

CHAPTER

6

Outpatient dialysis services

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

- 6** The Congress should eliminate the update to the outpatient dialysis payment rate for calendar year 2016.

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

Outpatient dialysis services

Chapter summary

Outpatient dialysis services are used to treat the majority of individuals with end-stage renal disease (ESRD). In 2013, about 376,000 beneficiaries with ESRD on dialysis were covered under fee-for-service (FFS) Medicare and received dialysis from about 6,000 dialysis facilities. For most facilities, 2013 was the third year that Medicare paid them using a new prospective payment system (PPS) that includes in the payment bundle certain dialysis drugs and ESRD-related clinical laboratory tests for which facilities and clinical laboratories previously received separate payments. In 2013, Medicare expenditures for outpatient dialysis services in the new payment bundle, including newly bundled items and services, were \$11 billion, a 3 percent increase compared with 2012.

Assessment of payment adequacy

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

Beneficiaries' access to care—Measures on 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. Growth in the number of dialysis treatment

In this chapter

- Are Medicare payments adequate in 2015?
.....
- How should Medicare payments change in 2016?
.....

stations has generally kept pace with growth in the number of dialysis beneficiaries.

- ***Volume of services***—Between 2012 and 2013, the number of FFS dialysis beneficiaries and dialysis treatments each grew by 2 percent. At the same time, the per treatment use of most dialysis injectable drugs, including erythropoiesis-stimulating agents (ESAs) that are used in anemia management, continued to decline but at a lower rate than between 2011 and 2012. The new dialysis PPS created an incentive for providers to be more judicious about their provision of dialysis drugs.

Quality of care—Using CMS data, we looked at changes in quality indicators between 2010 and 2013. Rates of emergency department use remained relatively constant, while rates of mortality and hospitalization declined. With regard to anemia management, negative cardiovascular outcomes associated with high ESA use have declined. There is increased use (from 8 percent of beneficiaries to 10 percent) of home dialysis, which is associated with improved patient satisfaction and quality of life.

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.

Medicare payments and providers' costs—Our analysis of Medicare payments and costs is based on 2012 and 2013 claims and cost report data submitted to CMS by freestanding dialysis facilities. During this period, cost per treatment increased by 1 percent, while Medicare payment per treatment increased by about 1.5 percent. Taking into account the sequester, we estimate that the aggregate Medicare margin was 4.3 percent in 2013, and the projected Medicare margin is 2.4 percent in 2015.

The evidence suggests that payments are adequate; the Commission judges that outpatient dialysis facilities can continue to provide beneficiaries with appropriate access to care with no update to the base payment rate in 2016. ■

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. Within these two types of dialysis, 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. New research also has increased interest in the use of "every-other-day" hemodialysis; reducing the two-day gap in thrice-weekly hemodialysis may be linked to improved outcomes.

PD, the most common form of home dialysis, uses the lining of the abdomen (peritoneum) as a filter to clear wastes and extra fluid and is usually performed

independently in the patient's home or workplace five to seven days a week. During treatments, a cleansing fluid (dialysate) is infused into the patient's abdomen through a catheter. This infusion process (an exchange) is done either manually (continuous ambulatory peritoneal dialysis) or using a machine (continuous cycler-assisted peritoneal dialysis).

Each dialysis method has advantages and disadvantages—no one method is best for everyone. People choose a particular dialysis method for many reasons, including quality of life, patients' awareness of different treatment methods and personal preferences, and physician training and recommendations. The use of home dialysis has grown modestly since 2009, a trend that has continued under the new PPS. 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 most 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 variation in patients' suitability for transplantation, 70 percent of ESRD patients undergo maintenance dialysis (see the text box). 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 2013, about 376,000 ESRD beneficiaries on dialysis were covered under fee-for-service (FFS) Medicare and received dialysis from about 6,000 dialysis facilities.² Since 2011, Medicare has been paying facilities using

a prospective payment system (PPS) that includes in the payment bundle dialysis drugs, for which facilities previously received separate payments, and services for which other Medicare providers (such as clinical laboratories) previously received separate payments.³ In 2013, Medicare Part B expenditures for outpatient dialysis services included in the payment bundle were \$11 billion. In addition, Part D payments for dialysis drugs—calcimimetics and phosphate binders—that will be included in the PPS payment bundle in 2025 totaled \$1 billion in 2012 (the most recent data available).

Characteristics of fee-for-service dialysis beneficiaries, 2013

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

**TABLE
6-1****FFS dialysis beneficiaries are disproportionately younger, male, and African American compared with all Medicare FFS beneficiaries, 2013**

	Percent of FFS:	
	Dialysis beneficiaries	All beneficiaries
Age		
Under 45 years	12%	4%
45–64 years	38	14
65–74 years	26	46
75–84 years	18	24
85+ years	7	12
Sex		
Male	55	46
Female	45	54
Race		
White	49	82
African American	36	10
All others	15	8
Residence, by type of county		
Urban	82	78
Rural micropolitan	11	13
Rural, adjacent to urban	5	6
Rural, not adjacent to urban	3	4
Frontier	1	1

Note: FFS (fee-for-service). Urban counties contain a cluster of 50,000 or more people, rural micropolitan counties contain a cluster of 10,000 to 50,000 people, rural adjacent counties are adjacent to urban areas and without a city of at least 10,000 people, and rural nonadjacent counties are not adjacent to an urban area and do not have a city with at least 10,000 people. 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 2013 claims submitted by dialysis facilities to CMS and the 2013 CMS denominator file.

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 2013, about 14 percent of ESRD beneficiaries were enrolled in MA plans; by comparison, about 28 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).

In 2013, a majority of FFS dialysis beneficiaries were enrolled in Part D or had other sources of creditable drug coverage: 81 percent of FFS dialysis beneficiaries were enrolled in Medicare's Part D program, and 4 percent received drug coverage through a retiree drug plan or other source of creditable coverage. In 2013, about 70 percent of FFS dialysis beneficiaries with Part D coverage received the low-income subsidy, and about 15 percent of FFS dialysis beneficiaries in 2013 had 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 2013, 76 percent of FFS dialysis beneficiaries were less than 75 years old, 55 percent were male, and 36 percent were African American. By comparison, of all FFS Medicare beneficiaries, 64 percent were less than 75 years old, 46 percent were male, and 10 percent were African American. A greater share of dialysis beneficiaries reside in urban areas compared with all FFS beneficiaries (82 percent vs. 78 percent, respectively). In 2013, FFS dialysis beneficiaries were more likely to be dually eligible for Medicaid and Medicare compared with all Medicare FFS beneficiaries (48 percent vs. 19 percent, respectively, data not shown).

Between 2002 and 2012 (most recent data available), the adjusted rate (or incidence) of new ESRD cases (which includes patients of all types of health coverage who initiate dialysis or receive a kidney transplant) decreased by 0.7 percent per year, from 378 per million people to 353 per million people (United States Renal Data System 2014). Since 2009, the adjusted rate of new ESRD cases has declined by 2 percent per year. This decline is seen across all races and ethnicities (White, African American, Asian Americans, Native American, and Hispanic) and all age groups.⁴ In 2013, we estimate that approximately 82,000 FFS dialysis beneficiaries were new to dialysis, and nearly half (46 percent) were under age 65 and thus entitled to Medicare based on ESRD (with or without disability).⁵

Better primary care management of the risk factors for kidney disease—particularly hypertension and diabetes, which together account for 7 of 10 new cases of ESRD—can help prevent or delay the illness's onset. Although risk-

factor control for hypertension and diabetes has improved for all racial and ethnic groups in Medicare, disparities remain between African Americans and other racial groups. The Commission has long argued that primary care providers are undervalued in Medicare's fee schedule and has made recommendations to support primary care.

Since 2011, CMS has paid most dialysis facilities under the new dialysis PPS

To treat ESRD, dialysis beneficiaries receive care from two principal groups of 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 this chapter 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 ESRD Comprehensive Care Initiative, which is a shared savings program involving facilities and nephrologists and is expected to begin in 2015.

To improve provider efficiency, in 2011 Medicare began a new PPS for outpatient dialysis services that expanded the payment bundle to include dialysis drugs, laboratory tests, and other ESRD items and services that were previously separately billable.⁶ In addition, beginning in 2012, outpatient dialysis payments are linked to the quality of care that dialysis facilities provide. These changes, mandated by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), were based on the Commission's recommendation to modernize the outpatient dialysis payment system (Medicare Payment Advisory Commission 2001). We contended that Medicare could provide incentives for the efficient delivery of quality care by broadening the payment bundle (to include commonly furnished drugs and services that providers formerly billed separately) and by linking payment to quality. The new PPS is designed to create incentives for facilities to provide services more efficiently by reducing incentives inherent in the former payment method to overuse drugs.

Under the outpatient dialysis PPS, the unit of payment is a single dialysis treatment, and the base payment rate is adjusted for patient-level characteristics—age, body measurement characteristics, onset of dialysis, and six acute and chronic comorbidities—and facility-level factors—low treatment volume and local input prices.⁷ Medicare pays facilities furnishing dialysis treatments in-facility or in a patient's home for up to three treatments per week, unless there is documented medical justification for more than three weekly treatments. In addition, in 2014, the ESRD Quality Incentive Program held facilities responsible for the quality of care they provide, using four 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://medpac.gov/documents/payment-basics/outpatient-dialysis-services-payment-system.pdf?sfvrsn=0>).

Effective 2014, the American Taxpayer Relief Act (ATRA) of 2012 mandated the rebasing (in effect, reducing) of the base payment rate to account for the decline in dialysis drug use under the new PPS. Based on the statutory and regulatory changes summarized in the text box (p. 144), the 2014 base prospective payment rate was \$239.02 per treatment.

Are Medicare payments adequate in 2015?

To address whether payments for 2015 are adequate to cover the costs that efficient providers incur and how much providers' costs should change in the update year (2016), we examine several indicators of payment adequacy. We assess beneficiaries' access to care by examining the treatment capacity of dialysis providers and changes over time in the volume of services provided, quality of care, providers' access to capital, and the relationship between Medicare's payments and providers' costs. Most of our payment adequacy indicators for dialysis services are positive:

- Provider capacity is sufficient.
- Volume growth as measured by the number of dialysis treatments has kept pace with growth in the number of beneficiaries.
- Some quality measures show improvement.

Rebasing the outpatient dialysis payment rate

Effective 2014, the American Taxpayer Relief Act (ATRA) of 2012 mandated that the Secretary rebase the base payment rate to reflect the reduction in the use of dialysis drugs between 2007 and 2012. CMS determined that the base payment rate should be reduced by \$29.93 (in 2014 estimated

prices) to reflect observed changes in drug utilization. The agency announced that it would phase-in the drug utilization adjustment over a three- to four-year period. The first-year (2014) drug utilization adjustment (reduction) was \$8.16 (3.3 percent) per treatment.⁸ ■

- Provider access to capital is sufficient.
- The 2013 Medicare outpatient dialysis margin is estimated at 4.3 percent, and the projected 2015 Medicare margin is 2.4 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 the number of dialysis beneficiaries suggests that between 2008 and 2013, 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 6-2). Capacity at facilities that were freestanding and for profit each grew by 4 percent annually. By contrast, capacity at facilities that were hospital based and nonprofit decreased annually (–4 percent and –2 percent, respectively). Capacity at urban facilities grew at 4 percent per year while capacity at rural facilities grew at 3 percent per year. Trends in supply between 2012 and 2013 were generally similar to those between 2008 and 2013.

Providers of outpatient dialysis services

In 2013, there were roughly 6,000 dialysis facilities in the United States. Since the late 1980s, for-profit, freestanding facilities have provided the majority of dialysis treatments (Rettig and Levinsky 1991). In 2013, freestanding facilities furnished 93 percent of FFS treatments, and for-profit facilities furnished about 89 percent (Table 6-2). In 2013, the capacity of facilities located in urban and rural

areas was generally consistent with where FFS dialysis beneficiaries lived.

Two large dialysis organizations dominate the dialysis industry, which has seen significant consolidation during the past decade.⁹ In 2013, the two largest dialysis organizations (LDOs) accounted for about 70 percent of all facilities and 75 percent of all Medicare treatments. Between 2011 and 2013, both LDOs acquired existing dialysis facilities. Smaller chains have also consolidated. For example, in August 2013, U.S. Renal Care doubled its patient population (to about 14,000) after it completed the acquisition of Ambulatory Services of America, which, in 2007 and 2011, had acquired two dialysis chains (Innovative Dialysis and Renal CarePartners, respectively).

In addition to operating most dialysis facilities, the two large organizations are each vertically integrated. One 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 company that focuses on the clinical development of new renal therapies. 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 groups. In 2012, DaVita acquired HealthCare Partners, a large operator of medical groups and physician networks; in 2014, Fresenius acquired or purchased majority stakes in multiple health care-related companies.

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

Each year, we assess what types of facilities closed and whether certain groups of Medicare dialysis beneficiaries

**TABLE
6-2****Increasing number and capacity of freestanding, for-profit, and large dialysis organizations**

	2013				Average annual percent change			
	Total number of FFS treatments (in millions)	Total number of facilities	Total number of stations	Mean number of stations	Number of facilities		Number of stations	
					2008–2013	2012–2013	2008–2013	2012–2013
All	44.0	6,000	106,500	18	3%	3%	3%	3%
Percent of total								
Freestanding	93%	92%	94%	18	4	4	4	4
Hospital based	7	8	6	14	–4	–4	–4	–5
Urban	84	79	83	19	3	4	4	3
Rural	16	21	17	15	2	2	3	3
For profit	89	86	87	18	4	4	4	4
Nonprofit	11	14	13	17	–3	–1	–2	–1
Two largest dialysis organizations	75	71	71	18	6	4	6	4
All others	25	29	29	17	–3	1	–2	1

Note: FFS (fee-for-service).

Source: Compiled by MedPAC from the 2008, 2012, and 2013 Dialysis Compare database from CMS and 2013 claims submitted by freestanding and hospital-based dialysis facilities to CMS.

are disproportionately affected by facility closures. Using facilities' claims submitted to CMS and CMS's Dialysis Compare database and Provider of Services file, we compare the characteristics of beneficiaries treated by facilities that closed in 2012 with those in facilities that provided dialysis in 2012 and 2013.

On net, between 2012 and 2013, the number of dialysis treatment stations—a measure of providers' capacity—increased by 3 percent. Compared with facilities that treated beneficiaries in both years, facilities that closed in 2012 (about 40 facilities) were more likely to be hospital based and nonprofit, which is consistent with long-term trends in supply of dialysis providers (Table 6-2).

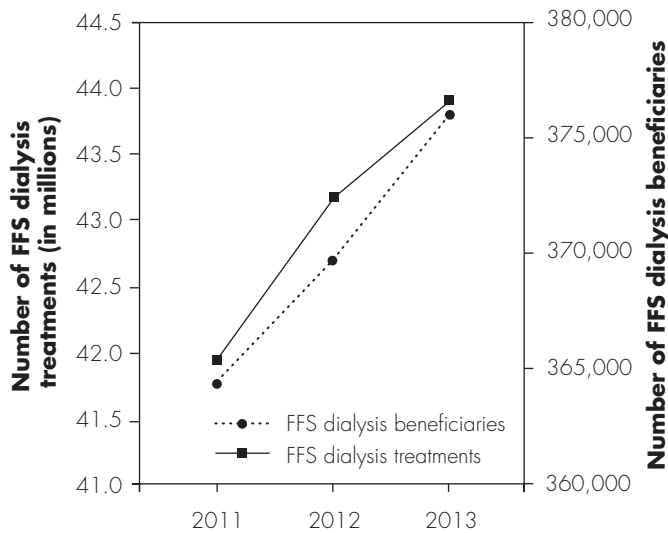
Measured by the number of dialysis treatment stations, closed facilities (which averaged 15 stations) were smaller than facilities open in 2012 and 2013 (which averaged 18 stations). Compared with the distribution of facilities in business both years, a greater proportion of facilities that

closed were in rural areas. However, between 2012 and 2013, the total number of rural facilities increased by 2 percent (Table 6-2).

About 2,600 dialysis beneficiaries were affected by facility closures in 2012. Our analysis found that racial minority groups and poorer patients (as measured by Medicaid eligibility) were not disproportionately affected by these closures. Beneficiary groups who were disproportionately affected included patients who were White and older. Our analysis of 2012 and 2013 claims data suggests that beneficiaries affected by these closures obtained care at other facilities.

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.

**FIGURE
6-1****Growth in the number of
FFS dialysis treatments and FFS
dialysis beneficiaries, 2011–2013**

Note: FFS (fee-for-service).

Source: MedPAC analysis of 2011–2013 claims submitted by dialysis facilities to CMS.

Trends in number of dialysis treatments provided

Between 2012 and 2013, total dialysis treatments grew at an average annual rate that kept pace with the average annual growth in the number of total FFS dialysis beneficiaries—about 2 percent (Figure 6-1). By contrast, between 2011 and 2013, the annual growth in total treatments slightly outpaced the annual growth in the number of FFS dialysis beneficiaries (2.4 percent per year vs. 1.7 percent per year, respectively). The greater treatment growth (compared with beneficiary growth) between 2011 and 2013 is associated with an increase in the number of dialysis treatments per beneficiary during this period (from about 115 dialysis treatments per beneficiary per year to 117 treatments per beneficiary per year, data not shown).

Use of most dialysis drugs has declined under the new outpatient dialysis PPS Because CMS based the per treatment bundled payment rate in the new PPS on 2007 use data, we examined changes between 2007 and 2013 (the most current year for which complete data are available) in the use per treatment for the leading 12 dialysis drugs and aggregated them into 4 therapeutic classes—erythropoiesis-stimulating agents (ESAs), iron agents, vitamin D agents, and antibiotics and all other

drugs.¹⁰ We also examined changes in the use of drugs between 2010, the year before the start of the new PPS, and 2013.

The new PPS increased the incentive for providers to be more judicious in providing dialysis drugs since they 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.

Between 2007 and 2013, the use of most dialysis drugs declined. During this period, use of eight drugs declined while three increased (ferumoxytol was not marketed in the United States in 2007) (Table 6-3). Per treatment dose of both ESAs declined—erythropoietin by 47 percent and darbepoetin alfa by 63 percent.

However, most of the decline in the use of dialysis drugs has occurred since 2010. For example, between 2010 and 2013, the mean per treatment units of both ESAs declined—erythropoietin by 44 percent and darbepoetin alfa by 55 percent. 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 changing the ESA label in 2011.

In addition, usage data suggest that the new PPS increased competition between the two principal vitamin D agents. Under the new PPS (between 2010 and 2013), per treatment use of paricalcitol, the more costly vitamin D drug (according to Medicare average sales price data), declined while per treatment use of doxercalciferol, the less costly vitamin D drug, increased (Table 6-3).

To measure changes in the use by drug class, we took the number of units of a drug provided and multiplied it by the 2014 Medicare price (based on the average of each products' quarterly average sales price).¹¹ On a per treatment basis, dialysis drug use was 45 percent lower in 2013 than in 2007. By drug class, on a per treatment basis between 2007 and 2013, the use of ESAs, injectable iron agents, vitamin D agents, and antibiotics and all other drugs declined by 49 percent, 12 percent, 20 percent, and 79 percent respectively (Figure 6-2, p. 148).

Quality of care: The impact of the new PPS

This year's quality analysis focuses on changes in quality indicators since CMS implemented the new payment method and, except where indicated, uses CMS's monthly

**TABLE
6-3****Use per treatment of dialysis drugs has declined under the new outpatient dialysis PPS**

Dialysis drug	Mean units per treatment*			Aggregate percent change		
	2007	2010	2013	2007-2010	2010-2013	2012-2013
ESAs						
Erythropoietin	5,532	5,214	2,917	-6%	-44%	-6%
Darbepoetin alfa	1.52	1.26	0.56	-17	-55	-15
Iron agents						
Sodium ferric gluconate	0.39	0.15	0.14	-62	-3	-16
Iron sucrose	12.3	16.0	12.6	30	-21	-1
Ferumoxylol**	N/A	0.8	0.024	N/A	-97	10
Vitamin D agents						
Paricalcitol	2.3	2.3	1.4	-2	-40	-5
Doxercalciferol	0.8	0.9	1.2	8	38	-0.2
Calcitriol	0.16	0.13	0.05	-17	-63	-18
Antibiotics						
Daptomycin	0.097	0.217	0.155	123	-29	-10
Vancomycin	0.029	0.024	0.019	-18	-22	-13
Other drugs						
Levocarnitine	0.017	0.010	0.003	-43	-68	-17
Alteplase	0.023	0.020	0.003	-12	-85	-59

Note: PPS (prospective payment system), ESA (erythropoiesis-stimulating agent), N/A (not available). Individual units per treatment are rounded; the aggregate percent change is calculated using unrounded units per treatment.

*Each drug is reported using its own drug units.

**Drug use not available because drug not marketed in the United States in 2007, 2008, and 2009.

Source: MedPAC and Acumen analysis of 2007–2013 claims submitted by dialysis facilities to CMS.

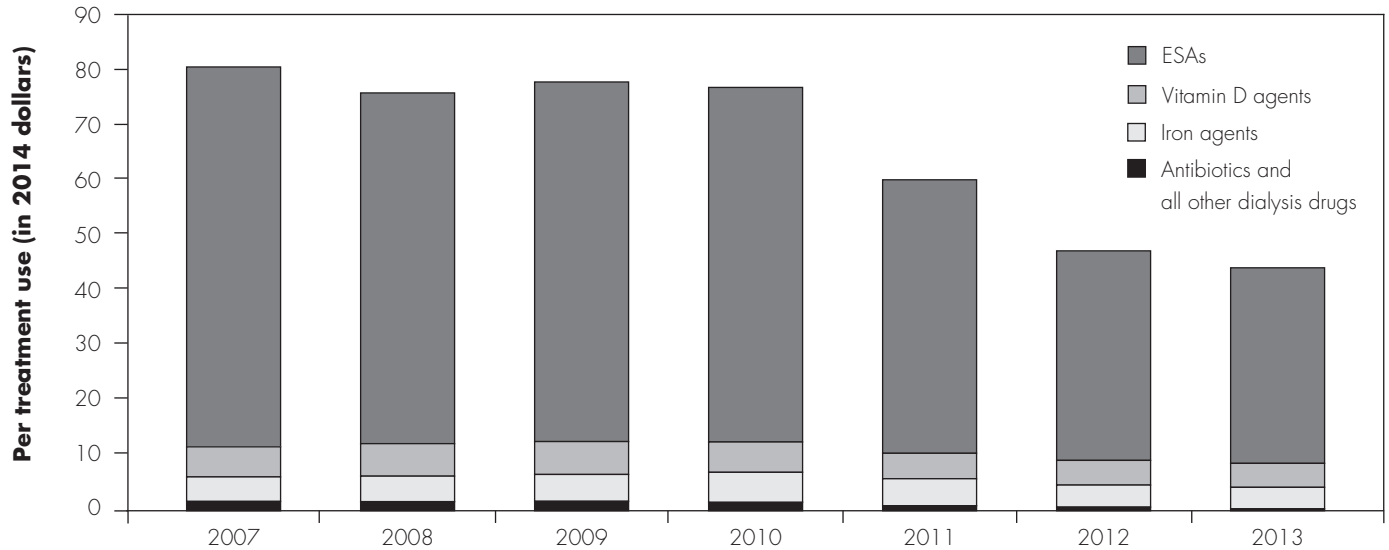
monitoring data (Centers for Medicare & Medicaid Services 2013). From 2010 to 2013, monthly mortality and hospitalization rates modestly declined; emergency department use remained relatively unchanged. Regarding anemia management, negative cardiovascular outcomes associated with high ESA use generally declined. During this period, use of home dialysis, which is associated with improved patient satisfaction and quality of life, modestly increased.

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 demand far outstrips supply. We also discuss CMS's new payment model, which is designed to improve the health outcomes of dialysis beneficiaries while lowering their total Medicare Part A and Part B per capita spending.

Quality under the new PPS

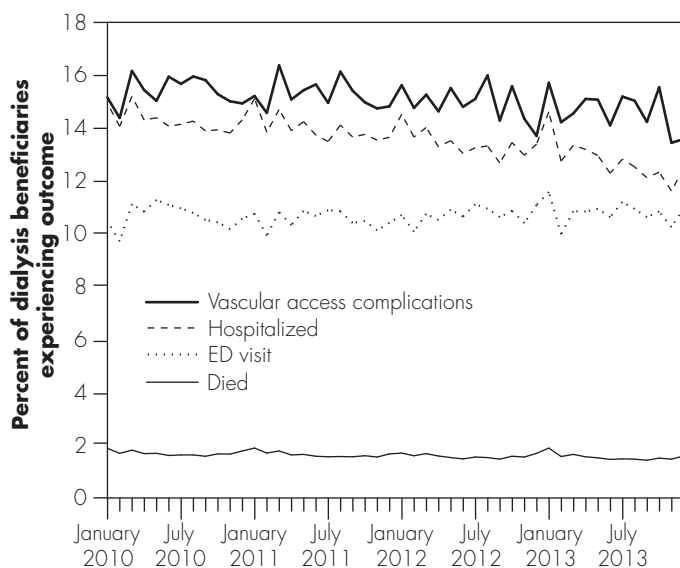
Figure 6-3 (p. 148) presents changes in key patient outcomes between 2010 and 2013; during this period, the proportion of dialysis beneficiaries who:

- died declined from an average of 1.7 percent per month to 1.5 percent per month.
- used the emergency department remained steady, averaging between 10.5 percent per month and 10.8 percent per month.
- were hospitalized declined each year from an average of 14.3 percent per month to 12.8 percent, respectively. This finding is consistent with the trend of declining inpatient admissions for all Medicare FFS beneficiaries during this period.

**FIGURE
6-2****Dialysis drug utilization, overall and by drug class, 2007–2013**

Note: ESA (erythropoiesis-stimulating agent). Per treatment use is estimated for each drug by dividing total units of that drug by total dialysis treatments and multiplying by the average of 2014 quarterly average sales prices. ESAs include erythropoietin and darbepoetin; vitamin D agents include calcitriol, doxercalciferol, and paricalcitol; iron agents include iron sucrose, sodium ferric gluconate, and ferumoxytol; antibiotics and all other drugs include daptomycin, vancomycin, levocarnitine, and alteplase.

Source: MedPAC analysis of 2007–2013 claims submitted by dialysis facilities to CMS and CMS's 2014 quarterly average sales price files.

**FIGURE
6-3****Changes in key outcomes for
dialysis beneficiaries, 2010–2013**

Note: ED (emergency department). Data are compiled on a monthly basis by CMS.

Source: CMS's end-stage renal disease prospective payment system overview of 2011–2013 claims-based monitoring program.

- experienced a vascular access complication on hemodialysis declined from an average of 15.4 percent per month to 14.7 percent per month.

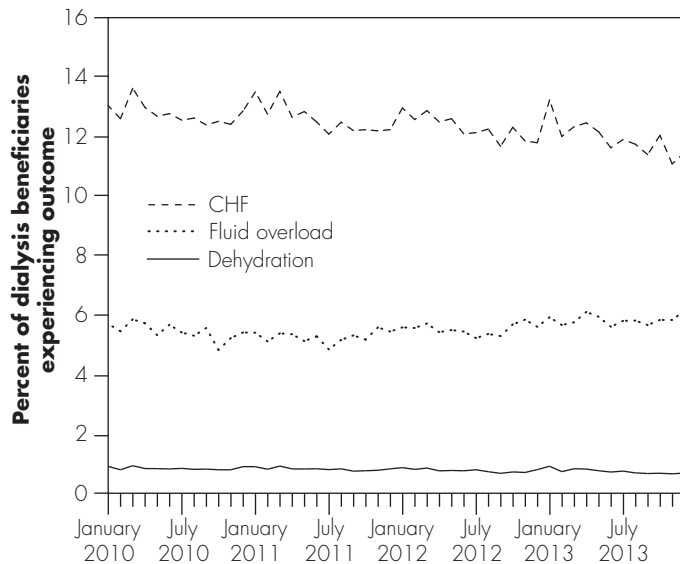
Beneficiaries' fluid management is related to factors such as the adequacy of the dialysis procedure and dietary management. Figure 6-4 shows that, between 2010 and 2013, the percentage of dialysis beneficiaries diagnosed with congestive heart failure or dehydration declined slightly while the percentage of beneficiaries diagnosed with fluid overload increased slightly.

Process and health outcome measures reflect the change in anemia management under the new PPS. From 2010 to 2013:

- Median monthly hemoglobin levels fell from 11.4 g/dL to 10.6 g/dL in 2012 and 2013.¹² Figure 6-5 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).

**FIGURE
6-4**

Changes in fluid management, 2010–2013



Note: CHF (congestive heart failure). Data are compiled on a monthly basis by CMS.

Source: CMS's end-stage renal disease prospective payment system overview of 2011–2013 claims-based monitoring program.

- The proportion of beneficiaries receiving blood transfusions increased from 2.7 percent to 3.4 percent in 2012 and then leveled off to 3.2 percent in 2013.¹³
- The cumulative share of beneficiaries experiencing negative cardiovascular outcomes—stroke, acute myocardial infarction, and heart failure—associated with higher ESA use generally declined.

As discussed in our June 2014 report, clinical process measures (such as hemoglobin levels) may exacerbate the incentives in FFS to overprovide and overuse services, including ESAs before 2011 (Medicare Payment Advisory Commission 2014). 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, may be a better indicator of anemia management in the dialysis population. The Commission believes that Medicare should transition over the next decade to a quality-measurement system that uses a small number of population-based outcome measures.

Figure 6-6 (p. 150) shows that between 2010 and 2013, the percentage of dialysis beneficiaries diagnosed with kidney stones, fracture, or peptic ulcers (outcome measures assessing bone and mineral disease management) remained at about the same level.

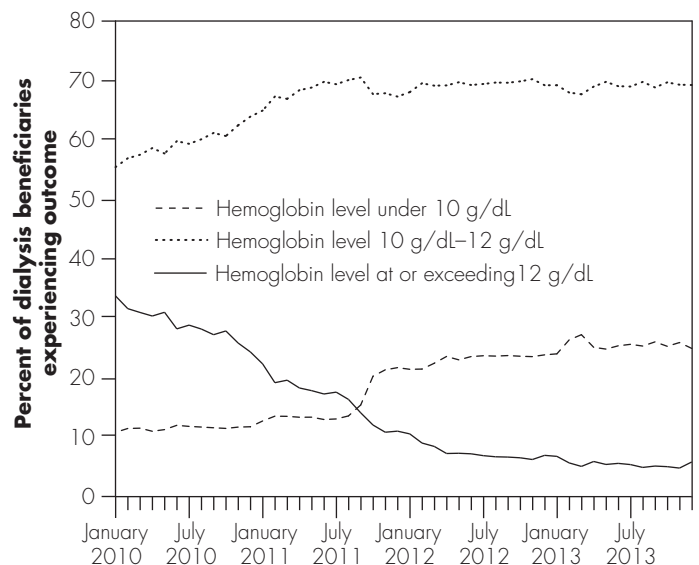
Figure 6-7 (p. 150) shows that from 2010 through 2013, the share of beneficiaries dialyzing at home steadily increased from a monthly average of 8.3 percent to 10.1 percent, respectively. While we are encouraged by this modest increase, we are concerned that differences by race continue; African Americans are consistently less likely to use home methods (data not shown).

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. However, demand for kidney transplantation exceeds supply. Factors that affect access to kidney transplantation include the clinical allocation process and donation rates; patients' health literacy, clinical characteristics, and preferences; the availability of patient educational efforts; clinician referral for transplant evaluation at a transplant center; and transplant center policies.

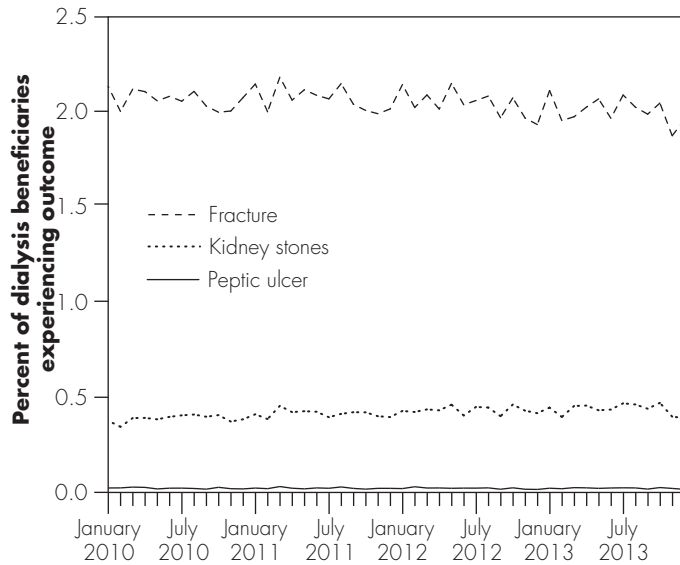
**FIGURE
6-5**

Changes in hemoglobin levels, 2010–2013



Note: Data are compiled on a monthly basis.

Source: MedPAC analysis of 2010–2013 claims submitted by dialysis facilities.

FIGURE 6-6**Changes in bone and mineral disease management outcomes, 2010–2013**

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

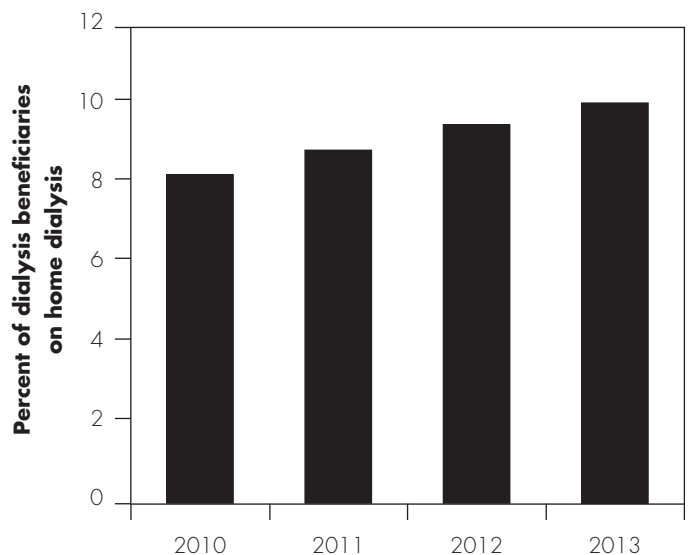
Source: CMS's end-stage renal disease prospective payment system overview of 2011–2013 claims-based monitoring program.

African Americans are less likely than Whites to receive kidney transplants despite their fourfold greater likelihood of developing ESRD. According to Ephraim and colleagues, the lower rates of kidney transplantation for African Americans 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).

In 2010, to help inform beneficiaries diagnosed with Stage IV chronic kidney disease (CKD) (the disease stage before ESRD) about managing CKD and related comorbidities and their options for care, Medicare began paying for up to six kidney disease education (KDE) sessions per beneficiary. Fewer beneficiaries were provided KDE services in 2013 than in 2011 and 2012—3,600 beneficiaries in 2013 compared with about 4,200 beneficiaries in 2011 and 2012. Medicare KDE spending in 2013 was about \$500,000.¹⁴

The ESRD Comprehensive Care Initiative

The relatively high rates of emergency department visits, hospital admissions, and hospital readmissions among beneficiaries on dialysis suggest that further improvements in quality are needed and that some dialysis beneficiaries might benefit from better care coordination. Developed under the authority of the Center for Medicare and Medicaid Innovation, the ESRD Comprehensive Care Initiative is expected to begin in 2015 and will test whether a new payment model implemented in FFS Medicare can improve the outcomes of dialysis beneficiaries as well as lower Medicare per capita spending for their care. Under this five-year initiative, ESRD Seamless Care Organizations (ESCOs), which will consist of at least one dialysis facility and one nephrologist, will be held accountable for the clinical and financial (Part A and Part B) outcomes of prospectively matched dialysis beneficiaries. ESCOs will be held to either one-sided risk-based payment (if the dialysis facility participating in the ESCO is not operated by an LDO) or two-sided risk-based payment (if the dialysis facility is affiliated with an LDO). The ESRD Comprehensive Care Initiative uses an approach similar to the Medicare Shared Savings Program to calculate the historical expenditure baseline. CMS expects to award

FIGURE 6-7**Increasing use of home dialysis, 2010–2013**

Note: Data represent yearly averages of data compiled by CMS on a monthly basis.

Source: CMS's end-stage renal disease prospective payment system overview of 2011–2013 claims-based monitoring program.

between 10 and 15 ESCOs in 2015. 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. Online Appendix 6-A, available at <http://www.medpac.gov>, has additional information about the ESRD Comprehensive Care Initiative.

While ESCOs will 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 the kidney disease risk factors discussed on p. 142.

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

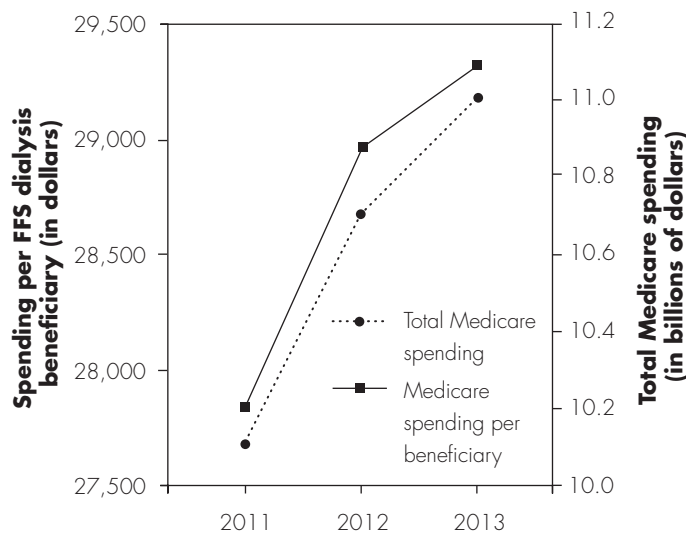
Providers need access to capital to improve their equipment and open new facilities so they can accommodate the growing number of patients requiring dialysis. The two largest dialysis organizations, as well as other renal companies, appeared to have adequate access to capital in 2014. For example, in 2014:

- Fresenius Medical Care announced it would invest up to \$140 million to open a new facility in Tennessee for manufacturing dialysis-related products.
- Fresenius Medical Care acquired or purchased majority stakes in (1) Sound Inpatient Physicians Inc., a hospitalist management organization with 1,000 physicians who provide care in over 100 hospitals and post-acute care centers; (2) MedSpring Urgent Care Centers, which operates 18 centers in Illinois and Texas; (3) National Cardiovascular Partners, which provides endovascular, vascular, and cardiovascular outpatient services and operates 21 outpatient vascular centers in 6 states in partnership with 200 physicians; and (4) Cogent Healthcare, which provides hospitalist and intensivist services by 650 providers in more than 80 hospitals.
- DaVita HealthCare Partners announced a joint venture with Colorado-based Centura Health, which operates 15 hospitals and is jointly owned by Englewood-based Catholic Health Initiatives, a not-for-profit health system, and Adventist Health System, Altamonte Springs, FL.

- Berkshire Hathaway continued its investment in DaVita by purchasing 1.13 million shares in February and an additional 944,000 shares in November. Such an investment suggests the financial attractiveness of the company and the positive economics associated with provision of dialysis services.
- Several private equity and venture capital firms provided growth financing (\$20 million dollars) for Pure Life Renal to launch and acquire dialysis centers. Pure Life Renal is a dialysis management company that furnishes in-center, home-based, and acute dialysis services.
- Dialysis Clinic Inc., the largest nonprofit dialysis chain, acquired the Rubin Dialysis Center and entered into a joint venture agreement with the Billings Clinic.
- NxStage, manufacturer of home hemodialysis equipment, will develop new products for the peritoneal dialysis market. In addition, NxStage, which operates seven dialysis care centers, opened five additional centers.
- Renal Ventures Management, which operates about 30 dialysis centers, opened its first vascular access center in Louisiana.

In public financial filings, the two largest dialysis organizations reported positive financial performance for 2013, including strong treatment (volume) growth, productivity improvements, and cost control initiatives. For example, Fresenius Medical Care announced that it expects to double its revenue between 2013 and 2020 (Zumoff 2014).

Factors unrelated to Medicare's payment policies could affect providers' access to capital. For example, circumstances can occur within a sector that can discourage outside investment because of the actions of certain providers. In 2014, DaVita Healthcare Partners Inc. paid \$350 million to the federal government to resolve claims that it violated the False Claims Act by paying physicians kickbacks to get patient referrals for its clinics and to reduce or eliminate competition from other dialysis centers. Under the settlement, DaVita entered into a Corporate Integrity Agreement with the Department of Health and Human Services Inspector General that includes the appointment of an independent monitor to prospectively review DaVita's arrangements with nephrologists and other health care providers for compliance with the Anti-Kickback Statute. Despite this

**FIGURE
6-8****Medicare FFS spending under
the new PPS, 2011–2013**

Note: FFS (fee-for-service), PPS (prospective payment system).

Source: MedPAC analysis of 2011–2013 claims submitted by dialysis facilities to CMS.

recent settlement, in 2014 assessments, investor analysts concluded that DaVita's core dialysis segment continues to perform very well, and they anticipate solid growth in the dialysis sector.

These current trends in the growth of for-profit providers and consolidation among dialysis providers suggest that the dialysis industry is an attractive business to for-profit providers and that efficiencies and economies of scale are attained in providing dialysis care.

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 2013 and examined trends in spending under the new PPS. We also reviewed evidence regarding providers' costs under the new PPS.

Medicare payments for outpatient dialysis services

Between 2012 and 2013, total Medicare spending increased by about 3 percent, from \$10.7 billion to \$11 billion, while per capita spending increased by 1 percent, from about \$28,900 to about \$29,300 (Figure 6-8). The

change in total and per capita spending reflects (1) the 2.3 percent statutory update to the payment rate in 2013, (2) the 2 percent growth in the number of beneficiaries and treatments, and (3) the 2 percent sequester reduction of Medicare's payment to providers that began in April 2013.

Part D spending for dialysis drugs

In 2012 (the most recent year data are available), Part D spending for dialysis drugs that will, on January 1, 2025, be included in the PPS payment bundle, totaled \$1 billion, an increase of 22 percent compared with 2011. Medicare spending for Part D dialysis drugs is not included in the Commission's analysis of Medicare's payments and costs for dialysis facilities. Online Appendix 6-B, available at <http://www.medpac.gov>, provides additional analysis of trends in Part D dialysis drug spending between 2007 and 2012.

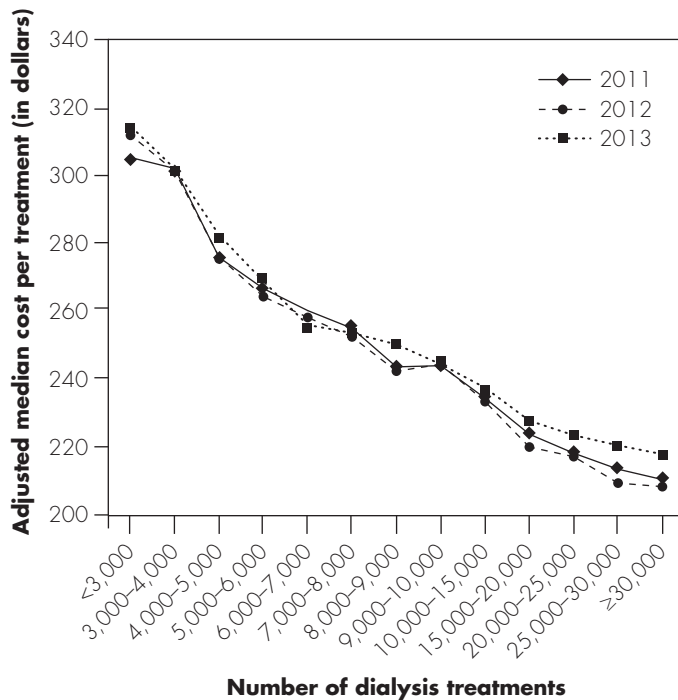
Providers' costs for outpatient dialysis services under the new PPS

To assess the appropriateness of costs for dialysis services paid for under the new 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 2012 and 2013 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 new PPS Between 2012 and 2013, the cost per treatment rose by about 1 percent, from about \$238 per treatment to \$240 per treatment. 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 2012 and 2013, per treatment costs decreased by 4 percent for facilities in the 25th percentile of cost growth and increased by 4 percent for facilities in the 75th percentile.

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 2013, a statistically significant relationship between total treatments and cost per treatment (correlation coefficient equaled -0.5) (Figure 6-9). That is, the greater the facility's service volume, the lower its costs per treatment.

**FIGURE
6-9****Higher volume dialysis
facilities had lower cost per
treatment, 2011-2013**

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 2011-2013 cost reports submitted by freestanding dialysis facilities to CMS and the end-stage renal disease wage index files.

facilities (4.9 percent and 0.6 percent, respectively); differences in total treatment volume reflect much of the differences observed between urban and rural facilities. Urban dialysis facilities are larger on average than rural facilities with respect to number of treatment stations and Medicare treatments provided. In 2013, urban facilities averaged 19 stations while rural facilities averaged 15 stations; urban facilities averaged 8,300 Medicare treatments while rural facilities averaged 5,700 Medicare treatments.

Projecting the Medicare margin for 2015

On the basis of 2013 payment and cost data, provider cost growth between 2012 and 2013, and policy changes that went into effect between 2013 (the year of our most recent margin estimates) and 2015, we project a 2.4 percent aggregate Medicare margin for dialysis facilities in 2015. The policy changes that are included in this projection include:

- statutory updates of 2.8 percent in 2014 and 0 percent in 2015;
- other policy changes that resulted in increased payments in 2014 and 2015 of 0.6 percent and 0.3 percent, respectively;

**TABLE
6-4****Medicare margin in 2013 varied by
type of freestanding dialysis facility**

Provider type	Medicare margin	Percent of freestanding dialysis facilities
All	4.3%	100%
Urban	4.9	80
Rural	0.6	20
Two largest dialysis organizations	4.1	77
All others	5.2	23
Treatment volume (quintile)		
Lowest	-12.3	20
Second	-3.8	20
Third	2.0	20
Fourth	6.0	20
Highest	9.7	20

Source: Compiled by MedPAC from 2013 cost report and outpatient claims submitted by facilities to CMS and the 2013 Dialysis Compare database.

Medicare margin for freestanding facilities in 2013

The Commission assesses current payments and costs for dialysis services for freestanding dialysis facilities by comparing Medicare's payments with providers' Medicare-allowable costs. The latest and most complete data available on payments and costs are from 2013. Our analysis includes only facilities that elected to be paid under the new PPS.

For 2013, we estimate that the aggregate Medicare margin was 4.3 percent (Table 6-4). The distribution of margins shows wide variation in performance among freestanding facilities. In 2013, one-quarter of facilities had margins at or below -6.5 percent, and one-quarter of facilities had margins of at least 12.2 percent.

Facility size accounted for the largest variation in freestanding dialysis facilities' margins; facilities with greater total treatment volume had higher margins on average. Urban facilities had higher margins than rural

- a 3.3 percent reduction in payments due to rebasing the payment rate in 2014 to account for the reduction in drug use under the new PPS;
- a reduction in payments due to the ESRD Quality Incentive Program (QIP) in 2014 and 2015 of 0.29 percent and 0.17 percent, respectively; and
- the sequester, which reduces Medicare’s program payments to providers by 2 percent.

How should Medicare payments change in 2016?

The Protecting Access to Medicare Act of 2014 sets the update to the outpatient dialysis payment rate at the market basket, less an adjustment for productivity and 1.25 percentage points. Based on CMS’s latest forecast of the ESRD market basket for calendar year 2016 (2.9 percent), the update to the 2016 payment rate would be 1.15 percent. In addition to this statutory provision, the ESRD QIP is expected to decrease total payments by 0.17 percent in 2016.

Update recommendation

The evidence on payment adequacy suggests that outpatient dialysis payments are adequate. It appears that facilities have become more efficient under the new payment method as measured by declining use of injectable dialysis drugs between 2010 and 2013.

RECOMMENDATION 6

The Congress should eliminate the update to the outpatient dialysis payment rate for calendar year 2016.

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 new payment system. The Medicare margin was 4.3 percent in 2013 and is projected to be 2.4 percent in 2015.

IMPLICATIONS 6

Spending

- In 2016, the statute sets the payment update at the market basket, net of the productivity adjustment, minus 1.25 percentage points. We expect that the Commission’s recommendation would lower federal program spending relative to the statutory update by between \$50 million and \$250 million over one year and by less than \$1 billion over five years.

Beneficiary and provider

- This recommendation may increase the financial pressure on providers but, overall, is expected to have a minimal effect on reasonably efficient providers’ willingness and ability to care for Medicare beneficiaries. We do not anticipate any negative effects on beneficiary access to care. ■

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 individuals who may or may not be covered by Medicare.
- 3 In this chapter, the term *providers* refers to freestanding and hospital-based dialysis facilities. Technically, under Medicare law, freestanding dialysis facilities are suppliers and hospital-based dialysis facilities are providers.
- 4 Age groups are 19 years or younger, 20 to 44 years, 45 to 64 years, 65 to 74 years, and 75 years or 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 those dialyzing at home.
- 6 In 2011, most dialysis facilities (about 93 percent) elected to be paid under the new PPS instead of the four-year transition rate.
- 7 Medicare pays dialysis facilities for uncollected deductibles and coinsurance (bad debt). Medicare paid 100 percent of allowable bad debt in fiscal year (FY) 2012, 88 percent in FY 2013, 76 percent in FY 2014, and will pay 65 percent in FY 2015 and beyond. Before FY 2012, Medicare capped bad debt reimbursement at a facility's unrecovered costs.
- 8 In addition to implementing the 2014 drug utilization adjustment, CMS implemented the statutory update of the base payment rate (by the market basket less the productivity offset) and other positive (regulatory) policy changes. These statutory and regulatory changes resulted in an overall impact of 0 percent compared with total payments in 2013.
- 9 According to CMS's *Provider Reimbursement Manual*, a chain organization consists of a group of two or more health care facilities or at least one health care facility and any other business or entity owned, leased, or, through any other device, controlled by one organization (Centers for Medicare & Medicaid Services 2012).
- 10 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.
- 11 Because units vary from drug to drug, we created a standard metric—the product of each drug's unit per treatment and 2014 average sales price—to measure changes in the use across all dialysis drugs.
- 12 Anemia is measured by a blood test to check the level of hemoglobin, the protein that carries oxygen in red blood cells.
- 13 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 to 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.
- 14 KDE services were most frequently provided by nephrologists, nurse practitioners, or physician assistants in an office setting. MIPPA does not permit dialysis facilities to bill for KDE services. This analysis used 100 percent of 2011 through 2013 carrier and outpatient claims submitted for KDE services.

References

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2013. *End-stage renal disease prospective payment system: Overview of 2011–2013 claims-based monitoring program*. Baltimore, MD: CMS.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2012. *Medicare provider reimbursement manual—Part 1*. Chapter 21. Baltimore, MD: CMS.

Ephraim, P. L., N. R. Powe, H. Rabb, et al. 2012. The Providing Resources to Enhance African American Patients' Readiness to Make Decisions about Kidney Disease (PREPARED) study: Protocol of a randomized controlled trial. *BMC Nephrology* 13: 135.

Medicare Payment Advisory Commission. 2014. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2001. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2000. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

Rettig, R. A., and N. G. Levinsky. 1991. *Kidney failure and the federal government*. Washington, DC: National Academy of Sciences.

United States Renal Data System, National Institute of Diabetes and Digestive and Kidney Diseases. 2014. *USRDS 2014 annual data report*. Bethesda, MD: NIDDK.

Zumoff, R. 2014. Fresenius Medical Care said it expects revenue to nearly double by 2020. *Nephrology News & Issues*, April 4.