CHAPTER 6

Outpatient dialysis services

RECOMMENDATION

6 For 2019, the Congress should update the calendar year 2018 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

CHAPTER 6

Outpatient dialysis services

Chapter summary

Outpatient dialysis services are used to treat the majority of individuals with end-stage renal disease (ESRD). In 2016, more than 390,000 beneficiaries with ESRD on dialysis were covered under fee-for-service (FFS) Medicare and received dialysis from more than 6,700 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 certain dialysis drugs and ESRD-related clinical laboratory tests that were previously paid separately. In 2016, Medicare expenditures for outpatient dialysis services were $11.4 billion, a 2 percent increase compared with 2015 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 2015 and 2016, growth in the number

In this chapter

- Are Medicare payments adequate in 2018?
- How should Medicare payments change in 2019?

of dialysis treatment stations grew faster than growth in the number of FFS dialysis beneficiaries.

- ***Volume of services*—**Between 2015 and 2016, the number of FFS dialysis beneficiaries grew by 1 percent, while the total number of treatments grew by 3 percent. 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.

***Quality of care*—**We looked at changes in quality indicators between 2011, when the outpatient dialysis PPS was implemented, and 2016. There was a declining trend in unadjusted mortality, hospitalization, and 30-day readmission rates, though emergency department use increased. With regard to anemia management, negative cardiovascular outcomes associated with high ESA use declined, and blood transfusion use, which initially increased under the PPS, has trended down since 2013. Between 2011 and 2016, beneficiaries' use of home dialysis, which is associated with improved patient satisfaction and quality of life, increased from 9 percent to 11 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.

***Providers' access to capital*—**Information from investment analysts suggests that access to capital for dialysis providers continues to be adequate. The number of facilities, particularly for-profit facilities, continues to increase. Since 2011, the two largest dialysis organizations have grown through acquisitions and mergers with midsized dialysis organizations and other providers, including physician services organizations.

***Medicare payments and providers' costs*—**Our analysis of Medicare payments and costs is based on 2015 and 2016 claims and cost report data submitted to CMS by freestanding dialysis facilities. During this period, cost per treatment decreased by 0.7 percent, while Medicare payment per treatment decreased by about 0.6 percent. We estimate that the aggregate Medicare margin was 0.5 percent in 2016, and the rate of marginal profit—that is, the rate at which Medicare payments exceed providers' marginal costs—was 17.2 percent. The 2018 aggregate Medicare margin is projected at 0.4 percent, approximately the same as the 2016 Medicare margin. The Commission's recommendation is that, for 2019, the Congress should update the 2018 dialysis 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 (Foley et al. 2011).

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. As we discuss later in this chapter, 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 advantages such 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.[1]

In 2016, about 392,000 ESRD beneficiaries on dialysis were covered under fee-for-service (FFS) Medicare and received dialysis from nearly 6,750 dialysis facilities.[2] 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 2016, Medicare Part B expenditures for outpatient dialysis services included in the payment bundle were $11.4 billion. In addition, Part D payments for dialysis drugs—a calcimimetic and multiple phosphate binders—that are not yet included in the PPS payment bundle totaled nearly $2.0 billion in 2015 (the most recent data available).

Characteristics of fee-for-service dialysis beneficiaries, 2016

Although Medicare generally does not provide disease-specific entitlement, the 1972 amendments to the Social Security Act extended Medicare benefits to people with

TABLE 6–1

FFS dialysis beneficiaries are disproportionately younger, male, and African American compared with all Medicare FFS beneficiaries, 2016

	Percent of FFS:	
	Dialysis beneficiaries	All beneficiaries
Age		
Under 45 years	11%	4%
45–64 years	38	13
65–74 years	27	49
75–84 years	18	23
85+ years	6	12
Sex		
Male	56	47
Female	44	53
Race		
White	48	81
African American	36	10
All others	17	9
Residence, by type of county		
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.

ESRD, including those under age 65. To qualify for the ESRD program, an individual must be fully or currently insured under the Social Security or Railroad Retirement program, entitled to benefits (i.e., meets the required work credits) under the Social Security or Railroad Retirement program, or be the spouse or dependent child of an eligible beneficiary.

Most dialysis beneficiaries have FFS coverage. The statute prohibits enrollment of individuals with ESRD in Medicare Advantage (MA) plans. However, beneficiaries who were enrolled in a managed care plan before an ESRD diagnosis can remain in the plan after they are diagnosed. In addition, Medicare permits the enrollment in MA of ESRD beneficiaries with a functioning kidney transplant. In 2016, about 18 percent of ESRD beneficiaries were enrolled in MA plans; by comparison, just over 30 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 lifts the prohibition on ESRD beneficiaries enrolling in MA beginning in 2021.

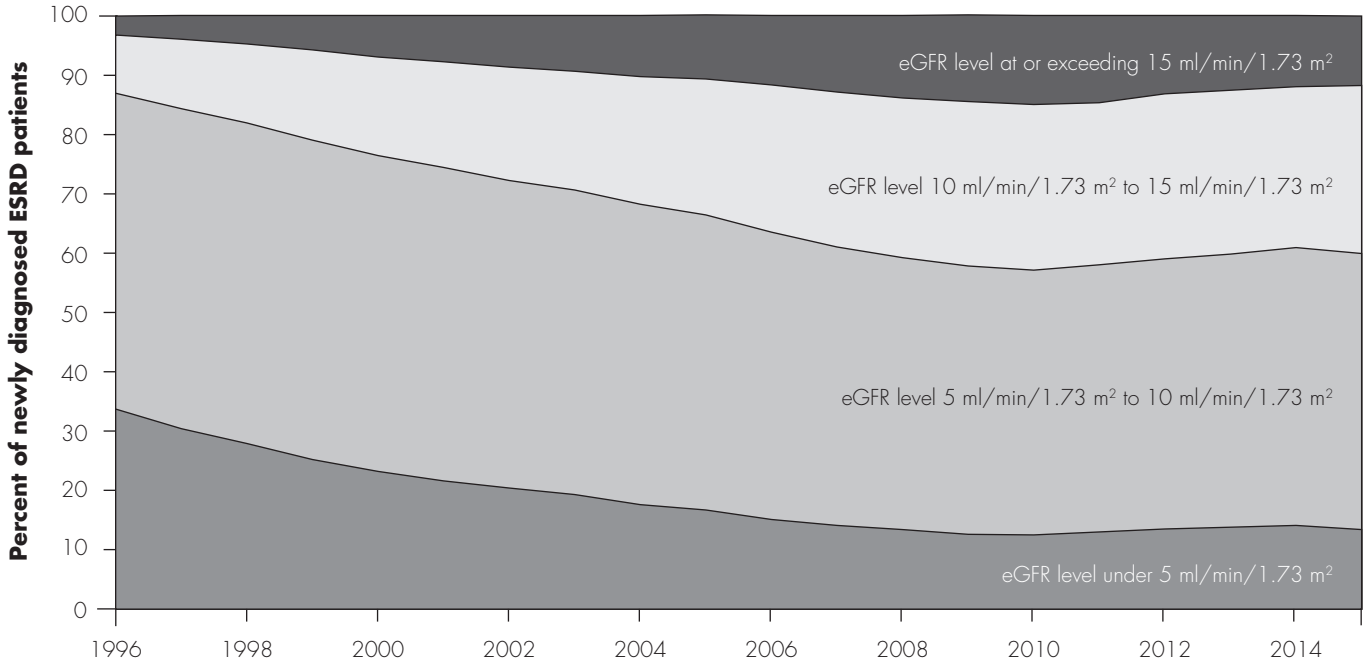
In 2016, most (about 90 percent) FFS dialysis beneficiaries were enrolled in Part D or had other sources of creditable drug coverage. In 2016, 70 percent of FFS dialysis beneficiaries with Part D coverage received the low-income subsidy, and about 10 percent of FFS dialysis beneficiaries in 2016 had either no Part D coverage or coverage less generous than Part D's standard benefit.

Compared with all Medicare FFS beneficiaries, FFS dialysis beneficiaries are disproportionately young, male, and African American (Table 6-1). In 2016, 76 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).

Between 2005 and 2015 (most recent data available), the adjusted rate (or incidence) of new ESRD cases (which includes patients who initiate dialysis or receive a kidney transplant and have any type of health insurance) decreased by 1 percent per year, from 393 per million people to 362 per million people (United States Renal Data System 2017).[3] Since peaking in 2006, the adjusted rate declined or remained the same across all races and ethnicities (White, African American, Asian American, Native American, and Hispanic) and all age groups (United States Renal Data System 2017).[4] In 2016, we estimate that approximately 83,000 FFS dialysis

FIGURE 6–1

Dialysis has been initiated with higher levels of residual kidney function since 1996



Note: eGFR (estimated glomerular filtration rate). "Higher levels of residual kidney function" refers to patients with an eGFR (a measure of residual kidney function) above 10 milliliters per minute per 1.73 square meters. (Lower values of this measure suggest reduced residual kidney function.) Population includes only newly diagnosed patients with CMS Form 2728.

Source: MedPAC analysis of Medicare's medical evidence form (Form 2728) submitted by dialysis providers to CMS.

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).[5]

Trend in starting dialysis earlier in the course of chronic kidney disease

Data from the mid-1990s through 2010 suggest a trend toward initiating dialysis earlier in the course of chronic kidney disease (CKD). The proportion of new dialysis patients with higher levels of residual kidney function steadily increased between 1996 and 2010, from 13 percent to 44 percent (Figure 6-1). Higher levels of residual kidney function refers to patients with an estimated glomerular filtration (eGFR) rate (a measure of residual kidney function) above 10 milliliters per minute per 1.73 square meters (lower values of this measure suggest comparatively less residual kidney function). While the share of patients initiating dialysis earlier in the course of CKD has decreased modestly (to 40 percent) between 2011 and 2015, the share remains three times higher than in 1996. Researchers have questioned this early initiation of dialysis in those with late-stage CKD, concluding that it is not associated with improved survival or clinical outcomes (Cooper et al. 2010, Evans et al. 2011, Kazmi et al. 2005, Stel et al. 2009, Traynor et al. 2002). For example, Cooper and researchers found that survival is similar between patients for whom dialysis is initiated early (with an eGFR equal to 10.0 to 14.0 ml per minute) and those for whom dialysis is electively delayed (with an eGFR equal to 5.0 to 7.0 ml per minute) and conclude that dialysis can be delayed for some patients until the eGFR drops below 7.0 ml per minute or until more traditional clinical indicators for the initiation of dialysis are present (Cooper et al. 2010). In the spring of 2018, the Commission intends to further explore clinical and nonclinical factors important to the optimal timing of dialysis initiation.

TABLE 6–2 **Payment adjustment factors for the dialysis PPS**

Payment adjuster	Value of payment adjuster
Age	
18–44 years	1.257
45–59 years	1.068
60–69 years	1.070
70–79 years	1.000
80+ years	1.109
Body surface area (per 0.1 m^2)	1.032
Underweight (body mass index < 18.5 kg/m^2)	1.017
Time since onset of dialysis (<4 months)	1.327
Comorbidities	
Pericarditis	1.040
Gastrointestinal tract bleeding	1.082
Hereditary hemolytic/sickle cell anemia	1.192
Myelodysplastic syndrome	1.095
Facility low-volume status	1.239
Facility rural status	1.008

Note: PPS (prospective payment system). Payment adjustment factors are for ages 18 and older. The base payment rate is also adjusted for local input prices on a facility-level basis.

Source: Centers for Medicare & Medicaid Services 2015.

Better primary care management of the risk factors for CKD—particularly hypertension and diabetes, which together are the primary cause of roughly 7 of 10 new ESRD cases—can help prevent or delay the illness's onset (United States Renal Data System 2017). For example, private payers are testing interventions in which primary care practitioners identify persons with early stages of CKD and implement interventions that are intended to prevent or slow its progression. 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 pays 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 that 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. 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 Initiative, 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 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

Significant changes to the outpatient dialysis PPS

Since its implementation in 2011, the dialysis prospective payment system (PPS) has undergone two significant changes. First, effective 2014, the base payment rate was rebased to account for the decline in dialysis drug use under the dialysis PPS. CMS set the 2014 base payment at $239.02, based on statutory and regulatory changes. 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).

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 may 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://medpac.gov/docs/default-source/reports/chapter-6-outpatient-dialysis-services-march-2016-report-.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). ■

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 then-current payment bundle (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 versus peritoneal dialysis).[6] Table 6-2 shows the PPS payment adjusters: 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) applied to the base payment rate in 2017. 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 necessity for additional treatments, which includes medical justification in the medical record. In addition, the ESRD Quality Incentive Program held facilities responsible for the quality of care they provide; in 2017, the program used eight clinical measures and three 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_17_dialysis_finald8a311adfa9c665e80adff00009edf9c.pdf?sfvrsn=0).

Since it was implemented in 2011, the outpatient dialysis PPS has undergone two significant changes—rebasing of the base payment rate in 2014 and recalibrating and redefining the payment adjusters in 2016. A text box on the dialysis PPS summarizes these changes.

Are Medicare payments adequate in 2018?

To address whether payments for 2018 are adequate to cover the costs that efficient providers incur and how much providers' costs should change in the update year (2019),

TABLE 6–3

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

	2016				Average annual percent change			
					Number of facilities		Number of stations	
	Total number of FFS treatments (in millions)	Total number of facilities	Total number of stations	Mean number of stations	2011–2015	2015–2016	2011–2015	2015–2016
All	46.4	6,745	117,200	17	3%	4%	3%	3%
	Percent of total							
Freestanding	94%	94%	95%	18	4	5	4	4
Hospital based	6	6	5	14	–6	–1	–6	–3
Urban	86	82	85	18	4	5	3	4
Micropolitan	10	11	10	16	1	2	2	2
Rural, adjacent to urban	3	5	4	13	2	2	2	2
Rural, not adjacent to urban	1	3	2	11	2	4	3	3
Frontier	0.2	0.5	0.3	10	2	0	2	0
For profit	90	88	88	17	4	5	4	4
Nonprofit	10	12	12	17	–2	–0.4	–2	–1
Two largest dialysis organizations	75	72	73	18	6	5	5	4
All others	25	28	27	17	–2	2	–2	2

Note: FFS (fee-for-service). Provider location reflects the provider'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: Compiled by MedPAC from the Dialysis Compare database from CMS and claims submitted by dialysis facilities to CMS.

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:

- Provider capacity is sufficient.
- Some quality measures show improvement, while others suggest additional potential for improvement.
- Provider access to capital is sufficient.
- The 2016 Medicare outpatient dialysis margin is estimated at 0.5 percent, and the rate of marginal profit is 17.2 percent.

Beneficiaries' access to care: Indicators continue to be favorable

Our analysis of access indicators—including the capacity of providers to meet beneficiary demand and changes in the volume of services—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 2011 and 2015, provider capacity kept up with demand for care. During that period, the number of facilities increased annually by 3 percent; facilities' capacity to provide care—as measured by dialysis treatment stations—also grew 3 percent annually (Table 6-3). Between 2011 and 2015, the number of FFS dialysis beneficiaries grew 2 percent annually (data not shown). In the same period, capacity at facilities that were freestanding and for profit each grew by 4 percent annually while capacity at facilities that were hospital based and nonprofit decreased annually (–6 percent and –2 percent, respectively). Between 2011 and 2015, capacity at urban facilities grew at 3 percent per year while capacity at rural facilities (data not shown) grew at 2 percent per year. Total dialysis capacity between 2015 and 2016 grew at rates similar to rates in 2011 to 2015.

Providers of outpatient dialysis services

In 2016, there were roughly 6,750 dialysis facilities in the United States that furnished about 46.4 million treatments to FFS beneficiaries. Medicare FFS accounted for nearly 65 percent of all treatments furnished in 2016.[7] According to CMS facility survey data, since the late 1980s, for-profit, freestanding facilities have provided the majority of dialysis treatments. In 2016, freestanding facilities furnished 94 percent of FFS treatments, and for-profit facilities furnished about 90 percent (Table 6-3). In 2016, the capacity of facilities located in urban and rural areas was generally consistent with where FFS dialysis beneficiaries lived.

Two large dialysis organizations (LDOs) dominate the dialysis industry. In 2016, these two LDOs accounted for about 72 percent of all facilities and 75 percent of all 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. Both organizations have, in recent years, acquired physician and hospital groups. 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.

Type of facilities that closed and their effect on beneficiaries' access to care

Each year, we assess the type 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 compared the characteristics of beneficiaries treated by facilities that closed in 2015 with the beneficiaries of facilities that provided dialysis in 2015 and 2016, the most current years for which complete data are available.

Between 2015 and 2016, 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 2015 (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 supply of dialysis providers (Table 6-3).

According to our analysis, few dialysis beneficiaries (roughly 2,000 individuals) were affected by facility closures in 2015. Our analysis found that beneficiary groups who were disproportionately affected included beneficiaries who were White and older. These findings are consistent with last year's analysis that compared the characteristics of beneficiaries treated by facilities that closed in 2014 with the beneficiaries of facilities that provided dialysis in 2014 and 2015 (Medicare Payment Advisory Commission 2017).

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 2015 and 2016, the annual growth of total dialysis treatments (3 percent) was greater than the annual growth of FFS dialysis beneficiaries (1 percent), and the non-annualized number of dialysis treatments per beneficiary increased from 116 treatments to 118 treatments (Table 6-4, p. 162).[8] This one-year change is consistent with the most recent five-year trend in the average annual growth of total treatments (3 percent per year) and beneficiaries (2 percent per year), and reverses

TABLE 6–4 **Annual growth in the number of FFS beneficiaries and treatments, 2011–2016**

	2011	2012	2013	2014	2015	2016
Percent annual growth in the number of beneficiaries	2%	2%	2%	2%	1%	1%
Percent annual growth in the number of total treatments	3	3	2	2	0.4	3
Number of non-annualized treatments per beneficiary	115	117	117	117	116	118

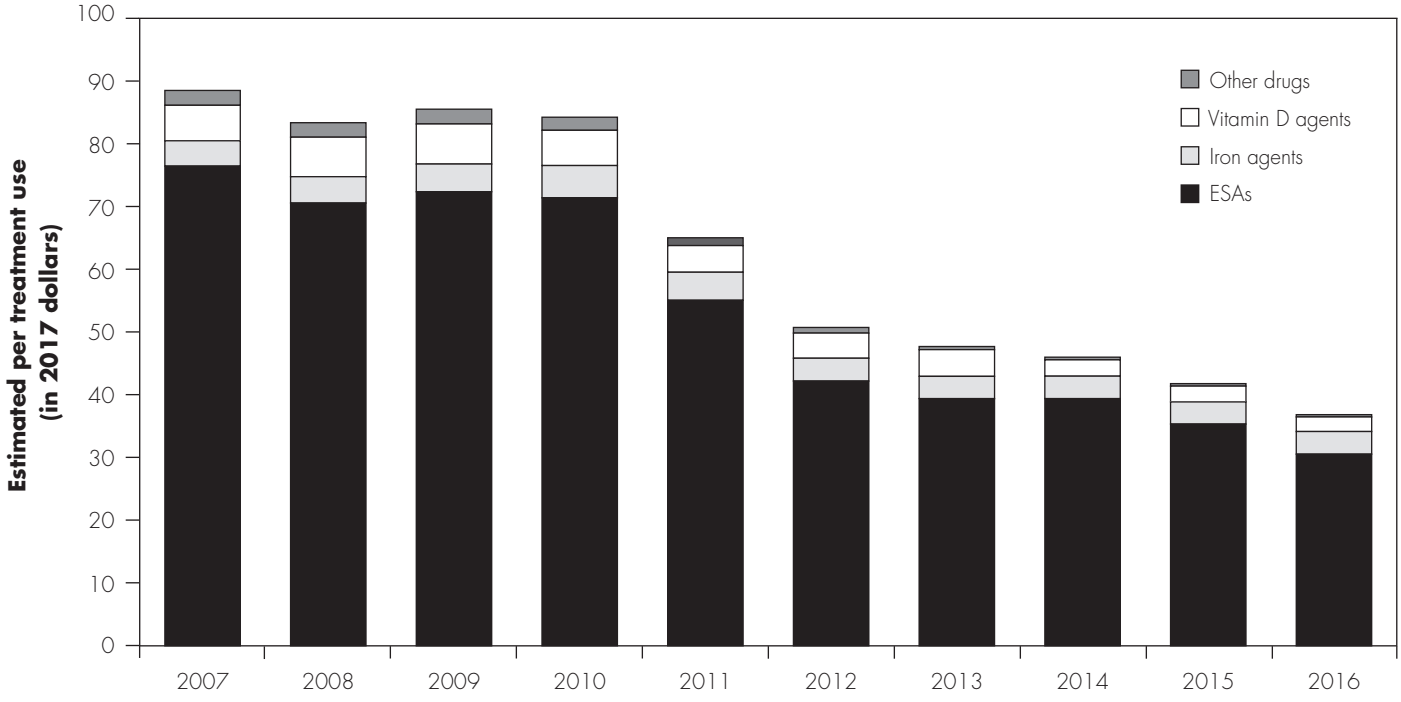
Note: FFS (fee-for-service). The growth rates reported reflect the percentage change between that year and the prior year.

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

the change between 2014 and 2015, in which treatment growth was less than the annual growth in beneficiaries.

Use of most dialysis drugs has declined under the outpatient dialysis PPS Because CMS based the bundled payment rate in the dialysis PPS on a per treatment basis and 2007 use data, we examined changes between 2007 and 2016 (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.[9] The dialysis PPS increased the incentive for providers to be more

FIGURE 6–2 **Use of dialysis drugs has declined under the PPS**



Note: PPS (prospective payment system), ESA (erythropoietin-stimulating agent). Dollars per treatment are calculated by multiplying drug units reported on claims by the 2017 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.

TABLE 6–5 **Use of dialysis drugs per treatment has declined under the outpatient dialysis PPS**

	Mean units per treatment*			Aggregate percent change	
Dialysis drug	**2010**	**2015**	**2016**	**2010–2015**	**2015–2016**
ESAs					
Epoetin alfa	5,214	2,197	1,383	–58%	–37%
Darbepoetin alfa	1.26	1.36	2.14	8	58
Epoetin beta**	N/A	1.35	3.02	N/A	124
Iron agents					
Sodium ferric gluconate	0.15	0.12	0.13	–21	9
Iron sucrose	16.0	12.8	13.0	–20	2
Ferumoxytol	0.8	0.009	0.009	–99	4
Ferric carboxymaltose	N/A	0.0003	0.0003	N/A	24
Vitamin D agents					
Paricalcitol	2.3	0.3	0.3	–86	1
Doxercalciferol	0.9	1.7	1.5	95	–12
Calcitriol	0.13	0.05	0.03	–65	–37
Antibiotics					
Daptomycin	0.22	0.13	0.11	–40	–11
Vancomycin	0.02	0.01	0.02	–38	8
Other drugs					
Levocarnitine	0.010	0.002	0.001	–80	–26
Alteplase	0.020	0.003	0.002	–87	–3

Note: PPS (prospective payment system), ESA (erythropoiesis-stimulating agent), N/A (not available). 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.

judicious in providing dialysis drugs since those are 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.

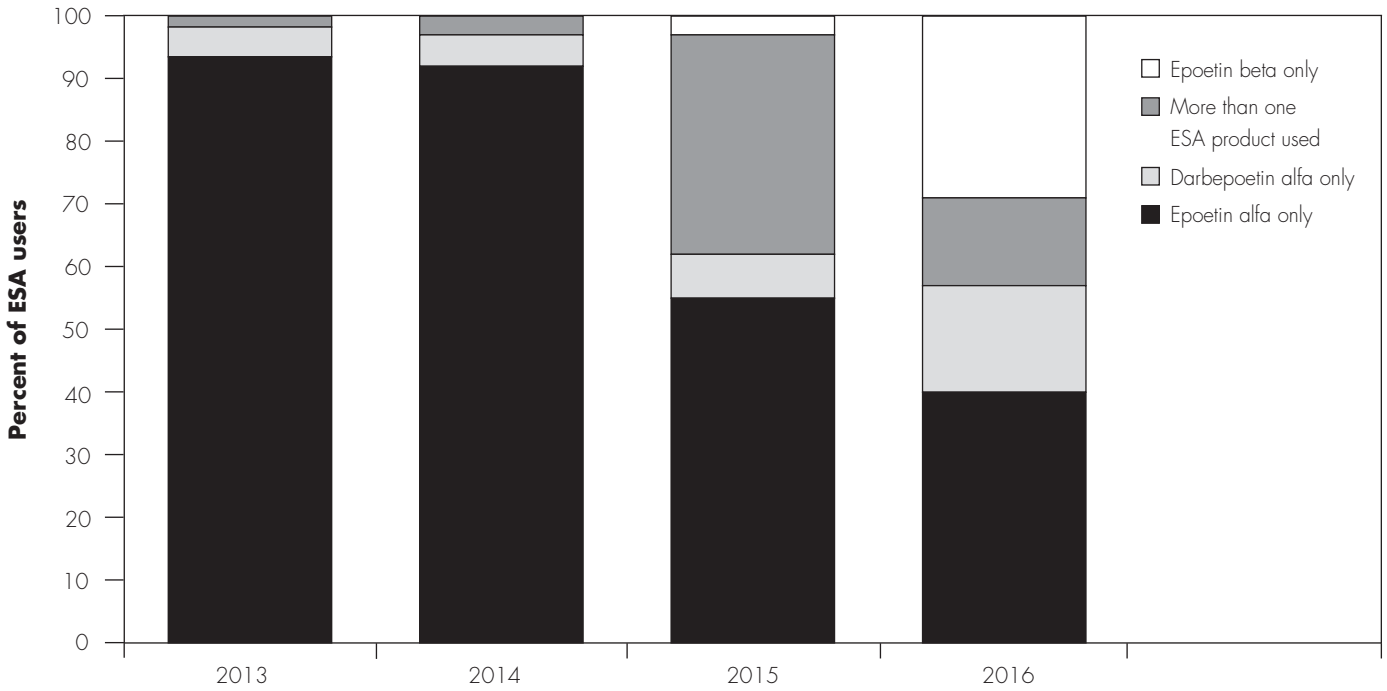
As shown in Figure 6-2, most of the decline in the per treatment use of dialysis drugs, which is estimated by multiplying drug units per treatment reported on CMS claims by each drug's 2017 average sales price (i.e., holding price constant), occurred in the early years of the PPS (implemented in 2011). For example, between 2010 and 2012, use per treatment across all therapeutic classes declined by 22 percent per year. Most of this decline was due to declining ESA use; between 2010 and 2012, the per treatment use of ESAs declined in aggregate by 23 percent per year. 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 2015 and 2016, holding price constant, the use of dialysis drugs overall declined by nearly 12 percent, which is comparable with the annual decline between 2010 and 2015 in drug use per treatment. Between 2015 and 2016, drug use declined for three of the four therapeutic classes (ESAs, vitamin D agents, and antibiotics) and increased only for iron agents (Figure 6-2). As shown in Table 6-5, per treatment drug use increased between 2015 and 2016 for:

- each of the iron agents,
- two of the ESAs—darbepoetin alfa and epoetin beta,

FIGURE 6–3

Shift in the use of ESAs among dialysis beneficiaries, 2013–2016



Note: ESA (erythropoietin-stimulating agent). Epoetin beta became available in the United States in 2015.

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

- one of the vitamin D agents—paricalcitol, and
- one of the antibiotics—vancomycin.

Some of the changes in drug use within the ESA and vitamin D therapeutic classes reflect increased competition and shifts in drug use within each class. Our analysis of ESA utilization since 2013 suggests that dialysis facilities and nephrologists have been switching 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). Several sources suggest that this LDO reduced its total ESA costs due to switching beneficiaries to epoetin beta (Reuters 2016, Seeking Alpha 2016). Our analysis of this company's cost reports submitted to CMS independently confirms these accounts, showing that its ESA cost per treatment declined between 2015 and 2016.

Our analysis of ESA utilization since 2013 shows that, among the beneficiaries who had at least one claim for an ESA in a given year, the share receiving only epoetin alfa between 2013 and 2016 declined from 94 percent to just over 40 percent (Figure 6-3). During the same period, the share receiving only darbepoetin alfa grew from 5 percent to 17 percent. Epoetin beta has also gained market share among dialysis beneficiaries since it entered the market in 2015, with nearly 30 percent of those receiving ESAs using the product by 2016. In our 2016 report to the Congress, we discussed the increased competition between the two principal vitamin D agents and the change in prescribing patterns of these two products (Medicare Payment Advisory Commission 2016b).

Notwithstanding these shifts within the ESA class between 2013 and 2016, the share of beneficiaries who received at least one ESA remained constant at about 90 percent in each year. While the share of beneficiaries prescribed ESAs has remained constant, overall use of ESAs declined by 8 percent per year during this period because of a reduction in the dose per beneficiary who received either epoetin alfa or darbepoetin alfa between 2013 and 2016.

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)—between 2011, the first year of the outpatient dialysis PPS, and 2016. Our analysis, except where indicated, is based on the Commission's analysis of Medicare FFS enrollment and claims data between 2011 and 2016, CMS's monthly monitoring data (Centers for Medicare & Medicaid Services 2017a), and data from the U.S. Renal Data System.

From 2011 to 2016, unadjusted mortality, hospitalization, and readmission rates declined while unadjusted emergency department (ED) use rose. During this period, use of home dialysis, which is associated with improved patient satisfaction and quality of life, increased. However, home dialysis growth slowed between 2014 and 2016, 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 generally declined, and blood transfusion use, which initially increased under the PPS, declined between 2013 and 2016.

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 new payment model—the Comprehensive ESRD Care (CEC) Initiative—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 quality measurement systems, the ESRD Quality Incentive Program (QIP) and the dialysis star ratings system.

Quality under the PPS

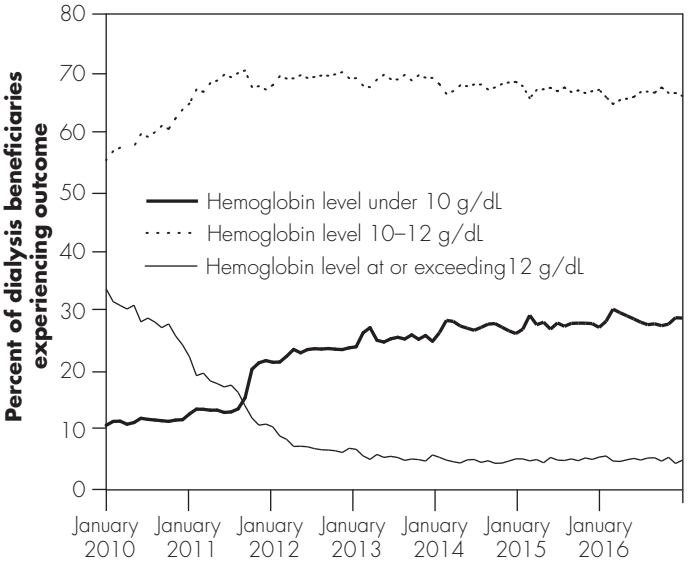
Between 2011 and 2016, through the Commission's analysis of claims data, mean all-cause hospital stays per beneficiary declined from 1.7 admissions per beneficiary to 1.5 admissions per beneficiary, respectively. This finding is consistent with the trend of declining inpatient admissions for all Medicare FFS beneficiaries during this period. In addition, between 2011 and 2015 (the most recent year data are available), U.S. Renal Data System data show that hospital admission rates also fell for ESRD-related complications and comorbidities (cardiovascular, infection, and vascular access events) (United States Renal Data System 2017).[10] Between 2011 and 2016, 30-day readmission rates also declined, from 23 percent to 21 percent, respectively, and unadjusted annual rates of mortality declined from 16 percent of dialysis beneficiaries to 15 percent. During that period, the proportion of dialysis beneficiaries who used the ED increased from an average of 10.4 percent per month to 11.8 percent 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 2011 and 2016, from 96 percent to 98 percent of hemodialysis beneficiaries and 88 percent to 93 percent of PD beneficiaries received adequate dialysis, defined as having enough waste removed from their blood. Between 2011 and 2016, 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 2017a).

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. According to the Commission's analysis, compared with 2010 (the year before the start of the dialysis PPS), median hemoglobin levels fell under the dialysis PPS to 10.5 g/dL in 2016 (from 11.4 g/dl in 2010). Figure 6-4 (p. 166) 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).[11] Compared with 2010, the proportion of beneficiaries receiving a blood transfusion increased during the initial years of the PPS to 3.4 percent per month in 2012 (from 2.7 percent per month

FIGURE 6–4

Changes in hemoglobin levels, 2011–2016



Note: Data are compiled on a monthly basis by CMS.

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

in 2010) (Centers for Medicare & Medicaid Services 2017a). However, between 2013 and 2016, the rate of blood transfusions declined from 3.1 percent to 2.3 percent of beneficiaries per month, respectively.[12] The cumulative share of beneficiaries experiencing negative cardiovascular outcomes—stroke, acute myocardial infarction, and heart failure—associated with earlier higher ESA use (before 2011) generally declined (Centers for Medicare & Medicaid Services 2017a). Two recently published studies found similar effects of the new outpatient dialysis PPS and the change in the FDA's ESA label on the outcomes of anemia management (Chertow et al. 2016, Wang et al. 2016).

As discussed in our June 2014 report, clinical process measures may 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 has stated that Medicare should transition over the next decade to a quality-measurement system that uses a small number of population-based outcome measures (Medicare Payment Advisory Commission 2014b).

According to separate analyses by CMS and the Commission, between 2011 and 2016, the share of beneficiaries dialyzing at home steadily increased from a monthly average of 8.9 percent to 10.8 percent (Centers for Medicare & Medicaid Services 2017a). 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 though they comprise about 36 percent of all dialysis beneficiaries. Other researchers have also found that, compared with White dialysis patients, African Americans and other racial/ethnic groups (including Hispanics and Asians) use home dialysis at lower rates (Mehrotra et al. 2016).

There are many factors that have been identified by researchers that affect the use of home dialysis, including clinical (patient's other health problems) and nonclinical (e.g,. physician training) factors. The text box provides a summary of the clinical and nonclinical factors. We also discuss the various Medicare policies that may affect the payment of home dialysis services.

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, may have slowed because of a shortage of solutions needed to perform this type of dialysis. Between 2014 and 2016, 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

Clinical and nonclinical factors affect 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—offers advantages and disadvantages. United States Renal Data System data for 2015 (the most current year available) show that 88 percent of dialysis patients used in-center hemodialysis, 10 percent used peritoneal dialysis, 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 United States (Burkart et al. 2017). In this text box, we explore some of the factors that affect the use of home dialysis. Whether a patient is treated with home dialysis is affected by clinical factors (e.g., patients' other health problems) and nonclinical factors (e.g., physician training). This summary is based on a review of the published literature and discussion by a panel, convened by Commission staff, 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). Medicare's policies may play a role in this determination, but the nonpayment policy factors likely carry more weight in the decision for many patients.

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. This brief summary is not a comprehensive list of the clinical and nonclinical factors that affect whether a patient uses home dialysis, but it provides some context before discussing the various Medicare policies that may 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 peritoneal dialysis 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. Patients, sometimes with the help of a caretaker, must be willing and able to conduct their own dialysis. For peritoneal dialysis, this includes maintaining the sterility of a

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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 exists for one (automated peritoneal dialysis) of the two PD types in 2017 (Baxter 2016, Food and Drug Administration 2017).[13]

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 2015, average Medicare spending for patients who had a functioning kidney transplant or received a kidney transplant was less than half the spending for dialysis patients ($36,389 vs. $93,064, respectively) (United States Renal Data System 2017). 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

Clinical and nonclinical factors affect the use of home dialysis (cont.)

catheter and conducting 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 may 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. Patients' nephrology care before dialysis may influence the dialysis treatment patients receive. Recent research has found that nephrology care before end-stage renal disease (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 peritoneal dialysis 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. Most physicians believe that peritoneal dialysis is underused in the United States (Mendelssohn 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 peritoneal dialysis patient (Rubin et al. 2004).

Dialysis facilities' staff experience. The education and experience of dialysis facilities' staff may 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 noted earlier in the chapter (see p. 166), since 2014, manufacturers have not produced enough dialysate, the solution used in peritoneal dialysis, to meet demand, which has limited recent growth in the use of peritoneal dialysis. Finally, according to Burkart and colleagues, delays to obtain the initial certification of new dialysis facilities is a barrier to developing home dialysis programs (Burkart et al. 2017).

Medicare policies that affect the payment of home dialysis services

Recently published research concluded that the dialysis prospective payment system (PPS) was associated with an overall increase in the use of home dialysis. In this section, we also discuss other Medicare policies that 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

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Clinical and nonclinical factors affect the use of home dialysis (cont.)

dialysis. When CMS established the dialysis 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. Lin and colleagues concluded that the dialysis 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.[14]

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 use 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 while an additional patient-year of peritoneal dialysis increased the margin by 0.08 percentage point. 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 2016a). 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.

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Clinical and nonclinical factors affect the use of home dialysis (cont.)

Physician payment for managing dialysis treatment. Medicare pays nephrologists a monthly amount for each beneficiary to manage dialysis treatment, which may 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 (ages 20 years or older), the monthly payment rate is set to be comparable with 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. Using 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).

Kidney disease education benefit. Medicare pays for up to six sessions of kidney disease education (KDE) per beneficiary, which is designed to inform Medicare beneficiaries with Stage IV chronic kidney disease (CKD) (the stage before ESRD) about their treatment options for managing the disease and related comorbidities. As noted later in the chapter (see p. 171), KDE has been provided to relatively few beneficiaries, about 3,500 in 2016. For context, about 83,000 fee-for-service Medicare beneficiaries were new to dialysis in 2016. Physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certain providers in rural areas can bill for providing KDE. Facilities are not allowed to bill for the service, although many provide their own educational information about treatment options.

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) peritoneal dialysis 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. The agency 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. ■

evaluation at a transplant center; and transplant center policies.

Between 2011 and 2016, according to the United Network for Organ Sharing (UNOS), the number of kidney transplants increased by 3 percent per year to 19,060 (Table 6-6) (United Network for Organ Sharing 2017). In 2016, African Americans were less likely than White patients to receive kidney transplants despite their fourfold greater likelihood of developing ESRD; however, between 2011 and 2016, the number of African Americans receiving a transplant grew by 4 percent per year (from 4,306 individuals to 5,137 individuals). According to Ephraim and colleagues, the lower rates of kidney transplantation for African Americans compared with other groups are 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 UNOS 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 earliest 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, 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 peritoneal dialysis or a preemptive kidney transplant (Fishbane et al. 2017).

In 2010, to help inform beneficiaries diagnosed with Stage IV CKD (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 both 2015 and 2016 compared with about 2,900 beneficiaries in 2013 and about 4,200 beneficiaries in 2011 and in 2012. Medicare KDE spending in both 2015 and 2016 was about $500,000.[15]

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 located in rural areas.[16] 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) but who have not started dialysis as well as individuals who have already initiated hemodialysis, might also benefit from Medicare KDE coverage.

TABLE 6–6

Between 2011 and 2016, the number of kidney transplants increased, and African Americans and Hispanics accounted for an increasing share

	2011	2016
Total transplants	16,816	19,060
Share of live donors	34%	30%
Share of:		
Whites	52	46
African Americans	26	27
Hispanics	15	18
Asians	6	6
Others	2	2

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

Source: United Network for Organ Sharing 2017.

The Comprehensive ESRD Care Initiative

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 CEC Initiative began October 1, 2015, and 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

TABLE 6–7

2016 financial results of ESCOs

	2016 financial results for the 13 ESCOs	
	Dollars (in millions)	**Percent of benchmark**
Benchmark	$1,415	100.0%
Actual spending	1,340	94.7
Savings	75	5.3
Paid to ESCOs	51	3.6
Returned to CMS	0.0	0.0
Net savings	24	1.7

Note: ESRD (end-stage renal disease), ESCO (ESRD Seamless Care Organization). Net savings result from actual spending plus the amount paid to ESCOs being below the benchmark and thus never leaving the U.S. Treasury.

Source: Centers for Medicare & Medicaid Services 2017b.

spending. The second round of the CEC Initiative began on January 1, 2017.

Under this five-year initiative, ESRD Seamless Care Organizations (ESCOs), which are accountable care organization–like models 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, which CMS designated as large because each organization operates more than 200 dialysis facilities, and 1 ESCO is operated by Rogosin Institute, which CMS designated as small because the company operates fewer than 200 dialysis facilities. For the first performance year, the CEC model has approximately 16,000 beneficiaries associated with the 13 ESCOs.

In the first round of the CEC Initiative, 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.) The initial agreement period lasts for three years; thereafter, CMS and the ESCOs have the option of extending the agreement for an additional two years based on the ESCOs' performance.

In payment year one (PY1) of the CEC Initiative, 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 2017b). The earned shared savings payments ranged from $1 million to $12 million, and totaled $51 million. Quality in PY1 (October 2015 to December 2016) 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. See Table 6-7 for a summary of financial results from 2016.

In the second round of the CEC Initiative, there are 24 new ESCOs for a total of 37 ESCOs. The second round includes three new small dialysis organizations—Northwest Kidney Centers, Atlantic Dialysis, and Centers for Dialysis Care—that are each sponsoring one ESCO. In addition, Dialysis Clinic Inc. and Fresenius, organizations that CMS considers to be large, expanded their presence in the second round. CMS awarded Fresenius an additional 18 ESCOs, giving the company a total of 24; it awarded Dialysis Clinic Inc. an additional 3 ESCOs, giving the company a total of 6. In Round 2, DaVita, an organization that CMS considers large, and the Rogosin Institute, a smaller dialysis organization, are continuing with the same number of ESCOs they sponsored in Round 1 (three ESCOs and one ESCO, respectively). For the second

payment year, CMS added an optional two-sided risk payment option (in addition to a one-sided payment track) for small dialysis organizations.

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 Initiative, dialysis beneficiaries in selected geographic areas also have access to ESRD special needs plans (SNPs). Between November 2016 and October 2017, enrollment in and the number of ESRD SNPs rose modestly. As of October 2017, about 4,600 dialysis beneficiaries were enrolled in 15 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 November 2016, about 3,500 dialysis beneficiaries were enrolled in 10 SNPs operated by 4 managed care organizations in 6 states (Arizona, California, Colorado, Nevada, North Carolina, and Texas). While the CEC Initiative and ESRD SNPs enroll only dialysis beneficiaries, other accountable care organization 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 ratings 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 ratings system, which CMS established through a subregulatory process in 2015. 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 and QIP scores diverge, which could occur because the measurement systems use different methods and measures to calculate a facility's performance score.

Providers' access to capital: Growth trends suggest 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 in 2017. For example, in 2017:

- DaVita completed its acquisition of Renal Ventures, gaining 31 dialysis facilities and divesting 7 facilities (as required by the Federal Trade Commission) (DaVita 2017b). In addition, DaVita acquired Purity Dialysis, which operates 10 facilities in Wisconsin (DaVita 2017a). The company also formalized a new business, DaVita Health Solutions, that provides care to high-risk clinically complex patients (with five or more chronic conditions) by means of home and outpatient-based care programs with the aim of improving care coordination and patient access to care. DaVita also acquired two physician practices, Park Avenue Medical Inc. and Winter Park Health Center Inc., each of which is located in Orlando, Florida. Internationally, DaVita acquired 53 dialysis facilities from a Polish dialysis provider (Zumoff 2017).
- Fresenius signed an agreement to acquire NxStage Medical Inc., a manufacturer of home dialysis equipment, for approximately $2 billion (Fresenius Medical Care 2017). The company acquired two hospital-based dialysis facilities in Texas (*Nephrology News & Issues* 2017a). Internationally, Fresenius acquired a majority stake in Cura Group, which operates 19 private day hospitals in Australia (*Nephrology News & Issues* 2017b).
- As measured by the total number of facilities, each of the three midsized chains, U.S. Renal Associates, DCI, and American Renal Associates, grew by 26 percent, 3 percent, and 10 percent, respectively, while DaVita and Fresenius each grew by 6 percent since 2016 (Neumann 2017).

Providers' access to capital can be affected by factors such as nongovernment and government investigations and legal claims. In January 2017, the U.S. Attorney's Office in Boston subpoenaed several dialysis organizations (including American Renal Associates, DaVita, and Fresenius) regarding arrangements in which their charitable donations fund dialysis treatment through a premium assistance program operated by the American Kidney Fund.[17] One organization stated that the subpoena is "…requesting information related to the company's payments and other interactions with the American Kidney Fund and any efforts to educate patients qualified

or enrolled in Medicare or Medicaid about enrollment in ACA [Affordable Care Act]-compliant individual marketplace plans…" (American Renal Associates Holdings 2017). Before the federal subpoena, CMS issued an interim final rule in December 2016 that would have implemented new requirements for dialysis facilities that make payments of premiums for individual market health plans (either directly or through a third party).[18] In January 2017, the federal court for the Eastern District of Texas issued a temporary restraining order that prevented the implementation of the interim final rule.

In addition to the federal subpoena, shareholders have filed suit against one LDO concerning the alleged practice of directing patients with government-subsidized health insurance into private plans, and a large private payer filed a lawsuit in U.S. District Court alleging that a midsized publicly traded dialysis organization switched patients from Medicare and Medicaid coverage to plans operated by the commercial payer (Mathews 2016).

In public financial filings, the two LDOs reported positive ("solid") financial performance related to their dialysis business for 2017, including strong organic volume and revenue growth—that is, growth achieved apart from mergers and acquisitions. 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 large dialysis organizations acquired midsized for-profit organizations: DaVita acquired DSI Renal and Renal Ventures, and Fresenius acquired Liberty Dialysis. In addition, both organizations acquired large physician services organizations: DaVita purchased HealthCare Partners, which was at the time an operator of medical groups and networks in several states, and Fresenius became a majority shareholder in Sound Physicians and acquired Cogent Healthcare.

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

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 2016 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 2016, Medicare spending for outpatient dialysis services increased to $11.4 billion, an increase of 2 percent compared with 2015. Per capita spending increased by 0.5 percent, from about $28,850 to about $29,000. The increase in per capita spending reflects two factors: (1) a small statutory update (of 0.15 percent) to the base dialysis payment rate in 2016 and (2) an increase (by about 2 percent) in the number of non-annualized dialysis treatments per beneficiary between 2015 and 2016.

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 2015 (the most recent year data are available), Part D spending for two categories of dialysis drugs (calcimimetics and phosphate binders) totaled nearly $2.0 billion, an increase of 23 percent per year compared with 2011. During this period, on a per treatment basis, Part D spending for dialysis drugs increased by 21 percent per year.[19] In addition, between 2011 and 2015, Part D spending for dialysis drugs grew more rapidly than spending for all other Part D drugs prescribed to dialysis beneficiaries (23 percent per year vs. 9 percent per year, respectively). In 2015, Part D spending for dialysis drugs constituted about 60 percent of dialysis beneficiaries' gross Part D spending. Medicare spending for Part D dialysis drugs is not included in the Commission's analysis of Medicare's payments and costs for dialysis facilities.

The Secretary intended that the dialysis PPS payment bundle, beginning in 2014, include Part D dialysis drugs. 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 the oral-only drug is approved by the FDA before 2025, CMS will include both the oral and non-oral versions in the PPS payment bundle (Centers for Medicare & Medicaid Services 2015).

In February 2017, the FDA approved etelcalcetide, the first calcimimetic intravenous product that is a counterpart to oral cinacalcet (paid for under Part D in 2017). Effective January 1, 2018, CMS pays for both the oral and intravenous calcimimetic under the dialysis PPS, using a transitional drug add-on payment adjustment (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 beginning January 1, 2018). According to CMS, these products qualify for a TDAPA because the base dialysis payment rate has not yet accounted for their costs. Under the TDAPA, CMS will pay providers separately for these drugs, using payment methodologies under Section 1847A of the Social Security Act, which includes average sales price and wholesale acquisition cost. Once sufficient claims data are available, CMS will conduct a rate-setting analysis and modify the dialysis PPS base rate, if appropriate, to account for the new products in the dialysis payment bundle.

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 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).[20] Between 2014 and 2015, Part D spending for cinacalcet increased by 23 percent to nearly $700 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.

In addition, including the multiple oral-only phosphate binders in the dialysis PPS bundle might increase price competition among the available products. (These products are not yet included in the dialysis PPS bundle.) According to researchers, the choice of which phosphate binder to prescribe is dependent on "physician preference, cost, reimbursement issues, tolerability, side effects, patient adherence, and other factors" (Nguyen et al. 2016). Palmer and colleagues (2016), in a recent meta-analysis of phosphate binders in patients with CKD, found no significant differences in all-cause mortality between any single agent versus placebo and concluded that "the failure of any agent to reduce mortality versus placebo suggests that a less aggressive approach to phosphate-lowering treatment may be entirely appropriate in all patients pending the availability of new evidence" (Palmer et al. 2016). Between 2014 and 2015, Part D spending for phosphate binders increased by nearly 30 percent to $1.3 billion.

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 2015 and 2016 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 2015 and 2016, the cost per treatment declined by 0.7 percent, from about $244 per treatment to $243 per treatment. During this period, the cost per treatment for ESAs and other dialysis-related drugs declined by 9 percent and 25 percent, respectively. These cost categories accounted for 11 percent and about 2 percent, respectively, of the total cost of treatment in 2016. The cost per treatment decline for ESAs and other injectable drugs somewhat offset increases in the other major cost categories:

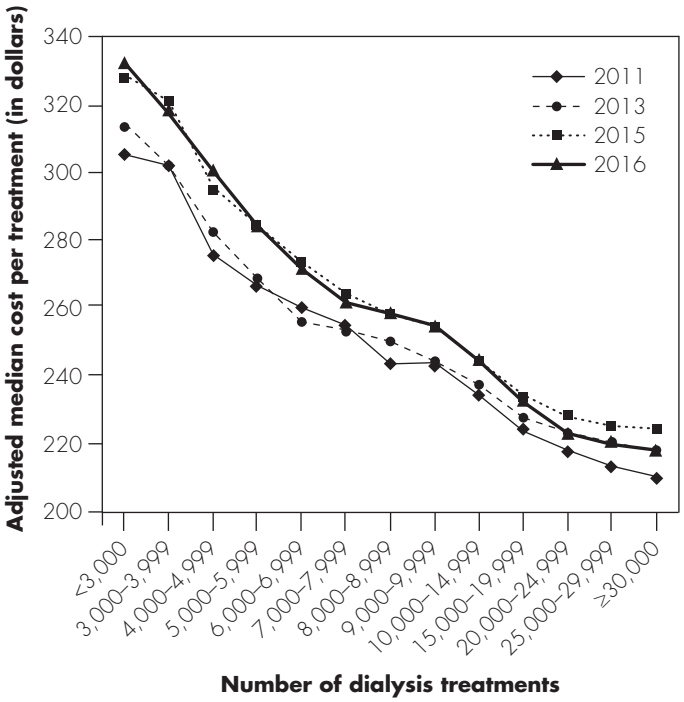
- Labor costs, which accounted for about 33 percent of the cost per treatment, increased by 4 percent.
- Administrative and general expenses and capital costs, which accounted for 25 percent and 17 percent of the cost per treatment, respectively, increased by 1 percent and 3 percent, respectively.
- Supply costs, which accounted for about 11 percent of the cost per treatment, increased by 1 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 2015 and 2016, per treatment costs decreased by 6.6 percent for facilities in the 25th percentile of cost growth and increased by 3.7 percent for facilities in the 75th percentile.

Whether the variation in costs among facilities is due to differences in the accuracy of the data that facilities report is unknown. In 2015 and 2016, 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

FIGURE 6–5

Higher volume dialysis facilities have lower cost per treatment, 2011–2016



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.

$25 among these organizations. We anticipate that CMS's audit of a representative sample of ESRD cost reports will examine the accuracy of facilities' cost reports.

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 2016, a statistically significant relationship between total treatments and cost per treatment (correlation coefficient equaled –0.5) (Figure 6-5). 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 and administrative and general services compared with all other facilities.

Medicare margin for freestanding facilities in 2016

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 2016. We estimate that the aggregate Medicare margin in 2016 was 0.5 percent (Table 6-8).[21] Margins decidedly varied by treatment volume; facilities in the lowest volume quintile had margins at or below –17.1 percent, and facilities in the top volume quintile had margins of 6.7 percent or higher.

Urban facilities had higher margins than rural facilities (1.3 percent and –4.9 percent, respectively). 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 with respect to number of treatment stations and total treatments provided. In 2016, urban facilities averaged 12,240 treatments, while rural facilities averaged 7,695 treatments (data not shown).

Another factor we consider when evaluating the adequacy of payments is whether providers have any 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. If we approximate marginal cost as total Medicare cost minus fixed building and equipment cost, then marginal profit is:

Marginal profit = (payments for Medicare services – (total Medicare costs – fixed building and equipment costs)) / Medicare payments

This formula gives a lower bound on the marginal profit because we ignore any potential labor costs that are fixed.

TABLE 6–8

Medicare margins in 2016 varied by type of freestanding dialysis facility

Provider type	Medicare margin	Percent of freestanding dialysis facilities	Percent of freestanding dialysis facility treatments
All	0.5%	100%	100%
Urban	1.3	82	88
Rural	–4.9	18	12
Treatment volume (quintile)			
Lowest	–17.1	20	7
Second	–7.9	20	12
Third	–2.6	20	17
Fourth	1.9	20	24
Highest	6.7	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.

For dialysis facilities, we find that excluding capital costs lowers the cost per treatment by nearly $40 and that Medicare payments exceed marginal costs by 17.2 percent, suggesting facilities with available capacity have an incentive to treat Medicare beneficiaries. This margin is a positive indicator of patient access.

Projecting the Medicare margin for 2018

The aggregate Medicare margin for 2018 is projected to be 0.4 percent, approximately the same as the 2016 margin (0.5 percent). This projection considers providers' historical cost growth and the following policy changes that went into effect between 2016 (the year of our most recent margin estimates) and 2018, including the following:[22]

- The Protecting Access to Medicare Act of 2014 (PAMA) sets the update to the dialysis base payment rate in 2017 and 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 1.25 percent in 2017 and 1.0 percent in 2018. The net payment update was 0.55 percent in 2017 and is 0.30 percent in 2018.
- For 2017 and 2018, payments were reduced by 0.13 percent and 0.14 percent, respectively, due to the ESRD QIP.
- Other regulatory changes implemented by CMS are expected to result in increased payments by about 0.2 percent in 2017 and 2018.
- The sequester, which is now fully reflected in Medicare's payments to providers, reduced Medicare payments to providers by 2 percent beginning April 2013.

How should Medicare payments change in 2019?

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 0.7 percent). Based on CMS's latest forecast of changes in the ESRD market basket costs for calendar year 2019 (2.1 percent), the update to the 2019 payment rate would be 1.4 percent. In addition to this statutory provision, the ESRD QIP is expected to decrease total payments by 0.15 percent in 2019.

Update 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.

RECOMMENDATION 6

For 2019, the Congress should update the calendar year 2018 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 0.5 percent in 2016 and is projected to be 0.4 percent in 2018. The 17.2 percent marginal profit is a positive indicator of beneficiary access.

IMPLICATIONS 6

Spending

- In 2019, 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 reasonably efficient providers' willingness and ability to care for Medicare beneficiaries. ■

Endnotes

1 The term *dialysis drugs* refers to the medications used to treat ESRD.

2 In this chapter, the term *beneficiaries* refers to individuals covered by Medicare, and *patients* refers to all individuals who have ESRD.

3 Incidence data are adjusted for age, sex, and primary ESRD diagnosis.

4 Age groups are 21 years and younger, 22 to 44 years, 45 to 64 years, 65 to 74 years, and 75 years and older.

5 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.

6 For pediatric dialysis beneficiaries (less than 18 years of age), the base rate is adjusted for age and type of dialysis.

7 This share is based on the Commission's analysis of Medicare and total treatments reported by freestanding facilities on cost reports submitted to CMS.

8 By *non-annualized*, we mean that treatments per beneficiary may not represent an entire year of treatment. Beneficiaries may not have an entire year of treatment data because they are new to dialysis during the year, receive a transplant during the year, and so forth.

9 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.

10 Between 2011 and 2015, adjusted hospitalization rates (per patient-year) for hemodialysis patients fell from 0.54 to 0.46 admissions for cardiovascular events, from 0.49 to 0.44 for infection events, and from 0.19 to 0.11 admissions for vascular access events. Adjusted admission rates (per patient-year) for PD patients also declined for these ESRD-related complications and comorbidities during this period (United States Renal Data System 2017).

11 According to the FDA, (1) in controlled trials, patients with chronic kidney disease experienced greater risks of death, serious adverse cardiovascular reactions, and stroke when administered ESAs to target a hemoglobin level of greater than 11 g/dL; (2) no clinical trial has identified a hemoglobin target level, ESA dose, or dosing strategy that does not increase these risks; and (3) providers should use the lowest ESA dose sufficient to reduce the need for red blood cell transfusions.

12 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.

13 To alleviate the shortage, Baxter (1) received FDA approval to import PD solutions from Ireland, (2) bought PD solutions from Fresenius to distribute to its customers (Seaborg 2015), and (3) announced additional manufacturing capacity in 2015 (Baxter 2014). In addition, Fresenius's PD manufacturing facility is on schedule to be operational in 2017, and the company announced in November 2015 its partnership with a Swiss manufacturer to develop a portfolio of peritoneal technologies (Fresenius Medical Care 2015, Zumoff 2015).

14 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).

15 This analysis used 100 percent of 2011 through 2015 carrier and outpatient claims submitted for KDE services.

16 MIPPA does not permit other providers (such as registered nurses, social workers, and dieticians) or dialysis facilities to bill for KDE services. In 2014, KDE services were most frequently provided by nephrologists, nurse practitioners, or physician assistants in an office setting.

17 The American Kidney Fund is a leading nonprofit organization that provides needs-based financial assistance to dialysis patients. The organization provides financial assistance to patients to help pay patients' treatment-related expenses, including health insurance premiums, transportation to and from treatment, medical supplies, and prescription drugs. In 2016, the American Kidney Fund provided nearly $290 million in direct patient aid.

18 In December 2016, CMS issued an interim final rule, which was to have gone into effect on January 13, 2017, that would have modified conditions for coverage for dialysis facilities that make payments of premiums for individual market health plans, directly or through a third-party organization. The interim final rule would have required dialysis facilities to inform insurers of individual market plans when they make

premium payments and to gain assurance that the health plans would accept such payment for the entire plan year. Under the rule, dialysis facilities would not have been able to make payments to plans that chose not to accept such payments. The interim final rule was promulgated without any prior opportunity for notice and comment on a proposed rule.

19 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.

20 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).

21 Based on the Commission's analysis of cost reports submitted by freestanding dialysis facilities to CMS, the all-payer margin was roughly 25 percent in 2016.

22 Because utilization data are not yet available, the projection does not reflect the impact on providers' payments and costs when Medicare, on January 1, 2018, began paying dialysis facilities for both the oral and intravenous calcimimetic under the dialysis PPS using a TDAPA. Once data become available, this factor will be considered in the Commission's assessment of payment adequacy.

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