CHAPTER 6

Outpatient dialysis services

RECOMMENDATION

6 The Congress should not increase the outpatient dialysis bundled payment rate for calendar year 2014.

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 2011, about 365,000 ESRD beneficiaries on dialysis were covered under fee-for-service (FFS) Medicare and received dialysis from about 5,600 dialysis facilities. For most facilities, 2011 is the first year that Medicare paid them using a modernized prospective payment system that includes, in the payment bundle, certain dialysis drugs and ESRD-related clinical laboratory tests that facilities and clinical laboratories previously received in separate payments. Medicare expenditures in 2011 for all outpatient dialysis services in the modernized payment bundle were $10.1 billion. Controlling for changes in the items and services included in the bundle, we estimate that payments increased about 1 percent between 2010 and 2011.

Assessment of payment adequacy

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

***Beneficiaries' access to care*—**Measures include examining the capacity and supply of providers, beneficiaries' ability to obtain care, and changes in the volume of services.

In this chapter

- ***Capacity and supply of providers*—**Dialysis facilities appear to have the capacity to meet demand. Growth in the number of dialysis treatment stations has generally kept pace with growth in the number of dialysis patients.
- ***Volume of services*—**Between 2009 and 2011, the number of FFS dialysis beneficiaries and dialysis treatments grew at similar rates (3 percent and 4 percent, respectively). Between 2009 and 2011, use of injectable dialysis drugs—including erythropoiesis-stimulating agents (ESAs)—declined. Some of this decline stems from new clinical evidence that higher doses of ESAs—the leading class of dialysis drugs—led to increased risk of morbidity and mortality; as a result, in 2011, the Food and Drug Administration recommended using more conservative doses of ESAs. In addition, some of this decline stems from providers realizing efficiencies under the modernized payment method.

***Quality of care*—**Dialysis quality has improved over time for some indicators, such as use of the recommended type of vascular access—the site on the patient's body where blood is removed and returned during dialysis. Other indicators, such as rates of hospitalization, suggest that improvements in quality are still needed.

***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 providers' costs is based on 2011 claims data submitted by freestanding dialysis facilities to CMS and 2010 cost report data from freestanding dialysis facilities (the most current data available). We estimate that the Medicare margin for outpatient dialysis services was between 2 percent and 3 percent in 2011 and project that the Medicare margin will be between 3 percent and 4 percent in 2013. This projection reflects statutory payment updates in 2012 and 2013 and regulatory changes by CMS, including the small payment reductions due to Medicare's quality incentive program in both years. ■

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. Different types of hemodialysis and PD are available.

Most dialysis patients travel to a facility to undergo hemodialysis three times per week, although hemodialysis can also be done in the patient's home. Hemodialysis uses an artificial membrane encased in a dialyzer to filter the patient's blood. Based on recent clinical findings, there has been 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 hemodialysis that patients experience when prescribed a thrice weekly regimen 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; it 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. The dialysate pulls the waste and extra fluid from the patient's blood into the peritoneal cavity, and when the dialysate is drained, the wastes and extra fluids are drained with it. This filling and draining process (an exchange) is done manually (continuous ambulatory peritoneal dialysis (CAPD)) or using a machine (continuous cycler-assisted peritoneal dialysis (CCPD)). With CAPD, patients typically undergo four exchanges during the day; with CCPD, dialysis is typically administered while patients sleep.

Each dialysis method has advantages and disadvantages; no one type of dialysis is best for everyone. People choose one type of dialysis over another for many reasons, including quality of life and personal preferences, patients' awareness of different treatment methods, and physician training and recommendation. Some patients switch from one method to another when their conditions or needs change. Although most dialysis patients undergo in-center dialysis, home dialysis should remain a viable option because it offers several advantages to those patients who are able to dialyze at home, including increased patient satisfaction and health-related quality of life. See online Appendix 6-A to this chapter (available at http://www.medpac.gov) for discussion of the use of more frequent hemodialysis and home dialysis by Medicare beneficiaries. ■

Background

End-stage renal disease (ESRD) is the last stage of chronic kidney disease and is characterized by permanent irreversible kidney failure. ESRD patients 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 (see text box). Because of the limited number of kidneys available for transplantation and variation in patients' suitability for transplantation, 70 percent of ESRD patients undergo dialysis. Patients receive additional items and services related to their dialysis treatments, including dialysis drugs to treat conditions such as anemia and bone disease resulting from the loss of kidney function.

In 2011, about 365,000 ESRD beneficiaries on dialysis were covered under fee-for-service (FFS) Medicare and received dialysis from about 5,600 dialysis facilities.[1] For most facilities, 2011 is the first year that Medicare paid them using a modernized prospective payment system (PPS) that includes, in the payment bundle, dialysis drugs for which facilities previously received separate payments and services for which other providers (such as clinical laboratories), not dialysis facilities, previously received separate payments. In 2011, Medicare expenditures for all outpatient dialysis services, including items and

TABLE 6–1

Characteristics of FFS dialysis beneficiaries and program eligibility, 2011

	Percent of all FFS dialysis beneficiaries
Age (in years)	
Under 45	12%
45–64	38
65–74	25
75–84	19
85+	7
Sex	
Male	54
Female	46
Race	
White	50
African American	36
All others	14
Residence, by type of county	
Urban	81
Rural micropolitan	11
Rural, adjacent to urban	5
Rural, not adjacent to urban	3
Frontier	1
Medicare as the secondary payer	9
Dually eligible for Medicaid	47
No supplemental insurance	8*
Prescription drug coverage status	
Enrolled in Part D	72
Coverage through employers that receive RDS	9
Coverage through other creditable sources	8
No creditable coverage	11
LIS	58

Note: FFS (fee-for-service), RDS (retiree drug subsidy), LIS (low-income subsidy). Urban areas contain a core area with a population of 50,000 or more; "rural micropolitan" areas contain at least one cluster of between 10,000 and 50,000 people; "rural, adjacent to urban" are counties that are adjacent to urban areas and do not have a city of 10,000 people in the county; and "rural, not adjacent to urban" are rural counties that are not adjacent to urban areas and do not have a city of 10,000 people. "Frontier" counties have six or fewer people per square mile. Having dual eligibility for Medicaid and having Medicare as the secondary payer are not mutually exclusive. Totals may not sum to 100 percent due to rounding. *2010 estimate.

Source: Data compiled by MedPAC from 2011 claims submitted by dialysis facilities to CMS, the 2011 CMS denominator file, and the 2010 Medicare Current Beneficiary Survey.

services that Medicare paid to other providers in prior years, were $10.1 billion.

The 1972 amendments to the Social Security Act extended Medicare benefits to people with ESRD who are eligible for Social Security benefits, including those under age 65 years. To qualify for the ESRD program, individuals must be fully or currently insured under the Social Security or Railroad Retirement program, entitled to benefits under the Social Security or Railroad Retirement program, or the spouse or dependent child of an eligible beneficiary.[2]

Most dialysis patients are enrolled in the Medicare program. According to CMS's 2011 renal facility survey, about 96 percent of all dialysis patients are covered by Medicare.[3] Most Medicare dialysis beneficiaries (about 87 percent) have FFS Medicare. In 2011, there were about 365,000 Medicare FFS dialysis beneficiaries. About 13 percent of Medicare dialysis beneficiaries were enrolled in Medicare Advantage (MA) plans (United States Renal Data System 2012). The statute prohibits enrollment of individuals with ESRD in MA plans.[4] However, beneficiaries who are enrolled in a managed care plan before ESRD diagnosis are permitted to remain in the plan after they are diagnosed. In 2000, the Commission recommended that the Congress lift the bar prohibiting ESRD beneficiaries from enrolling in MA (Medicare Payment Advisory Commission 2000).

Compared with all Medicare enrollees, FFS dialysis beneficiaries are disproportionately younger and African American. Nearly three-quarters of them are under 75 years old and 36 percent are African American (Table 6-1). About 89 percent are enrolled in Part D plans or have other sources of creditable drug coverage. In 2011, about 85,000 FFS dialysis beneficiaries were new to dialysis, and nearly half (46 percent) of them were under age 65 and thus entitled to Medicare based on ESRD (with or without disability).[5]

Between 2000 and 2010, the rate of new ESRD cases increased on average by 0.1 percent per year (Table 6-2) (United States Renal Data System 2012).[6] This growth rate masks two distinct trends. Between 2000 and 2006, with the exception of Native Americans, the rate of new ESRD cases increased across all demographic groups. By contrast, between 2006 and 2010, the rate of new ESRD cases, with the exception of young individuals (19 years or younger) and older individuals (85 years or older), declined across all demographic groups. Between 2000

TABLE 6–2 **Rate of new cases of end-stage renal disease, 2000–2010**

	Rate per million population			Average annual percent change		
	2000	2006	2010	2000–2006	2006–2010	2000–2010
All	343.7	362.0	347.8	0.9%	–1.0%	0.1%
Age (in years)						
0–19	14.2	14.4	15.5	0.2	1.8	0.9
20–44	120.1	129.3	127.6	1.2	–0.3	0.6
45–64	613.7	619.8	580.9	0.2	–1.6	–0.5
65–74	1,410.9	1,432.9	1,367.7	0.3	–1.2	–0.3
75–79	1,756.2	1,877.2	1,826.2	1.1	–0.7	0.4
80–84	1,778.9	2,011.0	1,956.9	2.1	–0.7	1.0
85+	1,203.5	1,518.3	1,535.8	3.9	0.3	2.5
Male	413.5	453.0	441.3	1.5	–0.7	0.7
Female	289.6	291.5	275.2	0.1	–1.4	–0.5
White	259.5	280.5	275.3	1.3	–0.5	0.6
African American	993.6	1,004.8	924.0	0.2	–2.1	–0.7
Native American	663.9	486.2	465.2	–5.1	–1.1	–3.5
Asian American	379.2	395.3	388.6	0.7	–0.4	0.2

Source: United States Renal Data System 2012.

and 2010, compared with all other demographic groups, the average annual rate of new ESRD cases grew fastest among older individuals (85 years or older) at 2.5 percent per year.

Data from the mid-1990s through 2010 suggest a trend toward initiating dialysis earlier in the course of chronic kidney disease (United States Renal Data System 2012). The proportion of patients with higher levels of residual kidney function steadily increased from 3.4 percent in 1996 to 16.0 percent in 2010. Researchers have questioned this early initiation of dialysis in those with late-stage chronic kidney disease, concluding that it was 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).[7]

To inform patients with chronic renal failure about their renal care options, there is increasing interest in the use of a shared decision-making process that includes patients, their families, caregivers, and physicians. Shared decision making is the process by which a health care provider communicates personalized information to patients about the risks and benefits of available treatment options, and patients communicate their values and the relative importance they place on benefits and harms. The goal of shared decision making is to improve patients' knowledge of their condition and ensure they have a realistic perception of care outcomes to enable them to make decisions with their physicians that reflect their values and preferences. Information is conveyed in part through patient decision aids that facilitate patients' discussions with their physicians by providing evidence-based objective information on all treatment options for a given condition. Such a process has the potential to help patients with chronic kidney disease understand all available ESRD care options (such as home and in-center dialysis, transplantation, and palliative care) and how each care option affects their quality of life. The American Board of Internal Medicine's "Choosing Wisely" campaign includes the use of a shared decision-making process when initiating dialysis as an opportunity for improving care (ABIM Foundation 2012). The Renal

Physicians Association has published a clinical practice guideline directed at physicians for using a shared decision-making process for initiation of and withdrawal from dialysis (Renal Physicians Association 2010).

To help pay for Part A and Part B cost sharing, most FFS dialysis beneficiaries have private or other public coverage that supplements the Medicare benefit package. According to data from the Medicare Current Beneficiary Survey and the denominator file, among FFS dialysis beneficiaries:

- About 8 percent lack any supplemental insurance.
- Forty-seven percent are dually eligible for Medicare and Medicaid.
- About half receive insurance from private or other government sources (the latter two categories are not mutually exclusive).

According to data from Medicare's denominator file, Medicare is the secondary payer (for Part A and Part B) for 9 percent of FFS dialysis beneficiaries who are insured by an employer group health plan (EGHP) at the time they are diagnosed with ESRD. If an EGHP covers a beneficiary at the time of ESRD diagnosis, it is the primary payer for the first 33 months of care (as long as the individual maintains the EGHP coverage). EGHPs include health plans that beneficiaries were enrolled in through their own employment or through a spouse's or parent's employment before becoming eligible for Medicare due to ESRD.

To treat ESRD, dialysis beneficiaries receive care from two principal providers: (1) the physicians (typically nephrologists) who prescribe and manage the provision of dialysis and establish the beneficiary's plan of care and (2) facilities that furnish dialysis treatments in a dialysis center or support and supervise the care of beneficiaries on home dialysis. Medicare uses different methods to pay for ESRD physician and facility services. Physicians and practitioners are paid a monthly capitated payment for outpatient-dialysis-related management services. The monthly payment amount varies based on the number of visits provided each month, the age of the dialysis beneficiary, and whether the beneficiary is receiving dialysis in a facility or at home.[8] Dialysis facilities, beginning in 2011, are paid under a modernized prospective payment method intended to cover all ESRD-related services on a per treatment basis. While this chapter focuses on Medicare's payments to facilities, it is important to recognize that facilities and physicians collaborate to care for dialysis beneficiaries.

In 2011, CMS paid most dialysis facilities under a modernized PPS

To improve provider efficiency, Medicare began in 2011 to phase in a modernized PPS for dialysis facilities. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) broadened the payment bundle to include dialysis drugs, laboratory tests, and other ESRD-related items and services that were previously separately billable. MIPPA also required CMS to implement a pay-for-performance program beginning in 2012. MIPPA's provisions are consistent with the Commission's recommendation to modernize the outpatient dialysis payment system (Medicare Payment Advisory Commission 2001). We contended that Medicare could provide incentives for controlling costs and promoting quality care by broadening the payment bundle and by linking payment to quality. The modernized bundled rate is designed to encourage facilities to furnish care more efficiently by reducing incentives inherent in the former payment method to overutilize drugs, tests, and other services.

Like the previous method, the new one pays facilities for a single dialysis treatment by using a prospective payment. However, the new payment method differs from the former one in the following ways: it (1) uses a broader payment bundle, (2) sets payment using a greater number of beneficiary-level payment adjusters, (3) provides an outlier payment for high-cost beneficiaries, (4) increases the base rate by a low-volume adjustment for certain low-volume facilities, and (5) links facilities' payments to the quality of care they furnish. The Commission's *Payment Basics* provides more information about Medicare's former and new methods for paying for outpatient dialysis services (available at http://medpac.gov/documents/MedPAC_Payment_Basics_12_dialysis.pdf).

Under the modernized PPS, facilities are paid a single, case-mix-adjusted payment for each dialysis treatment, which is intended to cover all ESRD-related services, including injectable drugs and clinical laboratory services that were previously separately billable. In 2013, the base prospective payment is $240.36 per treatment. For dialysis facilities that are paid under a four-year transition to the new payment method, in 2013, 75 percent of their payment is based on the new payment method and 25

percent of their payment is based on the former payment method.[9]

First-year experience under new dialysis payment method

According to data from CMS (the 2013 impact file) and the Commission's analysis of 2011 claims submitted by dialysis facilities to CMS, most dialysis facilities (about 93 percent) elected to be paid under the modernized PPS instead of the four-year transition. A greater proportion of freestanding facilities (95 percent) than hospital-based facilities (67 percent) elected to be paid under the modernized payment method. Both of the large dialysis organizations, which account for about two-thirds of all dialysis treatments furnished, elected to be paid under the modernized payment method.

We have identified three issues concerning implementation of the modernized payment method that we intend to monitor: (1) use of dialysis drugs, (2) the low-volume adjuster, and (3) outlier payments.

Use of dialysis drugs

As discussed on p. 136, the use of injectable dialysis drugs declined between 2010 and 2011. Some of this decline stems from new clinical evidence that found that higher doses of erythropoiesis-stimulating agents (ESAs)—the leading class of dialysis drugs—led to increased risk of morbidity and mortality, which led to the change in the ESA label in June 2011 by the Food and Drug Administration (FDA). In addition, some of this decline stems from providers realizing efficiencies under the modernized payment method. Under the prior payment method, providers had few incentives to control the costs of items and services for which they received separate payments (Medicare Payment Advisory Commission 2003).

Low-volume adjuster

Low-volume facilities meeting CMS's definition are paid an 18.9 percent adjustment to the base payment rate to account for the higher costs they incur.[10] CMS defined a low-volume facility based on the number of Medicare and non-Medicare treatments furnished in each of the three years before the payment year. Our analysis of 2011 claims data found that some facilities receiving the low-volume adjustment may be near other dialysis facilities. We found that of the roughly 330 facilities that received the low-volume payment adjustment in 2011, about 25 percent were within 1.7 miles of the next facility and 42 percent were within 5 miles of another facility. Medicare and dialysis beneficiaries might be better served by an adjuster that targets low-volume facilities that are not in close proximity to another facility. Only low-volume facilities that are necessary to maintain access—those located in isolated areas—should receive enhanced payment.

Outlier payments

Under the modernized payment method, a facility is eligible for outlier payments for services that were previously separately billable, including dialysis drugs. To implement the outlier adjustment in a budget-neutral fashion, CMS reduced the base payment rate by 1 percent to account for the proportion of estimated total payments expected to be made as outlier payments (Centers for Medicare & Medicaid Services 2010). However, according to CMS: (1) in 2011, about 0.3 percent of the 1 percent outlier pool was paid out to facilities; and (2) the 1 percent outlier pool was not achieved in 2011 because of the decline in utilization of outlier services associated with implementation of the modernized payment method (Centers for Medicare & Medicaid Services 2012b).[11] To address this issue, for payment year 2013, the agency updated the factors used to calculate outlier payments to reflect more current (2011) utilization data.

Are Medicare payments adequate in 2013?

To address whether payments for 2013 are adequate to cover the costs that efficient providers incur and how much providers' costs will change in the update year (2014), we examine several indicators of payment adequacy. We assess beneficiaries' access by examining the capacity of dialysis providers and changes over time in the volume of services furnished, 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 dialysis beneficiaries.
- Some improvements in quality have occurred.

TABLE 6–3 **Increasing number and capacity of freestanding, for-profit, and chain organizations**

	2011				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	2006–2011	2010–2011	2006–2011	2010–2011
All	42.0	5,560	98,603	18	4%	3%	4%	3%
	Percent of total							
Freestanding	92%	90%	92%	18	5	3	5	4
Hospital based	8	10	8	14	–2	–3	–2	–4
Residence, by type of county								
Urban	84	78	82	19	4	3	4	3
Rural micropolitan	11	14	12	16	3	1	4	3
Rural, adjacent to urban	3	5	4	13	4	3	5	3
Rural, not adjacent to urban	2	3	2	12	4	2	4	3
Frontier	0.3	0.6	0.3	10	1	3	3	9
For profit	85	84	85	18	5	4	5	4
Nonprofit	15	16	15	16	–1	–3	0.1	–2
Affiliated with any chain	87	82	85	18	5	4	5	4
Affiliated with 1 of 2 largest chains	66	62	64	18	4	5	4	5
Not affiliated with any chain	13	18	15	16	–1	–2	–1	–1

Note: FFS (fee-for-service). "Urban" areas contain a core area with a population of 50,000 or more; "rural micropolitan" areas contain at least one cluster of between 10,000 and 50,000 people; "rural, adjacent to urban" are counties that are adjacent to urban areas and do not have a city of 10,000 people in the county; and "rural, not adjacent to urban" are rural counties that are not adjacent to urban areas and do not have a city of 10,000 people. "Frontier" counties have six or fewer people per square mile.

Source: Compiled by MedPAC from the 2006, 2010, and 2011 Dialysis Compare database from CMS and 2011 claims submitted by freestanding and hospital-based dialysis facilities to CMS.

- Provider access to capital is sufficient.
- The 2011 Medicare margin is estimated at 2 percent to 3 percent, and the 2013 Medicare margin is projected at 3 percent to 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.

Supply has kept pace with patient demand

From 2006 to 2011, the number of facilities and their capacity to furnish care, as measured by dialysis treatment stations, each increased by 4 percent annually (Table 6-3). During this period, the capacity of facilities that were freestanding, for profit, and affiliated with a chain organization grew by 5 percent per year. By contrast, annual growth in the capacity of facilities that are hospital based, nonprofit, and not affiliated with a chain decreased or remained about the same (–2 percent, 0.1 percent, and –1 percent, respectively). Between 2006 and 2011, the capacities of urban and rural facilities grew at similar rates. Trends in supply between 2010 and 2011 are generally similar to those between 2006 and 2011.

Growth in the number of dialysis stations and dialysis patients suggests that provider capacity kept up with demand for care between 2006 and 2011. During this period, the number of all dialysis patients (those in FFS

Medicare, in MA, and not eligible for Medicare) and dialysis treatment stations increased by 4 percent per year. Annual growth in the number of treatment stations was faster than the 2 percent average annual growth in the number of FFS dialysis beneficiaries between 2006 and 2011.

Providers of outpatient dialysis services

In 2011, there were nearly 5,600 dialysis facilities in the United States (Table 6-3). Since the late 1980s, for-profit, freestanding facilities have provided the majority of dialysis treatments (Rettig and Levinsky 1991). In 2011, freestanding facilities furnished 92 percent of FFS treatments and for-profit facilities furnished about 85 percent. The share of facilities that are for profit and freestanding increased from 66 percent of all facilities in 1996 to nearly 85 percent in 2011. In 2011, the distribution of facilities located in urban and rural areas is generally consistent with where FFS dialysis beneficiaries live.

Chain organizations dominate this sector, which has seen significant industry consolidation. In 2005 and 2006, the four largest dialysis chains merged into two chains (referred to as the two largest dialysis organizations). Before the mergers (in 2004), the largest two organizations accounted for 37 percent of all facilities; after the mergers (in 2007), the largest two accounted for nearly 60 percent of all facilities.

In addition to operating most dialysis facilities in 2011, the two largest dialysis organizations are vertically integrated. One is the leading supplier of dialysis products, such as hemodialysis machines and dialyzers, and develops and distributes renal-related pharmaceutical products (e.g., phosphate binders) (Fresenius Medical Care AG & Co. KGaA 2006). Both organizations operate an ESRD-related laboratory, a pharmacy, and one or more centers that furnish vascular access services; provide ESRD-related disease management services; and operate dialysis facilities internationally.

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 specific groups of Medicare dialysis beneficiaries are disproportionately affected by facility closures. Using claims submitted by facilities to CMS and CMS's Dialysis Compare database and the ESRD facility survey, the analysis compares the characteristics of beneficiaries treated by facilities that closed in 2010 with those in facilities that furnished dialysis in 2010 and 2011.

On net, between 2010 and 2011, 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 2010 (nearly 90 units) were more likely to be hospital based and nonprofit, which is consistent with long-term trends in supply (as shown in Table 6-3). Closed facilities were smaller, as measured by the number of dialysis treatment stations, than facilities in business in 2010 and 2011 (12 stations vs. 18 stations). Closures did not disproportionately affect rural areas; 21 percent of closed facilities were located in rural areas while 22 percent of facilities in business both years were located in rural areas.

Our analysis of dialysis beneficiaries' demographic characteristics found that a greater proportion of African American FFS dialysis beneficiaries were treated at facilities that closed in 2010 than at facilities that remained open both years (43 percent compared with 38 percent). However, fewer than 1 percent of African Americans (about 1,700 beneficiaries) were affected by closures. Closed facilities and facilities in business both years had similar shares of the elderly and beneficiaries dually eligible for Medicare and Medicaid. There is no evidence that beneficiaries have been unable to obtain care at other facilities. For example, African Americans continued to obtain care from the two largest dialysis chains. In both 2010 and 2011, about 40 percent of beneficiaries served by these two providers were African American.

Volume of services

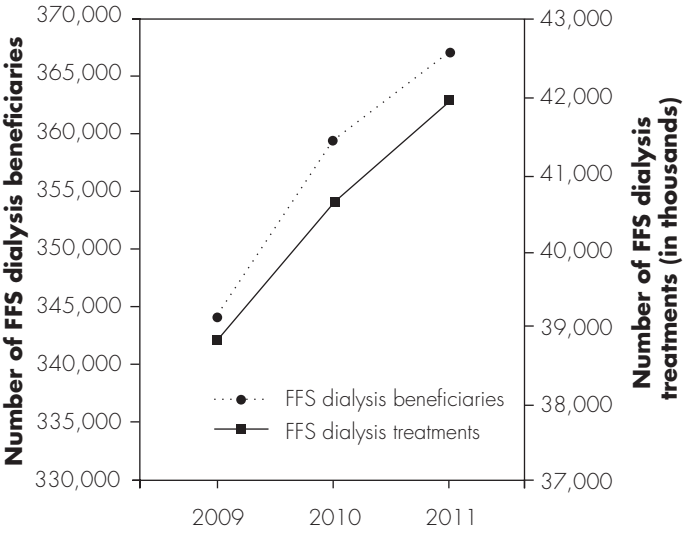
To assess changes in the volume of dialysis services, we examined recent trends in the number of dialysis treatments furnished to beneficiaries and in the use of injectable drugs administered during dialysis.

Trends in number of dialysis treatments furnished

Between 2009 and 2011, dialysis treatments grew at an average annual rate that kept pace with growth in the number of FFS dialysis beneficiaries (Figure 6-1, p. 136). During this period, the number of dialysis treatments grew at an average rate of 4 percent per year, while the number of dialysis beneficiaries grew at an average rate of 3 percent per year.

FIGURE 6–1

Growth in the number of FFS dialysis beneficiaries matches growth in the number of FFS dialysis treatments, 2009–2011



Note: FFS (fee-for-service).

Source: MedPAC analysis of 2009–2011 claims submitted by dialysis facilities to CMS.

Trends in use of injectable dialysis drugs Figure 6-2, which examines changes in the use of erythropoietin (the leading dialysis drug in terms of spending under the prior payment method) shows that the mean weekly dose per week per beneficiary remained fairly steady in 2009. In 2010, per beneficiary use of erythropoietin began to decline. We reported last year that between 2009 and 2010, the mean weekly erythropoietin dose furnished per beneficiary declined by 1.4 percent (Medicare Payment Advisory Commission 2012).

Between 2010 and 2011, the mean weekly erythropoietin dose declined by 15 percent (Figure 6-2). Some of this decline stems from new clinical evidence showing that higher doses of erythropoietin were associated with increased morbidity and mortality. On the basis of this new clinical evidence, in 2007 the FDA included a "black box warning" on ESA drug labels and in 2011 changed the drug's labeling information to reflect more conservative dosing guidelines. (Food and Drug Administration 2011).[12] In addition, some providers realized efficiencies under the new payment method.

Because CMS set the 2011 payment rate on a per treatment basis and based the rate on 2007 utilization data, we examined changes in the utilization per treatment with erythropoietin and the three leading dialysis drug therapeutic classes.[13] Regarding changes in erythropoietin use, we found that the average units per treatment declined from about 5,700 units in 2007 to 5,200 in 2010 and further to about 4,000 units in 2011. All told, units per treatment declined by nearly 30 percent between 2007 and 2011.

To measure utilization for each drug class, we multiplied the number of units of a drug furnished by the average price that Medicare paid for these drugs in 2011. On a per treatment basis, utilization of ESAs and injectable iron and vitamin D agents was 25 percent lower in 2011 than in 2007. Most of the decline in the use of these three drug classes occurred between 2010 and 2011 rather than between 2007 and 2010. We found that the use of these three drug classes declined by 6 percent per treatment between 2007 and 2010 and by 20 percent per treatment between 2010 and 2011. In each year, most of the decline was driven by the decline in ESA use per treatment.

Use, by drug class, on a per treatment basis changed as follows:

- Between 2007 and 2010, injectable iron and vitamin D agents increased by 9 percent and 1 percent per treatment, respectively, while ESAs decreased by 9 percent per treatment.
- Between 2010 and 2011, use of all three drug classes declined: injectable iron by 7 percent, vitamin D agents by 14 percent, and ESAs by 23 percent per treatment.
- Between 2007 and 2011, use of injectable iron agents increased by 1 percent per treatment, while use of vitamin D agents and ESAs declined by 13 percent and 30 percent, respectively. The modest increase in use of injectable iron stems from increased use in late 2010 and then decreased use in the last two quarters of 2011. Compared with the final quarter of 2007, utilization declined for all three drug classes in the final quarter of 2011 overall by 32 percent, for injectable iron by 12 percent, for vitamin D agents by 15 percent, and for ESAs by 37 percent.

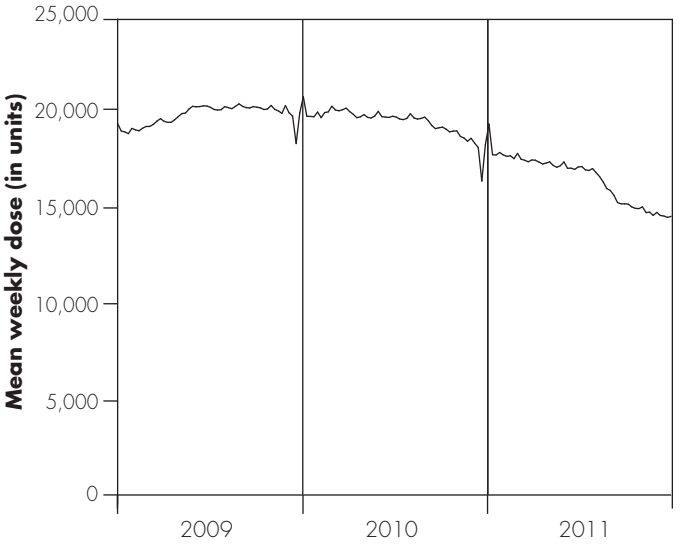
Other researchers have also found declining use of dialysis drugs since implementation of the modernized payment method. The Government Accountability Office (GAO)

measured utilization in dollars by multiplying the number of units per beneficiary of a drug administered in a given quarter by the price Medicare paid for these drugs in the first quarter of 2011. GAO found that in 2011, utilization of ESAs, injectable vitamin D drugs, and injectable iron drugs was 23 percent lower per beneficiary, on average, than it was in 2007 and that this decline was driven largely by a decline in ESA utilization (Government Accountability Office 2012). GAO also reported that from the third quarter of 2010 through the end of 2011, ESA utilization per beneficiary declined by about 30 percent.

The United States Renal Data System (USRDS) also found declining use of dialysis drugs. Among facilities opting into the new payment method, USRDS found a 16 percent decline in the weekly ESA dose per beneficiary between the third quarter of 2010 and the second quarter of 2011. USRDS also found that between the third quarter of 2010 and the second quarter of 2011, among facilities opting into the modernized payment method, mean weekly intravenous iron dose per beneficiary fell by 4 percent and mean weekly intravenous vitamin D dose per beneficiary fell by 12 percent (United States Renal Data System 2012).

FIGURE 6–2

Mean erythropoietin dose per dialysis beneficiary per week, 2009–2011



Source: MedPAC analysis of claims submitted by freestanding facilities to CMS, 2009–2011.

Quality of care: Some measures show progress, others need improvement

The Commission uses clinical performance and patient outcome measures to assess quality of care furnished to dialysis patients. This year, we also looked at changes in key quality indicators since CMS implemented the modernized payment method. This analysis uses data from CMS, USRDS, and ESRD networks (CMS's contractors that conduct quality improvement activities and other functions).[14]

We found the following trends in quality during the most recent five-year period for which data are available:

- The proportion of patients receiving adequate dialysis remains high, and improvements have been made in use of the recommended type of vascular access for hemodialysis patients, anemia management, and management of patients' nutritional status.
- Rates of mortality, although high, have declined; hospitalization rates remain high and relatively unchanged; the proportion of dialysis patients accepted on the kidney transplant waiting list has modestly increased, but the rate of kidney transplantation among dialysis patients has declined.

Changes in the quality of care between 2010 and 2011, the first year of the modernized payment method, include the following:

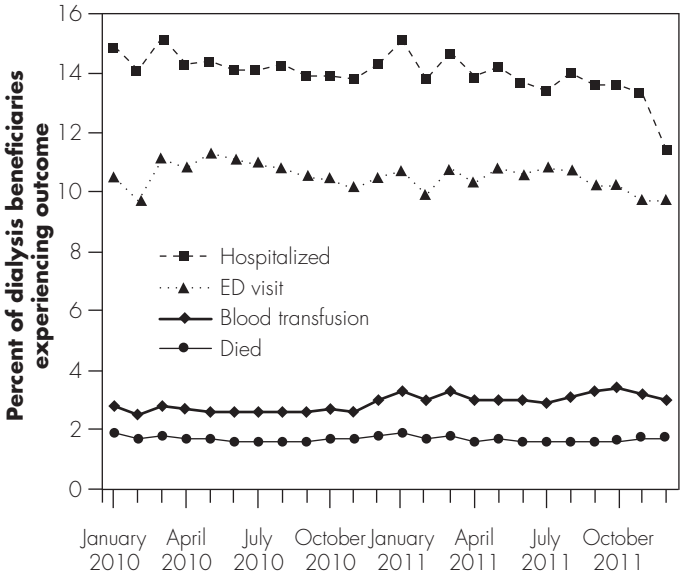
- Compared with 2010, monthly rates of beneficiaries who died, were hospitalized, or went to the emergency department in 2011 remained relatively steady.
- With regard to anemia, there was a small increase in the number of dialysis beneficiaries receiving blood transfusions and a large increase in the number of beneficiaries with lower hemoglobin values. This finding is not surprising given the decline in use of ESAs between 2010 and 2011.

Five-year trends in dialysis quality

The conclusions of this year's assessment of changes in quality are consistent with those in last year's report. Between 2007 and 2011, the proportion of patients receiving adequate dialysis (a measure of the effectiveness of the dialysis treatment in removing waste products from the body) remained high (Table 6-4, p. 139). According to this measure, 97 percent of hemodialysis patients and 91 percent of peritoneal dialysis patients received adequate dialysis. Also during this period, increasing proportions of

FIGURE 6–3

Changes in key outcomes for dialysis beneficiaries, 2010–2011



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

Source: Centers for Medicare & Medicaid Services 2012a.

dialysis patients had their anemia under control (i.e., had a mean hemoglobin between 10 grams per deciliter of blood (g/dL) and 12 g/dL). For hemodialysis patients, use of the recommended type of vascular access—the site on the patient's body where blood is removed and returned during dialysis—improved during the period. For most patients, an arteriovenous (AV) fistula is considered the best long-term vascular access for hemodialysis because it provides adequate blood flow, lasts a long time, and has a lower complication rate than other types of access (AV grafts and catheters) (National Institute of Diabetes and Digestive and Kidney Diseases 2008).[15] The goal of Fistula First—CMS's quality improvement initiative that promotes use of AV fistulas—is for 66 percent of all hemodialysis patients to have an AV fistula.

Between 2007 and 2011, there was a small increase in the proportion of patients achieving the mean serum albumin level (a marker used to identify nutritional concerns) that equals or exceeds the recommendation of the National Kidney Foundation.[16] Recently, some providers have begun to furnish oral nutritional supplements to dialysis beneficiaries. In July 2009, the Office of Inspector General of the Department of Health and Human Services, in an advisory opinion, said it would not subject such an arrangement to civil monetary penalties or administrative sanctions. Clinical indicators related to the management of bone and mineral disorders, a frequent comorbidity of kidney failure, have remained steady during this period.

In general, the five-year trends in rates of mortality, hospitalization, and access to kidney transplantation suggest that improvements in dialysis quality are still needed. Between 2006 and 2010, although overall adjusted mortality rates decreased across all race and age groups, rates remained high. Overall rates of hospitalization remained steady at about two admissions per dialysis patient per year. There was a modest decline in the 30-day rates of rehospitalization for dialysis patients overall and for cardiovascular, infection, and vascular access index admissions. We looked at several measures that examine access to kidney transplantation because it is widely considered the best treatment option for ESRD patients (Eggers 1988, Kasiske et al. 2000, Laupacis et al. 1996, Ojo et al. 1994). Between 2006 and 2010, the proportion of dialysis patients accepted on the kidney transplant waiting list modestly increased from 16.3 percent to 17.5 percent (Table 6-4). During the same period, overall rates of kidney transplantation decreased from 4.8 per 100 dialysis patient years to 3.9 per 100 dialysis patient years. Rates declined for all race groups. Online Appendix 6-B to this chapter (available at http://www. medpac.gov) summarizes issues related to the distribution of kidney transplantation across the ESRD population.

Effect of new payment method on dialysis quality

Data from CMS suggest that the modernized method, while affecting anemia management, has not substantially affected rates of mortality, inpatient admission, and emergency department use.

Compared with 2010, the proportion of dialysis beneficiaries in 2011 who died, were hospitalized, or used the emergency department either remained the same or modestly declined (Figure 6-3) (Centers for Medicare & Medicaid Services 2012a). Regarding indicators of anemia management, there was a small increase in the proportion of dialysis beneficiaries receiving blood transfusions, a large increase in those with lower hemoglobin values, and a large decrease in those with higher hemoglobin values. As shown in Figure 6-3, the proportion of beneficiaries (in a given month) receiving a blood transfusion ranged from 2.5 percent to 3.0 percent in 2010 and from 2.9 percent to 3.4 percent in 2011. As shown in Table 6-4, between 2010

TABLE 6–4 **Dialysis clinical indicators and outcomes continue to improve for some measures**

Outcome measure	2007	2008	2009	2010	2011
Percent of in-center adult hemodialysis patients:					
Receiving adequate dialysis (Kt/V ≥ 12)	94%	95%	95%	95%	97%
Anemia measures:					
Mean hemoglobin 10–12 g/dL	49	57	62	68	74
Mean hemoglobin ≥ 12 g/dL*	45	37	32	25	12
Mean hemoglobin < 10	6	6	6	7	14
Dialyzed with an AV fistula	47	50	53	56	59
Nutritional status	34	35	35	39	42
Phosphorus and calcium management	46	45	46	47	48
Percent of adult peritoneal dialysis patients:					
Receiving adequate dialysis	89%	88%	89%	89%	91%
Anemia measures:					
Mean hemoglobin 10–12 g/dL	48	52	57	58	61
Mean hemoglobin ≥ 12 g/dL*	45	39	33	31	21
Mean hemoglobin < 10	7	9	10	11	18
Nutritional status	20	19	18	20	21
Phosphorus and calcium management	46	45	47	47	47
	2006	**2007**	**2008**	**2009**	**2010**
Annual mortality rate per 100 dialysis patient years:*					
All	20.0%	19.2%	18.5%	18.0%	17.3%
White	21.6	20.7	20.0	19.5	18.9
African American	18.1	17.3	16.5	16.0	15.2
Other	14.8	14.1	13.7	13.4	12.6
45–64 years	16.3	15.6	14.9	14.5	13.9
65–74 years	26.4	25.1	24.3	23.8	23.1
75+ years	40.2	39.1	37.8	36.9	35.8
Inpatient admission rate per dialysis patient:*					
All	1.9	1.9	1.9	1.9	1.9
White	1.9	1.9	1.9	1.9	1.9
African American	2.0	2.0	2.0	1.9	1.9
Native American	1.8	1.7	1.7	1.8	1.7
Asian American	1.4	1.4	1.4	1.3	1.4
45–64 years	1.9	1.8	1.8	1.8	1.8
65–74 years	1.9	1.9	1.9	1.8	1.9
75+ years	2.1	2.0	2.1	2.0	1.9
Percent of discharges that were rehospitalized within 30 days:*					
All	N/A	35.8%	N/A	35.9%	33.4%
Cardiovascular (index hospitalization)	N/A	37.5	N/A	37.6	34.5
Infection (index hospitalization)	N/A	33.7	N/A	33.8	31.0
Vascular access (index hospitalization)	N/A	31.7	N/A	31.1	29.3
Percent of prevalent dialysis patients wait-listed for a kidney:					
All	16.3%	16.8%	17.0%	17.3%	17.5%
White	15.2	15.7	15.9	16.2	16.5
African American	16.7	17.3	17.5	17.7	17.9
Native American	14.5	15.1	15.5	14.9	15.0
Asian American	25.2	25.6	25.7	25.7	25.6
Renal transplant rate per 100 dialysis patient years:					
All	4.8	4.4	4.2	4.1	3.9
White	5.6	5.1	4.8	4.6	4.3
African American	3.2	3.0	2.9	2.9	2.9
Native American	4.5	4.2	4.2	4.8	4.1
Asian American	6.2	3.8	3.7	3.5	3.8

Note: Kt/V (dialyzer urea clearance x dialysis time/urea volume), g/dL (grams/deciliter), N/A (not available), AV (arteriovenous). "Other" includes Asian Americans and Native Americans. Data on dialysis adequacy, use of fistulas, and anemia management represent percent of patients meeting CMS's clinical performance measures. United States Renal Data System adjusts data by age, gender, race, and primary diagnosis of end-stage renal disease.
* Lower values indicate higher quality.

Source: Compiled by MedPAC from the 2010 and 2011 National Elab Reports, 2002–2009 Elab Trends Report, Fistula First 2012, and United States Renal Data System 2012.

and 2011, the proportion of adult hemodialysis patients with hemoglobin levels less than 10 g/dL increased from 7 percent to 14 percent, while the proportion of adult hemodialysis patients with hemoglobin levels greater than 12 g/dL declined from 25 percent to 12 percent. Hemoglobin levels less than 10 g/dL are often associated with lower use of ESAs, while hemoglobin levels greater than 12 g/dL are often associated with higher use of ESAs. The clinical indicator measuring the management of bone and mineral disorders remained at about the same level between 2010 and 2011.

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 2011 and 2012. For example:

- In 2012, DaVita completed its acquisition of HealthCare Partners, which runs medical groups and physician networks in California, Florida, and Nevada; has 700 employed physicians and a network of 8,300 independent doctors; and is one of the Pioneer Accountable Care Organizations (ACOs) and is in the ACO Pilot Project for People covered by Anthem Blue Cross, for roughly $4.4 billion.
- In 2011, DaVita purchased a company that owns two dialysis centers in Germany and manages two others.
- In February 2012, Fresenius completed the acquisition of Liberty Dialysis and Renal Advantage, which is expected to add annual revenues of around $700 million and 201 clinics.
- In 2011, Fresenius acquired American Access Care Holdings, which operates 28 freestanding outpatient clinics for procedures such as fistulas and grafts, for $385 million.
- In November 2012, Renal Ventures Management LLC, which operates 36 dialysis facilities, created a division of vascular access centers that are intended to open in 2013.
- In October 2012, a new dialysis provider, Corva Clinics LLC, and a private equity firm acquired the assets of Innovative Renal Care.
- In December 2011, Ambulatory Services of America acquired Renal CarePartners. Once the acquisition is complete, Ambulatory Services of America will operate 62 facilities.

These current trends in the profit status and consolidation among dialysis providers suggest that the dialysis industry is attractive to for-profit providers and that there are efficiencies and economies of scale in providing dialysis care. The attractiveness of these ventures is suggested by the statement from a midsized dialysis chain that new clinics become "EBITDA (earnings before interest, taxes, depreciation, and amortization) positive" within an average of 12 months of opening (American Renal Holdings 2011).

Finally, in 2012, Berkshire Hathaway, Inc., a multinational conglomerate holding company, increased its investment in one of the largest dialysis providers (Seeking Alpha 2012). Such an investment suggests the financial attractiveness of the company and the positive economics associated with provision of dialysis services.

Medicare payments and providers' costs

Each year, we assess the relationship between Medicare's provider payments and freestanding providers' costs by considering whether current costs approximate what efficient providers are expected to spend on delivering high-quality care. To make this assessment, we reviewed Medicare expenditures for outpatient dialysis services in 2011 and examined trends in spending during the past five-year period. We also reviewed evidence about providers' costs. Because of delays by CMS in processing the 2011 cost reports of freestanding dialysis facilities, the latest and most complete data available on freestanding providers' costs are from 2010.

Medicare payments for outpatient dialysis services

For most facilities, 2011 is the first year of the modernized PPS that includes, in the payment bundle, injectable dialysis drugs, laboratory tests, and supplies and other services for which facilities previously received separate payments. The modernized bundle also includes items and services for which other providers, not dialysis facilities, received separate payments in prior years. These items and services include (1) laboratory tests that physicians ordered in caring for dialysis beneficiaries (and clinical laboratories furnished), (2) durable medical equipment and supplies for some home dialysis beneficiaries, and (3) the oral equivalent of injectable dialysis drugs (calcitriol, doxercalciferol, paricalcitol, and levocarnitine). CMS

estimated that these items and services account for about 3.8 percent of the total payment per treatment (Centers for Medicare & Medicaid Services 2010).

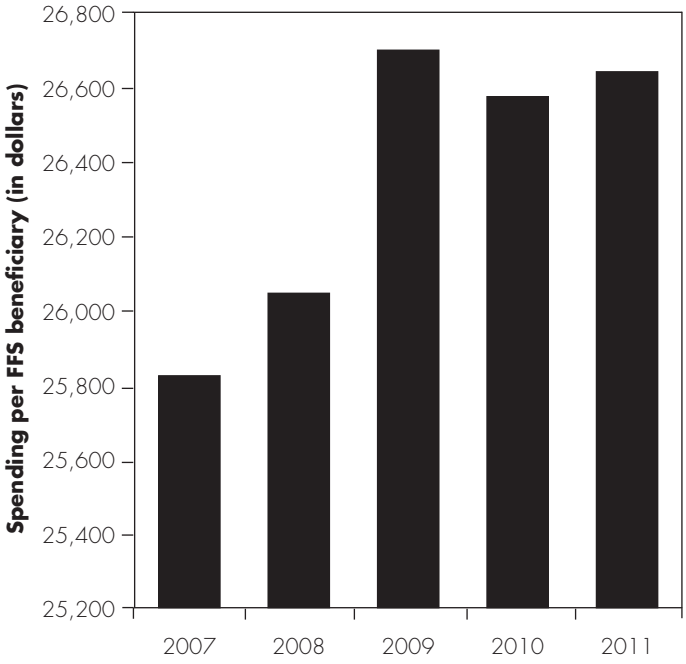
Excluding items and services that Medicare paid other providers (not dialysis facilities) to furnish in prior years, we estimate that in 2011, Medicare expenditures were about $9.6 billion, an increase of about 1 percent compared with 2010 spending levels. After those items and services were included in the new payment bundle, Medicare expenditures totaled $10.1 billion. Freestanding facilities accounted for 92 percent of the spending total (about $9.3 billion in 2011).

Between 2007 and 2009, per capita annual spending increased by an average of 1.7 percent per year, partly due to increasing use of injectable dialysis drugs (Figure 6-4). Between 2009 and 2010, spending per beneficiary decreased by 0.5 percent. The decline in per beneficiary spending in 2010 was primarily due to the lower volume of ESAs furnished to beneficiaries in 2010.

Excluding services furnished by other providers in prior years, we estimate that, in 2011, dialysis spending averaged about $26,600 per FFS dialysis beneficiary (Figure 6-4), a 0.3 percent increase from 2010. The change in total per beneficiary spending between 2010 and 2011 also reflects the MIPPA-mandated 2 percent reduction in total ESRD spending and a transitional budget-neutrality adjuster of 3.1 percent to the base payment rate that CMS implemented between January and March 2011.

FIGURE 6–4

Spending for dialysis services, 2007–2011



Note: FFS (fee-for-service). The payment per beneficiary for 2011 was adjusted by excluding the payment for services furnished by other providers in prior payment years (laboratory services, durable medical equipment, and the oral equivalent of Part B dialysis drugs). This adjustment was estimated based on CMS data reported in the 2010 final rule for the end-stage renal disease prospective payment system (Centers for Medicare & Medicaid Services 2010).

Source: MedPAC analysis of 2007–2011 claims submitted by dialysis facilities to CMS.

Summary of last year's analysis of Medicare payments and providers' costs

In our March 2012 report, we found that:

- Between 2005 and 2010, the cost per treatment for services paid under the former composite rate payment system using the composite rate rose by an average of 2.5 percent per year. Variation from this average across freestanding dialysis facilities shows that some facilities were able to hold their cost growth well below that of others. For example, between 2005 and 2010, per treatment costs increased by 0.7 percent per year for facilities in the 25th percentile of cost growth, compared with 4.2 percent for facilities in the 75th percentile.
- For 2010, we estimated the Medicare margin for composite rate services and dialysis drugs at 2.3 percent. The distribution of margins in 2010 showed wide variation in performance among freestanding facilities. One-quarter of facilities had margins at or below –6.7 percent and one-quarter of facilities had Medicare margins of at least 11.9 percent.
- On the basis of 2010 payment and cost data, we projected a 2012 aggregate margin of 2.7 percent.

Outpatient dialysis Medicare margins for 2011 and 2013

Our estimate of the Medicare margin is based on the most current cost and payment data available for freestanding dialysis facilities: 2010 cost reports and 2011 Medicare claims data. Because 2011 dialysis facility cost reports are not yet available, we estimate a range for the 2011 Medicare margin of 2 percent to 3 percent, and we project that the 2013 Medicare margin will be in the range of 3 percent to 4 percent. The lower end of the range reflects a more conservative assumption about the efficiencies

anticipated under the modernized payment bundle. The 2013 Medicare margin includes the following policy changes: (1) the increase in the payment rate via the statutory update for 2012 and 2013 (of 2.1 percent and 2.3 percent, respectively), (2) the estimated decrease in total payments due to the quality incentive program in 2012 and 2013 (0.2 percent and 0.3 percent, respectively), and (3) the increase in payments due to the 2013 transitional budget-neutrality factor that CMS finalized for the 2013 payment year (of 0.1 percent).

How should Medicare payments change in 2014?

Two major provisions under current law affect the 2014 outpatient dialysis payment rate. First, the American Taxpayer Relief Act of 2012 rebases the outpatient dialysis payment rate effective 2014 to reflect more current utilization of dialysis drugs and other services. The law mandates that the Secretary (1) rebase the outpatient dialysis payment rate effective 2014 based on changes between 2007 and 2012 in the utilization of ESAs, other drugs and biologicals, and diagnostic laboratory tests; and (2) delay the inclusion of oral-only ESRD-related drugs into the payment bundle until 2016.

Second, MIPPA and the Patient Protection and Affordable Care Act of 2010 mandated, beginning in 2012, that the Secretary annually update the outpatient dialysis payment rate by an ESRD market basket index reduced by a productivity adjustment. CMS measures price inflation for ESRD goods and services associated with the modernized prospective payment bundle. CMS's latest forecast of this index for calendar year 2014 is 2.8 percent. Under current law, the ESRD update is subject to a productivity adjustment, currently estimated at 0.4 percent.

Update recommendation

Our payment adequacy indicators suggest that payments are adequate. It is also relevant to note that over 90 percent of the industry opted to be paid fully under the new payment system rather than go through a transition. It also appears that facilities have become more efficient under the new payment method as measured by declining use of injectable dialysis drugs between 2010 and 2011.

RECOMMENDATION 6

The Congress should not increase the outpatient dialysis bundled payment rate for calendar year 2014.

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 realized efficiencies under the modernized payment method as evidenced by declining use of injectable dialysis drugs. The Medicare margin is estimated at 2 percent to 3 percent in 2011 and projected at 3 percent to 4 percent in 2013.

Current law mandates that rebasing begin in 2014. On the one hand, prompt rebasing of the dialysis PPS may prevent overpayment of these providers, and the fact that nearly all dialysis facilities elected to be paid under the modernized payment method suggests that the base payment rates under the modernized payment method are more generous than the previous system. On the other hand, it may be too early to determine how much rebasing is needed without 2011 dialysis facility cost reports, which would help to provide a more complete picture of facilities' response to the modernized payment method. We will reevaluate the adequacy of Medicare's payments for outpatient dialysis services and the need for and level of rebasing when we have more information.

IMPLICATIONS 6

Spending

- Under current law, the payment rate would be (1) rebased in 2014 to reflect changes between 2007 and 2012 in the use of dialysis drugs and diagnostic laboratory tests and (2) updated by the ESRD market basket less a productivity adjustment, which is currently estimated at 2.4 percent. This recommendation, which holds the 2014 payment rate at the 2013 level, would increase federal program spending relative to the statutory update law by between $50 million and $250 million for one year and by less than $1 billion over five years.

Beneficiary and provider

- We do not anticipate any negative effects on beneficiary access to care. This recommendation is not expected to affect providers' willingness or ability to serve beneficiaries.

Future research agenda

To address the high and unchanging rates of inpatient admission, the Commission intends to explore the effectiveness of payment approaches that have the potential to improve dialysis quality by decreasing the

high inpatient admission rate. Such approaches include expanding the dialysis payment bundle to include outpatient services that have the potential to affect the high rate of inpatient morbidity, such as vascular access services (Medicare Payment Advisory Commission 2008). We also intend to consider an even larger payment bundle that could, for example, include all services needed to treat dialysis beneficiaries during the course of a month. One example of such a larger payment bundle is the ESRD special needs plans—a subcategory of coordinated care plans in MA. In this report, we recommend that the Congress continue chronic special needs plans only for a small number of conditions, including ESRD (see Chapter 14). ESRD ACOs represent another payment approach of a larger payment bundle that ESRD industry representatives have proposed as a means to improve dialysis quality and control costs (Nissenson et al. 2012). ■

Endnotes

1 In this chapter, we use the terms "beneficiaries" to refer to individuals covered by Medicare and "patients" for individuals who may or may not be covered by Medicare. As we discuss later in this chapter, most dialysis patients are covered by Medicare as the primary or secondary payer.

2 To become eligible for Medicare, individuals with ESRD who are less than 65 years of age do not necessarily have to be receiving Social Security disability insurance benefits. In 2011, about 20 percent of all dialysis beneficiaries were eligible for Medicare benefits due to ESRD alone, about 30 percent were eligible due to disability (with or without ESRD), and the remainder were eligible due to age (being 65 years or older).

3 This estimate remained relatively steady between 2006 and 2011 (the most recent five-year period for which data are available).

4 According to CMS's Medicare Managed Care Manual, an individual who receives a kidney transplant and no longer requires a regular course of dialysis to maintain life is not considered to have ESRD for purposes of MA eligibility. Such individuals may elect to enroll in an MA plan, if they meet other applicable MA eligibility requirements.

5 For individuals entitled to Medicare due to ESRD only or ESRD and disability, 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 For this analysis, new patients with ESRD include those who (1) are Medicare eligible and not Medicare eligible and (2) initiate dialysis or receive a kidney transplant.

7 Patients with higher levels of residual kidney function were those who started dialysis with an estimated glomerular filtration rate (a measure of residual kidney function calculated using the Chronic Kidney Disease Epidemiology Collaboration formula) above 15 milliliters per minute per 1.73 square meters (United States Renal Data System 2012). Clinicians consider the estimated glomerular filtration rate the best measure of residual kidney function; lower values of this measure suggest reduced residual kidney function.

8 In 2011, 85 percent of Medicare's payments for monthly capitated payment services were billed by nephrologists.

9 In 2013, under the former method (i.e., basic case-mix-adjusted composite rate system), the base composite rate is $165.62 per treatment, including a 14 percent drug add-on payment. Separately billable dialysis drugs are paid according to the Part B average sales price.

10 CMS defined a low-volume facility as one that furnishes fewer than 4,000 treatments (including those for non-Medicare patients) in each of the three years before the payment year and that has not opened, closed, or received a new provider number due to a change in ownership during the three-year period. Facilities under common ownership and within 25 road miles of each other are treated as if they were one unit for purposes of applying the low-volume adjustment; facilities certified for Medicare participation before January 1, 2011, are exempt from this provision. Pediatric dialysis treatments are not eligible for the low-volume adjustment.

11 For payment years 2011 and 2012, CMS used 2007 utilization data to calculate the outlier payment factors.

12 In March 2007, the FDA included a "black box warning" on ESA drug labels advising physicians that the risks of death and serious cardiovascular events are greater when ESAs are administered to achieve higher target hemoglobin levels (compared with lower hemoglobin levels) and that dosing should be individualized to maintain hemoglobin levels between 10 grams per deciliter of blood (g/dL) and 12 g/dL. Changes to the ESA label in 2011 include recommendations that providers consider starting ESA treatment for patients with chronic kidney disease when the hemoglobin level is less than 10 g/dL and use the lowest dose of ESA sufficient to reduce the need for red blood cell transfusions.

13 These three drug classes accounted for nearly all dialysis drug spending (about 97 percent) in 2010, the year before the start of the modernized payment method.

14 To assess how facilities meet Medicare's clinical performance measures, we used data from the Elab Project, in which nearly all dialysis facilities provide the ESRD networks with patient-level laboratory data on clinical indicators, such as dialysis adequacy and anemia status. We used data from CMS's quality project, Fistula First, to monitor changes in the types of vascular access hemodialysis patients used. To assess trends in hospitalization, mortality, and renal transplantation overall for all patients, we used data from USRDS. We used data from CMS and the Elab Project to assess clinical outcomes under the modernized payment method (since 2010).

15 Surgeons create an AV fistula by joining an artery to a vein under the patient's skin (frequently in the forearm). A few months are usually needed to allow the AV fistula to properly develop before it can be used during dialysis. Surgeons may

implant an AV graft for certain patients (including those with small or weak veins) who are not candidates for an AV fistula. Like AV fistulas, AV grafts are implanted under the skin, usually in the patient's forearm. AV grafts use a soft plastic tube to join an artery and a vein. Compared with AV fistulas, AV grafts can be used sooner after placement, often in two to three weeks. A catheter placed in the patient's neck, chest, or leg is used as a temporary access when a patient needs dialysis immediately and is waiting for an AV fistula or AV graft to mature. A catheter is also used when an AV fistula or AV graft fails.

16 Researchers have found a strong inverse correlation between dialysis patients' albumin levels and mortality. However, inflammation and infection can affect albumin levels.

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