

CHAPTER

6

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**Outpatient dialysis services**

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

- 6** For calendar year (CY) 2020, the Congress should update the CY 2019 Medicare end-stage renal disease prospective payment system base rate by the amount determined in current law.

**COMMISSIONER VOTES: YES 17 • NO 0 • NOT VOTING 0 • ABSENT 0**

# Outpatient dialysis services

## Chapter summary

Outpatient dialysis services are used to treat the majority of individuals with end-stage renal disease (ESRD). In 2017, nearly 395,000 beneficiaries with ESRD on dialysis were covered under fee-for-service (FFS) Medicare and received dialysis from approximately 7,000 dialysis facilities. Since 2011, Medicare has paid for outpatient dialysis services using a prospective payment system (PPS) that is based on a bundle of services. The bundle includes dialysis drugs and ESRD-related clinical laboratory tests that were previously paid separately. In 2017, Medicare expenditures for outpatient dialysis services were \$11.4 billion, a 0.4 percent increase over 2016 expenditures.

## 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 2016 and 2017, the number of dialysis treatment stations grew faster than the number of FFS dialysis beneficiaries.
- **Volume of services**—Between 2016 and 2017, growth in the number of FFS dialysis beneficiaries and total number of treatments was relatively

## In this chapter

- Are Medicare payments adequate in 2019?
- How should Medicare payments change in 2020?

flat. At the same time, dialysis drug use (including erythropoiesis-stimulating agents (ESAs), which are used in anemia management) continued to decline, but at a slower rate than during the initial years of the dialysis PPS (2011 and 2012). The dialysis PPS created an incentive for providers to be more judicious about their provision of dialysis drugs.

- ***The marginal profit***—Medicare payments exceeded marginal costs by about 17 percent in 2017, suggesting that providers have an incentive to treat Medicare beneficiaries.

***Quality of care***—Between 2012 and 2017, there were declines in mortality, hospitalization, and 30-day readmission rates, though the proportion of FFS dialysis beneficiaries using the emergency department increased. With regard to anemia management, negative cardiovascular outcomes associated with high ESA use generally declined, and blood transfusion use, which initially increased under the PPS, has trended downward since 2013. Between 2012 and 2017, beneficiaries' use of home dialysis, which is associated with improved patient satisfaction and quality of life, increased from 9.5 percent to 11.0 percent of dialysis beneficiaries. Since 2014, a shortage of dialysis solutions needed for the predominant home method, peritoneal dialysis, has slowed this modality's growth. The first-year results of the ESRD Seamless Care Organizations (ESCOs), modeled like accountable care organizations, were positive; for example, there were fewer inpatient admissions for beneficiaries, and all 13 ESCOs produced savings relative to the benchmarks. It is not clear whether this trend will continue since the results for 2017 and 2018 are not yet available.

***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 dialysis 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 2016 and 2017 claims and cost report data submitted to CMS by freestanding dialysis facilities. During this period, cost per treatment increased by 2 percent, while Medicare payment per treatment increased by 0.6 percent. We estimate that the aggregate Medicare margin was –1.1 percent in 2017, and the 2019 Medicare margin is projected at –0.4 percent. The Commission's recommendation for 2020 is that the Congress update the ESRD PPS base rate by the amount determined under current law. ■

## Dialysis treatment choices

**D**ialysis 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. Patients may select various protocols for each of these two dialysis types.

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.

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 to treat conditions such as anemia and bone disease resulting from the loss of kidney function.

In 2017, nearly 395,000 ESRD beneficiaries on dialysis were covered under fee-for-service (FFS) Medicare and

received dialysis from about 7,000 dialysis facilities.<sup>1</sup> Since 2011, Medicare has been paying facilities using a prospective payment system (PPS) payment 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. In 2017, Medicare Part B spending for outpatient dialysis services included in the payment bundle was \$11.4 billion. In addition, Part D payments for dialysis drugs that are not yet included in the PPS payment bundle—a calcimimetic and multiple phosphate binders—totaled nearly \$2.3 billion in 2016 (the most recent data available).

## Characteristics of fee-for-service dialysis beneficiaries, 2017

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

**TABLE  
6-1**

**FFS dialysis beneficiaries are disproportionately younger, male, and African American compared with all Medicare FFS beneficiaries, 2017**

	Percent of FFS:	
	Dialysis beneficiaries	All beneficiaries
<b>Age</b>		
Under 45 years	11%	4%
45–64 years	38	12
65–74 years	28	50
75–84 years	18	23
85+ years	6	11
<b>Sex</b>		
Male	56	47
Female	44	53
<b>Race</b>		
White	48	81
African American	36	10
All others	16	9
<b>Residence, by type of county</b>		
Urban	84	80
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. Totals 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.

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.<sup>2</sup>

Most dialysis beneficiaries have FFS coverage. The statute currently prohibits enrollment of individuals with ESRD 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 MA enrollment of ESRD beneficiaries with a functioning kidney transplant. In 2017, about 19 percent of ESRD beneficiaries were enrolled in MA plans; by comparison, just over 31 percent of all 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 of 2016 lifts the prohibition on ESRD beneficiaries enrolling in MA beginning in 2021.

In 2017, most FFS dialysis beneficiaries (about 90 percent) were enrolled in Part D or had other sources of creditable drug coverage. About 10 percent of FFS dialysis beneficiaries in 2017 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 in 2017.

Compared with all Medicare FFS beneficiaries, FFS dialysis beneficiaries are disproportionately young, male, and African American (Table 6-1). In 2017, 77 percent of FFS dialysis beneficiaries were less than 75 years old, 56 percent were male, and 36 percent were African American. By comparison, of all FFS Medicare beneficiaries, 66 percent were less 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 (84 percent vs. 80 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. 18 percent, respectively; data not shown).

The adjusted rate (or incidence) of new ESRD cases (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 2006 and 2016 (most recent year available), the adjusted incidence rate decreased by 1 percent per year, from 399 per million people to 355 per million people (United States Renal Data System 2018).<sup>3</sup> We estimate that in 2017, about 83,000 FFS beneficiaries were new to dialysis, and nearly half (45 percent) were under age 65 and thus entitled to Medicare based on ESRD (with or without disability).<sup>4</sup>

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).<sup>5</sup> 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 dialysis 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 varies based on the number of visits per month, the beneficiary’s age, and whether the beneficiary receives dialysis in a facility or at home.<sup>6</sup> 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 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 include dialysis drugs, laboratory tests, and other ESRD treatment items and services that were previously billable separately. In addition, effective in 2012, outpatient dialysis payments are linked to the quality of care that dialysis facilities provide. These changes, mandated by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), were 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.

Under the outpatient dialysis 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 (i.e., hemodialysis vs. peritoneal 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).<sup>7</sup> 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. In addition, the ESRD Quality Incentive Program holds facilities responsible for the quality of care they provide; in 2018, the program used 11 clinical measures and 5 reporting measures. Up to 2 percent of a facility’s payment is linked to these quality measures. 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\\_18\\_dialysis\\_final\\_sec.pdf?sfvrsn=0](http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_18_dialysis_final_sec.pdf?sfvrsn=0)).

Since it was implemented in 2011, the outpatient dialysis PPS has undergone several significant changes. In 2014, CMS rebased the base payment rate, and in 2016, the agency recalibrated and redefined the payment adjusters. A text box on the dialysis PPS (p. 161) summarizes these two significant changes.

The most recent change to the dialysis PPS will occur in 2020, when CMS expands its transitional drug add-on payment adjustment (TDAPA); the agency will pay providers separately for all dialysis drugs and biologics, including biosimilars and generic drugs, that the Food and Drug Administration approves on or after January 1, 2020. Payment will equal the product’s average sales price. There will be no reduction to the base rate even when a new dialysis product falls into 1 of the 11 functional categories of products that have been included in the payment bundle since 2011. The TDAPA will apply to a

new product that fits into one of the existing functional categories for two years;<sup>8</sup> thereafter, the product will be included in the PPS payment bundle without any change to the base rate. For a product that does not fit into one of the existing functional categories, the TDAPA will apply until sufficient claims data for rate-setting analysis are available, but not for less than two years. Once sufficient claims data are available, CMS will modify the base rate, if appropriate, to account for the new product in the payment bundle.

In our comment letter to CMS regarding the agency's TDAPA proposal, the Commission 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). The Commission believes that it is important to maintain the structure of the dialysis 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 technologies. Access to new dialysis products is favorable under the dialysis PPS. For example, in 2015, nearly one-quarter of all dialysis beneficiaries received epoetin beta, which was introduced to the U.S. market in that year. The Commission's comment letter can be found at [http://www.medpac.gov/docs/default-source/comment-letters/08312018\\_esrd\\_cy2019\\_dme\\_medpac\\_comment\\_v2\\_sec.pdf?sfvrsn=0](http://www.medpac.gov/docs/default-source/comment-letters/08312018_esrd_cy2019_dme_medpac_comment_v2_sec.pdf?sfvrsn=0).

In our comment letter, we objected to the TDAPA proposal because:

- Although new dialysis drugs could improve patient outcomes, the proposal does not require that the new drugs be more effective than current treatments to qualify for the TDAPA. Under CMS's policy, the only proposed standard for paying the TDAPA is that a drug is new.
- The policy duplicates payment that is already made as part of the dialysis PPS payment bundle. Beneficiaries and taxpayers already pay for drugs in each functional category because they are included in the payment bundle. Essentially, the TDAPA policy will make a second (duplicative) payment for new drugs that treat the same clinical condition as drugs already included in the payment bundle.

- The policy would undermine competition with existing drugs included in the ESRD bundle. The Commission has documented the changes in drug use due to increased price competition with the vitamin D and ESA therapeutic classes (Medicare Payment Advisory Commission 2018c).

In our comment letter, we asserted that if CMS decides to proceed with this proposed policy, at a minimum several modifications to the proposal would be necessary:

- CMS should require that the new product be an advance in medical technology that substantially improves beneficiaries' outcomes relative to technologies in the PPS payment bundle. CMS could structure such a policy similar to the standard that the agency uses to pay for new technologies under the inpatient PPS and devices under the outpatient PPS. CMS elected to not include this modification to the final policy, 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 2018b).
- CMS should not make duplicative payments for a new product (assigned to a functional category) by paying under the TDAPA for two years *and* paying for its functional category under the dialysis 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 to not include these modifications to the final policy, stating that the policy is temporary and not duplicative because, at the end of the TDAPA 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 2018b).
- CMS should publish in the final rule an estimate of the increase in beneficiaries' and taxpayers' spending due to the proposed policy change and the method used to develop the estimate. According to the agency, an estimate of expected spending changes was not

## Significant changes to the outpatient dialysis PPS in 2014 and 2016

Since its implementation in 2011, the dialysis prospective payment system (PPS) has undergone two significant changes, in 2014 and 2016. First, effective 2014, the base payment rate was rebased to account for the decline in dialysis drug use under the dialysis PPS. Based on statutory and regulatory changes, CMS set the 2014 base payment at \$239.02. 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](http://medpac.gov/docs/default-source/reports/mar14_ch06.pdf?sfvrsn=0)).

Second, beginning in 2016, CMS uses recalibrated and redefined patient-level and facility-level payment adjustments to calculate each patient's adjusted

payment per treatment. These adjusters are applied to the base payment rate to account for factors that can affect treatment costs. 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](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>). ■

included because the TDAPA policy addresses drugs and biologics that have not been developed (Centers for Medicare & Medicaid Services 2018b).

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

### Are Medicare payments adequate in 2019?

To address whether payments for 2019 are adequate to cover the costs that efficient providers incur and how much providers' costs should change in the update year (2020), 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

#### Capacity has kept pace with patient demand

Growth in the number of dialysis facilities and treatment stations alongside growth in the number of dialysis beneficiaries suggests that, between 2012 and 2016, provider capacity kept up with demand for care. During that period, the number of facilities increased annually by 5 percent; facilities' capacity to provide care—as measured by dialysis treatment stations—grew 4 percent annually (Table 6-2, p. 162). By contrast, between 2012 and 2016, the number of FFS dialysis beneficiaries grew 1 percent annually (data not shown).<sup>9</sup> In the same period, capacity at facilities that were freestanding and for profit each grew by 5 percent annually, while capacity at facilities that were hospital based and nonprofit decreased annually (–5 percent and –1 percent, respectively). Between 2012 and 2016, capacity at urban facilities grew 4 percent per year, while capacity at all rural facilities grew about 2 percent per year. Between 2016 and 2017, total dialysis capacity grew by 3 percent, while the number of FFS dialysis beneficiaries grew more slowly (by 0.4 percent; data not shown).

**TABLE  
6-2**

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

	2017				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	
					2012-2016	2016-2017	2012-2016	2016-2017
All	45.3	7,014	120,900	17	5%	4%	4%	3%
	<b>Percent of total</b>							
Freestanding	95%	94%	95%	17	6	4	5	4
Hospital based	5	6	5	13	-4	-2	-5	-4
Urban	86	82	85	18	5	5	4	4
Micropolitan	10	11	10	16	2	1	2	0.5
Rural, adjacent to urban	3	4	3	13	2	2	2	0.2
Rural, not adjacent to urban	1	2	2	11	3	0	3	-0.3
Frontier	0.2	0.5	0.3	9	3	3	3	-1
For profit	91	88	89	17	6	5	5	4
Nonprofit	9	12	11	16	-1	-2	-1	-2
Two largest dialysis organizations	76	73	74	18	6	6	5	5
All others	24	27	26	16	2	-1	2	-2

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. Totals 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.

**Providers of outpatient dialysis services**

In 2017, there were roughly 7,000 dialysis facilities in the United States that furnished about 45.3 million Medicare-paid treatments to FFS dialysis beneficiaries. Medicare FFS accounted for about 62 percent of all treatments furnished in 2017.<sup>10</sup> According to CMS facility survey data, since the late 1980s, for-profit, freestanding facilities have provided the majority of dialysis treatments. In 2017, freestanding facilities furnished 95 percent of FFS treatments, and for-profit facilities furnished about 91 percent (Table 6-2). In 2017, the capacity of facilities in urban and rural areas was generally consistent with where FFS dialysis beneficiaries lived.

Two large dialysis organizations (LDOs) dominate the dialysis industry. In 2017, these LDOs accounted for about 73 percent of facilities and 76 percent of 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 and distributes renal-related pharmaceutical products (e.g., phosphate binders), 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 assess 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 the Medicare Provider of Services file, we compared the characteristics of beneficiaries treated at facilities that closed in 2016 with those at facilities that provided dialysis in 2016 and 2017, the most current years for which complete data are available.

Between 2016 and 2017, the number of dialysis treatment stations—a measure of providers' capacity—increased by 3 percent. There was a net increase in the number of facilities that were freestanding, for profit, and located in both urban and rural areas. Compared with facilities that treated beneficiaries in both years, facilities that closed in 2016 (about 40 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 (Table 6-2).

According to our analysis, few dialysis FFS beneficiaries (roughly 1,600 individuals) were affected by facility closures in 2016. Our analysis found that beneficiary groups who were disproportionately affected included beneficiaries who were African American and younger (ages 45 to 64). By contrast, findings from our prior three analyses found that groups disproportionately affected by closures included beneficiaries who were White and older (Medicare Payment Advisory Commission 2018c, Medicare Payment Advisory Commission 2017, Medicare Payment Advisory Commission 2016b). 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.

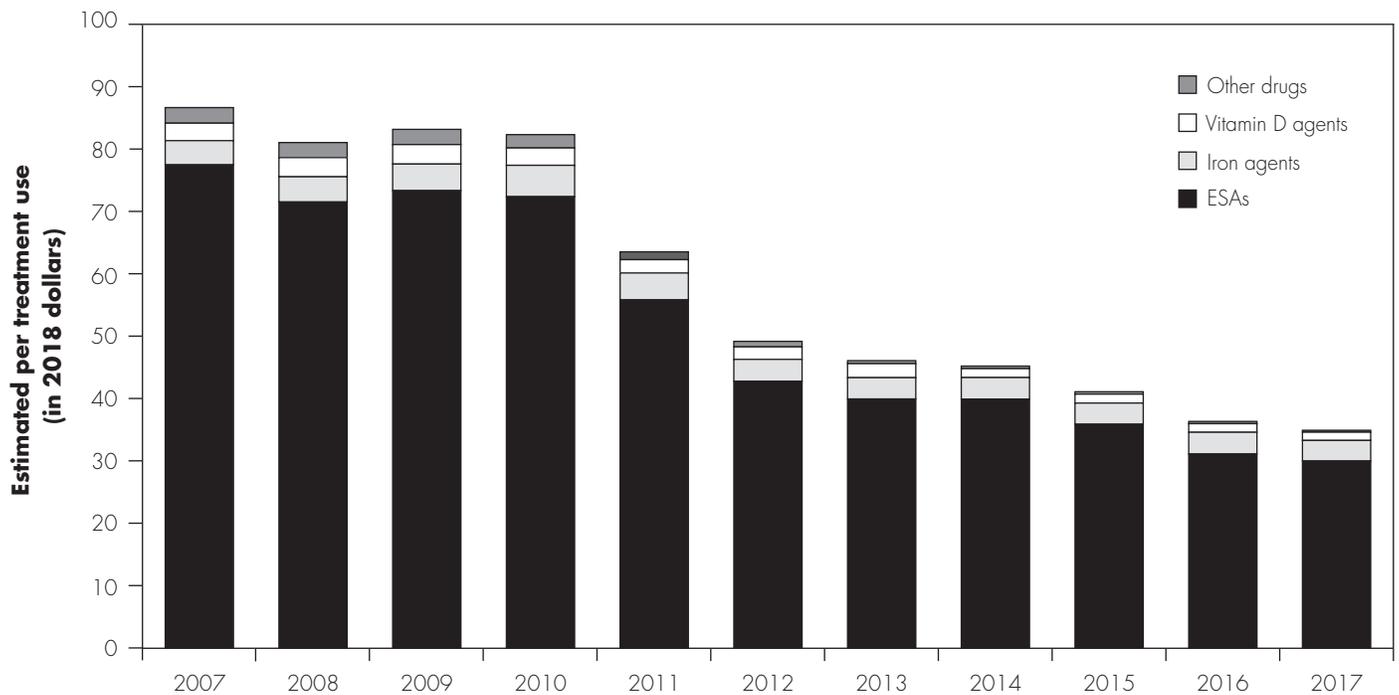
### **Trends in number of dialysis treatments provided**

Between 2016 and 2017, 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 each year).<sup>11</sup> The number of nonannualized dialysis treatments per beneficiary remained steady at 115. Over the most recent five-year period (2012 to 2017), the number of FFS dialysis beneficiaries and total dialysis treatments each increased by 1 percent per year, while the number of nonannualized treatments per beneficiary declined from 116 to 115. The slight decline in per beneficiary treatment growth may be associated with:

- CMS's restatement (in the rule-making process) of its policy for paying for dialysis furnished more than thrice weekly (Centers for Medicare & Medicaid Services 2014). The agency said that facilities must provide medical justification to be paid for furnishing more than three dialysis treatments per week and that the choice of dialysis modalities that require more than three treatments per week does not constitute medical justification.
- In 2015, CMS's contractors issued local coverage determinations (LCDs) that required certain conditions, including heart failure, to be reported on dialysis facility claims for Medicare to cover and pay for dialysis treatments exceeding thrice weekly (Centers for Medicare & Medicaid Services 2018b).
- In 2017, CMS's contractors issued draft LCDs that would have covered and paid for dialysis treatments more than thrice weekly only for acute conditions outside the patient's plan of care; these LCDs have yet to be finalized.
- In 2017, there was one fewer dialysis treatment day (based on a thrice weekly treatment schedule) compared with 2012.

### **Use of most dialysis drugs has declined under the outpatient dialysis PPS**

When CMS broadened the payment bundle in 2011 to include separately billable dialysis-related drugs, 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 dialysis PPS, the statute required that CMS rebase the PPS base rate by comparing drug use in 2007 with such use in 2012. Subsequently, we examined changes between 2007 and

**FIGURE 6-1****Use of dialysis drugs has declined under the outpatient dialysis PPS**

Note: PPS (prospective payment system), ESA (erythropoiesis-stimulating agent). Dollars per treatment calculated by multiplying drug units reported on claims by 2018 average sales price. Drugs included are epoetin alfa, epoetin beta, darbepoetin (ESAs); 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.

2017 (the most current year for which complete data are available) in the use per treatment of the leading dialysis drugs and aggregated them into four therapeutic classes—erythropoiesis-stimulating agents (ESAs), iron agents, vitamin D agents, and antibiotics.<sup>12</sup> The dialysis PPS increased the incentive for providers to be more judicious in providing dialysis drugs included in the payment bundle. Under the prior payment method, 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.

As shown in Figure 6-1, most of the decline in the per treatment use of dialysis drugs—which was estimated by multiplying drug units per treatment reported on CMS claims by each drug’s 2018 average sales price (to hold price constant)—occurred in the early years of the PPS (implemented in 2011). 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 Food and Drug Administration (FDA) changing the ESA label in 2011.

Between 2016 and 2017, holding price constant, the use of all dialysis drugs declined by nearly 4 percent. During this period, drug use declined for each of the four therapeutic classes (ESAs, vitamin D agents, iron agents, and all other drugs) (Figure 6-1). As shown in Table 6-3, per treatment drug use increased for only three products—ESAs epoetin beta and darbepoetin alfa and vitamin D agent calcitriol. However, under the PPS (between 2010 and 2017), per treatment use of calcitriol declined.

**TABLE  
6-3**

**Use of dialysis drugs per treatment has declined under the outpatient dialysis PPS**

Dialysis drug	Mean units per treatment*			Aggregate percent change	
	2010	2016	2017	2010-2016	2016-2017
ESAs					
Epoetin alfa	5,214	1,383	1,269	-76%	-8%
Darbepoetin alfa	1.26	2.14	2.17	72	1
Epoetin beta**	N/A	3.02	3.16	N/A	5
Iron agents					
Sodium ferric gluconate	0.15	0.13	0.11	-26	-14
Iron sucrose	16.0	13.0	12.4	-22	-4
Ferumoxytol	0.8	0.0092	0.0073	-99	-20
Ferric carboxymaltose	N/A	0.00031	0.00008	N/A	-74
Vitamin D agents					
Paricalcitol	2.3	0.3	0.3	-87	-5
Doxercalciferol	0.9	1.5	1.3	54	-10
Calcitriol	0.13	0.03	0.05	-64	63
Antibiotics					
Daptomycin	0.22	0.11	0.09	-58	-20
Vancomycin	0.02	0.02	0.01	-42	-14
Other drugs					
Levocarnitine	0.010	0.001	0.001	-88	-18
Alteplase	0.020	0.002	0.002	-89	-9

Note: 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.

\*Each drug is reported using its own drug units.

\*\*Epoetin beta was introduced to the U.S. market in 2015.

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

Prior Commission analysis showed that the outpatient dialysis 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 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). 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).

**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.<sup>13</sup>

For dialysis facilities, in 2017 Medicare payments exceed marginal costs by 17 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 (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 between 2012 and 2017 and of U.S. Renal Data System (USRDS) data between 2011 and 2016.

For the most recent five-year period that data are available, rates of mortality and of hospitalization and readmission declined, while emergency department (ED) use rose. Use of home dialysis, which is associated with improved patient satisfaction and quality of life, 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). The negative cardiovascular outcomes associated with high ESA use have generally declined or remained constant, and blood transfusion use, which initially increased under the PPS, has declined since 2013.

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, and demand far outstrips supply. We also discuss CMS’s payment model—the Comprehensive ESRD Care Model—that aims to improve the health outcomes of dialysis beneficiaries while lowering the total Medicare Part A and Part B per capita spending on these beneficiaries. Last, we discuss CMS’s two renal quality measurement systems, the ESRD Quality Incentive Program (QIP) and the dialysis star rating system.

### Quality under the PPS

Between 2012 and 2017, through the Commission’s analysis of claims data, mean all-cause hospital stays per

beneficiary declined from 1.7 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. USRDS data show that hospital admission rates fell for ESRD-related complications and comorbidities (cardiovascular, infection, and vascular access events) during the most recent five-year period for which data are available (2011 to 2016) (United States Renal Data System 2018).<sup>14</sup> Between 2012 and 2017, 30-day readmission rates declined slightly (from 22 percent of admissions to 21 percent of admissions), while the proportion of dialysis beneficiaries who used the ED increased from an average of 11 percent per month to about 12 percent per month. Between 2011 and 2016, adjusted annual rates of mortality per 100 dialysis beneficiaries declined from 18 to 16 (United States Renal Data System 2018).

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 2012 and 2017, from 97 percent to 98 percent of hemodialysis beneficiaries and 91 percent to 93 percent of PD beneficiaries received adequate dialysis, defined as having enough waste removed from their blood. Between 2012 and 2017, the share of dialysis beneficiaries diagnosed with dehydration declined slightly, while the share of beneficiaries diagnosed with fluid overload increased slightly (Centers for Medicare & Medicaid Services 2018a).

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 dialysis 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 declined, and the proportion with lower hemoglobin levels increased (which is generally associated with lower ESA use). During the initial years of the dialysis PPS, blood transfusion rates increased (from 2.7 percent per month in 2010 to 3.4 percent per month in 2012). However, since 2013, the proportion of beneficiaries receiving a blood transfusion declined (from 3.3 percent per month to 2.3 per month) (Centers for Medicare & Medicaid Services 2018a).<sup>15</sup>

Stroke, acute myocardial infarction, and heart failure are cardiovascular outcomes associated with anemia management. Under the dialysis PPS, the cumulative

share of beneficiaries experiencing stroke declined, while the share experiencing acute myocardial infarction has remained relatively constant. Until 2015, the share of beneficiaries with heart failure decreased. However, there has been an increasing trend between 2015 and 2017 (Centers for Medicare & Medicaid Services 2018a).<sup>16</sup>

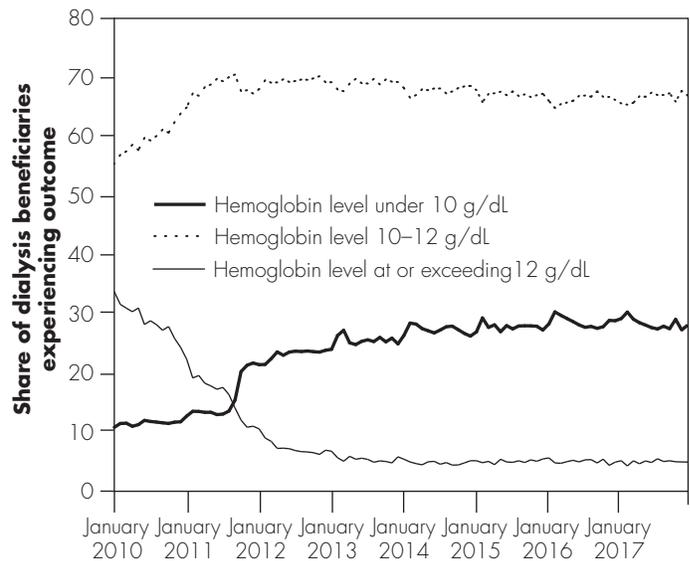
As discussed in our June 2014 report, clinical process measures can exacerbate the incentives in FFS to overprovide and overuse services (Medicare Payment Advisory Commission 2014b). For example, before 2011, targeting higher hemoglobin levels was associated with higher ESA use among dialysis beneficiaries. In addition, some clinical process measures may be only weakly correlated with better health outcomes. A given hemoglobin level may reflect adequate anemia management for one patient, whereas the same level may lead to a different response in a different patient. 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).

According to separate analyses by CMS and the Commission, between 2012 and 2017 the share of beneficiaries dialyzing at home steadily increased from a monthly average of 9.5 percent to 11.0 percent (Centers for Medicare & Medicaid Services 2018a). While we are encouraged by this modest 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 about 36 percent of all dialysis beneficiaries.

Researchers have identified many factors that affect the use of home dialysis, including factors both clinical (patients’ other health problems and prior nephrology care) and nonclinical (e.g., patients’ social circumstances, physician’s training and preference, dialysis facility’s staff experience). The dialysis PPS is associated with an overall increase in the use of home dialysis (Lin et al. 2017). The Commission’s recent discussions of these factors can be found in our March 2018 report to the Congress (located

**FIGURE 6-2**

**Changes in hemoglobin levels under the dialysis PPS**



Note: PPS (prospective payment system), g/dL (grams per deciliter). Data are compiled on a monthly basis by CMS.

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

at [http://medpac.gov/docs/default-source/reports/mar18\\_medpac\\_ch6\\_sec.pdf?sfvrsn=0](http://medpac.gov/docs/default-source/reports/mar18_medpac_ch6_sec.pdf?sfvrsn=0)).

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, the growth in PD, the predominant home method, slowed because of a shortage of solutions needed to perform this type of dialysis. Between 2014 and 2017, 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 for how many new patients could be started on PD based on the provider’s history of growth during the first six months of 2014 (Seaborg 2015). Although steps have been taken to increase the supply of PD solutions, a shortage of solutions continues to exist for one of the two

**TABLE  
6-4**

**Between 2012 and 2017,  
the number of kidney transplants  
increased, and African Americans,  
Hispanics, and Asian Americans  
accounted for an increasing share**

	2012	2017
Total transplants	16,487	19,849
Share of live donors	34%	29%
Share of:		
Whites	52	47
African Americans	25	27
Hispanics	16	18
Asians	6	7
Others	2	2

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

Source: Organ Procurement and Transplantation Network 2018.

PD types (automated peritoneal dialysis) in 2018 (Food and Drug Administration 2018).

### 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 half the spending for dialysis patients (\$25,942 vs. \$89,367) (United States Renal Data System 2018). However, demand for kidney transplantation exceeds supply. Factors that affect access to kidney transplantation besides donation rates 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 2012 and 2017, according to the Organ Procurement and Transplantation Network, the number of kidney transplants increased by 4 percent per year to 19,849 (Table 6-4) (Organ Procurement and Transplantation Network 2018). In 2017, African

Americans were less likely than White patients to receive kidney transplants despite their fourfold greater likelihood of developing ESRD; however, between 2012 and 2017, the number of African Americans receiving a transplant grew by 5 percent per year (to 5,276 individuals, data not shown). According to Ephraim and colleagues, compared with other groups, the lower rates of kidney transplantation for African Americans 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 waiting list, 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 following implementation and a decrease in the rate of kidney transplantation for Whites. Before the new system, the average monthly transplantation rate was significantly higher among Whites (1.07 percent) compared with African Americans or Hispanics (0.80 percent and 0.79 percent, respectively). After implementation of the system, the monthly rates changed significantly for all groups: 0.95 percent for Whites, 0.96 percent for African Americans, and 0.91 percent for Hispanics (Melanson et al. 2017).

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 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 IV CKD (chronic kidney disease), the disease stage before ESRD, about their treatment options and managing the disease and related comorbidities, 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. About 3,500 beneficiaries were provided such services in each year between 2015 and 2017, compared with about 4,200 beneficiaries in 2012. In 2017, Medicare KDE spending was under \$500,000.<sup>17</sup>

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.<sup>18</sup> MIPPA also specified that beneficiaries with Stage IV CKD are eligible for the benefit. Some stakeholders contend that other categories of beneficiaries, including those with Stage V 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.

### **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 the Center for Medicare & Medicaid Innovation, the first round of the Comprehensive ESRD Care (CEC) Model began October 1, 2015, and will continue through December 31, 2020. The CEC 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.

Under this five-year initiative, ESRD Seamless Care Organizations (ESCOs)—which, like accountable care organizations (ACOs), are specific to the dialysis population—consist of at least one dialysis facility and one nephrologist, and they 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. Enrollment in the CEC Model increased from approximately 16,000 beneficiaries in the first performance year (October 2015 to December 2016) to roughly 55,000 beneficiaries in the second performance year (Centers for Medicare & Medicaid Services 2016, Kalantar-Zadeh 2018).

In the CEC Model's first round, Dialysis Clinic Inc., DaVita, and Fresenius—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. (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 it does share in the gains.) In the CEC Model's second round, small dialysis organizations have the option of one-sided or two-sided risk.

In payment year 1 (PY1) of the CEC Model, all 13 ESCOs produced savings relative to their benchmarks, with 12 ESCOs producing enough savings to earn shared savings payments (Centers for Medicare & Medicaid Services 2017). The earned shared savings payments ranged from \$1 million to \$12 million and totaled \$51 million. Quality measurement in PY1 was essentially pay for reporting; thus, all the ESCOs received a 100 percent score for quality. In total, the demonstration saved 1.7 percent relative to a spending benchmark. It is not clear whether this trend will continue since the results for 2017 and 2018 are not yet available.

According to CMS's contractor, in the ESCOs' first year, there was a statistically significant decline of \$153 in total Part A and Part B spending per beneficiary per month (PBPM) ( $p < 0.10$ ) (Marrufo et al. 2017). The contractor attributed this reduction to a statistically

significant decline in spending for acute inpatient services ( $-\$102$  PBPM,  $p < 0.01$ ) and post-acute care services ( $-\$59$  PBPM,  $p < 0.05$ ).

The Commission has said that, if structured properly, a shared savings program—in this case, for ESRD providers—could present an opportunity to correct some of the undesirable incentives inherent in FFS payment and reward providers who are doing their part to control costs and improve quality.

In addition to the CEC Model, dialysis beneficiaries in selected geographic areas also have access to ESRD special needs plans (SNPs). Between October 2017 and October 2018, enrollment increased and the number of ESRD SNPs remained steady. 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). By comparison, as of October 2017, about 4,600 dialysis beneficiaries were enrolled in 15 ESRD SNPs operated by 6 managed care organizations in the same states with ESRD SNPs in 2018. While the CEC Model and ESRD SNPs enroll only dialysis beneficiaries, other ACO models, such as those participating in the Medicare Shared Savings Program, might provide opportunities for beneficiaries with earlier stages of kidney disease to receive better care coordination, particularly in the management of kidney disease risk factors.

### **The ESRD QIP and the dialysis star rating system**

CMS measures quality for each dialysis facility using two measurement systems, the ESRD QIP, which was mandated by MIPPA and implemented in 2012, and the dialysis star rating system, which CMS established through a subregulatory process in 2015. CMS assigns from 1 to 5 stars; more stars mean that a dialysis facility performs better on quality measures compared with the national average. 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 score diverge, which could occur because the measurement systems use different methods and measures to calculate a facility's performance score. 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.

### **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 adequate access to capital. For example, in 2017 and 2018:

- Fresenius Medical Care took a \$150 million stake in the tissue engineering firm Humacyte Inc. and will become the exclusive distributor of the company's bioengineered blood vessels once the FDA approves the product. These blood vessels are currently being tested in the last of three phases that are typically required for market approval in the United States and Europe.
- Vifor Fresenius Medical Care Renal Pharma—a joint venture between Fresenius Medical Care and Vifor Pharma Group—acquired the international license to Cara Therapeutics' investigational opioid analgesic that treats pruritus (severe itching) associated with renal disease in hemodialysis patients. Vifor Fresenius Medical Care Renal Pharma paid Cara Therapeutics \$50 million in advance and will invest an additional \$20 million in Cara common stock to market the drug in countries outside the United States, Japan, and South Korea. Cara will solely promote the product in facilities not operated by Fresenius Medical Care in the United States. Vifor Fresenius Medical Care Renal Pharma Ltd. and Cara will promote the investigational medicine to Fresenius Medical Care dialysis clinics under a profit-sharing arrangement.
- DaVita completed its acquisition of Renal Ventures, gaining 31 dialysis facilities and divesting 7 facilities (as required by the Federal Trade Commission), and acquired Purity Dialysis, which operates 10 facilities in Wisconsin. In 2017, DaVita sold its subsidiary, DaVita Medical Group, to Optum for \$4.9 billion.
- Baxter, a manufacturer of renal products including peritoneal dialysis machines, and the Mayo Clinic announced the development of a new renal care center

of excellence that will be located at the Mayo Clinic’s dialysis center in Jacksonville, FL.

- Dialyze Direct LLC, a provider of staff-assisted home hemodialysis services in skilled nursing facilities (SNFs), signed a definitive agreement to acquire Affiliated Dialysis Centers LLC (a dialysis provider in the Midwest that furnishes outpatient clinic dialysis, home dialysis, and SNF dialysis services through its associated entities, and currently serves more than 400 patients).
- Cricket Health, a provider of integrated kidney care, announced funding of \$24 million that will be used partially to create new home and in-center dialysis programs.
- CVS Health announced an initiative that will focus on the development of home dialysis technology. In 2018, the company plans to initiate 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.
- Outset Medical said it raised \$132 million in equity financing, with funds slated to accelerate the commercial expansion of its Tablo hemodialysis system.

In public financial filings, the two LDOs (Fresenius Medical Care and DaVita) reported positive financial performance related to their dialysis business for 2018, including strong organic volume and revenue growth—that is, growth achieved apart from mergers and acquisitions. In addition, since 2010, the two LDOs have grown through large acquisitions and mergers of other dialysis facilities and other health care organizations. For example, during this period, both of the largest dialysis organizations acquired mid-sized 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 to CMS by freestanding dialysis facilities, we estimate that the 2017 all-payer margin was roughly 20 percent.<sup>19</sup> In their financial documents, dialysis providers reported that FFS Medicare payment rates are significantly lower than commercial rates (DaVita 2018).

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

## 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 2017 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 2017, Medicare spending for outpatient dialysis services was \$11.4 billion, an increase of 0.4 percent compared with 2016. Per capita spending held steady at roughly \$29,000 in 2016 and 2017. The trend in total and per capita spending reflects two factors: (1) a statutory update (of 0.55 percent) to the base dialysis payment rate in 2017 and (2) the number of dialysis treatments per beneficiary, which held steady in 2016 and 2017.

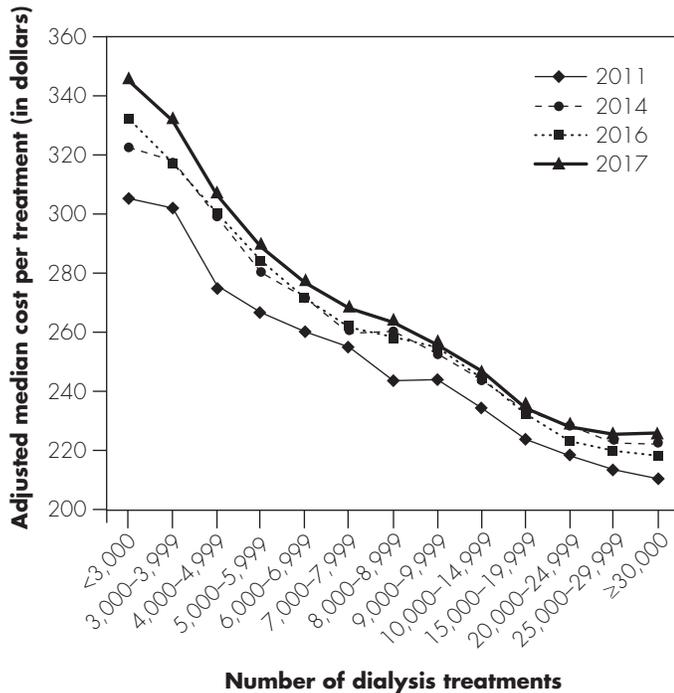
Beginning in 2017, dialysis facilities are able to furnish dialysis to beneficiaries with acute kidney injury (AKI), as mandated by the Trade Preferences Extension Act of 2015. In 2017, Medicare spending for outpatient dialysis services for beneficiaries with AKI was nearly \$40 million. Medicare pays facilities the dialysis PPS base rate adjusted by the PPS wage index for the treatment of beneficiaries with AKI.<sup>20</sup> 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.

### Part D spending for dialysis drugs

Under the dialysis 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 2016 (the most recent year for which data are available), Part D spending for two categories of dialysis drugs (calcimimetics and phosphate binders) totaled \$2.3 billion, an increase of 22 percent per year compared since 2011. During this period, on a per treatment basis, Part D spending for all dialysis drugs increased by 20 percent per year.<sup>21</sup> In addition, between 2011 and 2016, total Part D spending for dialysis drugs grew more rapidly than spending for all other Part D drugs prescribed to dialysis beneficiaries (22 percent per year vs. 11 percent per year). In 2016, spending for Part D dialysis drugs constituted about 60 percent of dialysis beneficiaries’ gross Part D spending. Medicare

**FIGURE 6-3**

**Higher volume dialysis facilities have lower cost per treatment, 2011-2017**



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).

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

spending for Part D dialysis drugs is not included in the Commission’s analysis of Medicare’s payments and costs for dialysis facilities.

In 2011, the Secretary included Part D oral-only dialysis drugs and biologics (calcimimetics and phosphate binders) in the expanded payment bundle but delayed paying for them under the dialysis PPS until January 1, 2014 (to permit sufficient time to address data and pricing issues). The Stephen Beck Jr. Achieving a Better Life Experience Act of 2014 delayed bundling these drugs until 2025. However, if an injectable equivalent (or form of administration other than an oral form) of a dialysis oral-only drug is approved by the FDA before 2025, CMS will include both the oral and non-oral dialysis drugs in the PPS payment bundle (Centers for Medicare & Medicaid Services 2015).

In February 2017, the FDA approved the first calcimimetic injectable product (etelcalcetide) that is a counterpart to oral cinacalcet (paid for under Part D in 2017). Consequently, beginning January 2018, CMS pays for both the oral and intravenous calcimimetics under the dialysis PPS using a TDAPA until sufficient claims data (at least two years’ worth) for rate-setting analysis are available. (Additionally, Part D plans will no longer pay for oral cinacalcet for dialysis beneficiaries after 2018). According to CMS, these products qualify for a TDAPA because the base dialysis payment rate has not yet accounted for their costs. For these products, CMS is paying providers 106 percent of the drug’s average sales price.

Including dialysis drugs covered under Part D in the dialysis 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. The efficiency of dialysis care may improve after calcimimetics are included in the dialysis PPS payment bundle. For example, based on the results of a multicenter, prospective, randomized, placebo-controlled trial, some clinicians concluded that the routine use of cinacalcet may not be warranted (Palmer et al. 2013).<sup>22</sup> Between 2015 and 2016, Part D spending for cinacalcet increased 27 percent to roughly \$875 million. Giving the Secretary the flexibility to rebase the payment bundle after oral-only dialysis drugs are included in the dialysis PPS payment bundle might lead to savings for beneficiaries and taxpayers.

**Providers’ costs for outpatient dialysis services under the outpatient dialysis PPS**

To assess the appropriateness of costs for dialysis services paid for under the dialysis 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 2016 and 2017 cost reports 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 2016 and 2017, the cost per treatment increased by 2 percent, from about \$243 per treatment to nearly \$248 per treatment. During this period, the cost per treatment for ESAs and other dialysis-related drugs declined by 10 percent and 4 percent, respectively. These cost categories accounted for 9 percent

and about 2 percent, respectively, of the total cost of treatment in 2017. The decline in cost per treatment for ESAs and other injectable drugs somewhat offset increases in the other cost categories:

- Administrative and general expenses and capital costs, which accounted for 26 percent and 17 percent of the cost per treatment, respectively, increased by 5 percent and 6 percent, respectively.
- Labor costs, which accounted for about 33 percent of the cost per treatment, increased by 3 percent.
- Supply and lab costs, which accounted for 11 percent and 2 percent of the cost per treatment, respectively, increased by less than 1 percent and 2 percent, respectively.

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 2016 and 2017, per treatment costs decreased by 3 percent for facilities in the 25th percentile of cost growth and increased by 5 percent for facilities in the 75th percentile.

It is unknown to what extent some of the variation in costs among facilities results from differences in the accuracy of facilities' reported data. In 2016 and 2017, we found substantial variation in the level of selected cost categories reported by the five largest dialysis organizations. For example, the cost per treatment for administrative and general services and for capital services each differed by roughly \$30 per treatment among these organizations. We anticipate that CMS's audit of a representative sample of facilities' ESRD cost reports will examine their accuracy. Consistent with our 2014 recommendation, the Protecting Access to Medicare Act of 2014 (PAMA) funded CMS to audit a representative sample of ESRD facility cost reports beginning in 2012.

**Cost per treatment is correlated with facility service volume** Cost per treatment is correlated with the total number of treatments a facility provides. For this analysis, 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 2017, a statistically significant relationship between total treatments and cost per treatment (correlation coefficient equaled  $-0.5$ ) (Figure 6-3). 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 costs per treatment for capital and administrative and general services compared with all other facilities.

### **Medicare margins for freestanding facilities in 2017**

The Commission assesses current payments and costs for dialysis services for freestanding dialysis facilities by comparing Medicare's payments with facilities' Medicare-allowable costs. The latest and most complete data available on payments and costs are from 2017. We estimate that the aggregate Medicare margin in 2017 was  $-1.1$  percent (Table 6-5, p. 174). Margins decidedly varied by treatment volume; facilities in the lowest volume quintile had margins at or below  $-21.3$  percent, and facilities in the top volume quintile had margins of 5.4 percent or more.

Urban facilities had higher margins than rural facilities ( $-0.4$  percent vs.  $-5.5$  percent). Much of the difference in margins between urban and rural facilities is accounted for by differences in total treatment volume. Urban dialysis facilities are larger on average than rural facilities in the number of treatment stations and total treatments provided. In 2017, urban facilities averaged about 12,000 treatments, while rural facilities averaged about 7,800 treatments (data not shown).

The Commission is concerned about the gap in the Medicare margin between urban and rural facilities. Although some rural facilities have benefited from the dialysis 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 2016a, 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 a low-volume facility (Government Accountability Office 2013). The text box (p. 175) provides more information about the low-volume and rural payment adjustments used in the dialysis PPS. The Commission intends to continue to monitor the adequacy of Medicare's payments for rural and urban facilities in the upcoming years. In addition, we intend to consider alternative approaches that would better target low-volume, geographically isolated facilities.

**TABLE  
6-5**

**Medicare margins in 2017 varied by type of freestanding dialysis facility**

Provider type	Medicare margin	Percent of freestanding dialysis facilities	Percent of freestanding dialysis facility treatments
All	-1.1%	100%	100%
Urban	-0.4	82	88
Rural	-5.5	18	12
Treatment volume (quintile)			
Lowest	-21.3	20	7
Second	-10.6	20	12
Third	-3.4	20	17
Fourth	0.8	20	24
Highest	5.4	20	39

Note: Totals 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.

### Projecting the Medicare margin for 2019

The aggregate Medicare margin for 2019 is projected to be -0.4 percent, slightly greater than the 2017 Medicare margin (-1.1 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:

- PAMA set the update to the dialysis base payment rate in 2018 to account for the reduced drug utilization under the dialysis PPS. This rebasing adjustment reduced the statutory update (based on the ESRD market basket offset by a productivity adjustment) by 1.0 percent in 2018. The net payment update was 0.3 percent in 2018.
- In 2019, the statutory dialysis base payment rate (based on the ESRD market basket offset by a productivity adjustment) increased by 1.3 percent.
- For 2018 and 2019, CMS estimates that payments will be reduced by 0.14 percent and 0.15 percent, respectively, due to the ESRD QIP.
- Other regulatory changes implemented by CMS are expected to result in payments increased by about 0.2 percent in 2018 and 0.3 percent in 2019.

### How should Medicare payments change in 2020?

PAMA sets the update to the outpatient dialysis payment base rate equal to the ESRD market basket index, less an adjustment for productivity (currently estimated at 0.5 percent). Based on CMS's latest forecast of changes in the ESRD market basket costs for calendar year 2020 (2.4 percent), the update to the 2020 payment rate would be 1.9 percent. In addition to this statutory provision, the ESRD QIP is expected to decrease total payments by 0.35 percent in 2020. And beginning in 2020, Medicare will pay dialysis facilities separately for all new drugs and biologics based on the product's average sales price for at least a two-year period. This policy will likely increase Medicare payments to facilities because CMS will not offset the dialysis PPS base rate (even for new drugs that fall into 1 of the 11 functional categories that are already included in the payment bundle).

### Recommendation

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.

## The low-volume and rural payment adjustments should focus on protecting only facilities critical to beneficiary access

The 23.9 percent low-volume and 0.8 percent rural payment adjustments under the dialysis prospective payment system (PPS) are not targeting facilities that are critical to beneficiary access. CMS defines a low-volume facility as one that provides fewer than 4,000 treatments (Medicare and non-Medicare) in each of the three years before the payment year and has not opened, closed, or received a new provider number because of a change in ownership during the three-year period. For payment year 2016, CMS revised the distance requirement used to determine eligibility for this payment adjustment by (1) including, for the purposes of determining a facility's eligibility, treatments furnished by the facility in question and other facilities under common ownership that are within five road miles of the facility in question; and (2) applying the five-mile distance criterion to all facilities, regardless of when the facility was certified. Before payment year 2016, the dialysis PPS used a 25-mile distance criterion and applied that criterion to only facilities certified on or after January 1, 2011.

Since 2016, all rural facilities, irrespective of their treatment volume or proximity to other dialysis facilities, receive an adjustment of 0.8 percent. Before 2016, the dialysis PPS did not include such an adjustment. The Commission is concerned that neither the low-volume adjustment nor the rural adjustment are targeting facilities that are critical to beneficiary access. A prior Commission analysis that used facility and claims data from 2013 found that:

- About 47 percent of the facilities that receive the low-volume adjustment are within five miles of the next closest facility. The median distance between the facility that would receive the proposed adjustment and the next closest facility is six miles.
- About 28 percent of all rural facilities are within five miles of the next closest facility, and nearly 20 percent of facilities located in rural areas are high volume (Medicare Payment Advisory Commission 2015). ■

### RECOMMENDATION 6

**For calendar year (CY) 2020, the Congress should update the CY 2019 Medicare end-stage renal disease prospective payment system base rate by the amount determined in 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 -1.1 percent in 2017 and is projected to be -0.4 percent in 2019. The 17 percent marginal profit is a positive indicator of beneficiary access.

### IMPLICATIONS 6

#### Spending

- In 2020, 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 do not anticipate any negative effects on beneficiary access to care. This recommendation is expected to have a minimal effect on providers' willingness and ability to care for Medicare beneficiaries. ■

## Endnotes

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- 1 In this chapter, the term *beneficiaries* refers to individuals covered by Medicare, and *patients* refers to all individuals who have ESRD.
- 2 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.
- 3 Incidence data are adjusted for age, sex, and primary ESRD diagnosis.
- 4 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.
- 5 For example, the Center for Medicare & Medicaid Innovation awarded a three-year cooperative agreement in 2014 to 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) that aimed to (1) better prepare patients for ESRD care by improving patient education and shared decision making; (2) increase the share of patients who select home dialysis or a preemptive kidney transplant; (3) increase the rate of arteriovenous fistulas; (4) increase patients' quality of life scores; and (5) 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) (Schneider and Lines 2018). 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). Other providers have developed similar interventions that emphasize early patient education and shared decision making (Dialysis Clinic Inc. 2019, Kaiser Permanente 2017).
- 6 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 at least a monthly face-to-face visit for the first three months of home dialysis and once every three months thereafter.
- 7 For pediatric dialysis beneficiaries (less than 18 years of age), the base rate is adjusted for age and type of dialysis.
- 8 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.
- 9 Over a five-year period ending in 2016 (the most recent data available), the number of dialysis patients with any type of insurance coverage grew by 4 percent per year (United States Renal Data System 2018).
- 10 These figures are based on the Commission's analysis of Medicare and total treatments reported by freestanding facilities on cost reports submitted to CMS.
- 11 Analysis of treatment growth is based on Medicare-covered treatments in each year. An analysis of both Medicare-covered and noncovered treatments finds that total treatments declined by 1 percent and the nonannualized dialysis treatments per beneficiary declined from 118 to 116 between 2016 and 2017.
- 12 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.
- 13 If we approximate marginal cost as total Medicare costs minus fixed building and equipment costs, then marginal profit can be calculated as follows:  $\text{Marginal profit} = (\text{payments for Medicare services} - (\text{total Medicare costs} - \text{fixed building and equipment costs})) / \text{Medicare payments}$ . This comparison is a lower bound on the marginal profit because we do not consider any potential labor costs that are fixed.
- 14 Between 2011 and 2016, adjusted hospitalization rates (per patient year) for hemodialysis patients fell from 0.49 to 0.45 admissions for cardiovascular events, from 0.48 to 0.44 for infection events, and from 0.21 to 0.13 admissions for vascular access events. Adjusted admission rates for PD patients also declined for these ESRD-related complications and comorbidities during this period (United States Renal Data System 2018).
- 15 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.

- 16 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 2018b).
- 17 This analysis used 100 percent of 2012 through 2017 carrier and outpatient claims submitted for KDE services.
- 18 MIPPA does not permit other providers (such as registered nurses, social workers, and dieticians) or dialysis facilities to bill for KDE services.
- 19 In 2018, both LDOs and several midsized organizations contributed more than \$100 million to defeat a public referendum in California that would have capped payments at 15 percent above patient care costs for dialysis patients with commercial coverage.
- 20 In addition, for beneficiaries with AKI, Medicare pays dialysis facilities separately for drugs, biologics, and laboratory services that are not renal dialysis services.
- 21 Part D spending per dialysis treatment is calculated by dividing total Part D 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.
- 22 The Evaluation of Cinacalcet Hydrochloride Therapy to Lower Cardiovascular Events trial—a multicenter, prospective, randomized, placebo-controlled trial—found that cinacalcet did not significantly reduce the risk of death or major cardiovascular events in patients with moderate to severe secondary hyperparathyroidism undergoing dialysis (Chertow et al. 2012).

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