machine (automated peritoneal dialysis).

Each dialysis method has advantages and disadvantages; no one method is best for everyone. People choose a particular dialysis method for many reasons, including quality of life, patients' awareness of different treatment methods and personal preferences, and physician training and recommendations. The use of home dialysis has grown since 2009, a trend that has continued under the dialysis prospective payment system. Some patients switch methods when their conditions or needs change. Although most patients still undergo in-center dialysis, home dialysis remains a viable option for many patients because of such advantages as increased patient satisfaction, better health-related quality of life, and fewer transportation challenges compared with in-center dialysis. ■

Background

End-stage renal disease (ESRD) is the last stage of chronic kidney disease and is characterized by permanent irreversible kidney failure. Patients with ESRD include those who are treated with dialysis—a process that removes wastes and fluid from the body—and those who have a functioning kidney transplant. Because of the limited number of kidneys available for transplantation and the variation in patients' suitability for transplantation, about 70 percent of ESRD patients undergo maintenance dialysis (see text box on dialysis treatment choices). Patients receive additional items and services related to their dialysis treatments, including dialysis drugs and biologics to treat conditions such as anemia and bone disease resulting from the loss of kidney function.

In 2018, nearly 395,000 ESRD beneficiaries on dialysis were covered under fee-for-service (FFS) Medicare and

received dialysis from about 7,400 dialysis facilities.¹ Since 2011, Medicare has been paying facilities using a prospective payment system (PPS) bundle that includes dialysis drugs (for which facilities previously received separate payments) and services for which other Medicare providers (such as clinical laboratories) previously received separate payments.² In 2018, Part B spending for Medicare-covered outpatient dialysis services was \$12.7 billion. This total includes payments of \$1.2 billion paid for the two dialysis drugs classified as calcimimetics—Sensipar (cinacalcet) and Parsabiv (etelcalcetide)—that qualified, beginning in 2018, for Part B transitional drug add-on payment adjustments (TDAPAs) under the ESRD PPS. In addition, Part D payments for dialysis drugs that were not yet included in the PPS in 2017—multiple phosphate binders—totaled nearly \$1.4 billion (the most recent data available). As of December 2019, the calcimimetics' add-on payment is the first and only TDAPA that CMS has implemented under the ESRD PPS.

**TABLE
6-1**

FFS dialysis beneficiaries are disproportionately younger, male, and African American compared with all Medicare FFS beneficiaries, 2018

	Percent of FFS:	
	Dialysis beneficiaries	All other beneficiaries
Age		
Under 45 years	10%	4%
45–64 years	38	12
65–74 years	28	50
75–84 years	18	23
85+ years	6	11
Sex		
Male	56	47
Female	44	53
Race		
White	47	81
African American	35	10
Hispanic	8	3
Asian	4	2
All others	6	5
Residence, by type of county		
Urban	83	79
Micropolitan	10	11
Rural, adjacent to urban	5	5
Rural, not adjacent to urban	2	3
Frontier	1	1

Note: FFS (fee-for-service). Beneficiary location reflects the beneficiary's county of residence in one of four categories (urban, micropolitan, rural adjacent to urban, and rural nonadjacent to urban) based on an aggregation of the urban influence codes. Frontier counties have six or fewer people per square mile. Components may not sum to 100 percent due to rounding.

Source: Data compiled by MedPAC from enrollment data and claims submitted by dialysis facilities to CMS.

Most dialysis beneficiaries have FFS coverage. The statute currently prohibits individuals with ESRD from enrolling in Medicare Advantage (MA) plans. However, beneficiaries who were enrolled in a managed care plan before receiving an ESRD diagnosis can remain in the plan after they are diagnosed. In addition, Medicare permits ESRD beneficiaries with a functioning kidney transplant to enroll in MA. In 2018, about 21 percent of ESRD beneficiaries were enrolled in MA plans; by comparison, roughly one-third of Medicare beneficiaries were enrolled in MA plans. In 2000, the Commission recommended that the Congress lift the prohibition on ESRD beneficiaries enrolling in MA (Medicare Payment Advisory Commission 2000). The 21st Century Cures Act allows ESRD beneficiaries to enroll in MA beginning in 2021.

Although they cannot currently enroll in MA plans, dialysis beneficiaries residing in selected geographic areas have access to ESRD special needs plans (SNPs), a type of chronic condition SNP (C-SNP). As of October 2019, few dialysis beneficiaries—about 5,400—were enrolled in 10 ESRD SNPs operated by 8 managed care organizations in 6 states (California, Connecticut, Nevada, New Jersey, Texas, and Virginia).⁴ The Commission recommended that Medicare maintain C-SNPs for beneficiaries with ESRD, HIV/AIDS, or chronic and disabling mental health conditions (Medicare Payment Advisory Commission 2013).

In 2018, about 90 percent of FFS dialysis beneficiaries were enrolled in Part D or had other sources of creditable drug coverage. About 10 percent of FFS dialysis beneficiaries in 2018 had either no Part D coverage or coverage less generous than Part D's standard benefit. About 70 percent of FFS dialysis beneficiaries with Part D coverage received the low-income subsidy (LIS) in 2018. By contrast, among all Part D enrollees in FFS Medicare, 28 percent received the LIS in 2018.

Compared with all other Medicare FFS beneficiaries, FFS dialysis beneficiaries are disproportionately younger, male, and African American (Table 6-1). In 2018, 76 percent of FFS dialysis beneficiaries were younger than 75 years old, 56 percent were male, and 35 percent were African American. By comparison, of all FFS Medicare beneficiaries, 66 percent were younger than 75 years old, 47 percent were male, and 10 percent were African American. A greater share of dialysis beneficiaries resided in urban areas compared with all FFS beneficiaries

Characteristics of fee-for-service dialysis beneficiaries, 2018

The 1972 amendments to the Social Security Act extended Medicare benefits to people with ESRD, including those under age 65. For an individual with ESRD to qualify for Medicare, he or she must be fully or currently insured under the Social Security or Railroad Retirement program or be the spouse or dependent child of an eligible beneficiary.³

(83 percent vs. 79 percent, respectively). FFS dialysis beneficiaries were more likely to be dually eligible for Medicaid and Medicare, compared with all Medicare FFS beneficiaries (48 percent vs. 17 percent, respectively; data not shown).

The adjusted rate of new ESRD cases (or incidence rate) (which includes patients of all types of health coverage who initiate dialysis or receive a kidney transplant) rose sharply in the 1980s and 1990s, leveled off in the early 2000s, and has declined slightly since its peak in 2006. Between 2007 and 2017 (most recent year of data available), the adjusted incidence rate decreased by 1 percent per year, from 376 per million people to 341 per million people (the lowest incidence rate since 1998) (United States Renal Data System 2019).⁵ We estimate that in 2018, about 84,000 FFS beneficiaries were new to dialysis, and about half (46 percent) were under age 65 and thus entitled to Medicare based on ESRD (with or without disability).⁶

Better primary care management of the risk factors for chronic kidney disease (CKD)—particularly hypertension and diabetes, which together are the primary causes of roughly 7 of 10 new ESRD cases—can help prevent or delay the illness’s onset. Payers and dialysis providers are testing interventions among CKD patients to improve their clinical outcomes (e.g., by reducing hospitalizations), prevent or slow kidney disease progression, and increase their preparedness for ESRD (e.g., by educating patients about treatment alternatives, including transplantation and home dialysis). The Centers for Medicare & Medicaid Innovation (CMMI) has sponsored several models to manage the care of individuals with late-stage CKD and with ESRD (these models are described at the end of the chapter (pp. 193–198)). The Commission has long argued that primary care services are undervalued in Medicare’s fee schedule and has made recommendations to support primary care, which in turn could support better management of kidney disease risk factors.

Since 2011, Medicare has paid for dialysis services under the ESRD PPS

To treat ESRD, dialysis beneficiaries receive care from two principal providers: (1) the clinicians (typically nephrologists) who prescribe and manage the provision of dialysis and establish the beneficiary’s plan of care; and (2) facilities that provide dialysis treatments in a dialysis center or support and supervise the care of beneficiaries on home dialysis. Medicare uses different methods to

pay for ESRD clinician and facility services. Clinicians receive a monthly capitated payment established in the Part B physician fee schedule for outpatient dialysis-related management services (which includes managing the dialysis prescription and prescribing dialysis drugs), which varies based on the number of visits per month, the beneficiary’s age (adults vs. pediatric patients under 20 years of age), and whether the beneficiary receives dialysis in a facility or at home.⁷ While our work in this report focuses on Medicare’s payments to facilities, it is important to recognize that facilities and clinicians collaborate to care for dialysis beneficiaries. One acknowledgment of the need for collaboration is Medicare’s Comprehensive ESRD Care Model, a shared savings program that began in October 2015, involving facilities and nephrologists.

To improve provider efficiency, in 2011 Medicare began a PPS for outpatient dialysis services that expanded the prospective payment bundle to add (1) Part B dialysis drugs, laboratory tests, and other ESRD items and services that were previously billable separately and (2) Part D dialysis oral drugs—including calcimimetics and phosphate binders. Clinicians use drugs in these two therapeutic classes to manage mineral bone disorders, a complication of advanced CKD. Statutory provisions delayed the inclusion of dialysis oral-only drugs under the ESRD PPS until 2025.

Under the outpatient ESRD PPS, the unit of payment is a single dialysis treatment. For adult dialysis beneficiaries (18 years or older), the base payment rate does not differ by type of dialysis—in-center dialysis versus home dialysis—but rather by patient-level characteristics (age, body measurement characteristics, onset of dialysis, and selected acute and chronic comorbidities) and facility-level factors (low treatment volume, rural location, and local input prices).⁸ Medicare pays facilities furnishing dialysis treatments in the facility or in a patient’s home for up to three treatments per week, unless there is documented medical justification for more than three weekly treatments. The Commission’s *Payment Basics* provides more information about Medicare’s method of paying for outpatient dialysis services (available at http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_19_dialysis_final_sec.pdf?sfvrsn=0).

Since it was implemented in 2011, the outpatient ESRD PPS has undergone several significant changes. In 2014, CMS rebased the base payment rate, as mandated by the

American Taxpayer Relief Act of 2012, to account for the decline in dialysis drug use under the ESRD PPS.⁹ In 2016, the agency recalibrated and redefined the patient-level and facility-level payment adjusters that are used to calculate each patient's adjusted payment per treatment.¹⁰

In addition, in 2016 CMS established a drug designation process (as mandated by the Protecting Access to Medicare Act of 2014) for determining when ESRD-related oral-only drugs—calcimimetics and phosphate binders—are no longer oral only and therefore must be paid under the ESRD PPS. Under the process, once the Food and Drug Administration (FDA) approves an equivalent injectable product (or other non-oral forms), the agency pays facilities for both the oral and non-oral products under a TDAPA until sufficient claims data (at least two years' worth) for rate-setting analysis are available; thereafter, these drugs (calcimimetics and phosphate binders) will be included in the outpatient dialysis prospective payment bundle.¹¹ With the 2017 approval by the FDA of an injectable calcimimetic, CMS has paid, as of 2018, for both the oral and injectable forms under the ESRD PPS using a TDAPA based on each product's average sales price (ASP). Calcimimetics are the only drugs to have gone through the ESRD drug designation process to date. 2020 is the third year that CMS uses a TDAPA policy to pay for calcimimetics. The agency has not set forth the methods of the rate-setting analysis that will incorporate calcimimetics into the payment bundle.

The drug designation process that CMS established in 2016 also implemented a process for including new ESRD-related injectable and intravenous drugs into the prospective payment bundle, if the new ESRD-related injectable drug does not fit into 1 of 11 ESRD-related functional categories. (Functional categories are similar to therapeutic classes of drugs.) Such drugs are eligible for a TDAPA for at least two years, until sufficient rate-setting data are available. When the TDAPA period ends, CMS includes the drug in the prospective payment bundle (by adding a new functional category or modifying an existing one) and adjusts the PPS base rate, if appropriate, to reflect changes to the functional categories.¹² As described in the text box on transitional add-on payment adjustments for new dialysis technologies, beginning in 2020 CMS will revise the drug designation process and expand the TDAPA for new ESRD-related drugs and will introduce a transitional add-on payment for new and innovative equipment and supplies (TPNIES).

Since 2012, outpatient dialysis payments are linked to the quality of care that facilities provide under the ESRD Quality Incentive Program (QIP). Under statutory provisions, the maximum payment reduction that CMS can apply to any facility is 2 percent. In 2019, the QIP assessed quality using:

- clinical measures that assess dialysis adequacy, vascular access among hemodialysis beneficiaries, hospital readmission rates, blood transfusion rates, presence of hypercalcemia, bloodstream infections among hemodialysis beneficiaries, and the quality of care that in-center hemodialysis beneficiaries report that they receive from their nephrologist and dialysis facility; and
- process measures that assess whether dialysis facilities report on pain assessment, clinical depression screening, anemia management, bone mineral metabolism, and disease management; the influenza vaccination among their health care personnel; and infection events (reported to the Centers for Disease Control and Prevention's National Healthcare Safety Network).

In 2019, of the 6,800 facilities with a QIP performance score, 73 percent had no payment reduction, 18 percent had their Medicare outpatient dialysis payments reduced by 0.5 percent, 6 percent had payments reduced by 1.0 percent, 2 percent of facilities had payments reduced by 1.5 percent, and 1 percent of facilities had payments reduced by the maximum, 2 percent. About 260 facilities lacked a QIP performance score (because they did not meet the minimum data requirements necessary to calculate a score) and thus had no payment reduction in 2019.

In addition to the QIP, since 2015 CMS uses a second measurement system, the dialysis star ratings system, to assess the quality of care furnished by dialysis facilities. This second measurement system, which CMS established through a subregulatory process, assigns each facility from 1 to 5 stars; more stars mean that a dialysis facility performs better on quality compared with all other facilities. In its comment letter to CMS, the Commission questioned why CMS finds a second quality system necessary for dialysis facilities (Medicare Payment Advisory Commission 2014a). We also raised concerns that beneficiaries and their families might be confused if a facility's star rating and QIP scores diverge, which could

Expanded transitional add-on payment adjustments for new dialysis technologies begins in 2020

Beginning in 2020, certain new dialysis drugs (that are not generics) will be eligible for an expanded transitional drug add-on payment adjustment (TDAPA), and some new dialysis equipment and supplies will be eligible for a

transitional add-on payment for new and innovative equipment and supplies (TPNIES) (Table 6-2).

Under the expanded TDAPA policy, the agency includes a payment adjustment in addition to the base

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**TABLE
6-2**

Summary of add-on payment policies for new technology—drugs, biologics, equipment, and supplies—to the ESRD PPS in 2020

	New ESRD-related injectable drugs that:			New ESRD-related equipment and supplies designated as a renal dialysis service
	Do not fit into an existing ESRD PPS functional category	Fit into an existing ESRD PPS functional category		
Oral-only ESRD drugs and their injectable equivalent (calcimimetics and phosphate binders)				
Name of add-on payment	TDAPA	TDAPA	TDAPA	TPNIES
Year add-on payment began	2018 (for calcimimetics) ^a	2016 (no products eligible for TDAPA through 2019)	2020	2020
Is a substantial clinical improvement standard used?	No	No	No ^c	Yes
Payment rate of add-on	ASP ^b	ASP ^b	ASP	MACs will use manufacturers' invoices and other sources of prices
Length of add-on payment period	At least two years (until sufficient rate-setting data are available)	At least two years (until sufficient rate-setting data are available)	Two calendar years	Two calendar years
Is the new technology included in the PPS payment bundle at the end of the add-on payment period?	Yes	Yes	Yes	Yes
Is the PPS base rate updated at the end of add-on payment period? ^d	Yes	Yes	No	No

Note: ESRD (end-stage renal disease), PPS (prospective payment system), TDAPA (transitional drug-add-on payment policy), TPNIES (transitional add-on payment for new and innovative equipment and supplies), ASP (average sales price), MAC (Medicare administrative contractor).

^aPhosphate binders will be paid through a TDAPA in 2025, or earlier if the Food and Drug Administration approves an injectable formulation.

^bIn 2016, CMS set payment based on 106 percent of each drug's ASP. As of 2020, CMS will set payment based on 100 percent of each drug's ASP.

^cCMS excludes certain new drugs from receiving a TDAPA according to the pathway and classification code that the Food and Drug Administration assigns to drugs in its approval process. New drugs that are not eligible for a TDAPA include generic drugs (approved under Section 505(j) of the Federal Food, Drug, and Cosmetic Act), new drugs approved for a new dosage form (assigned New Drug Classification Type 3), and new drugs approved for a new formulation (assigned New Drug Classification Type 5).

^dAccording to CMS, a new dialysis drug that is not considered included in the ESRD PPS base rate is paid the TDAPA until sufficient claims data for rate-setting analysis for the new drug is available, but not for less than two years. After the payment of the TDAPA, the ESRD PPS base rate will be modified, if appropriate, to account for the new renal dialysis drug or biological in the ESRD PPS bundled payment.

Source: MedPAC analysis of final ESRD payment rules for 2016, 2019, and 2020.

Expanded transitional add-on payment adjustments for new dialysis technologies begins in 2020 (cont.)

rate that pays facilities for certain new dialysis drugs and biologics, including biosimilars, that the Food and Drug Administration (FDA) approves on or after January 1, 2020, and that fall into 1 of the 11 functional categories of products that define the drugs included in the end-stage renal disease (ESRD) prospective payment bundle since 2011.¹³ Based on FDA drug approval pathways, the expanded TDAPA policy includes new molecular entities, drugs with a new active ingredient, and biosimilars, among others. The expanded TDAPA policy will not apply to new generic drugs and certain other drugs.¹⁴ The TDAPA will apply for two years, with payment set at each drug's average sales price. After two years, CMS will include the drug in the prospective payment system (PPS) payment bundle without any change to the base rate. The drug designation and TDAPA process that CMS established in 2016 for a new dialysis drug that does not fit into 1 of the existing 11 functional categories is unchanged.

Under the TPNIES policy, the agency includes a payment adjustment in addition to the base rate that pays facilities separately for certain new and innovative renal dialysis equipment and supplies under the ESRD PPS. ESRD-related equipment or supplies will be eligible for the TPNIES if the item:

- is new, defined as granted marketing authorization by the FDA on or after January 1, 2020,
- has applied for a Healthcare Common Procedure Coding System billing code,
- is not a capital-related asset,¹⁵ and
- is truly innovative, defined as meeting the substantial clinical improvement criteria that are based on the same criteria used to determine eligibility for the new technology add-on payment under the inpatient PPS.

Specifically, CMS considers a technology innovative if it represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. The TPNIES will apply for two calendar years; thereafter, the product will be included in the PPS payment bundle without any change to the base rate. The TPNIES payment will be based on 65 percent of the price established by the Medicare administrative contractors using information from sources that include the invoice amount, facility charges for the item net of discounts and rebates and payment amounts determined by other payers.

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occur because the measurement systems use different methods and measures to calculate a facility's performance score.¹⁶

The establishment of the ESRD PPS in 2011 and the QIP in 2012 were mandated by the Medicare Improvements for Patients and Providers Act of 2008 and based on the Commission's recommendation to modernize the outpatient dialysis payment system (Medicare Payment Advisory Commission 2001). We contended that Medicare could provide incentives for the efficient delivery of quality care by broadening the payment bundle existing at the time (to include commonly furnished drugs and services that providers formerly billed separately) and by

linking payment to quality. The PPS is designed to create incentives for facilities to provide services more efficiently by reducing previous incentives, inherent in the former payment method, to overuse drugs.

Are Medicare payments adequate in 2020?

To address whether payments for 2020 are adequate to cover the costs that efficient providers incur and how much providers' costs should change in the update year (2021),

Expanded transitional add-on payment adjustments for new dialysis technologies begins in 2020 (cont.)

Under current policy, beneficiaries appear to have good access to new dialysis products. For example, in 2015, nearly one-quarter of dialysis beneficiaries received epoetin beta, which was introduced to the U.S. market in that year. In our comment letters regarding the TDAPA and TPNIES policies, the Commission said that it is important to maintain the structure of the ESRD PPS and not create policies that would unbundle services covered under the PPS or create incentives that encourage high launch prices of new drugs and other technologies. Specific to the TDAPA proposal, we strongly urged CMS not to proceed with its proposal to apply the policy to new renal dialysis drugs that fit into a functional category (including composite rate drugs, which have never been paid separately by Medicare) and urged the agency to withdraw the proposal (Medicare Payment Advisory Commission 2018a).¹⁷ We asserted that if CMS decided to proceed with both the TDAPA and TPNIES policies, several modifications to the proposal would be necessary, at a minimum:

CMS should require the new product to be an advance in medical technology that substantially improves beneficiaries' outcomes relative to technologies in the PPS payment bundle. In the final TDAPA policy, CMS elected not to include this modification, stating

that (1) its final policy will provide an opportunity for new drugs to compete with other similar drugs in the market, which could result in lower prices for all drugs, and (2) the effectiveness of drugs can depend on age, gender, race, genetic predisposition, and comorbidities (Centers for Medicare & Medicaid Services 2018).

CMS should not make duplicative payments for a new technology (new drugs that fall within an existing functional category and new equipment and supplies) by paying under the TDAPA or TPNIES for two years and paying for products and items with a similar purpose or use that is already paid under the ESRD PPS base rate. For example, the agency could reduce the TDAPA amount to reflect the amount already included in the base rate. In addition, CMS could consider paying a reduced share of the estimated incremental cost of the new drug as a way to share risk with dialysis providers and provide some disincentive for the establishment of high launch prices. CMS elected not to include these modifications to the TDAPA or TPNIES final policies, stating that the policy is temporary and not duplicative because, at the end of the two-year period, there is no additional money added to the base rate for those drugs that fall within an existing functional category (Centers for Medicare & Medicaid Services 2018). ■

we examine several indicators of payment adequacy. We assess beneficiaries' access to care by examining the capacity of dialysis facilities and changes over time in the volume of services provided. We also examine quality of care, providers' access to capital, and the relationship between Medicare's payments and facilities' costs. Most of our payment adequacy indicators for dialysis services are positive.

Beneficiaries' access to care: Indicators continue to be favorable

Our analysis of access indicators—including the capacity of providers to meet beneficiary demand, changes in

the volume of services, and the marginal profitability of Medicare dialysis beneficiaries under the PPS—shows that beneficiaries' access to care remains favorable.

Capacity has kept pace with patient demand

Growth in the number of dialysis facilities and treatment stations alongside growth in dialysis beneficiaries suggests that, between 2013 and 2018, provider capacity kept up with demand for care. During that period, the number of facilities and their capacity to provide care—as measured by in-center dialysis treatment stations—each increased by 4 percent annually (Table 6-3, p. 178). By contrast, between 2013 and 2018, the number of FFS

**TABLE
6-3****Increasing number and capacity of freestanding, for-profit, and largest dialysis organizations**

	2018				Average annual percent change			
	Total number of FFS treatments (in millions)	Total number of facilities	Total number of stations	Mean number of stations	Number of facilities		Number of stations	
					2013-2018	2017-2018	2013-2018	2017-2018
All	45.5	7,441	130,300	18	4%	5%	4%	6%
Percent of total								
Freestanding	96%	95%	96%	18	5	6	4	7
Hospital based	4	5	4	14	-4	-6	-4	-3
Urban	86	83	86	18	5	6	4	7
Micropolitan	10	11	9	16	2	3	2	4
Rural, adjacent to urban	3	4	3	14	2	2	2	4
Rural, not adjacent to urban	1	2	2	11	2	-2	2	-1
Frontier	0.2	0.5	0.3	10	1	0	1	7
For profit	88	88	89	18	5	5	4	6
Nonprofit	12	12	11	17	-0.4	2	0.3	5
Two largest dialysis organizations	75	74	75	18	5	6	5	7
All others	25	26	25	17	2	1	2	3

Note: FFS (fee-for-service). Provider location reflects the county where the provider is located in one of four categories (urban, micropolitan, rural adjacent to urban, and rural nonadjacent to urban) based on an aggregation of the urban influence codes. Frontier counties have six or fewer people per square mile. Components may not sum to 100 percent due to rounding.

Source: Compiled by MedPAC from the Dialysis Compare database from CMS and claims submitted by dialysis facilities to CMS.

dialysis beneficiaries grew 1 percent annually (data not shown). In the same period, capacity at facilities that were freestanding and for profit each grew by 4 percent per year, while capacity at facilities that were hospital based decreased by 4 percent per year and capacity at nonprofit facilities grew by less than 1 percent per year. Between 2013 and 2018, capacity at urban facilities grew 4 percent per year, while capacity at all rural facilities grew at 2 percent per year. Between 2017 and 2018, total dialysis capacity grew by 6 percent, while the number of FFS dialysis beneficiaries grew more slowly (by 0.2 percent, data not shown). The Commission intends to develop a measure assessing facilities' capacity to furnish home dialysis in the future.

Providers of outpatient dialysis services In 2018, there were roughly 7,400 dialysis facilities in the U.S. that furnished about 45.5 million Medicare-paid treatments to FFS dialysis beneficiaries. FFS Medicare accounted for about 60 percent of all treatments furnished in 2018.¹⁸ According to CMS facility survey data, since the late 1980s, for-profit, freestanding facilities have provided the majority of dialysis treatments. In 2018, freestanding facilities furnished 96 percent of FFS treatments, and for-profit facilities furnished 88 percent (Table 6-3). In 2018, the capacity of facilities in urban and rural areas was generally consistent with where FFS dialysis beneficiaries lived.

Two large dialysis organizations (LDOs)—Fresenius Medical Care and DaVita—dominate the dialysis industry. In 2018, these LDOs accounted for three-quarters of facilities and Medicare treatments. In addition to operating most dialysis facilities, the two LDOs are each vertically integrated. Both organizations operate an ESRD-related laboratory, a pharmacy, and one or more centers that provide vascular access services; they provide ESRD-related disease management services; and they operate dialysis facilities internationally. One LDO manufactures, acquires, licenses, and distributes dialysis-related pharmaceutical products (e.g., phosphate binders and iron replacement products); is the leading supplier of dialysis products (such as hemodialysis machines and dialyzers) to other dialysis companies; and operates a Phase I–IV drug and device clinical development company that focuses on the clinical development of new renal therapies.

Types of facilities that closed and their effect on beneficiaries' access to care Each year, we examine the types of facilities that closed and whether certain groups of Medicare dialysis beneficiaries are disproportionately affected by facility closures. Using facilities' claims submitted to CMS and CMS's Dialysis Compare database and provider of service file, we compare the characteristics of beneficiaries treated by facilities that closed in 2017 with beneficiaries treated at facilities that provided dialysis in 2017 and 2018.

Between 2017 and 2018, the number of dialysis treatment stations—a measure of providers' capacity—increased by 6 percent (Table 6-3). There was a net increase in the number of facilities that were freestanding and located in both urban and rural areas. Compared with facilities that treated beneficiaries in both years, facilities that closed in 2017 (70 facilities) were more likely to be hospital based, nonprofit, and smaller (as measured by the number of dialysis treatment stations), which is consistent with long-term trends in the supply of dialysis providers.

According to our analysis, few dialysis FFS beneficiaries (roughly 2,500 individuals) were affected by facility closures in 2017. Our analysis found that beneficiary groups who were disproportionately affected included beneficiaries who were African American and younger (under the age of 65 years), which is consistent with last year's findings (Medicare Payment Advisory Commission 2019). However, less than 1 percent of FFS beneficiaries in these two groups were affected by facility closures. Our analysis of claims data suggests that beneficiaries affected by these closures obtained care elsewhere.

Volume of services

To assess changes in the volume of dialysis services, we examined recent trends in the number of dialysis treatments provided to beneficiaries and in the use of injectable drugs administered during dialysis.

Trends in number of dialysis treatments provided Between 2017 and 2018, there was little change in the number of FFS dialysis beneficiaries (0.4 percent) and total Medicare-covered dialysis treatments (45.3 million treatments in 2017 and 45.5 million treatments in 2018). The number of dialysis treatments per beneficiary remained steady at 115.¹⁹ Over the most recent five-year period for which we have data (2013 to 2018), the number of FFS dialysis beneficiaries and total dialysis treatments each increased by 1 percent per year, while the number of treatments per beneficiary slightly declined from 116 to 115.

Use of most dialysis drugs in the outpatient ESRD

PPS bundle has declined with no sustained negative changes in beneficiaries' outcomes Under the ESRD payment method used before 2011, dialysis drugs were paid according to the number of units of the drug administered: In other words, the more units of a drug provided, the higher the Medicare payment. The ESRD PPS increased the incentive for providers to be more judicious in providing dialysis drugs included in the payment bundle. When CMS broadened the payment bundle in 2011 to include ESRD-related drugs that were separately billable under the prior payment method, the agency set the PPS payment rate based on a per treatment basis using claims data from 2007. In 2014, to account for the decline in dialysis drug use under the ESRD PPS, the statute required that CMS rebase the PPS base rate by comparing drug use in 2007 with such use in 2012. Consequently, we examined changes between 2007 and 2018 (the most current year for which complete data are available) in the use per treatment for the leading dialysis drugs and aggregated them into four therapeutic classes—erythropoiesis-stimulating agents (ESAs), iron agents, vitamin D agents, and antibiotics.²⁰

As shown in Table 6-4 (p. 180), between 2017 and 2018, per treatment drug use increased for only four products—epoetin beta, ferric carboxymaltose, iron sucrose, and daptomycin. However, use of all dialysis drugs available between 2010 and 2018 declined except for two products: darbepoetin alfa and doxercalciferol. The increased use of these drugs is linked to increased price competition within the ESA and vitamin D classes.

**TABLE
6-4****Use per treatment of dialysis drugs has declined under the outpatient ESRD PPS**

Dialysis drug	Mean units per treatment ^a			Aggregate percent change	
	2010	2017	2018	2010–2018	2017–2018
ESAs					
Epoetin alfa	5,214	1,269	1,239	-76%	-2%
Darbepoetin alfa	1.26	2.2	1.6	28	-26
Epoetin beta ^b	N/A	3.2	3.9	N/A	22
Iron agents					
Sodium ferric gluconate	0.15	0.1	0.1	-41	-20
Iron sucrose	16.0	12.4	12.6	-21	1
Ferumoxytol	0.8	0.007	0.004	-99	-42
Ferric carboxymaltose ^c	N/A	0.0001	0.0001	N/A	40
Vitamin D agents					
Paricalcitol	2.3	0.3	0.3	-88	-10
Doxercalciferol	0.9	1.3	1.3	49	-3
Calcitriol	0.13	0.05	0.03	-76	-34
Antibiotics					
Daptomycin	0.22	0.1	0.1	-51	17
Vancomycin	0.02	0.01	0.01	-49	-13
Other drugs					
Levocarnitine	0.010	0.001	0.001	-91	-27
Alteplase	0.020	0.002	0.002	-89	-4

Note: ESRD (end-stage renal disease), PPS (prospective payment system), ESA (erythropoiesis-stimulating agent), N/A (not applicable). Individual units per treatment are rounded; the aggregate percentage change is calculated using unrounded units per treatment.

^aEach drug is reported using its own drug units.

^bEpoetin beta was introduced to the U.S. market in 2015.

^cFerric carboxymaltose was introduced to the U.S. market in 2014.

Source: MedPAC analysis of claims submitted by dialysis facilities to CMS.

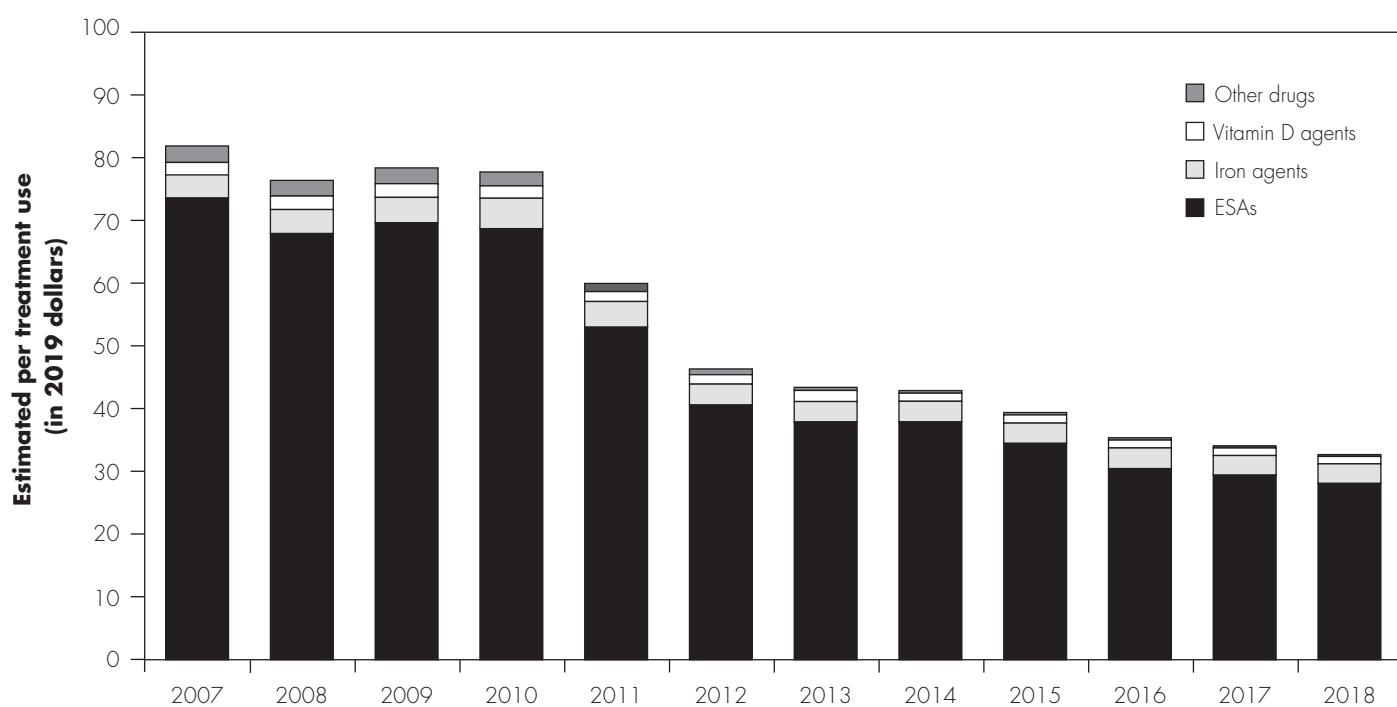
As shown in Figure 6-1, most of the decline in the per treatment use of dialysis drugs—which is estimated by multiplying drug units per treatment reported on CMS claims by each drug’s 2019 average sales price (i.e., holding price constant)—occurred in the early years of the PPS (implemented in 2011).²¹ For example, between 2010 and 2012, use per treatment across all therapeutic classes declined by 23 percent per year. Most of this decline was due to declining ESA use, which also fell by 23 percent per year during the same period. For ESAs, some of this decline may also have stemmed from clinical evidence showing that higher doses of these drugs led to increased risk of morbidity and mortality, which resulted in the FDA changing the ESA label in 2011. Between 2017 and 2018,

holding price constant, the use of all dialysis drugs in the four classes declined by 4 percent. Although the ESRD PPS impacted use of certain ESRD-related services, particularly the provision of drugs paid under the bundle, CMS has concluded that the agency’s claims-based monitoring program has revealed no sustained negative changes in beneficiary health status between 2011 and 2018 (Centers for Medicare & Medicaid Services 2019).

Prior Commission analysis showed that the outpatient ESRD PPS increased price competition within the ESA and vitamin D therapeutic classes. For example, our analysis of ESA utilization since 2013 shows that dialysis facilities and nephrologists switched beneficiaries from epoetin alfa to darbepoetin alfa or epoetin beta. In at

**FIGURE
6-1**

Use of dialysis drugs in the payment bundle has declined under the outpatient ESRD PPS



Note: ESRD (end-stage renal disease), PPS (prospective payment system), ESA (erythropoiesis-stimulating agent). To estimate drug use by therapeutic class, we hold the price of each drug constant and multiply drug units reported on claims in a given year by 2019 average sales price. The dialysis drugs in this analysis are all included under the outpatient ESRD PPS bundle and paid under the base payment rate. That is, included drugs are those that Medicare paid dialysis facilities separately prior to the ESRD PPS or in one of the 11 functional categories of drugs included in the ESRD PPS bundle. Drugs included are epoetin alfa, epoetin beta, darbepoetin [ESAs (erythropoietin stimulating agents)]; iron sucrose, sodium ferric gluconate, ferumoxytol, ferric carboxymaltose (iron agents); calcitriol, doxercalciferol, paricalcitol (vitamin D agents); daptomycin, vancomycin, alteplase, levocarnitine (all other drugs).

Source: MedPAC analysis of 100 percent claims submitted by dialysis facilities to CMS.

least one situation, switching was an explicit goal: One of the LDOs announced its intent to have more than 70 percent of the company's ESA patients (110,000 patients) switched to epoetin beta (from epoetin alfa) by the end of the first quarter of 2016 (Reuters 2016).²² According to several sources, the LDO reduced its total ESA costs by switching beneficiaries to epoetin beta (Reuters 2016, Seeking Alpha 2016). A midsized chain recently announced that between 85 percent and 90 percent of its facilities will have switched to epoetin beta by the end of 2018 (Seeking Alpha 2018). With the FDA approval of a biosimilar for epoetin alfa in 2018, competition among ESA products could increase (and ESA costs for facilities could drop further) in the future (Pfizer 2018).

Use of dialysis drugs paid under the TDAPPA Our analysis of dialysis drug use also examines beneficiaries' use of the calcimimetics paid for under the TDAPPA policy—Sensipar (cinacalcet) (the oral product) and Parsabiv (etelcalcetide) (the injectable product). Before 2018, Medicare covered the oral calcimimetic Sensipar under Part D. After the FDA approved the injectable calcimimetic Parsabiv in 2017, Medicare began to pay for both products under the ESRD PPS (Medicare Part B) in 2018. Under the TDAPPA in 2018 and 2019, CMS paid facilities 106 percent of each drug's ASP. In 2020, CMS reduced payment to 100 percent of each drug's ASP.²³ CMS will include both products in the PPS bundle once the agency has sufficient utilization claims data for a rate-setting analysis.

**TABLE
6-5****Use of calcimimetics has increased between 2013 and 2018**

	2013	2017	2018	Average annual percent change	
				2013–2017 under Part D	2017–2018 under Part B and Part D
Spending per treatment	\$11	\$22	\$26	20%	17%
Share of calcimimetic users	23%	26%	28%		
Sensipar units per treatment	21	24	22	4%	-11%

Note: Calcimimetics are Sensipar (cinacalcet) (oral form) and Parsibiv (etelcalcetide) (injectable form). Units per treatment is only reported for Sensipar (cinacalcet), the only calcimimetic available in each year between 2013 and 2018. Parts B and D spending per treatment is calculated by dividing total spending in each year by the total number of Part B dialysis treatments furnished by dialysis facilities to Medicare beneficiaries. The percent change is calculated using unrounded numbers.

Source: MedPAC analysis of Medicare claims submitted by dialysis facilities to CMS.

Use of calcimimetics has grown under both the Part B and Part D programs (Table 6-5). Under Part D (between 2013 and 2017), spending per capita increased rapidly, by 20 percent per year.²⁴ In 2018, the first year of coverage under Part B, spending grew slightly more slowly at 17 percent. The number of dialysis beneficiaries receiving a calcimimetic has grown under both Part B and Part D. Between 2013 and 2018, the share of beneficiaries with at least one claim for a calcimimetic increased from 23 percent to 28 percent. Use of Sensipar (cinacalcet), the only calcimimetic available in each year between 2013 and 2018, has remained relatively constant, with mean units per dialysis treatment ranging from 21 units (milligrams) to 24 units over this five-year period.

Dialysis marginal profitability suggests incentive to serve Medicare beneficiaries Another measure of access is whether providers have a financial incentive to expand the number of Medicare beneficiaries they serve. In considering whether to treat a patient, a provider with excess capacity compares the marginal revenue it will receive (i.e., the Medicare payment) with its marginal costs—that is, the costs that vary with volume. If Medicare payments are larger than the marginal costs of treating an additional beneficiary, a provider has a financial incentive to increase its volume of Medicare patients. In contrast, if payments do not cover the marginal costs, the provider may have a disincentive to care for Medicare beneficiaries.²⁵

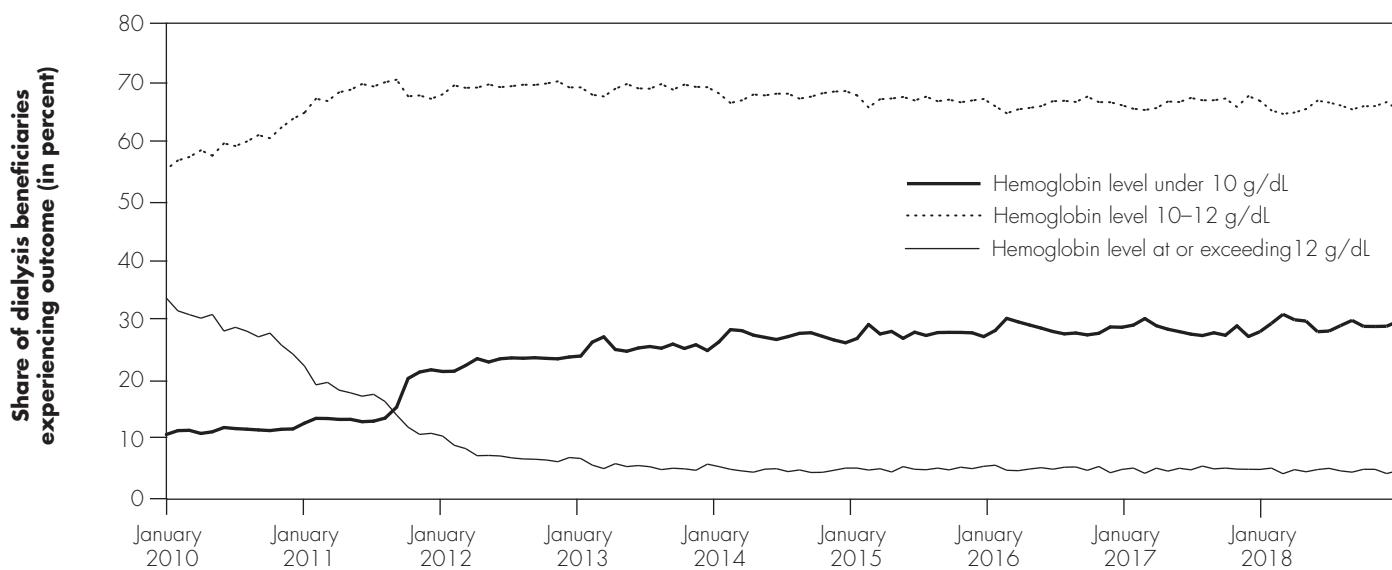
For dialysis facilities, Medicare payments exceed marginal costs by 18 percent, a positive indicator of patient access because it means facilities with available capacity have an incentive to treat Medicare beneficiaries.

Quality of care

Our analysis focuses on changes in quality indicators—including mortality and morbidity, process measures that assess dialysis adequacy and anemia management, and treatment utilization (including home dialysis and kidney transplantation rates). The analysis, except where indicated, is based on the Commission’s analysis of Medicare FFS enrollment and claims data and CMS’s monthly monitoring data for dialysis beneficiaries between 2013 and 2018.

For the most recent five-year period that data are available, rates of hospitalization declined while emergency department (ED) use rose. Mortality remained relatively steady. Use of home dialysis increased. However, home dialysis growth slowed between 2014 and 2017, partly because of a shortage of the solutions needed for the predominant home method, peritoneal dialysis (PD).

In assessing quality, we also examine the multiple factors that affect access to kidney transplantation. This procedure is widely regarded as a better ESRD treatment option than dialysis in terms of patients’ clinical and quality of life outcomes and Medicare spending, but demand far outstrips supply.

**FIGURE
6-2****Changes in hemoglobin levels under the ESRD PPS**

Note: ESRD (end-stage renal disease), PPS (prospective payment system), g/dL (grams per deciliter).

Source: MedPAC analysis of Medicare claims submitted by dialysis facilities.

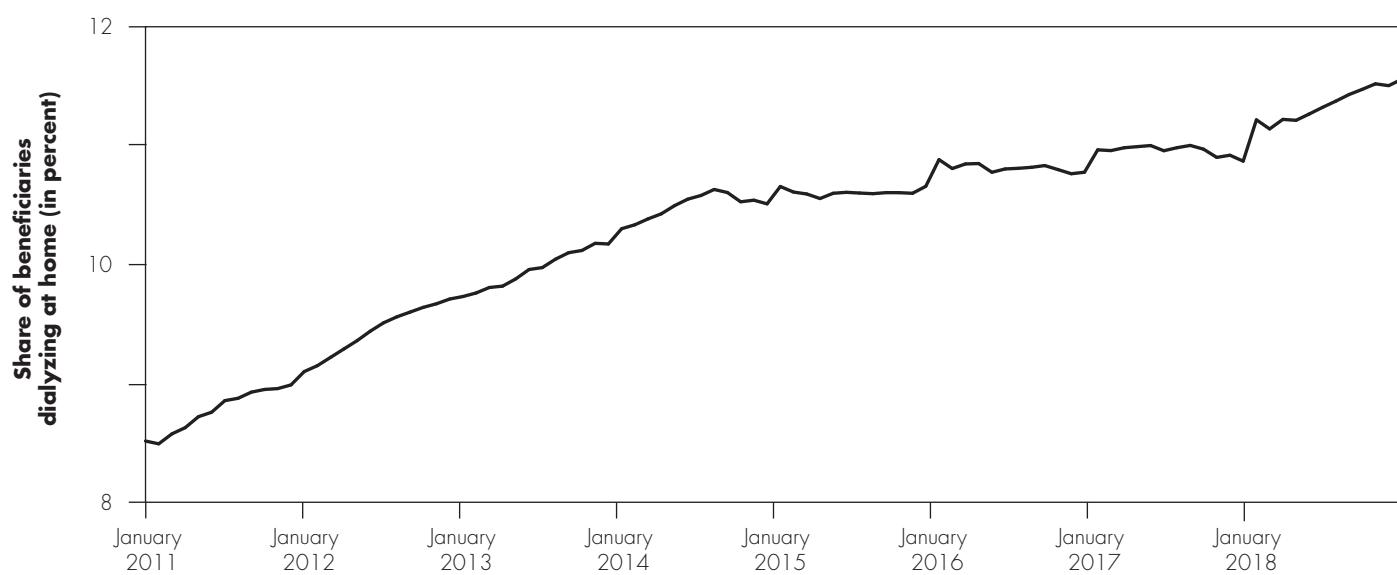
Quality under the ESRD PPS

Between 2013 and 2018, through the Commission's analysis of claims data, mean all-cause hospital stays per beneficiary slightly declined from 1.6 admissions per beneficiary to 1.5 admissions per beneficiary, respectively. This finding is consistent with the trend of declining inpatient admissions for all Medicare FFS beneficiaries during this period. U.S. Renal Data System (USRDS) data show that dialysis patients are most frequently hospitalized for cardiovascular conditions and infections (United States Renal Data System 2018). Between 2013 and 2018, CMS's monitoring data for cardiovascular outcomes among dialysis beneficiaries show that monthly hospitalization rates for stroke and acute myocardial infarction remained steady while heart failure hospitalizations declined until 2013 and then increased.²⁶ USRDS data show that rates of hospitalization due to infection declined during the most recent five-year period of available data (2011 to 2016). Between 2013 and 2018, 30-day readmission rates remained relatively steady at 22 percent of admissions, while the proportion of dialysis beneficiaries who used the ED on an outpatient basis increased from an average of 11 percent per month

to 12 percent per month. Rates of mortality during this period remained relatively unchanged at 1.5 percent of beneficiaries per month.

Beneficiaries' fluid management is related to factors such as the adequacy of the dialysis procedure and dietary management. According to the Commission's analysis, between 2013 and 2018, from 97 percent to 98 percent of hemodialysis beneficiaries and from 91 percent to 93 percent of PD beneficiaries received adequate dialysis, defined as having enough waste removed from their blood. Between 2013 and 2018, the share of dialysis beneficiaries diagnosed with dehydration declined slightly, while the share of beneficiaries diagnosed with fluid overload increased.

Process and health outcome measures reflect the change in anemia management under the PPS. Anemia is measured by a blood test to check the level of hemoglobin, the protein that carries oxygen in red blood cells. Median hemoglobin levels fell during the initial years of the ESRD PPS; since 2014, levels have remained steady at 10.5 g/dL. Figure 6-2 shows that the proportion of dialysis beneficiaries with higher hemoglobin levels

**FIGURE
6-3****Home dialysis use has increased under the ESRD PPS**

Note: ESRD (end-stage renal disease), PPS (prospective payment system).

Source: MedPAC analysis of Medicare claims submitted by dialysis facilities to CMS.

declined, and the proportion with lower hemoglobin levels increased (which is generally associated with lower ESA use). During the initial years of the ESRD PPS, blood transfusion rates increased (from 2.7 percent per month to 3.4 percent per month). However, since 2013, the proportion of beneficiaries receiving a blood transfusion declined (from 3.3 percent per month to 2.2 per month).²⁷

As discussed in our June 2014 report, clinical process measures can exacerbate the incentives in FFS to overprovide and overuse services (Medicare Payment Advisory Commission 2014b). For example, before 2011, targeting higher hemoglobin levels was associated with higher ESA use among dialysis beneficiaries. In addition, some clinical process measures are only weakly correlated with better health outcomes. A given hemoglobin level could reflect adequate anemia management for one patient, whereas the same level in a different patient could lead to a different response. Focusing on clinical outcomes, such as rates of stroke, is a better indicator of anemia management in the dialysis population. The Commission recently stated that quality measurement should be patient oriented, encourage coordination, and

promote delivery system change and that Medicare quality incentive programs should use a small set of population-based measures (e.g., outcomes, patient experience, value) to assess quality of care across settings and populations (Medicare Payment Advisory Commission 2018b).

Access to home dialysis

Researchers have shown that the ESRD PPS is associated with an overall increase in the use of home dialysis (Lin et al. 2017). The share of beneficiaries dialyzing at home increased from a monthly average of nearly 10 percent in January 2013 to 11.6 percent in December 2018 (Figure 6-3). In aggregate, home dialysis use increased from 10 percent of all dialysis beneficiaries to 12 percent during this five-year period. While we are encouraged by this increase, differences by race persist: African Americans are less likely to use home methods. According to the Commission's analysis, African Americans account for 26 percent of home dialysis beneficiaries compared with 35 percent of all dialysis beneficiaries. Researchers have shown that under the ESRD PPS, racial and ethnic differences in beginning home dialysis decreased over

time from 2005 to 2013, although between 2011 and 2013 (under the ESRD PPS), African Americans were still less likely to use home dialysis as their initial modality compared with other groups (Whites, Asians, and Hispanics) (Shen et al. 2019).

Researchers have identified many factors that affect the use of home dialysis, including both clinical (patients' other health problems and prior nephrology care) and nonclinical (e.g., patients' social circumstances and knowledge about treatment options and physician's training and preference). Facility factors, such as unused in-center capacity or additional in-center shifts and dialysis facility's staff experience, can also affect use of home dialysis (Walker et al. 2010). Some beneficiaries report that they were never informed about their options. At the end of the chapter (pp. 198–201), we provide an overview of the factors that affect use of home dialysis and factors associated with discontinuation of home dialysis for some patients.

However, some clinical and nonclinical factors affecting home dialysis use are not immutable. For example, between 2008 and 2018, under an integrated care delivery system (Kaiser Permanente Northern California), peritoneal dialysis use among new dialysis patients more than doubled, from 15 percent to 34 percent. To augment the use of home dialysis, the health care system implemented a multidisciplinary, system-wide approach that increased patient and family education, educated health care professionals about the importance of PD, adopted operational improvements, monitored outcomes, and shared best practices with staff (Pravoverov et al. 2019).

Since 2014, one nonclinical factor—the availability of solutions needed to perform peritoneal dialysis—may have affected the growth in home dialysis. Beginning around September 2014, growth in the use of PD, the predominant home method, slowed because of a shortage of solutions needed to perform this type of dialysis. Between 2014 and 2018, the total number of home dialysis patients increased by 3 percent per year; by contrast, between 2012 and 2014, the total number of home patients increased by 7 percent per year. The supply shortage resulted from the product's leading manufacturer (Baxter) experiencing increased PD demand and limited manufacturing capacity (Baxter 2014, Neumann 2014). Because of the shortage, beginning in August 2014, the manufacturer gave each dialysis provider an allocation of supply for new patients

based on the provider's history of growth during the first six months of 2014 (Seaborg 2015). Although manufacturing steps have been taken to increase the supply of PD solutions, as of December 2019, the FDA's website indicates that a shortage of solutions continues to exist but that PD solutions are either “available to current customers by allocation” or “available”(Food and Drug Administration 2019).

With respect to their clinical outcomes, it is challenging to measure differences in mortality and hospitalization between home dialysis patients and in-center dialysis patients because the clinical and demographic characteristics of the two patient populations differ; for example, in-center dialysis patients tend to be older, sicker (i.e., have greater levels of baseline comorbidities), and less likely to have received pre-ESRD nephrology care compared with home dialysis patients.

A review of the numerous observational studies comparing outcomes associated with PD (primarily furnished at home) compared with hemodialysis (primarily furnished in center) shows mixed results; that is, neither dialysis modality has consistently been shown to confer a clear benefit to patient survival. For example, Wong and colleagues found that among all incident patients, PD was associated with a lower risk for death among patients younger than 65 years compared with hemodialysis (Wong et al. 2018). However, after excluding incident patients deemed to be ineligible for PD, the modalities were associated with similar survival regardless of age. Data from the USRDS (which is based on 100 percent Medicare FFS data) show that, between 2011 and 2016, the most recent five-year period for which national data are publicly available, rates of mortality and inpatient hospital admission were lower among PD patients compared with hemodialysis patients (United States Renal Data System 2018). However, these data are adjusted only for differences in patient age, sex, race, ethnicity, primary cause of ESRD, and how long a patient has been on dialysis; the data do not account for other factors that can explain differences between use of in-center and home dialysis, such as access to nephrology care before ESRD diagnosis and the appropriateness of home dialysis for a given patient.

CMS does not require the collection of quality of life data for dialysis beneficiaries. Although the In-Center Dialysis CAHPS® (Consumer Assessment of Healthcare Providers and Systems®), which measures patients' perspectives on

**TABLE
6-6**

**Between 2013 and 2018,
the number of kidney transplants
increased, and African Americans,
Hispanics, and Asian Americans
accounted for an increasing share**

	2013	2018
Total transplants	16,896	21,167
Share of live donors	34%	30%
Share of transplants, by race:		
Whites	51	46
African Americans	25	26
Hispanics	16	19
Asians	6	7
Others	2	2

Source: Organ Procurement and Transplantation Network 2019.

dialysis care, is a component of the ESRD QIP, currently no data are available for home patients (because there is no available home dialysis CAHPS survey). The Commission intends to analyze the changes over time in in-center beneficiaries' perceptions of dialysis care in the next cycle.

Access to kidney transplantation

Kidney transplantation is widely regarded as a better ESRD treatment option than dialysis in terms of patients' clinical and quality of life outcomes. In addition, transplantation results in lower Medicare spending. In 2016, average Medicare spending for patients who had a functioning kidney transplant was less than a third of the spending for dialysis patients (\$25,942 vs. \$89,367) (United States Renal Data System 2018). However, demand for kidney transplantation exceeds supply. Besides donation rates, factors that affect access to kidney transplantation include the clinical allocation process; patients' health literacy, clinical characteristics, and preferences; the availability of education for patients; clinician referral for transplant evaluation at a transplant center; and transplant center policies.

Between 2013 and 2018, according to the Organ Procurement and Transplantation Network, the number of kidney transplants increased by 5 percent per year to

21,167 (Table 6-6). In 2018, African Americans were less likely than White patients to receive kidney transplants despite their fourfold greater likelihood of developing ESRD; however, between 2013 and 2018, the number of African Americans receiving a transplant grew by 6 percent per year (to 5,556 individuals, data not shown). According to Ephraim and colleagues, the lower rates of kidney transplantation for African Americans compared with other groups have been associated with multiple factors, including immunological incompatibility with deceased donor kidneys, lower rates of referral for transplantation, lower rates of cadaver kidney donation, and lack of knowledge and suboptimal discussions about kidney transplantation among recipients, their families, and health care providers (Ephraim et al. 2012).

A new kidney allocation system implemented in 2014 by the United Network for Organ Sharing led to a narrowing of the disparities in national kidney transplant rates among Whites, African Americans, and Hispanics on the transplant waitlist, according to a new analysis (Melanson et al. 2017). Under the new system, the starting point for calculating waiting time was changed from the date the patient was put on the waiting list to the earlier of either that date or the date the patient started regular dialysis treatments. The new system led to a substantial increase in the kidney transplant rate for African Americans and Hispanics in the months after implementation and a decrease in the rate of kidney transplantation for Whites.

Education efforts directed at patients can be effective in encouraging them to make an informed decision about their treatment, including home dialysis, in-center dialysis, kidney transplantation, and conservative care. For example, a recent review of educational interventions found a strong association between patient-targeted dialysis modality education and choosing and receiving PD (Devoe et al. 2016). An augmented nurse care management program that targeted persons with late-stage chronic kidney disease (CKD) resulted in a statistically significant reduction in the number of hospitalizations during the intervention period and, for those who required renal replacement therapy, higher use of PD or a preemptive kidney transplant (Fishbane et al. 2017).

In 2010, to help inform beneficiaries diagnosed with Stage 4 CKD (the disease stage before ESRD) about their treatment options and managing the disease and related comorbidities, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) established

Medicare payment for up to six sessions of kidney disease education (KDE) per beneficiary. Since its implementation, relatively few beneficiaries have been provided KDE services. The number of beneficiaries receiving such services has declined by 2 percent per year to about 3,250 in 2018. In 2018, Medicare KDE spending was roughly \$400,000.²⁸

According to the Government Accountability Office, payment limitations on the providers who can furnish KDE services and the beneficiaries who are eligible might constrain the service's use (Government Accountability Office 2015). MIPPA specified the categories of providers who can furnish KDE services—physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certain providers of services in rural areas.²⁹ MIPPA also specified that beneficiaries with Stage 4 CKD are eligible for the benefit. Some stakeholders contend that other categories of beneficiaries, including those with Stage 5 CKD (i.e., ESRD) who have not started dialysis as well as individuals who have already initiated hemodialysis, might also benefit from Medicare KDE coverage.

Providers' access to capital: Growth trends indicate access is adequate

Providers need access to capital to improve their equipment and open new facilities so they can accommodate the growing number of patients requiring dialysis. The two LDOs as well as other renal companies appear to have had adequate access to capital. For example, in 2018 and 2019:

- CVS Health initiated a pivotal clinical trial to demonstrate the safety and efficacy of a new home hemodialysis device in support of a planned FDA submission to obtain market clearance.
- Fresenius Medical Care invested in BioIntelliSense, a company developing a remote, continuous health monitoring data platform, which provides predictive analytics, clinical insights, and real-time data through medical-grade sensors. According to Fresenius Medical Care, this investment is intended to improve monitoring, treatment, and outcomes for patients with kidney disease.
- DaVita entered into a \$5.5 billion senior secured credit agreement with several financial institutions. The company plans to use the proceeds from the secured credit agreement to fund its repurchasing of 21.8

million shares of its common stock (for a total cost of \$1.2 billion excluding fees and expenses related to the buy-back), to replenish its balance sheet for future share repurchases and acquisitions, and for other general corporate purposes.

- Dialyze Direct LLC completed its acquisition of Affiliated Dialysis Centers LLC, an established dialysis provider in the Midwest, making Dialyze Direct the largest provider of staff-assisted home hemodialysis services in skilled nursing facilities in the U.S. A long-term care company, Signature HealthCARE, is collaborating with Dialyze Direct to provide on-site hemodialysis for dialysis patients who reside in short-term, long-term, and rehabilitation facilities.

Another indicator of the relatively good access to capital is that during the past decade several companies—both small and large—have entered the renal care field aiming to improve treatment of individuals with CKD and ESRD, including Outset Medical (in 2010), Cricket Health (in 2015), Somatus (in 2016), and CVS Health (in 2018).

In addition to private sector investment in renal care, in 2018, a public–private partnership between the U.S. Department of Health and Human Services and the American Society of Nephrology was initiated to accelerate innovation in the prevention, diagnosis, and treatment of kidney diseases. This initiative—referred to as the Kidney Innovation Accelerator (KidneyX)—has committed \$2,265,000 in prize money for “KidneyX: Redesign Dialysis,” a competition that challenges the public to develop better treatment options for patients with kidney failure. This competition is the first in a planned series of KidneyX prize competitions designed to develop innovative solutions that can prevent, diagnose, or treat kidney diseases.

In public financial filings, the two LDOs (Fresenius Medical Care and DaVita) reported generally positive financial performance related to their dialysis business for 2019, including improvements in productivity and revenue growth—that is, growth achieved apart from mergers and acquisitions. In addition, since 2010, the two LDOs have grown through large acquisitions of and mergers with other dialysis facilities and other health care organizations. For example, during this period, both of the largest dialysis organizations acquired midsized for-profit organizations: DaVita acquired Purity and Renal Ventures, and Fresenius Medical Care acquired Liberty Dialysis.

Another positive indicator of the dialysis sector's strong access to capital is its all-payer margin. Using cost report data submitted by freestanding dialysis facilities to CMS, we estimate that the 2018 all-payer margin was roughly 20 percent. In their financial documents, dialysis providers reported that FFS Medicare payment rates were significantly lower than commercial rates (DaVita 2018).

An issue facing the dialysis industry is a new law enacted in California in October 2019 that requires dialysis providers to charge Medicare rates to commercial health plans for dialysis treatments furnished to patients who obtain insurance premium assistance from third-party organizations, such as the American Kidney Fund. The law also requires providers to disclose to health care plans which patients are receiving premium assistance from third-party payers. The law is intended to address the encouragement of patients to enroll in commercial insurance coverage for the financial benefit of the provider and the rapid increase of provider-funded groups that pay health insurance premiums in California's individual and group health insurance markets on behalf of individuals with very high-cost conditions. In December 2019, a federal court in California granted a preliminary injunction to prevent the law from taking effect pending the outcome of a lawsuit that asserted several constitutional challenges associated with the law.

In general, current growth trends among dialysis providers indicate that the dialysis industry is attractive to for-profit facilities and investors.

Medicare payments and providers' costs

Each year, we examine the relationship between Medicare's payments and providers' costs as part of our assessment of payment adequacy. To make this assessment, we reviewed Medicare expenditures for outpatient dialysis services in 2018 and examined trends in spending under the PPS. We also reviewed evidence regarding providers' costs under the PPS.

Medicare payments for outpatient dialysis services

In 2018, Medicare spending for outpatient dialysis services was \$12.7 billion, an increase of 11 percent compared with 2017. Per capita spending increased by 10 percent to \$32,000 in 2018. Nearly all of this growth in spending is due to Medicare Part B TDAPA payments for two calcimimetics, which equaled \$1.2 billion in 2018. Between 2017 and 2018, dialysis spending outside of the

TDAPA grew by 0.5 percent, a rate similar to the growth seen between 2016 and 2017. In addition to the 2018 Part B TDAPA payments, other factors affecting spending growth include a statutory update (of 0.3 percent) to the base dialysis payment rate in 2018 and the number of dialysis treatments per beneficiary holding steady in 2017 and 2018.

Beginning in 2017, dialysis facilities are able to furnish dialysis to beneficiaries with acute kidney injury (AKI), as mandated by the Trade Preferences Extension Act of 2015. AKI is the sudden loss of kidney function typically caused by an event that leads to kidney malfunction, such as dehydration, blood loss from major surgery or injury, or the use of medicines. By contrast, CKD is usually caused by a long-term disease, such as hypertension or diabetes, that slowly damages the kidneys and reduces their function over time. AKI is more commonly reversible than late-stage CKD.

In 2017, Medicare spending for outpatient dialysis services for beneficiaries with AKI was nearly \$40 million, and in 2018, AKI spending increased to \$58 million. Medicare pays facilities the ESRD PPS base rate adjusted by the PPS wage index for the treatment of beneficiaries with AKI.³⁰ Medicare spending for treatment of AKI by dialysis facilities is not included in the Commission's analysis of Medicare's payments and costs for dialysis facilities.

Comparing spending for ESRD drugs paid under the ESRD PPS with spending under Part D

Under the ESRD PPS, the use of dialysis drugs included in the PPS payment bundle declined. By contrast during this period, the use (as measured by Medicare spending) of Part D dialysis drugs that are not yet included in the PPS payment bundle increased. In 2017—the most recent year for which Part D data are available—Part D spending for two categories of dialysis drugs (calcimimetics and phosphate binders) totaled \$2.4 billion, an aggregate increase of nearly 90 percent since 2013 (Table 6-7). In addition, between 2013 and 2017, Part D spending for dialysis drugs grew more rapidly than spending for all other Part D drugs prescribed to dialysis beneficiaries (90 percent vs. 44 percent) (data not shown). In 2017, spending for Part D dialysis drugs constituted 60 percent of dialysis beneficiaries' gross Part D spending. Medicare spending for dialysis drugs under Part D is not included in the Commission's Medicare analysis of dialysis facilities' financial performance under the ESRD PPS.

**TABLE
6-7****Spending for calcimimetics and phosphate binders, 2013–2018**

	Medicare spending (in billions)			Aggregate spending growth	
	2013	2017	2018	2013–2017 under Part D	Under Part D in 2017 and Part B in 2018
Calcimimetics					
Under Part D	\$0.5	\$1.0	*	116%	
Under Part B	*	*	\$1.2		17%
Phosphate binders					
Under Part D	\$0.8	\$1.4	**	74	**

Note: Under statute, oral phosphate binders will be covered under Part D until 2025 unless the Food and Drug Administration approves a non-oral equivalent of the drug prior to 2025, in which case the oral and non-oral formulations will be covered under the Part B end-stage renal disease (ESRD) prospective payment system (PPS). The aggregate spending growth is calculated using unrounded numbers.

*Before 2018, Medicare paid for calcimimetics for dialysis beneficiaries under Part D. Beginning in 2018, Medicare paid for calcimimetics for dialysis beneficiaries under the Part B ESRD PPS.

**2018 Part D claims data are not available for analysis; thus, Part D spending for phosphate binders is not yet available.

Source: MedPAC analysis of Medicare claims submitted by dialysis facilities to CMS.

Based on results of a multicenter prospective, randomized placebo-controlled trial (published after FDA approval), some clinicians concluded that the routine use of the calcimimetic cinacalcet may not be warranted (Palmer et al. 2013). This trial found that cinacalcet did not significantly reduce the risk of death or nonfatal cardiovascular events in patients with moderate to severe secondary hyperparathyroidism undergoing dialysis (Chertow et al. 2012). The FDA approved both calcimimetics based on a surrogate measure (the level of parathyroid hormone, which, if elevated, may contribute to bone and cardiovascular disorders), not based on clinical outcomes (e.g., risk of cardiovascular events).

Including phosphate binders covered under Part D in the ESRD PPS bundle may lead to better management of drug therapy and improve beneficiaries' access to these medications since some beneficiaries lack Part D coverage or have coverage less generous than the Part D standard benefit.

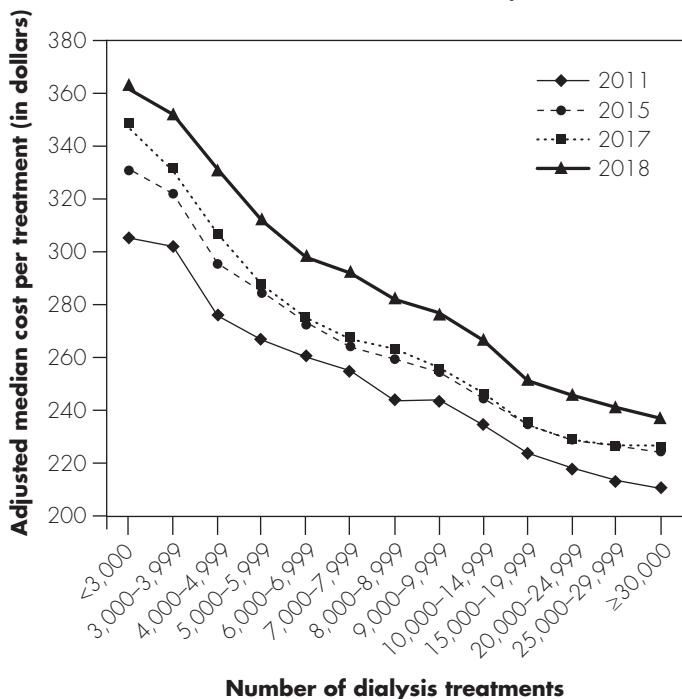
Providers' costs for outpatient dialysis services under the ESRD PPS

To assess the appropriateness of costs for dialysis services paid for under the ESRD PPS, we examine whether aggregate dialysis facility costs reflect costs that efficient

providers would incur in furnishing high-quality care. For this analysis, we use 2017 and 2018 cost reports and claims submitted to CMS by freestanding dialysis facilities. For those years, we look at the growth in the cost per treatment and how total treatment volume affects that cost.

Cost growth under the PPS Between 2017 and 2018, the cost per treatment increased by 7 percent, from nearly \$248 per treatment to about \$267 per treatment, a higher pace of growth than in previous recent years. Cost per treatment increased primarily due to Medicare's coverage of calcimimetics under the TDAPA that began in 2018. We estimate, based on cost reports submitted by freestanding dialysis facilities, that calcimimetics accounted for about 6 percent of the cost per treatment (at roughly \$15 per treatment) in 2018.³¹ Excluding providers' estimated costs of calcimimetics, we estimate that the cost per treatment would have increased by about 1.4 percent between 2017 and 2018, a growth rate in line with trends in the growth in cost per treatment seen in prior years. For example, between 2016 and 2017, cost per treatment increased by 2 percent.

Between 2017 and 2018, the cost per treatment for ESAs and lab costs declined by 8 percent and 5 percent, respectively. These cost categories accounted for 8 percent

**FIGURE
6-4****Higher volume dialysis facilities have lower cost per treatment, 2011–2018**

Note: Cost per treatment is adjusted to remove differences in the cost of labor. Dialysis treatments include those paid for by all sources (not just Medicare-paid treatments). The increase in cost per treatment in 2018 is due to Medicare's coverage of calcimimetics in the end-stage renal disease prospective payment system.

Source: MedPAC analysis of cost reports submitted by freestanding dialysis facilities to CMS and the end-stage renal disease wage index files.

and about 1 percent, respectively, of the total cost of treatment in 2018. The decline in cost per treatment for ESAs and lab services somewhat offset increases in the other cost categories:

- Administrative and general expenses and capital costs, which accounted for 24 percent and 17 percent of the cost per treatment, respectively, increased by 1 percent and 2 percent, respectively.
- Labor costs, which accounted for about 32 percent of the cost per treatment, increased by 3 percent.
- Supply costs, which accounted for 11 percent increased by 5 percent.

- Composite rate drugs, which accounted for a very small dollar amount of the total cost per treatment (about 0.5 percent), increased by about 20 percent.

Variation in cost growth across freestanding dialysis facilities shows that some facilities were able to hold their cost growth well below that of others. For example, between 2017 and 2018, per treatment costs increased by 1 percent for facilities in the 25th percentile of cost growth compared with 12 percent for facilities in the 75th percentile.

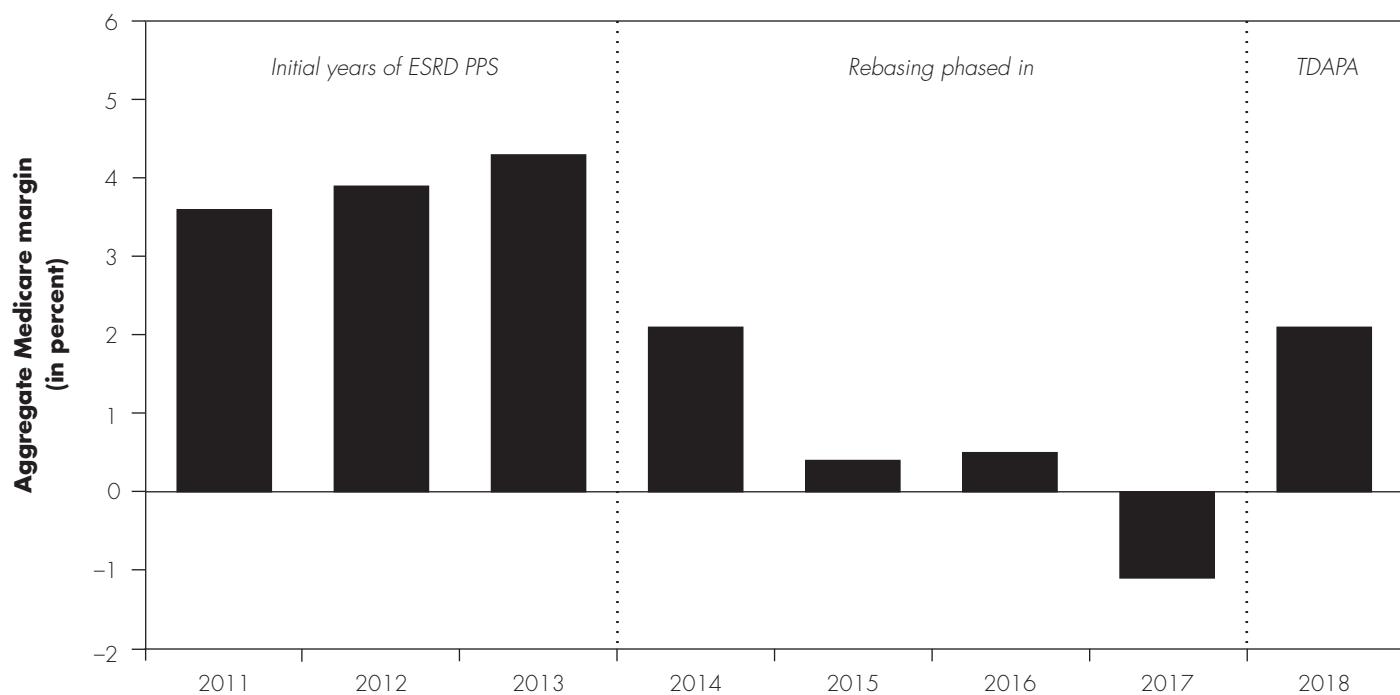
The extent to which some of the variation in costs among facilities results from differences in the accuracy of facilities' reported data is unknown. We have found substantial variation, under the ESRD PPS, in the level of selected cost categories reported by the five largest dialysis organizations. For example, in 2018, the cost per treatment for administrative and general services differed by roughly \$20 per treatment among these organizations. We anticipate that CMS's audit of a representative sample of facilities' ESRD cost reports will examine their accuracy. In the final rule for the calendar year 2019 ESRD PPS, CMS said that the audit process is complete and the audit staff are reviewing the findings. Consistent with our 2014 recommendation, the Protecting Access to Medicare Act of 2014 funded CMS to audit a representative sample of ESRD facility cost reports.³²

Cost per treatment is correlated with facility service volume

Cost per treatment is correlated with the total number of treatments a facility provides. To examine this relationship, we adjusted the cost per treatment to remove differences in the cost of labor across areas and included all treatments regardless of payer. Our analysis showed, in each year from 2011 through 2018, a statistically significant relationship between total treatments and cost per treatment (correlation coefficient equaled -0.5) (Figure 6-4). That is, the greater the facility's service volume, the lower its costs per treatment. Facilities that qualified for increased Medicare payment due to low volume had substantially higher cost per treatment for capital as well as administrative and general services compared with all other facilities.

Trend in the aggregate Medicare margin for freestanding dialysis facilities

The Commission assesses current payments and costs for dialysis services for freestanding dialysis facilities by comparing Medicare's payments with facilities' Medicare-

**FIGURE
6-5****Aggregate Medicare margin changed in response to payment policies**

Note: ESRD (end-stage renal disease), PPS (prospective payment system), TDAPA (transitional drug add-on payment adjustment).

Source: Compiled by MedPAC from cost reports and claims submitted by facilities to CMS and the Dialysis Compare database.

allowable costs. The latest and most complete data available on payments and costs are from 2018.

Under the ESRD PPS, dialysis facilities' financial performance under Medicare has varied due to statutory and regulatory changes and the use and profitability of certain dialysis drugs (Figure 6-5). During the initial years of the ESRD PPS, the aggregate Medicare margin increased, particularly because of declining use of dialysis drugs between 2011 and 2012 (Table 6-4, p. 180). Between 2014 and 2017, facilities' financial performance under Medicare reversed, with the aggregate Medicare margin declining from 2.1 percent to -1.1 percent. This decline was not unexpected given the payment adjustments required by statute. To reflect more current use of dialysis drugs, the American Taxpayer Act of 2012 required that CMS rebase the base payment rate effective 2014, and the Protecting Access to Medicare Act of 2014 lowered the statutory updates (based on the ESRD market basket offset by a productivity adjustment) to 0 percent in 2015, and

by 1.25 percent in 2016 and 2017, and by 1.0 percent in 2018.³³

Between 2017 and 2018, the aggregate Medicare margin increased due to the profitability of the calcimimetics paid under the TDAPA policy. We estimate that the aggregate Medicare margin in 2018 was 2.1 percent. Excluding calcimimetics payments and costs, we estimate that the 2018 aggregate Medicare margin would have been about -2 percent.

Medicare margin by type of freestanding facility in 2018

Aggregate Medicare margins in 2018 decidedly varied by treatment volume; facilities in the lowest volume quintile had margins at or below -19 percent, while facilities in the top volume quintile had margins of nearly 9 percent or higher (Table 6-8, p. 192). Urban facilities had higher margins than rural facilities (2.8 percent vs. -2.8 percent). Total treatment volume accounted for much of the

**TABLE
6-8****Medicare margins in 2018 varied by type of freestanding dialysis facility**

Provider type	Medicare margin	Percent of freestanding dialysis facilities	Percent of freestanding dialysis facility treatments
All	2.1%	100%	100%
Urban	2.8	83	88
Rural	-2.8	17	12
Treatment volume (quintile)			
Lowest	-19.3	20	7
Second	-8.0	20	12
Third	-0.1	20	17
Fourth	4.2	20	24
Highest	8.7	20	39

Note: Components may not sum to 100 percent due to rounding.

Source: Compiled by MedPAC from cost reports and outpatient claims submitted by facilities to CMS and the Dialysis Compare database.

difference in margins between urban and rural facilities. Urban dialysis facilities are larger on average than rural facilities in the number of treatment stations and total treatments provided. For example, in 2018, urban facilities averaged nearly 12,000 treatments, while rural facilities averaged about 7,800 treatments (data not shown). And, as shown in Figure 6-4 (p. 190), higher volume facilities have lower cost per treatment.

The Commission is concerned about the gap in the Medicare margin between urban and rural facilities. Although some rural facilities have benefited from the ESRD PPS's 23.9 percent low-volume adjustment and 0.8 percent rural adjustment, the Commission has stated that neither adjustment targets low-volume, geographically isolated facilities that are critical to beneficiary access (Medicare Payment Advisory Commission 2016, Medicare Payment Advisory Commission 2015, Medicare Payment Advisory Commission 2014a). In addition, the design of the low-volume adjustment provides facilities with an adverse incentive to restrict their service provision to avoid reaching 4,000 treatments, the threshold that CMS defines as low volume (Government Accountability Office 2013). The Commission intends to continue to monitor the adequacy of Medicare's payments for rural and urban facilities and will consider alternative approaches that

would better target low-volume, geographically isolated facilities.

Projecting the Medicare margin for 2020

The aggregate Medicare margin for 2020 is projected to be 2.4 percent, greater than the 2017 Medicare margin (2.1 percent). This projection considers providers' historical cost growth and the following policy changes that went into effect between 2017 (the year of our most recent margin estimates) and 2019:

- In 2019 and 2020, the statutory dialysis base payment rate (based on the ESRD market basket offset by a productivity adjustment) will increase by 1.3 percent and 1.7 percent respectively.
- For 2019 and 2020, CMS estimates that payments will be reduced by 0.15 percent and 0.35 percent, respectively, due to the ESRD QIP.
- Other regulatory changes implemented by CMS are expected to result in higher payments by about 0.3 percent in 2019 (due to refining the outlier payment policy) and lower payments by 0.1 percent in 2020 (due to the combined effect of lowering of payment for calcimimetics from ASP + 6 percent to ASP + 0 percent and refining the outlier payment policy).

- New factors that are not included in the projection: the positive effect on margin due to calcimimetics, the potential positive effect of other drugs paid for under the TDAPA and new equipment and items paid for under the TPNIES policy.

How should Medicare payments change in 2021?

Under current law, the update to the outpatient dialysis payment base rate for 2021 is equal to the ESRD market basket index, less an adjustment for productivity (currently estimated at 0.4 percent). Based on CMS's latest forecast of changes in the ESRD market basket costs for calendar year 2021 (2.4 percent), the update to the 2021 payment rate would be 2.0 percent. In addition to this statutory provision, the ESRD Quality Incentive Program is expected to decrease total payments by 0.38 percent in 2021. And beginning in 2020:

- In addition to the base payment rate, Medicare includes a payment adjustment under the ESRD PPS that pays dialysis facilities for certain new drugs and biologics based on the product's average sales price for a two-year period. This policy will likely increase Medicare payments relative to facilities' costs because CMS will not offset the ESRD PPS base rate (even for new drugs that fall into 1 of the 11 functional categories that are already included in the payment bundle).
- In addition to the base payment rate, Medicare includes a payment adjustment under the ESRD PPS that pays dialysis facilities for new and innovative equipment and supplies based on the product's invoice price for a two-year period. This policy may raise Medicare payments relative to facilities' costs because CMS will not offset the ESRD PPS base rate.

The evidence on payment adequacy suggests that outpatient dialysis payments are adequate. It appears that facilities have become more efficient under the PPS, as measured by declining use of most injectable dialysis drugs.

RECOMMENDATION 6

For calendar year 2021, the Congress should update the calendar year 2020 Medicare end-stage renal disease prospective payment system base rate by the amount determined under current law.

RATIONALE 6

Most of our indicators of payment adequacy are positive, including beneficiaries' access to care, the supply and capacity of providers, volume of services, quality of care, and access to capital. Providers have become more efficient in the use of dialysis drugs under the PPS. The Medicare margin was 2.1 percent in 2018 and is projected to be 2.4 percent in 2020. The 18 percent marginal profit is a positive indicator of beneficiary access.

IMPLICATIONS 6

Spending

- In 2021, the statute sets the payment update at the market basket, net of the productivity adjustment. The Commission's recommendation would have no effect on federal program spending relative to the statutory update.

Beneficiary and provider

- We expect beneficiaries to continue to have good access to outpatient dialysis care. Relative to current law, this recommendation will have no effect on reasonably efficient providers' willingness and ability to care for Medicare beneficiaries.

Medicare's efforts to improve management of late-stage chronic kidney disease and end-stage renal disease

The goals of care for patients with CKD are to delay progression to ESRD, reduce complications, educate patients about their treatment options for ESRD, and to ensure a timely transition to transplantation or dialysis, while optimizing patients' independence (Levin et al. 2014). Models designed by the Center for Medicare & Medicaid Innovation (CMMI)—including the Comprehensive ESRD Care Initiative and several voluntary models—aim to improve the quality of care and lower Medicare spending for individuals with late-stage CKD and for individuals with ESRD.

The Comprehensive ESRD Care Model

The relatively high resource use by dialysis beneficiaries, particularly rates of hospital admissions and hospital readmissions, suggests that further improvements in quality are needed and that some dialysis beneficiaries might benefit from better care coordination. Under the

authority of CMMI, the first round of the Comprehensive ESRD Care (CEC) Model began October 1, 2015, and will continue through December 31, 2020. The model is testing whether a new payment model implemented in FFS Medicare can improve the outcomes of dialysis beneficiaries as well as lower their Medicare per capita spending. A second round of the CEC Model began on January 1, 2017. CMS has no current plans for another round of solicitation.

Under this five-year initiative, ESRD Seamless Care Organizations (ESCOs)—which are like accountable care organizations (ACOs) but are specific to the dialysis population—consist of at least one dialysis facility and one nephrologist and are held accountable for the clinical and financial (Part A and Part B) outcomes of prospectively matched dialysis beneficiaries. Of the 13 ESCOs participating in the first round, 12 are operated by Dialysis Clinic Inc., DaVita, and Fresenius Medical Care, all of which CMS designated as large because each organization operates more than 200 dialysis facilities; 1 ESCO is operated by Rogosin Institute, which CMS designated as small because the company operates fewer than 200 dialysis facilities. For the second performance round, 24 additional ESCOs joined the model. Of the 37 participating ESCOs in the second round, 33 are operated by large organizations while 4 are operated by small organizations—Rogosin, Centers for Dialysis Care, Atlantic Dialysis, and Northwest Kidney Centers. By the second performance year (PY), enrollment in the CEC Model was 40,000 beneficiaries (roughly 10 percent of all FFS dialysis beneficiaries).

Most participants in the CEC Model's first and second rounds were held to two-sided risk-based payment. (Under two-sided risk, the provider is at financial risk if specified goals are not achieved but is rewarded if the goals are met. Under one-sided risk, the provider is not penalized financially if goals are not met but does share in the gains.) In the CEC Model's first round, Dialysis Clinic Inc., DaVita, and Fresenius Medical Care—the ESCOs that CMS considers large—were held to two-sided risk-based payment, while Rogosin Institute, a small dialysis organization, was held to one-sided risk-based payment. In the model's second round, small dialysis organizations were given the option to be held to two-sided risk; all but 1 of the 37 ESCOs were held to two-sided risk-based payment.

The first two years of the CEC Model produced savings relative to a spending benchmark. However, when taking into account shared savings payments to ESCOs, Medicare

experienced an aggregate net loss. The ESCOs that participated in PY 1 were more likely to produce savings in PY 2 relative to a spending benchmark than ESCOs that first participated in the model in PY 2.

- In the CEC Model's first PY (October 2015 to December 2016), 12 of the 13 ESCOs produced enough savings compared with their benchmark to earn shared savings payments (Centers for Medicare & Medicaid Services 2017). These payments ranged from \$1 million to \$12 million and totaled \$51 million. Quality in PY 1 was essentially pay for reporting; thus, all the ESCOs received a 100 percent score for quality. In total, the first year of the demonstration saved 1.7 percent relative to a spending benchmark.
- In the CEC Model's second performance year (2017), 24 of the 37 ESCOs produced enough savings compared with their benchmark to earn shared savings payments, ranging from about \$400,000 to \$13 million and totaling \$63 million. Six of the 37 ESCOs incurred financial losses that exceeded their medical loss rate; under the model, these organizations are accountable to CMS for a portion of their losses. Quality scores in PY 2 for the ESCOs that participated in PY 1 averaged 81 percent and ranged from 76 percent to 92 percent. Quality scores for the ESCOs new to the CEC Model in PY 2 were pay for reporting; thus, these ESCO received a 100 percent score for quality. In total, the second year of the demonstration saved 1.3 percent relative to a spending benchmark.

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, including hospital inpatient admissions, and Medicare spending relative to the comparison group (Marrufo et al. 2019). By contrast, the use of home dialysis and rate of mortality remained unchanged. According to CMS's contractor, in the CEC Model's first two years, there was a statistically significant decline of \$68 million in aggregate or \$114 per beneficiary per month. In PY 2, these results were primarily driven by ESCOs that participated in both years of the model. Both payment years saw a statistically significant decline in spending for acute inpatient services and post-acute care services (Table 6-9). The share of beneficiaries with at least one ED visit or readmission decreased. Additionally, ESCOs reported interventions to improve dialysis adherence, which resulted in an increase

**TABLE
6-9****In performance years 1 and 2, ESRD CEC Model improved some quality and health care utilization measures**

Findings across performance years 1 and 2		
Measure	Decreased	Increased
Dialysis care	Catheter use	Dialysis sessions
Coordination of care beyond dialysis	Opioid overuse Office visits	HbA1C tests Dilated eye exams Lipid testing Phosphate binder adherence
Hospitalization and ED visits	Hospitalizations ED visits Readmissions Hospitalizations for ESRD complications	
Medicare spending	Total A and B spending* Acute inpatient services Office visits PAC services Hospitalizations for ESRD complications	Home health visits Dialysis services

Note: ESRD (end-stage renal disease), CEC (Comprehensive ESRD Care), ED (emergency department), PAC (post-acute care). All measures are statistically significant with p -values < 0.10. CMS's contractor used a difference-in-differences approach to estimate the impact of the CEC on outcomes and spending relative to a comparison group. This statistical method quantifies the impact of an intervention—the CEC model—by comparing changes in risk-adjusted outcomes for CEC beneficiaries, before and after implementation of the intervention compared to changes in outcomes for similar beneficiaries in a comparison group.

*Marrufo and colleagues (2019) concluded that when taking into account shared savings payments to the ESRD Seamless Care Organizations, Medicare experienced aggregate net losses of \$46 million.

Source: Marrufo et al. 2019.

in the number of dialysis treatments and dialysis spending but a decrease in spending for hospitalizations associated with dialysis complications. However, the contractor also reported that when taking into account shared savings payments to the ESCOs, Medicare experienced aggregate net losses of \$46 million.

Beneficiary quality of life in the second performance year, as measured by the Kidney Disease Quality of Life-36 survey, remained largely unchanged (Marrufo et al. 2019). Compared with ESRD beneficiaries not participating in the model, CEC beneficiaries were slightly less likely to be bothered by the kidney disease symptoms or report limitations due to their physical health. Although statistically significant, CMS's contractor said that the

differences were small in magnitude and judged not to be clinically meaningful. The CEC beneficiaries and comparator beneficiaries not enrolled in the model did not differ in terms of the overall burden of kidney disease in their life or their reported mental health, and there were no differences in mortality rates or use of home dialysis.

For beneficiaries with ESRD, the CEC Model performed better than ACOs (Marrufo et al. 2019).³⁴ The CEC Model resulted in statistically significant reductions in Part A and Part B spending and utilization (hospitalizations and ED visits), while primary care ACOs resulted in no statistically significant reductions. Neither model resulted in affecting quality, as measured by the use of fistulas and catheters for hemodialysis beneficiaries.

Proposed ESRD Treatment Choices Model

With the CEC Model scheduled to end on December 31, 2020, CMS proposed a mandatory payment model, the ESRD Treatment Choices (ETC) Model, that would begin January 1, 2020, and end June 2026. The ETC Model would test whether financial incentives result in increased home dialysis use and kidney transplantation among adult ESRD beneficiaries. The mandatory model would include ESRD facilities and managing clinicians (typically nephrologists who receive a monthly capitated payment (MCP) established in the Part B physician fee schedule for outpatient dialysis-related management services). Payments to participants in the model would be adjusted upward or downward based on their home dialysis and kidney transplant rates.

Under this model, CMS selects participants—ESRD facilities and managing clinicians—according to their location in geographic areas (306 hospital referral regions (HRRs)) that themselves are randomly selected, stratified by region, so as to account for approximately half of adult ESRD beneficiaries in the 50 states and the District of Columbia. CMS applies the following two payment adjustments to participants' base payment rate:

- The home dialysis payment adjustment (HDPA) increases the managing clinician's MCP rate for home dialysis patients and the ESRD facility's base rate for home dialysis treatments under the ESRD PPS by 3 percent in 2020, 2 percent in 2021, and 1 percent in 2022.
- The performance payment adjustment (PPA) will apply to payments for all dialysis treatments beginning June 30, 2021; could be either positive or negative for a participant but would be net negative across all participants (asymmetric); and would be applied to each participant's base payment rate. The PPA will be determined by comparing each participant's rate of home dialysis and kidney transplant to a benchmark (calculated based on the rates of home dialysis and kidney transplantation for a control group ESRD facilities and managing clinicians not included in the ETC Model). For managing clinicians only, the rate of kidney transplant will include both dialysis beneficiaries who receive a transplant as well as beneficiaries with advanced CKD (and not yet on dialysis) who receive a transplant.

Dialysis facilities and managing clinicians not selected as participants in the ETC will continue to be paid under

the ESRD PPS (for facilities) and Part B physician fee schedule (for clinicians); Medicare will not adjust their payments using the HDPA or the PPA.

CMS randomly assigns the 306 HRRs in the United States into treatment groups (those participating in the ETC Model) and control groups. CMS believes that random assignment will account for relevant differences in the measurement.

The PPA will have the largest effect on program spending of any ETC Model component. Over the course of the model, CMS estimates that the PPA will reduce Medicare payments to facilities by \$220 million and to managing clinicians by \$8 million and the HDPA will increase Medicare payments to facilities by \$39 million and to managing clinicians by \$4 million. On net, by means of the PPA and HDPA adjustments, Medicare spending to participants (dialysis facilities and managing clinicians) will be reduced by \$185 million over the 6.5-year model.

In a comment letter to the agency, the Commission raised significant methodological issues about the payment model, including the reliability of the outcome measures (home dialysis and transplant measures), the comparison-to-control-group benchmarks and scoring method, and the risk adjustment method.³⁵ In addition, we raised concerns about the alignment of incentives for participants. For example, for midsized and large dialysis organizations that will likely operate facilities assigned to the treatment group in some HRRs and the control group in other HRRs, the design of the model (i.e., the set of financial incentives) could put these providers in the awkward position of exerting additional effort to increase home dialysis rates in treatment HRRs and maintaining a status quo level of effort in control HRRs. These diverging incentives could affect organizational decisions such as the opening or closing facilities, the location of home dialysis programs, and a myriad of other decisions about the allocation of organizational resources. These concerns also apply to transplant rate measurement.

Consequently, we urged CMS not to implement the ETC and instead to implement an approach similar to CMMI's CEC Model that could (1) provide a holistic approach to the care of beneficiaries with CKD, who often have multiple comorbidities in addition to kidney disease; and (2) hold both dialysis facilities and managing clinicians jointly accountable for the outcomes (quality, utilization, and financing) of beneficiaries with CKD, including rates of home dialysis and transplantation. Kidney transplant

centers, a key participant in the transplant process, should also be considered for participation in such a model. As of January 2020, CMS has not finalized the ETC in the rulemaking process.

CMMI's newly released voluntary models for CKD and ESRD

In 2019, CMMI announced the Kidney Care Choices (KCC) Model to align incentives for providers who treat patients with late-stage CKD through dialysis, transplantation, or end-of-life care. CMMI hopes to improve beneficiaries' overall quality of care during this treatment period and reduce the costs of care associated with kidney disease. The model has two sets of options for providers: the Kidney Care First (KCF) option and the Comprehensive Kidney Care Contracting (CKCC) options. The KCC Model will have an implementation period occurring in 2020, and the performance period will begin on January 1, 2021. The performance period will go through December 31, 2023, with the option for a one-year or two-year extension period.

KCF will pay nephrologists and nephrology practices adjusted monthly and quarterly capitated payments for managing beneficiaries with late stage CKD through dialysis, transplantation, or end of life care. The capitated payment that participants receive will be adjusted, up or down, based on their performance on quality and utilization measures. The performance-based adjustment could increase a participant's revenue by up to 30 percent of its combined monthly and quarterly payments or reduce that revenue by as much as 20 percent of those payments. In addition, participating practices will receive a bonus payment for every patient aligned to them who receives a kidney transplant. During each performance year, KCF practices must provide care to a minimum of 500 (aligned) beneficiaries with late stage CKD and 200 (aligned) ESRD beneficiaries. This model is designed to mirror the basic design of the Primary Care First model. KCF is expected to be an advanced alternative payment model (A-APM) beginning in 2021.

CKCC involves nephrologists and nephrology practices partnering with transplant providers, and possibly partnering with dialysis facilities and other providers and suppliers, to form Kidney Contracting Entities (KCEs). This model is designed to build off of the CEC Model and the Direct Contracting model (a set of voluntary payment model options that CMMI will implement with the goal of reducing expenditures and preserving or enhancing

quality of care for FFS beneficiaries). Participating nephrologists will receive adjusted capitated payments for managing beneficiaries with CKD Stages 4 and 5 (with and without ESRD). KCEs must provide services to a minimum of 1,000 aligned Medicare beneficiaries with CKD Stages 4 or 5 and 350 ESRD beneficiaries during each performance year. There is no requirement for a minimum number of aligned transplant beneficiaries. The KCE will select a total cost of care accountability framework, and their payments under the model will be adjusted based on their performance on quality measures. KCE participants can choose to be in the graduated option, the first year of which is modeled on the one-sided risk track in the CEC Model, or the professional option or the global option, both of which are based on options of the Direct Contracting model. Each option will use the same benchmark process, based on the prospective benchmark calculation used in the Direct Contracting model. The CKCC options will be A-APMs beginning in 2021, with the exception of the first level of the graduated option.

In both CKCC options, CMS will pay participants a quarterly capitation payment, which combines payment for several different outpatient evaluation and management codes and other care management codes. In addition, participants will be paid an adjusted monthly capitation payment for managing dialysis care for beneficiaries receiving dialysis and are eligible for a bonus payment for every aligned beneficiary who receives a kidney transplant and does not return to dialysis. KCEs will also have shared savings/shared losses payments based on the option of the model they choose to participate in.

Completed model to improve care of CKD beneficiaries

Earlier efforts to improve late-stage CKD include CMMI's three-year cooperative agreement in 2014 with Northwell Health to implement the Healthy Transitions program for adults with late-stage CKD (with an estimated glomerular filtration rate of less than 30 ml/min), which aimed to

- better prepare patients for ESRD care by improving patient education and shared decision-making,
- increase the share of patients who select home dialysis or a preemptive kidney transplant,
- increase the rate of arteriovenous fistulas,
- increase patients' quality of life scores, and

- generate savings to Medicare (e.g., by reducing hospitalizations and emergency department visits).

CMS's contractor concluded that the health system was successful in implementing its program (e.g., effectively delivered the intervention by using nurse case managers). However, due to too few treatment beneficiaries, the contractor does not anticipate being able to conduct a rigorous impact analysis of this program (Schneider and Lines 2018).

Factors affecting the use of home dialysis

There is no best dialysis method for all patients. Each method—in-center hemodialysis, home hemodialysis, and home peritoneal dialysis (PD)—offers advantages and disadvantages. USRDS data for 2017 (the most current year available) shows that 88 percent of dialysis patients used in-center hemodialysis, 10 percent used PD, and 2 percent used home hemodialysis. General consensus suggests that established provider infrastructure would support a home dialysis population of at least 20 percent in the U.S. (Burkart et al. 2017). Whether a patient is treated with home dialysis is affected by clinical factors (e.g., the patient's other health problems) and nonclinical factors (e.g., physician training).³⁶

Clinical and nonclinical factors affect the use of home dialysis

Many factors—patient's health and social circumstances, care before the start of dialysis, where the patient lives, physician preferences— influence the selection of one type of treatment over another. Our list of factors is not comprehensive but provides some context for understanding how the various Medicare policies could affect the coverage and payment of home dialysis services.

Patients' characteristics

Patients' characteristics influence the choice of dialysis method. Among newly diagnosed patients, Lin and colleagues found that being older, male, or African American decreased the likelihood of home dialysis. Patients living in more affluent areas, areas with a lower share of people who are unemployed, and rural areas were more likely to use home dialysis (Lin et al. 2017). These researchers also reported lower home dialysis use among patients with comorbidities—including diabetes, coronary

artery disease, heart failure, and peripheral vascular disease—and institutionalized patients. Heaf reported that about one-fifth of dialysis patients are not suitable for PD because of abdominal problems, physical disabilities, or psychological problems (such as dementia) (Heaf 2004).

Social circumstances

Social circumstances also influence the choice of dialysis method. Home patients, sometimes with the help of a caretaker, must be willing and able to conduct their own dialysis. For PD, the patient must be able to maintain the sterility of a catheter and conduct nighttime treatments that fill the patient's abdomen with approximately two liters of fluid. Both types of home dialysis usually require patients to operate a medical device in their home and monitor certain clinical signs during or after treatment. A patient's home needs to support the proper functioning of this device, which could include a stable electric current, a water purification process, or a place to store large quantities of dialysis supplies (e.g., peritoneal dialysate). Some patients feel comfortable with the process of home dialysis, others prefer not to have medical equipment in their home, and some prefer the social aspect of in-center treatment. Even patients and caregivers who are comfortable with the process can become “burned out” on home dialysis and frequently switch to in-center hemodialysis.

Prior nephrology care

A patients' nephrology care before dialysis may influence the dialysis treatment they receive. Recent research has found that nephrology care before ESRD increased the use of home dialysis (Gillespie et al. 2015, Lin et al. 2017). Likewise, an earlier Commission analysis showed that 2.3 percent of patients who saw a nephrologist when starting dialysis treatment chose PD compared with 5.8 percent of patients who saw a nephrologist more than 12 months before the start of dialysis (Medicare Payment Advisory Commission 2004).

Nephrology training

Nephrologist training of home dialysis modalities varies widely across academic medical centers and contributes to a population of nephrologists that includes both champions for the use of home dialysis and those who are not comfortable prescribing and monitoring home dialysis for any patients. According to Blake, some nephrologists may perceive that, compared with PD, it is easier to initiate ESRD patients on hemodialysis, it requires less effort to

manage them, and the influence over the patient is greater (Blake 2009). In addition, some nephrologists prefer having in-center patients seen thrice weekly by facility staff (Blake 2009).

Most physicians believe that PD is underused in the U.S. (Mendelsohn et al. 2001). Initiatives by professional societies to provide home dialysis-specific education for physicians have the potential to increase home dialysis use (Burkart et al. 2017, Lin et al. 2017).

Providers' incentive to furnish in-center dialysis

Historically, economics influenced the use of home dialysis versus in-center care. The rapid growth in the number of dialysis facilities throughout the 1990s and 2000s created an incentive to direct patients to treatment in centers so that facilities would operate at capacity. Rubin and colleagues concluded that financial incentives may encourage clinicians to choose hemodialysis because, once substantial investment in a facility has been made, the marginal costs of treating an additional patient are likely lower for a new hemodialysis patient than for a new PD patient (Rubin et al. 2004). That is, a dialysis facility with an in-center hemodialysis unit incurs fixed costs whether its in-center capacity is utilized at half capacity or full capacity.

In addition, some physicians have entered into joint ventures with dialysis organizations. For example, in its 2018 10-K filing with the Securities and Exchange Commission, DaVita reported that the company's joint ventures with physicians represented approximately 25 percent of the company's net dialysis and related lab services revenues in the U.S. (DaVita 2019). Other dialysis organizations, including Fresenius Medical Care, American Renal Associates, and U.S. Renal Care, also establish joint ventures with physicians. Joint ventures allow participating partners to share in the management, profits, and losses (Berns et al. 2018). There is concern that joint ventures between physicians and dialysis companies leads to financial incentives for participating physicians, which could inappropriately influence decisions about patient care (Berns et al. 2018). Under federal disclosure requirements, a dialysis facility must report certain ownership information to CMS and its state survey agency but is not required to disclose such information to their patients, researchers, or members of the public (Centers for Medicare & Medicaid Services 2008, 42 CFR 494.180(j)). In 2009, the Commission recommended that the Congress require all hospitals

and other entities that bill Medicare to annually report the ownership share of each physician who directly or indirectly owns an interest in the entity (excluding owners of publicly traded stock) and that the Secretary should post this information on a searchable public website (Medicare Payment Advisory Commission 2009). Berns and colleagues concluded that there is a "striking lack of transparency" regarding joint venture arrangements that currently exist since patients cannot find out whether nephrologists referring them to a dialysis facility have financial incentives to do so (Berns et al. 2018).

Dialysis facilities' staff experience

The education and experience of dialysis facilities' staff can affect patients' knowledge and perception of home dialysis. According to Golper and colleagues, inexperienced staff might present negative views about home dialysis, which could be minimized by educating all clinical providers about home dialysis (Golper et al. 2011).

Other factors

As of 2014, manufacturers have not produced enough dialysate, the solution used in PD, to meet demand, which has limited recent growth in the use of PD. In addition, according to Burkart and colleagues, delay in the initial certification of new dialysis facilities is a barrier to developing home dialysis programs (Burkart et al. 2017).

Clinical and nonclinical factors affect patients' retention on home dialysis

As with a patient's decision regarding their modality of dialysis treatment, both clinical and nonclinical factors affect the success (i.e., retention) of home dialysis. Switching from home to in-center dialysis is an important contributor to the relatively low rate of home dialysis. While there are no publicly available data to determine the rate of retention across all home dialysis patients, a review of the literature suggests that within the first year of home dialysis, discontinuation is reported to occur at rates of roughly between 20 percent to 25 percent (Seshasai et al. 2016, Weinhandl et al. 2018).

Demographic and socioeconomic factors influence patients' retention on home dialysis. Patients who are older, male, and African American are more likely to discontinue home dialysis (Chidambaram et al. 2011, Shen et al. 2013). Other related factors associated with higher rates of discontinuation are low levels of education, disabilities, unemployment, Medicaid status, and poor

social or familial support systems, including lack of a care partner (Chidambaram et al. 2011, Shen et al. 2013, Young et al. 2012). Other patient-level reasons for a modality change from home to in-center dialysis include a patient's inability to cope, loss of social support, nonadherence, and patient choice (Pauly et al. 2019).

Patients' retention on home dialysis can also be linked to clinical reasons. Some researchers have found that patients with diabetes have an increased risk of discontinuing home dialysis, while patients who were listed for a kidney transplant at the time of home dialysis initiation reduced the risk of discontinuation (Seshasai et al. 2016).

A patient's success with home dialysis is also affected by system-related factors, including the referring physician's volume of home dialysis patients, the physician's treatment experience, and the dialysis practice's size and experience with home dialysis (Shen et al. 2013). Practices with greater volumes of patients using home dialysis and physicians with more experience treating patients with home dialysis increase a patient's rate of success with the modality. Modality-specific factors also affect patients' retention on home dialysis. Clinical complications of the modality that have been identified as reasons for patients on PD to switch to hemodialysis include peritonitis, other infections, inadequate dialysis, ultrafiltration failure, and catheter malfunction. For home hemodialysis, each additional day of dialysis treatment per week over a baseline of three treatments has been found to increase patients' discontinuation of home dialysis (Pauly et al. 2019).

Medicare policies that affect the payment of home dialysis services

Recently published research found that the ESRD PPS was associated with an overall increase in the use of home dialysis (Lin et al. 2017). Other Medicare policies affect the payment of home dialysis services, including the add-on payment to the base dialysis payment rate for providing home dialysis training services and payment for physicians caring for dialysis beneficiaries.

Dialysis facility payment for dialysis treatment bundle

Medicare pays dialysis facilities the same amount whether a patient uses in-center hemodialysis or home dialysis. When CMS established the ESRD PPS in 2011, the agency stated that its decision to set a single payment rate for adults, regardless of the dialysis type, would give

dialysis providers the incentive to encourage the use of home dialysis. The agency's cost analysis showed that PD costs were 11 percent lower than hemodialysis costs (Centers for Medicare & Medicaid Services 2009).³⁷ Lin and colleagues concluded that the ESRD PPS was associated with a large increase in home dialysis use among newly diagnosed patients starting dialysis between 2006 and 2013 (Lin et al. 2017). The researchers reported an absolute increase in home dialysis use of 5.8 percent among the Medicare population.³⁸

The increase in home dialysis use is partly associated with the inclusion of dialysis drugs in the PPS's payment bundle. The profitability of dialysis drugs before the PPS (when Medicare paid facilities based on the number of units of each drug administered to a beneficiary) may have given some providers an incentive to furnish in-center dialysis instead of home dialysis because in-center patients on average used more dialysis drugs per treatment than home dialysis patients.

According to the Government Accountability Office (GAO), the dialysis PPS likely gives facilities financial incentives to provide home dialysis. However, these incentives may have a limited impact in the short term because expanding the provision of in-center hemodialysis at a facility increases that facility's Medicare margin more than if the facility expanded the provision of home dialysis (Government Accountability Office 2015). Based on 2012 Medicare cost reports, GAO found an additional patient-year of in-center hemodialysis increased the margin by 0.15 percentage point compared with an increased margin of 0.08 percentage point for an additional patient-year of PD. An additional patient-year of home hemodialysis had no statistically significant effect on the margin (Government Accountability Office 2015).

Dialysis facility add-on payment for training a home dialysis patient

For beneficiaries who transition to home dialysis after at least 120 days of in-center hemodialysis, Medicare pays an additional amount for each treatment to cover the cost of training the patient to conduct dialysis. The number of training add-on payments is capped at 15 for peritoneal dialysis and 25 for home hemodialysis. CMS computes the training add-on payment adjustment by using the national average hourly wage for nurses from the Bureau of Labor Statistics. The payment accounts for nursing time for each training treatment that is furnished and is adjusted by the geographic area wage index.

Lin and colleagues found that the training add-on adjustment was not associated with additional increases in home dialysis use. Specifically, the researchers reported that although home dialysis use grew under the training add-on, it was not associated with any increases beyond what was predicted under the PPS (Lin et al. 2017).

Some stakeholders have raised concerns about the adequacy of training payments (Centers for Medicare & Medicaid Services 2016, Centers for Medicare & Medicaid Services 2013). In response to public comments, CMS increased the training add-on payment rate in a budget-neutral manner in 2014 and 2017. The increased rate in 2017 (from \$50.16 per treatment to \$95.57 per training treatment) reflects an updated national mean wage for registered nurses and a modified assumption that the number of training hours provided is equal to the treatment time. In our comment letter to CMS about this change in payment, the Commission suggested that CMS first collect reliable data on the cost of providing home dialysis training and then reassess the need to adjust the training add-on payment amount (Medicare Payment Advisory Commission 2016). GAO noted that CMS lacks reliable data on the cost of training and lacks consistent data on the staff time required to provide home dialysis training (Government Accountability Office 2015).

During the first 120 days of dialysis, Medicare pays an additional amount for each treatment for all patients (i.e., both in-center and home patients) to cover clinical and educational costs, which can be higher for a new dialysis patient. For patients who are trained to conduct home dialysis during this period, Medicare makes no additional training payment.

Physician payment for managing dialysis treatment

Medicare pays nephrologists a monthly amount for each beneficiary to manage dialysis treatment, which can

include monitoring clinical data, adjusting medications, or determining whether dialysis treatment is adequate. For in-center patients, the monthly amount varies by the number of visits a physician or clinical assistants make to a beneficiary—one visit, two to three visits, or four or more visits—and most patients receive four visits per month (Government Accountability Office 2015). For home patients, only one face-to-face visit is required per month. For adult home patients (20 years of age or older), the monthly payment rate is set comparable to the rate for two to three in-center visits, an amount that is roughly \$50 less than the rate for four in-center visits.

GAO concluded that Medicare's monthly physician payment policy may give physicians a disincentive for prescribing home dialysis. Based on 2013 Medicare fee schedule data, GAO found that the payment rate for managing adult home patients was lower than the average payment and maximum payment for managing adult in-center patients (Government Accountability Office 2015).

Paying for more than three treatments per week

Currently, Medicare's payment rate is based on a regimen of three dialysis treatments per week. The Medicare Benefit Policy Manual states that (1) the usual pattern of hemodialysis consists of three treatments weekly, and these treatments are covered routinely; (2) PD sessions are covered routinely at the same frequency as hemodialysis; and (3) Medicare's administrative contractors shall consider requiring medical justification in instances that exceed this frequency. CMS has also stated that the choice of dialysis modalities requiring more than three treatments per week—including short frequent hemodialysis and every-other-day hemodialysis—does not constitute medical justification. Currently, several Medicare administrative contractors have each issued local coverage determinations on the conditions that would constitute medical justification. ■

Endnotes

- 1 In this chapter, the term *beneficiaries* refers to individuals covered by Medicare, and *patients* refers to all individuals who have ESRD.
- 2 In this chapter, the term *drugs* refers to both drugs and biologics.
- 3 Generally, individuals are fully insured under Social Security if they have 40 credits of covered employment (i.e., the individual is employed in a job that pays Social Security taxes). Individuals are currently insured under Social Security if they have a minimum of six credits of covered employment in the three years before ESRD diagnosis.
- 4 Between October 2018 and October 2019, enrollment in and the number of ESRD SNPs declined. As of October 2018, about 5,600 dialysis beneficiaries were enrolled in 15 ESRD SNPs operated by 6 managed care organizations in 9 states (Arizona, California, Colorado, Illinois, Nevada, New Jersey, New York, North Carolina, and Texas).
- 5 Incidence data are adjusted for age, sex, and race.
- 6 For individuals entitled to Medicare based on ESRD, Medicare coverage does not begin until the fourth month after the start of dialysis, unless the individual had a kidney transplant or began training for self-care, including dialyzing at home.
- 7 Under the Bipartisan Budget Act of 2018, beginning January 2019, clinicians who manage home dialysis beneficiaries can furnish their visits through telehealth (rather than in person). Beneficiaries are required to receive a face-to-face visit for the first three months of home dialysis and once every three months thereafter.
- 8 For pediatric dialysis beneficiaries (younger than 18 years), the base rate is adjusted for age and type of dialysis.
- 9 The Commission's March 2014 report to the Congress provides more information about the rebasing of the dialysis base payment rate (available at http://medpac.gov/docs/default-source/reports/mar14_ch06.pdf?sfvrsn=0).
- 10 More information about these payment changes can be found in the Commission's March 2016 report to the Congress (available at http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_17_dialysis_finald8a311adfa9c665e80adff00009edf9c.pdf?sfvrsn=0). The Commission's methodological concerns about these patient-level and facility-level refinements can be found in our comment letter to CMS (available at <http://medpac.gov/docs/default-source/comment-letters/medpac-comment-on-cms-s-proposed-rule-on-the-end-stage-renal-disease-prospective-payment-system-and-.pdf?sfvrsn=0>).
- 11 According to CMS, these products qualify for a TDAPA because the base dialysis payment rate has not yet accounted for their costs.
- 12 Under the drug designation process established in 2016, new injectable drugs used to treat or manage a condition that fit into an existing ESRD-related functional category are considered in the PPS payment bundle and thus not eligible for a TDAPA. CMS expanded the drugs eligible for a TDAPA beginning in 2020.
- 13 Currently, drugs and biologics reported on dialysis facility claims are categorized into 1 of the following 11 functional categories: access management, anemia management, bone and mineral metabolism, cellular management, antiemetic, anti-infective, antipruritic, anxiolytic, excess fluid management, fluid and electrolyte management, and pain management.
- 14 New drugs not eligible for a TDAPA in 2020 include generic drugs, which the FDA approves under Section 505(j) of the Federal Food, Drug, and Cosmetic Act, and drugs approved for a new dosage form (e.g., pill size, time-release forms, chewable or effervescent pills; new drugs approved for a new formulation (e.g., new inactive ingredient); new drugs approved that were previously marketed without a new drug application (NDA); and new drugs approved that changed from prescription to over-the-counter availability. CMS will identify these drugs using the NDA classification code that the FDA assigns to an NDA.
- 15 CMS defines a capital-related asset as an asset that a provider has an economic interest in through ownership (as set forth in the *Provider Reimbursement Manual*, Chapter 1, Section 104.1). The agency includes the following items as examples of capital-related assets: dialysis machines, water purification systems, and systems designed to clean dialysis filters for reuse.
- 16 For example, a Commission analysis found that in 2017, 30 percent of facilities assigned only 1 star did not have a QIP payment reduction in that payment year. Conversely, nearly 10 percent of facilities assigned 4 or 5 stars had some QIP payment reduction. The correlation coefficient between a facility's star rating and QIP score was 0.36, which means there is a positive but somewhat weak correlation between the two quality programs.

- 17 The Commission's comment letters on the revisions to the TDAPA policy and the new TPNIES policy can be found at http://www.medpac.gov/docs/default-source/comment-letters/08312018_esrd_cy2019_dme_medpac_comment_v2_sec.pdf?sfvrsn=0 and http://www.medpac.gov/docs/default-source/comment-letters/09202019_esrd_cy2020_medpac_comment_v2_sec.pdf?sfvrsn=0.
- 18 Based on the Commission's analysis of Medicare and total treatments reported by freestanding facilities on cost reports submitted to CMS.
- 19 Treatments are non-annualized, meaning that the calculation does not account for each beneficiary's length of dialysis in a given year.
- 20 These drug classes accounted for nearly all dialysis drug spending (about 97 percent) in 2010, the year before the start of the new payment method.
- 21 To measure changes in the use of drugs in the payment bundle, we combine drugs within therapeutic classes by multiplying the number of drug units reported on claims in a given year by each drug's 2019 average sales price. By holding the price constant, we account for the different billing units assigned to a given drug.
- 22 The FDA approved epoetin beta under the biologics license application process, not under the biosimilar process.
- 23 According to CMS, the agency decreased the TDAPA payment for calcimimetics from ASP plus 6 percent to ASP because (1) facilities have had sufficient opportunity to address any administrative complexities and overhead costs associated with the provision of calcimimetics; and (2) the agency needs to take into account the financial burden that increased payments place on beneficiaries and Medicare.
- 24 Part D spending per dialysis treatment for 2013 and 2017 is calculated by dividing total spending for dialysis drugs by the total number of Part B dialysis treatments furnished by dialysis facilities to Medicare beneficiaries with and without Part D.
- 25 If we approximate marginal cost as total Medicare costs minus fixed building and equipment costs, then marginal profit can be calculated as follows: Marginal profit = (payments for Medicare services – (total Medicare costs – fixed building and equipment costs)) / Medicare payments. This comparison is a lower bound on the marginal profit because we do not consider any potential labor costs that are fixed.
- 26 According to CMS, the increasing cumulative share of beneficiaries with heart failure beginning in 2015 could be associated with the issuance of local coverage determinations in that year by CMS's contractors that required certain conditions, including heart failure, to be reported on dialysis facility claims for Medicare to cover dialysis treatments exceeding thrice weekly (Centers for Medicare & Medicaid Services 2018).
- 27 Blood transfusions are of concern to patients because they (1) carry a small risk of transmitting blood-borne infections to the patient, (2) may cause some patients to develop a reaction, and (3) are costly and inconvenient for patients. Blood transfusions are of particular concern for patients seeking kidney transplantation because they increase a patient's alloantigen sensitization, which can require a patient to wait to receive a transplant.
- 28 This analysis used 100 percent of 2013 through 2018 carrier and outpatient claims submitted for KDE services.
- 29 MIPPA does not permit other providers (such as registered nurses, social workers, and dieticians) or dialysis facilities to bill for KDE services.
- 30 In addition, for beneficiaries with AKI, Medicare pays dialysis facilities separately for drugs, biologicals, and laboratory services that are not renal dialysis services.
- 31 Freestanding dialysis facility cost reports do not collect the cost of calcimimetics separately from other injectable drugs. To estimate providers' cost of calcimimetics, we determined the difference between 2017 and 2018 in the cost per treatment for other injectable drugs (that are neither ESAs nor composite-rate drugs). Between 2014 and 2017, the cost per treatment for other injectable drugs declined by 13 percent per year.
- 32 Given the vertical integration of the outpatient dialysis sector, such an audit could assess the reporting of costs by facilities for services purchased by a related organization. Under current regulation, if a provider obtains services from an organization that is owned or controlled by the owner of the provider, reimbursable cost should include the costs for these items at the cost to the supplying organization. However, if the price in the open market for comparable services is lower than the cost to the supplier, the allowable cost to the provider may not exceed the market price.
- 33 As a result of rebasing, in 2014, CMS reduced the base payment rate by \$8.16 to \$239.02.

- 34 Analysis is based on a difference-in-differences analysis that compared outcomes across ESRD beneficiaries newly aligned to a CEC model or ACO provider or were in FFS. ACO providers included Pioneer; Shared Savings Program Tracks 1, 2, and 3; and Next Generation ACO. Compared with the pre-model period, spending for ESRD beneficiaries in the first year of the CEC Model decreased by \$110 per beneficiary per month, and the likelihood of having ED visits and inpatient admissions decreased by about 5 percent.
- 35 The Commission's comment letter can be found at http://www.medpac.gov/docs/default-source/comment-letters/09032019_specialtycaremodels_medpac_comment_v2_sec.pdf?sfvrsn=0.
- 36 Our discussion of these factors is based on a review of the published literature and a Commission-convened panel of clinicians who treat home dialysis patients and a patient representative (details of which can be found at http://medpac.gov/docs/default-source/reports/mar13_ch06_appendix.pdf?sfvrsn=0).
- 37 CMS determined differences in the cost per treatment between hemodialysis and peritoneal dialysis based on cost reports that facilities submitted to the agency between 2004 and 2006.
- 38 The researchers found statistically similar increases in home dialysis use in the newly diagnosed Medicare and non-Medicare populations, indicating significant spill-over effects on non-Medicare patients (Lin et al. 2017).

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