CHAPTER 6

Outpatient dialysis services

RECOMMENDATION

6 The Congress should update the outpatient dialysis payment rate by 1 percent for calendar year 2013.

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

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 2010, more than 355,000 ESRD beneficiaries on dialysis were covered under fee-for-service (FFS) Medicare and received dialysis from about 5,500 ESRD facilities. In that year, Medicare expenditures for outpatient dialysis services, including separately billable drugs administered during dialysis, were $9.5 billion, an increase of 4 percent from 2009 spending levels. For most facilities, 2010 is the last year that Medicare paid them a prospective payment for each dialysis treatment furnished and separate payments for furnishing certain drugs during dialysis. The modernized prospective payment system began in 2011 and includes dialysis drugs for which facilities previously received separate payments in the payment bundle.

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 2010, the number of FFS dialysis patients and dialysis treatments grew at similar rates (4 percent and 5 percent, respectively). Per capita use of erythropoiesis-stimulating agents, the drug class accounting for three-quarters of dialysis drug spending, declined during this time. This decline is linked to clinical evidence showing that higher use of these drugs is associated with increased risk of cardiovascular events. It also may be linked to facilities' and physicians' modifying their prescribing patterns in anticipation of the new payment method that began in 2011 that no longer pays separately for these drugs.

***Quality of care*—**Dialysis quality has improved over time for some measures, such as use of the recommended type of vascular access—the site on the patient's body where blood is removed and returned during hemodialysis. Other measures, such as rates of rehospitalization within 30 days, suggest that improvements in quality are still needed.

***Providers' access to capital*—**Information from investment analysts suggests that dialysis providers continue to have adequate access to capital. The number of facilities, particularly for-profit facilities, continues to increase.

***Medicare payments and providers' costs*—**In 2010, the Medicare margin for dialysis services and drugs was 2.3 percent for freestanding dialysis facilities. We project the Medicare margin for outpatient dialysis services will be 2.7 percent in 2012. This projection reflects payment updates of 2.5 percent in 2011 and 2.1 percent in 2012; the 2 percent reduction in total spending that the Medicare Improvements for Patients and Providers Act of 2008 mandated in 2011; the 3.1 percent transitional budget-neutrality adjustment in effect between January and March 31, 2011; the estimated 0.2 percent payment reduction due to Medicare's quality incentive program in 2012; and a conservative behavioral offset to account for efficiencies in the use of drugs that are anticipated under the new dialysis payment method. ■

Dialysis treatment choices

Dialysis replaces the filtering function of the kidneys when they fail. The two types of dialysis—peritoneal dialysis and hemodialysis—remove waste products from the bloodstream differently. Peritoneal dialysis uses the lining of the abdomen as a filter to clear wastes and extra fluid and is usually performed independently in the patient's home (or work place) several times a day five to seven days a week.

Hemodialysis uses an artificial membrane encased in a dialyzer to filter the patient's blood. Although hemodialysis is usually provided in dialysis facilities, it can also be done in the patient's home. Most hemodialysis patients receive treatments thrice weekly (three to four hours per treatment) in a dialysis facility. Studies showing reduced mortality have increased interest in two types of more frequent hemodialysis administered five or more times at night weekly (six to eight hours per treatment) or during the day (two to three hours per treatment). Both nocturnal and short daily hemodialysis can be furnished in either a patient's home or a dialysis facility.

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, patients' awareness of different treatment methods and personal preferences, and physician training and recommendation. Mehrotra and colleagues concluded that many U.S. training programs either do not have an appropriate number of peritoneal dialysis patients or do not allocate appropriate time to ensure the preparedness of fellows in providing independent care for patients undergoing peritoneal dialysis (Mehrotra et al. 2002). Some patients switch from one method to another when their conditions or needs change. ■

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. Because of the limited number of kidneys available for transplantation and because of potential patients' suitability for transplantation, 70 percent of ESRD patients undergo dialysis. The text box (above) summarizes the different types of 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.

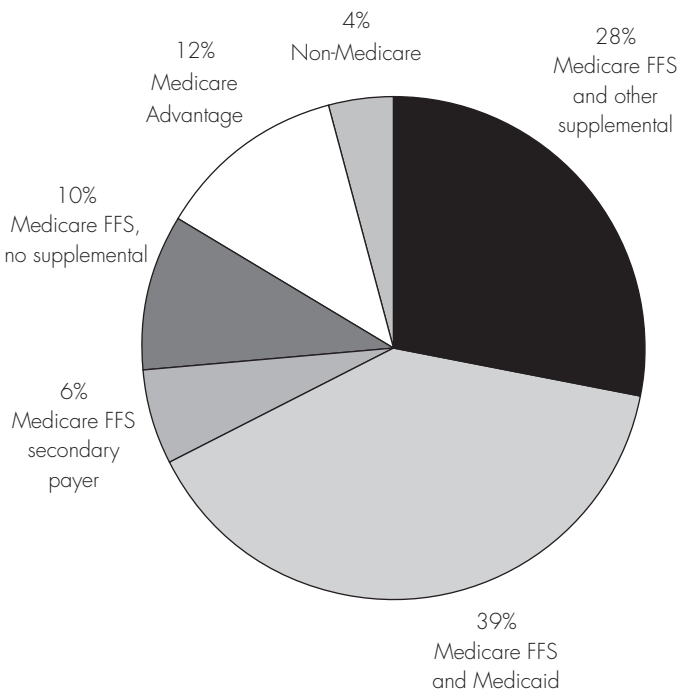
The 1972 amendments to the Social Security Act extended Medicare benefits to people with ESRD who are eligible for Social Security benefits, including those under age 65 years. To qualify for the ESRD program, individuals must be fully or currently insured under the Social Security or Railroad Retirement program, entitled to benefits under the Social Security or Railroad Retirement program, or the spouse or dependent child of an eligible beneficiary.[1] ESRD patients entitled to Medicare due to kidney disease alone have the same benefits as other Medicare patients.

For individuals entitled to benefits due to ESRD alone, 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. About half of new ESRD patients each year are under age 65 and thus are entitled to Medicare because they have chronic renal failure. In 2009, there were about 113,000 new dialysis patients, inclusive of individuals covered by Medicare and those not covered by Medicare.[2] According to the U.S. Renal Data System (USRDS), between 2008 and 2009, the rate of new ESRD cases increased by 1 percent to 355 per million population (United States Renal Data System 2011).

Most dialysis patients—more than 355,000 patients in 2010—are covered by fee-for-service (FFS) Medicare as the primary or secondary payer (Figure 6-1, p. 144). Compared with all Medicare patients, FFS dialysis patients are disproportionately younger and African American (Table 6-1, p. 145). Nearly three-quarters of FFS dialysis patients are less than 75 years old and 36 percent are African American. About 91 percent of FFS

FIGURE 6–1

In 2010, we estimate that Medicare was the primary or secondary payer for most dialysis patients



Note: FFS (fee-for-service). Total may not sum to 100 percent due to rounding.

Source: Source of insurance estimated from USRDS 2011, CMS's 2009 renal facility survey, 2008 Medicare Current Beneficiary Survey, 2010 Medicare denominator file, and 2010 claims submitted by dialysis facilities to CMS.

dialysis patients are enrolled in Part D plans or have other sources of creditable drug coverage.

To help pay for Part A and Part B cost sharing, most FFS dialysis patients have supplemental insurance. About 47 percent of patients are dually eligible for Medicare and Medicaid. According to the 2008 Medicare Current Beneficiary Survey, 11 percent of Medicare ESRD patients lack supplemental insurance. Medicare is the secondary payer (for Part A and Part B) for 7 percent of FFS dialysis patients who are insured by an employer group health plan (EGHP) at the time they are diagnosed with ESRD.[3] 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.

Although most dialysis patients who are entitled to Medicare are enrolled in FFS, in recent years, the share of Medicare dialysis patients in Medicare Advantage (MA) plans has increased. In 2009, nearly 13 percent of Medicare dialysis patients were enrolled in MA plans, an increase from 7 percent in 2005 (United States Renal Data System 2011).[4]

According to CMS's renal facility survey, about 96 percent of all patients are covered by Medicare. The share of dialysis patients not covered by Medicare (as either the primary or the secondary payer) between 2004 and 2009 (the most recent five-year period for which data are available) remained relatively steady, ranging between 4 percent and 5 percent.

The two principal providers of dialysis care are the facilities that furnish dialysis treatments and the physicians (often nephrologists, who specialize in the treatment of kidney diseases) who prescribe and manage the provision of dialysis and establish the patient's plan of care. Medicare uses separate methods to pay for these services. Under the new payment method, Medicare pays facilities a prospective payment for each dialysis treatment they furnish. By contrast, physicians and practitioners are paid a monthly rate for outpatient dialysis-related management services. The monthly payment amount varies based on the number of visits provided each month, the age of the beneficiary, and whether the patient is receiving dialysis in a facility or at home. While this chapter focuses on the fee that Medicare pays to facilities, it is important to recognize that facilities and physicians collaborate to care for dialysis patients and only together can they improve quality in the long term.

In 2011, CMS paid most dialysis facilities under a new outpatient dialysis payment policy

In 2011, to improve efficiency, Medicare began to phase in a new prospective payment system (PPS) for dialysis facilities. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) updated the outpatient dialysis payment method by broadening the payment bundle in 2011 to include dialysis drugs and laboratory tests that were previously separately billable and implementing a pay-for-performance program in 2012. MIPPA's provisions are consistent with the Commission's long-standing 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 to include drugs, laboratory services, and other commonly furnished items that providers formerly billed separately and by linking payment to quality. The new bundled rate is designed to create incentives for facilities to furnish services more efficiently by reducing incentives inherent in the former payment method to overutilize drugs.

Table 6-2 (p. 146) compares features of the new and former payment methods. Like the new method, the previous one pays facilities for a single dialysis treatment by using a prospective payment—often referred to as the composite rate. However, the new payment method differs from the former one in the following ways: (1) it uses a broader payment bundle, (2) it sets payment using a greater number of patient-level payment adjusters, (3) it provides an outlier payment for high-cost patients, (4) it increases the base rate by a low-volume adjustment for certain low-volume facilities, and (5) it 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_11_dialysis.pdf).

In 2011, most dialysis facilities (about 87 percent), including the two largest dialysis organizations, elected to be paid under the new PPS instead of the four-year transition (Centers for Medicare & Medicaid Services 2011b). In 2012, under the new PPS, the base prospective payment is $234.81 per treatment, which includes all ESRD-related services, including injectable drugs and selected laboratory services that were previously separately billable. For the 13 percent of all dialysis facilities that are paid under the four-year transition to the new payment method, in 2012, 50 percent of their payment is based on the new payment method and 50 percent of their payment is based on the former payment method. In 2012, under the former method (i.e., basic case-mix adjusted composite rate system), the base composite rate (including the drug add-on payment) is about $162 per treatment.[5] Separately billable dialysis drugs are paid according to the Part B average sales price, and separately billable laboratory tests are paid according to the laboratory fee schedule.

TABLE 6–1

Characteristics of FFS dialysis patients and program eligibility, 2010

	Percent of all FFS dialysis patients
Age	
Under 45 years	12%
45–64 years	37
65–74 years	25
75–84 years	19
85+ years	7
Sex	
Male	54
Female	46
Race	
White	51
African American	36
All others	14
Residence	
Urban county	81
Rural county, micropolitan	11
Rural county, adjacent to urban	5
Rural county, not adjacent to urban	3
Frontier county	1
Medicare as the secondary payer	7*
Prescription drug coverage status	
Enrolled in Part D	74
Coverage through employers that receive RDS	10
Coverage through other creditable sources	12
No creditable coverage	9
LIS	55*
Dually eligible for Medicaid	47

Note: FFS (fee-for-service), RDS (retiree drug subsidy), LIS (low-income subsidy). Urban counties contain a core area with 50,000 or more population, rural micropolitan counties contain at least one cluster of at least 10,000 and less than 50,000 population, rural counties adjacent to urban areas do not have a city of 10,000 people in the county, and rural counties not adjacent to urban areas do not have a city of 10,000 people. Frontier counties are counties with six or fewer people per square mile. Totals may not sum to 100 percent due to rounding.
*2009 estimates

Source: Data compiled by MedPAC from 2010 claims submitted by dialysis facilities to CMS and the CMS denominator file.

Concerns about the new dialysis prospective payment method

We have identified three issues concerning the new payment method that we intend to continue to follow. We anticipate addressing them again in 2012 after we evaluate the first-year experience with the new payment method using 2011 claims and cost report data. These issues are:

- *Lower use of dialysis drugs:* If the trend in the decline in the use of dialysis drugs continues, Medicare might consider using some of the associated savings

TABLE 6–2

New dialysis payment method broadens the payment bundle and includes more beneficiary-level adjustments, a low-volume adjustment, and payment for high-cost outliers

Payment method feature	Composite rate payment method: 1983–2010	New outpatient dialysis PPS: 2011 and beyond
Payment bundle	Composite rate services, which include: nursing, dietary counseling and other clinical services, dialysis equipment and supplies, social services, and certain laboratory tests and drugs	• Composite rate services • Separately billable (Part B) injectable dialysis drugs and their oral equivalents • ESRD-related laboratory tests • Selected renal-related oral-only Part D drugs (in 2014)
Unit of payment	Single dialysis treatment	Single dialysis treatment
Drug add-on payment to the composite rate	Yes	None
Self-dialysis training services adjustment	Yes	Yes
Beneficiary-level adjustments	• For adults: age, body surface area, and body mass • For pediatric beneficiaries: none	• For adults: age, dialysis onset, body surface area, body mass, and 6 comorbidities* • For pediatric patients: age and dialysis method
Facility-level adjustments	• Wage index	• Wage index • Low-volume adjustment
Outlier policy	None	Applies to the portion of the broader payment bundle comprising the drugs and services that were formerly billed separately
Quality incentive program	None	• Begins in 2012, uses 3 measures: percentage of patients with hemoglobin less than 10.0 g/dL, percentage of patients with hemoglobin greater than 12.0 g/dL, percentage of patients with URR greater than 65 percent • In 2013, uses 2 measures: percentage of patients with hemoglobin greater than 12.0 g/dL and percentage of patients with URR greater than 65 percent • In 2014 uses 6 measures: percentage of patients with URR greater than 65 percent, percentage of patients with hemoglobin greater than 12 g/dL, percentage of patients receiving treatment through an AV fistula or catheter, whether the facility reports certain dialysis-related infections to the CDC's National Healthcare Safety Network, whether the facility administers a patient experience of care survey, whether the facility monitors phosphorus and calcium levels on a monthly basis
Update	No statutory provision	Begins in 2012, set at ESRD market basket less productivity adjustment

Note: PPS (prospective payment system), ESRD (end-stage renal disease), URR (urea reduction ratio), AV (arteriovenous), g/dL (grams/deciliter), CDC (Centers for Disease Control and Prevention).
*Payment for adults is not adjusted by dialysis method.

Source: MedPAC analysis of CMS 2011 final ESRD rule.

to pay for other renal-related services, such as the oral-only Part D drugs that CMS intends to include in the payment bundle in 2014 and more frequent hemodialysis.

- *The quality incentive program (QIP):* In 2013 and 2014, the QIP lacks measures that hold providers accountable for undertreatment of anemia and bone disease, two common renal comorbidities.
- *The low-volume adjuster:* This adjuster does not yet consider the distance between a low-volume facility and the next closest facility. Consequently, Medicare may be subsidizing some low-volume facilities, particularly those located in urban and rural micropolitan areas, which are near another facility.

In addition to these three issues, industry representatives of dialysis facilities are concerned that they often lack the necessary documentation to bill Medicare for the six patient-level comorbidity adjustments under the requirements of the new payment method. CMS requires dialysis facilities to provide documentation in the patient's medical record to support any diagnosis recognized for a payment adjustment (Centers for Medicare & Medicaid Services 2010). As a result, they contend that Medicare's payments for dialysis services may be less than what was intended in 2011.

Lower use of dialysis drugs Since 2009, per capita use of certain dialysis drugs, particularly erythropoiesis-stimulating agents (ESAs), which are used to treat anemia, declined. Our analysis of Medicare claims data shows that between 2009 and 2010, the average erythropoietin dose per patient per week declined by 1.4 percent. Between January 2010 and December 2010, our analysis finds that the average dose per patient declined by 7 percent. According to industry data, between January and June 2011, the erythropoietin dose per patient per week fell by an additional 4 percent for the two largest dialysis organizations (Dialysis Outcomes and Practice Patterns Study 2011).

If the trend in lower drug use continues, some of the potential savings might offset some of the cost associated with including the oral-only Part D drugs in the bundle, which CMS intends to do in 2014.[6] (CMS delayed including the oral-only Part D drugs in the bundle in order to complete an evaluation of the drugs' pricing data and address operational concerns.) Some of the savings might also be used to pay for more frequent hemodialysis.

The quality incentive program Under the new payment method, with dialysis drugs in the broader payment bundle, some providers may have an incentive to reduce their use to the extent clinically possible. However, the QIP in 2013 and 2014 does not include measures that hold facilities accountable for the undertreatment of anemia and bone disease.

In 2012, the QIP measures the undertreatment of anemia—expressed as the percentage of patients receiving ESAs with an average hemoglobin less than 10.0 grams per deciliter (g/dL) of blood. CMS is not using this measure in the 2013 and 2014 QIPs because (1) it cannot identify a specific hemoglobin lower bound level that has been proven safe for all patients treated with ESAs and (2) it contends that, based on the revision of the ESA label by the Food and Drug Administration (FDA) in 2011, it would not be appropriate for the QIP to continue encouraging providers to achieve hemoglobin levels above 10 g/dL in all patients. In addition, the QIP does not hold dialysis providers accountable for the outcomes of undertreatment of anemia, such as blood transfusions and hospitalizations. CMS proposed, but did not implement, a standardized hospitalization ratio measure for the 2014 QIP.

In 2014, the QIP will measure whether facilities monitor two clinical outcomes (phosphorus and calcium levels) of bone disease and mineral management. But the QIP will not require that facilities submit data on mineral metabolism levels nor will it hold providers accountable for the outcomes of undertreatment.

The 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. 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 are one unit when applying the low-volume adjustment; facilities certified for Medicare participation before January 1, 2011, are exempt from this provision.

Our analysis of 2007–2009 cost reports submitted by facilities to CMS found that (1) 25 percent of low-volume facilities were within 1.2 miles of the next facility and (2) low-volume facilities located in urban and rural micropolitan areas were more likely to be in close

TABLE 6–3 **Some low-volume facilities are in close proximity to another facility**

Facility location	Percent of all low-volume facilities	Distance to closest facility (in miles)		
		Mean	Median	25th percentile
All low-volume facilities	100%	18.0	5.4	1.2
Urban county	57	5.9	2.1	0.8
Rural county, micropolitan	17	38.4	11.6	1.5
Rural county, adjacent to urban	17	23.7	23.5	18.1
Rural county, not adjacent to urban	10	43.9	37.4	30.0

Note: Urban counties contain a core area with 50,000 or more population, rural micropolitan counties contain at least one cluster of at least 10,000 and less than 50,000 population, rural counties adjacent to urban areas do not have a city of 10,000 people in the county, and rural counties not adjacent to urban areas do not have a city of 10,000 people.

Source: Data compiled by MedPAC from 2007–2009 cost reports submitted by facilities to CMS.

proximity to another facility (Table 6-3). Medicare and dialysis patients might be better served by an adjuster that targets low-volume facilities that are not in close proximity to another facility.

Industry concerns about patient comorbidity payment adjusters Under the new payment method, CMS has designated three chronic conditions—hereditary hemolytic or sickle cell anemia, myelodysplastic syndromes, and monoclonal gammopathy—and three acute conditions—bacterial pneumonias, gastrointestinal tract bleeding with hemorrhage, and pericarditis—as beneficiary payment adjusters. These adjusters were intended to recognize the increased costs incurred by facilities when treating patients with these conditions. Some industry representatives contend that (1) they lack sufficient documentation (e.g., chest X-ray for bacterial pneumonia) to bill CMS for a comorbidity adjustment, as these conditions are typically diagnosed at other provider sites (e.g., hospital, physician office), and (2) the high labor costs incurred to collect the documentation often offset Medicare's comorbidity payment adjustments.[7]

CMS included these conditions as case-mix adjusters based on regression analyses assessing the relationship between facilities' cost per treatment for composite rate services and facilities' payment per treatment for separately billable drugs and labs. These comorbidities had a statistically significant association with facilities' costs and payments. Once 2011 claims data become available, the Commission intends to analyze the billing patterns of facilities under the new payment method and the prevalence of these conditions across other Part B providers.

Medicare spending on outpatient dialysis services

In 2010, Medicare spending for dialysis services, including dialysis drugs, totaled about $9.5 billion, an increase of 4 percent compared with 2009. Freestanding facilities accounted for 91 percent of the spending total (about $8.7 billion in 2010). Payments for composite rate services accounted for 69 percent of the total, and separately billable dialysis drugs accounted for the remainder. Three drug classes accounted for nearly all (98 percent) dialysis drug spending:

- ESAs accounted for 73 percent of total dialysis drug spending and nearly one-quarter of total dialysis spending.
- Injectable vitamin D agents accounted for 15 percent of dialysis drug spending and 5 percent of total dialysis spending.
- Injectable iron agents accounted for 10 percent of dialysis drug spending and 3 percent of total dialysis spending.

In 2010, total dialysis spending averaged $26,575 per FFS dialysis patient (Figure 6-2), a 0.5 percent decline from 2009. This modest decline in total per capita spending resulted from dialysis drug spending decreasing by nearly 5 percent; by contrast, composite rate per capita spending increased by 1 percent. The decline in per patient spending for dialysis drugs was primarily due to the lower volume of ESAs furnished to patients in 2010.

The decrease in the use of ESAs in 2010 is partly linked to some physicians and facilities phasing in new prescribing protocols for dialysis drugs in anticipation of Medicare's change to a bundled payment method in 2011. However, between 2006 and 2008, on a per patient basis, the mean dose per week of erythropoietin declined (by 3 percent annually) because of new clinical evidence demonstrating an association between higher use of ESAs and increased risk of cardiovascular morbidity and mortality (Food and Drug Administration 2011, United States Renal Data System 2011).

Providers of outpatient dialysis services

In 2011, there were nearly 5,600 dialysis facilities in the United States (Table 6-4, p. 150). Since the late 1980s, for-profit, freestanding facilities have provided the majority of dialysis treatments (Rettig and Levinsky 1991). In 2011, freestanding facilities furnished 91 percent of FFS treatments and for-profit facilities furnished 83 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.

Although Medicare is the primary payer for the majority of dialysis patients that facilities cared for in 2010 (Figure 6-1, p. 144), information from the two largest dialysis organizations suggests that Medicare revenues accounted for only 53 percent to 63 percent of their revenues (DaVita Inc. 2010, Fresenius Medical Care AG & Co. KGaA 2010). One of the large dialysis organizations states that "although commercial payment rates vary significantly, average commercial payment rates are generally significantly higher than Medicare rates" (DaVita Inc. 2010).

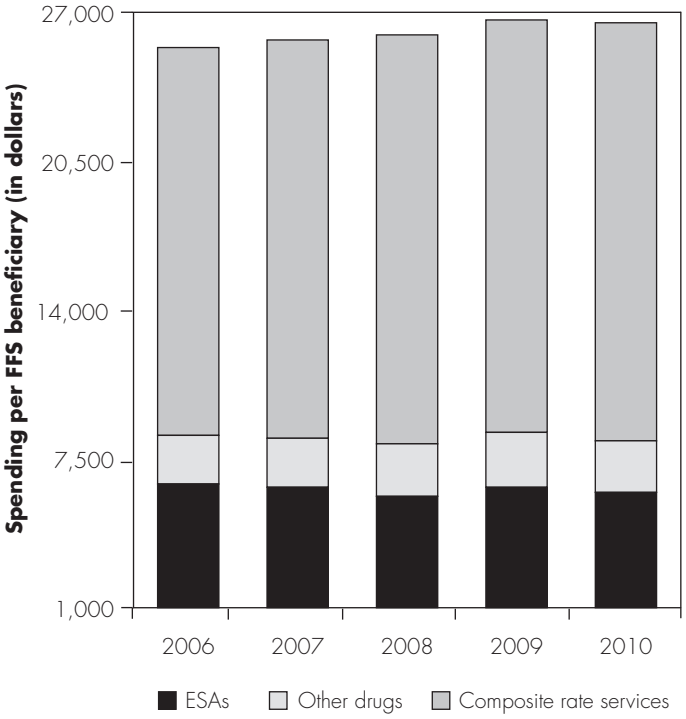
Chain organizations have also dominated this sector, with the first one established in 1970. In 2011, 81 percent of facilities were affiliated with a chain organization (i.e., multifacility enterprise), and chains furnished 86 percent of FFS treatments. In 2011, the two largest dialysis chains (Fresenius Medical Care North America and DaVita) were for profit; each owned more than 1,600 clinics, which accounted for nearly 70 percent of freestanding facilities and 60 percent of all facilities, and they furnished 66 percent of FFS treatments. In 2011, 9 of the 10 largest chains were for profit.

The distribution of facilities located in urban and rural areas is generally consistent with where FFS dialysis patients live (Table 6-1, p. 145):

- 81 percent of FFS dialysis patients reside in and 78 percent of facilities are located in urban areas,
- 11 percent of FFS dialysis patients reside in and 14 percent of facilities are located in rural micropolitan areas,
- 5 percent of FFS dialysis patients reside in and 5 percent of facilities are located in rural counties adjacent to urban areas, and
- 3 percent of FFS dialysis patients reside in and 3 percent of facilities are located in rural counties not adjacent to urban areas.

Not surprisingly, the average number of dialysis treatment stations decreases as the area where facilities are located becomes more rural. On average, urban facilities had 19 treatment stations, facilities in rural micropolitan areas had 16 stations, facilities in rural counties adjacent to urban areas had 13 stations, and facilities in rural counties not adjacent to urban areas had 12 stations.

FIGURE 6–2 **Per capita spending for composite rate services and dialysis drugs, 2006–2010**



Note: ESAs (erythropoiesis-stimulating agents). ESAs include erythropoietin and darbepoetin alpha.

Source: MedPAC analysis of 2006–2010 claims submitted by dialysis facilities to CMS.

TABLE 6–4 **Increasing number and capacity of freestanding, for-profit, and chain organizations**

	2010	2011			Average annual percent change			
					Number of facilities		Number of stations	
	Total number of FFS treatments*	Total number of facilities	Total number of stations*	Mean number of stations	2006–2011	2010–2011	2006–2011	2010–2011
All	40.2	5,560	98.6	18	4%	3%	4%	3%
	Percent of total							
Freestanding	91%	90%	92%	18	5	3	5	4
Hospital based	9	10	8	14	–2	–3	–2	–4
Location								
Urban county	84	78	82	19	4	3	4	3
Rural county, micropolitan	12	14	12	16	3	1	4	3
Rural county, adjacent to urban	3	5	4	13	4	3	5	3
Rural county, not adjacent to urban	2	3	2	12	4	2	4	3
Frontier county	0	1	0.3	10	1	3	3	9
For profit	83	83	84	18	5	4	5	4
Nonprofit	17	17	16	16	–1	–3	0.2	–2
Affiliated with any chain	86	81	83	18	5	4	5	5
Affiliated with one of 2 largest chains	66	62	63	18	4	5	4	5
Not affiliated with any chain	14	19	17	16	0	4	0.2	–4

Note: FFS (fee-for-service). Urban counties contain a core area with 50,000 or more population, rural micropolitan counties contain at least one cluster of at least 10,000 and less than 50,000 population, rural counties adjacent to urban areas do not have a city of 10,000 people in the county, and rural counties not adjacent to urban areas do not have a city of 10,000 people. Frontier counties are counties with six or fewer people per square mile.
*Total number of treatments are in millions. Total number of stations are in thousands.

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

There has been significant industry consolidation in this sector. 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 organizations 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 of the largest dialysis organizations 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). Each of the two largest dialysis organizations (1) operates an ESRD-related laboratory, a pharmacy, and one or more centers that furnish vascular access services; (2) provides ESRD-related disease management services; and (3) operates dialysis facilities internationally.

Although large-chain organizations dominate this sector, an individual dialysis facility is relatively small compared with other institutional providers, such as PPS hospitals. On average, in 2010, a facility provided nearly 10,600 treatments to 75 patients per year. Smaller facilities (in the 25th percentile of all treatments and patients) provided about 5,560 treatments to 40 patients per year, while

larger facilities (in the 75th percentile of all treatments and patients) provided nearly 14,000 treatments to nearly 100 patients per year.

As mentioned earlier, physicians collaborate with facilities to care for dialysis patients. As we describe in the online appendix to this chapter (available at http://www.medpac.gov), in many instances, this collaboration includes physicians having financial or ownership interests in dialysis facilities that chain organizations operate. The statute permits physicians who refer patients to a dialysis facility to have financial and ownership interests in the facility. For example, joint ventures are a common business model in the dialysis sector, in which physicians own a minority stake and chain organizations own a majority stake in a dialysis facility. Physicians with financial and ownership interests share similar incentives with the dialysis chains to be efficient in furnishing services. Such incentives could affect the delivery of services, such as leading to overfurnishing dialysis drugs under the former payment method (when Medicare paid for them on a per unit basis) and underfurnishing them under the new payment method (when Medicare pays for them in the payment bundle). Such incentives may also affect the type of dialysis that is recommended to the patient. Complete data are lacking to assess the specific financial relationships between physicians and dialysis chain organizations. Disclosure of such information, as recommended by the Commission in 2009, would help CMS and other payers determine whether physician ownership might influence the quality of care and overall spending.

Are Medicare payments adequate in 2012?

To address whether payments for 2012 are adequate to cover the costs that efficient providers incur and how much providers' costs should change in the update year (2013), we examine several indicators of payment adequacy. Specifically, we assess patients' access to care by examining the 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 (the number of dialysis treatments) has kept pace with growth in the number of beneficiaries, some improvements in quality have occurred, and provider access to capital is sufficient. In 2010, we estimate the Medicare margin for composite rate services and dialysis services was 2.3 percent, and we project it will be 2.7 percent in 2012.

Beneficiaries' access to care: Indicators continue to be favorable

Our analysis of access indicators—including the capacity of providers to meet patient demand, changes in patients' ability to obtain different types of dialysis, and changes in the volume of services—shows that patients' access to care remains favorable.

Capacity of facilities that are freestanding, for profit, and affiliated with a chain is growing and 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 6-4). 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, the 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, 0.2 percent, and 0.2 percent, respectively). Between 2006 and 2011, the capacities of urban and rural facilities grew at similar rates. The capacities of urban facilities grew by 4 percent per year while the capacities of rural facilities grew at an average annual rate of 4 percent to 5 percent. Between 2010 and 2011, the growth in dialysis capacity grew by 3 percent, 1 percentage point slower than the growth in capacity between 2006 and 2011.

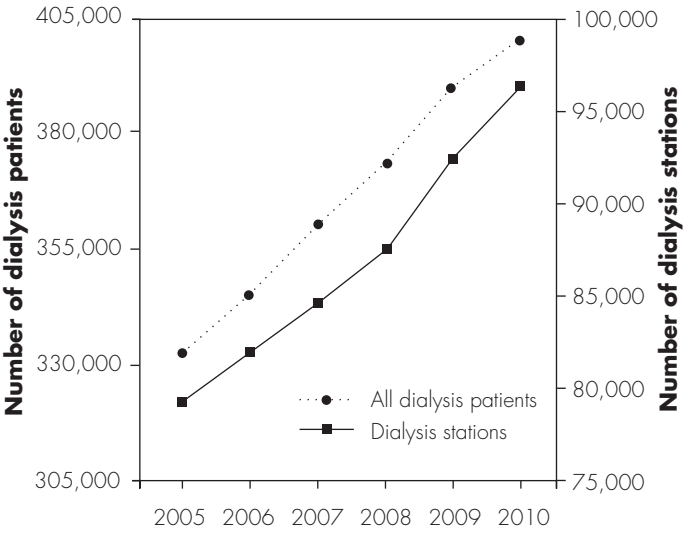
Growth in the numbers of dialysis stations and dialysis patients suggests that provider capacity kept up with demand for care between 2005 and 2010. During this period, the numbers of all dialysis patients (those in FFS Medicare, in MA, and not eligible for Medicare) and dialysis treatment stations increased by 4 percent per year (Figure 6-3, p. 152). Annual growth in the number of treatment stations was faster than the 2 percent annual growth in the number of FFS dialysis beneficiaries.

Most dialysis patients continue to receive thrice weekly in-center hemodialysis, but interest in other dialysis methods continues

During the most recent five-year period for which data are available (2006–2011), at least 96 percent of facilities

FIGURE 6–3

Growth in the number of dialysis stations has kept pace with growth in the number of all dialysis patients



Note: All dialysis patients include those individuals covered by Medicare under the fee-for-service and Medicare Advantage programs and individuals not covered by Medicare.

Source: Compiled by MedPAC from United States Renal Data System 2011, 2011 Elab Project, and 2005–2010 Dialysis Compare.

are certified to offer in-center hemodialysis and 46 percent are certified to offer some type of peritoneal dialysis—continuous cycle peritoneal dialysis or continuous ambulatory peritoneal dialysis (Centers for Medicare & Medicaid Services 2011a). Between 2006 and 2011, the proportion of facilities certified to offer home hemodialysis training increased from 13 percent to 23 percent. According to CMS, since 2006, facilities certified to offer home hemodialysis dialysis training programs grew by 17 percent per year, while facilities offering peritoneal dialysis grew by 4 percent annually.

Industry data examining trends in home hemodialysis suggest greater growth in the number of midsized and large facilities offering more frequent home hemodialysis (five or more times weekly) than conventional home hemodialysis (three times per week) (Home Dialysis Central 2011). Between 2006 and 2011, the number of midsized and large facilities offering nocturnal home hemodialysis, short daily home hemodialysis, and conventional home hemodialysis grew annually by 38 percent, 52 percent, and 21 percent, respectively.

As we describe in the text box (opposite page), interest in the use of more frequent hemodialysis (administered at a patient's home or in a facility) has grown because of studies showing favorable clinical outcomes and quality of life compared with conventional hemodialysis. Nonetheless, relatively few patients receive more frequent hemodialysis. According to CMS, in 2009, about 2,600 patients received hemodialysis more than four times per week. In the coming year, the Commission intends to discuss obstacles in the diffusion of more frequent hemodialysis with clinicians and other dialysis representatives.

There is continued interest in the use of home dialysis methods. Compared with in-center dialysis, studies conclude that home-based dialysis offers patients greater autonomy, improved quality of life, and enhanced satisfaction. Nonetheless, most patients receive dialysis in facilities. In 2009 (the most recent year for which data are available), 92 percent of dialysis patients received hemodialysis in a facility, while 7 percent received peritoneal dialysis (at home), and 1 percent received home hemodialysis (United States Renal Data System 2011). Between 1999 and 2009, the number of patients receiving hemodialysis in a facility increased by 4 percent per year, while the number of patients treated at home grew by 1 percent per year.

Factors contributing to greater use of in-center dialysis include patients' preference for in-center versus home dialysis, availability of caregivers, patients' lack of knowledge about home-based dialysis, and some physicians' lack of familiarity with home modalities, which may make them less likely to discuss this option with their patients. Medicare's former dialysis payment method was also a factor in the decline in home-based methods. The profitability of separately billable dialysis drugs provided an incentive to focus on in-center programs rather than on home-based ones. On average, peritoneal dialysis patients use fewer dialysis drugs than in-center hemodialysis patients. The new payment method might result in increased use of home methods over time. Providers' costs to furnish the most common home-based method—peritoneal dialysis—are less than for in-center hemodialysis. In addition, in 2010, Medicare began to pay for educating pre-ESRD beneficiaries about kidney disease. Researchers report that inadequate education is one of the barriers to increasing the use of home dialysis (Golper et al. 2011).[8]

Use of more frequent hemodialysis by Medicare patients

During the past few years, the use of more frequent hemodialysis (furnished at home or in a center five or more times per week compared with the thrice weekly regimen) has modestly increased. According to CMS, the number of patients receiving hemodialysis more than four times per week increased from 1,700 patients in 2007 to about 2,600 patients in 2009.

Interest in more frequent hemodialysis regimens has grown during the past decade because of studies showing improved outcomes and quality of life. By smoothing out fluctuations in fluid levels and toxins between dialysis sessions, hemodialysis five or more times per week may better approximate the organic kidney than thrice weekly treatment. Until 2007, the body of evidence demonstrating improved clinical outcomes and quality of life associated with more frequent hemodialysis consisted of uncontrolled studies. However, two randomized controlled studies—one conducted between 2004 and 2006 and the other conducted between 2006 and 2010—demonstrated improved clinical outcomes and quality of life associated with more frequent hemodialysis compared with thrice weekly hemodialysis.

The first controlled trial compared outcomes of 52 patients randomized to receive either frequent nocturnal hemodialysis or conventional hemodialysis (Culleton et al. 2007). Compared with conventional hemodialysis, frequent nocturnal hemodialysis improved left ventricular mass, reduced the need for blood pressure medications, improved some measures of mineral metabolism, and improved selected measures of quality of life.

The second controlled trial, funded by the National Institutes of Health (NIH), found that 125 patients randomized to receive short daily hemodialysis (six times per week) had improvements in the coprimary outcomes (which include mortality, left ventricular mass, and self-reported physical health) compared with the 120 patients who received hemodialysis thrice weekly (National Institutes of Health 2010). The more frequent treatments helped avoid excessive phosphate levels in the blood (hyperphosphatemia) and improved control of blood pressure, which are often problems for patients on dialysis. The only downside was that access to blood vessels needed to be adjusted about twice as often in patients who received more treatments.

However, a related NIH-sponsored study reported no differences in the coprimary outcomes among 87 patients randomized to receive either nocturnal hemodialysis six times per week or conventional hemodialysis (Rocco et al. 2011). The researchers found that patients in the nocturnal group had improved control of hyperphosphatemia and hypertension (secondary outcome measures).

Despite these generally favorable findings, relatively few patients receive this type of dialysis. One obstacle in the diffusion of more frequent hemodialysis is CMS's policy of capping payment for dialysis services at a rate of thrice weekly. Medicare's contractors have the discretion to pay for a fourth dialysis treatment if there is sufficient medical justification, such as fluid overload and congestive heart failure.

Finally, researchers might be better able to retrospectively evaluate the outcomes of patients on more frequent hemodialysis using the claims facilities submit for payment if the coding (based on the Healthcare Common Procedure Coding System) is more specific about the dialysis type. Although Medicare uses codes differentiating hemodialysis from peritoneal dialysis, specific codes are lacking to distinguish among patients on nocturnal, short daily, and conventional hemodialysis. ■

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

Each year, we assess whether specific groups of patients are disproportionately affected by facility closures. Specifically, we compare the characteristics of dialysis patients treated by facilities that were open in 2009 and 2010, that newly opened in 2010, and that closed in 2009. This analysis uses claims submitted by facilities to CMS and CMS's Dialysis Compare database and the ESRD facility survey.

Compared with facilities that remained open, facilities that closed in 2009 (90 units) were more likely to be

hospital based and nonprofit, which is consistent with long-term trends in supply (as shown in Table 6-4, p. 150). In contrast, facilities that opened in 2010 (260 units) were more likely to be freestanding and for profit, which is also consistent with the long-term trends in supply.

On net, between 2009 and 2010, the number of dialysis treatment stations, a measure of providers' capacity, increased by 4 percent. On average, facilities that closed had less capacity than new facilities and those that remained open in both years. In 2009, closures disproportionately occurred in more rural areas. Of closed facilities, 16 percent were located in rural (micropolitan) counties with a town of 10,000 people or more, 9 percent were located in rural counties adjacent to urban areas, and 6 percent were in rural counties not adjacent to urban counties. By comparison, among facilities that remained open in 2009 and 2010, 14 percent were in rural micropolitan counties, 5 percent were in rural counties adjacent to urban areas, and 3 percent were in rural counties not adjacent to urban counties.

Facility closures in 2009, which affected about 3,600 FFS dialysis patients, did not appear to affect any demographic group disproportionately, including the elderly, females, and patients dually eligible for Medicare and Medicaid. In contrast to last year's findings, this year's analysis does not find that African Americans were disproportionately affected by facility closures. African American patients represented 38 percent of patients treated at facilities that remained in business and 30 percent of patients treated at facilities that closed. About 1,000 FFS dialysis patients were affected by rural facilities that closed in 2009.

Finally, 61 percent of facilities in business in 2009 and 2010 were operated by the two largest dialysis chains; only 29 percent of facilities that closed in 2009 were operated by the two largest organizations. Consistent with our findings from last year's analysis, all demographic groups continued to obtain care from the two largest dialysis organizations that serve the majority of FFS beneficiaries.

Volume of services

To assess changes in the volume of dialysis services, we examined trends in the number of dialysis treatments furnished to beneficiaries and in the use of drugs administered during dialysis between 2009 and 2010.

Between 2009 and 2010, dialysis treatments grew at an average annual rate that kept pace with the growth in the number of FFS dialysis patients. During this period, the number of dialysis treatments grew by 5 percent per year, while the number of FFS dialysis patients grew by 4 percent per year.

Between 2009 and 2010, the mean weekly erythropoietin dose per patient declined by 1.4 percent. The slowdown in the volume of ESAs administered is linked to some physicians and facilities phasing in new prescribing protocols for dialysis drugs in anticipation of Medicare's change to a bundled payment method in 2011. In addition, new clinical evidence that demonstrated an association between higher use of ESAs and increased risk of cardiovascular morbidity and mortality may have contributed to the slowdown, as it did between 2006 and 2008 when the mean dose per patient fell by 3 percent per year (United States Renal Data System 2011).

Our analysis finds that erythropoietin use declined in 2010 across all demographic groups. We examined the subset of FFS dialysis patients who received erythropoietin in January and December 2010. There was an overall 7 percent decline in the units of erythropoietin per patient per month (Table 6-5). The decline was slightly larger for younger patients than for older patients and for African Americans than for whites.

Since 2011, industry data suggest that erythropoietin use continues to decline. Between January and June 2011, the average erythropoietin dose per patient per week furnished by the two largest dialysis chains decreased by 4 percent (Dialysis Outcomes and Practice Patterns Study 2011).

Between 2009 and 2010, the volume of all other dialysis drugs also declined (by 1 percent). For this analysis, we held the drug payment rate constant and looked at the dollar change in the total volume of the products. Rates of volume change differed by drug class. The volume of vitamin D analogs fell by 2 percent, while the volume of iron agents increased by 1 percent. The increase in iron volume is not unexpected, as researchers have shown that its use is associated with reduced average ESA dose (Hasegawa et al. 2010).

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

The Commission assesses quality of care furnished to dialysis patients using a variety of measures (clinical performance measures and beneficiaries' outcomes) and

from different perspectives (trends for all patients and patients according to type of facility).

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.[9] 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 and by facility type, we used data from the USRDS. We used industry data from the Dialysis Outcomes and Practice Patterns Study (DOPPS) to assess clinical outcomes under the new payment method (since 2011).

The conclusions of this year's assessment of changes in quality are consistent with those in last year's report. Dialysis adequacy remains high and improvements have been made in the proportion of all patients meeting the FDA's anemia status recommendations and using the type of vascular access recommended by renal clinicians. Between 2003 and 2009, mortality, while high, trended downward and hospitalization rates remained about the same. Rates of kidney transplantation increased for Asian Americans and Native Americans, remained about the same for African Americans, and decreased for whites. Some types of facilities achieved statistically significantly lower rates of standardized hospitalization and mortality rates than others.

TABLE 6–5

Monthly units of erythropoietin declined between January and December 2010

	Change in monthly units between January and December 2010
All FFS patients	–7%
Age	
Under 45 years	–8
45–64 years	–7
65–74 years	–6
75+ years	–6
Sex	
Male	–7
Female	–7
Race	
White	–5
African American	–8
Affiliated with one of 2 largest chains	–6
All other freestanding facilities	–9

Note: FFS (fee-for-service). Analysis includes FFS dialysis patients who received erythropoietin in January and December 2010 at a freestanding dialysis facility.

Source: Compiled by MedPAC from 2010 claims submitted by freestanding dialysis facilities to CMS.

Trends in clinical indicators of dialysis quality

Between 2003 and 2010, the quality of some aspects of dialysis care remained high. The proportion of dialysis patients receiving adequate dialysis (a measure of the effectiveness of the dialysis treatment in removing waste products from the body) remained high (Table 6-6, p. 156). According to this measure, from 93 percent to 95 percent of hemodialysis patients and 88 percent to 90 percent of peritoneal dialysis patients received adequate dialysis.

Also during this period, increasing proportions of dialysis patients had their anemia under control (i.e., with a mean hemoglobin between 10 g/dL and 12 g/dL). Nearly all dialysis patients have anemia because diseased kidneys typically do not produce sufficient amounts of a hormone that stimulates production of red blood cells, leading to the development of anemia. Providers furnish ESAs and injectable iron to treat anemia.

Use of the recommended type of vascular access—an arteriovenous (AV) fistula—also improved during this period. Hemodialysis patients require vascular access—the site on the patient's body where blood is removed and returned during dialysis. The three basic types of vascular access are AV fistulas, AV grafts, and catheters.[10] For most patients, the 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 (National Institute of Diabetes and Digestive and Kidney Diseases 2008). 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. Factors affecting the use of AV fistulas include certain medical contraindications preventing their use (e.g., small or weak veins) and patients' attitudes

TABLE 6–6

Dialysis clinical indicators and outcomes continue to improve for some measures

Outcome measure	2003	2005	2007	2008	2009	2010
Percent of in-center hemodialysis patients:						
Receiving adequate dialysis	94%	93%	94%	95%	95%	95%
Anemia measures						
Mean hemoglobin 10–12 g/dL	48	44	49	57	62	68
Mean hemoglobin ≥ 13 g/dL*	15	17	14	9	7	5
Mean hemoglobin < 10 g/dL*	6	5	6	6	6	7
Dialyzed with an AV fistula	33	39	47	50	53	56
Nutritional status	37	33	34	35	35	39
Phosphorus and calcium management	39	42	46	45	46	47
Percent of peritoneal dialysis patients:						
Receiving adequate dialysis	N/A	90%	89%	88%	89%	89%
Anemia measures						
Mean hemoglobin 10–12 g/dL	45%	44	48	52	57	58
Mean hemoglobin ≥ 13 g/dL*	21	22	18	14	12	11
Mean hemoglobin < 10 g/dL*	7	7	7	9	10	11
Nutritional status	21	20	20	19	18	20
Phosphorus and calcium management	40	44	46	45	47	47
	2003	**2005**	**2006**	**2007**	**2008**	**2009**
Percent of prevalent dialysis patients wait-listed for a kidney:						
All	15.2%	15.9%	16.3%	16.8%	17.0%	17.3%
White	14.2	14.8	15.2	15.7	15.9	16.2
African American	15.5	16.3	16.7	17.3	17.5	17.7
Native American	14.0	14.2	14.5	15.0	15.5	14.9
Asian American	24.4	25.2	25.2	25.6	25.6	25.7
Renal transplant rate per 100 dialysis patient years:						
All	4.8	4.8	4.8	4.4	4.2	4.1
White	5.9	5.7	5.6	5.1	4.8	4.6
African American	3.1	3.2	3.2	3.0	2.9	2.9
Native American	3.3	3.4	4.6	4.4	4.3	4.9
Asian American	5.3	5.5	6.6	7.5	7.2	7.3
One-year survival for new dialysis patients						
All	78.1%	78.9%	79.6%	79.9%	80.6	N/A
White	77.0	77.7	78.5	78.6	79.3	N/A
African American	79.3	80.3	81.0	81.5	82.6	N/A
Other race	84.2	85.0	85.3	86.1	85.8	N/A
45–64 years	84.6	85.3	85.9	86.0	86.7	N/A
65–74 years	75.5	76.5	77.5	77.5	77.9	N/A
75+ years	64.0	64.7	65.2	65.8	67.2	N/A
Annual mortality rate per 100 dialysis patient years*						
All	21.4	20.5	20.0	19.2	18.5	18.0
White	23.2	22.2	21.6	20.8	20.1	19.6
African American	19.2	18.7	18.1	17.3	16.5	16.0
Other race	16.4	15.4	14.8	14.1	13.7	13.4
45–64 years	17.4	16.6	16.3	15.6	15.0	14.5
65–74 years	28.4	27.4	26.4	25.2	24.4	23.8
75+ years	41.9	41.0	40.3	39.2	38.0	37.0
Inpatient admission rate per dialysis patient*						
All	2.0	2.0	1.9	1.9	1.9	1.8
White	2.0	2.0	1.9	1.9	1.9	1.8
African American	2.0	2.1	2.0	2.0	2.0	1.9
Native American	1.9	1.9	1.8	1.7	1.7	1.8
Asian American	1.4	1.4	1.4	1.4	1.4	1.3
45–64 years	1.9	1.9	1.9	1.8	1.8	1.8
65–74 years	2.0	2.0	1.9	1.9	1.9	1.8
75+ years	2.1	2.2	2.1	2.0	2.1	1.9
Percent of discharges that were rehospitalized within 30 days*						
All	35.8%	36.1%	N/A	35.8%	N/A	35.9%
Cardiovascular (index hospitalization)	37.2	37.7	N/A	37.5	N/A	37.6
Infection (index hospitalization)	33.6	33.9	N/A	33.7	N/A	33.8
Vascular access (index hospitalization)	32.0	31.9	N/A	31.7	N/A	31.1

Note: 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 (USRDS) adjusts data by age, gender, race, and primary diagnosis of end-stage renal disease.
* Lower values indicate higher quality.

Source: Compiled by MedPAC from 2009 Elab Project Report, Fistula First 2010, and USRDS 2010.

about using AV fistulas (American Association of Kidney Patients 2011, Xi et al. 2011).

Between 2009 and 2010, there was a modest increase in the proportion of patients achieving the mean albumin level that equals or exceeds the recommendation of the National Kidney Foundation. The level of albumin in the blood has been used by CMS and ESRD networks as a marker of nutritional status for patients. Researchers find a strong inverse correlation between albumin levels and mortality. Inflammation and infection can also affect albumin levels.

Clinical indicators related to the management of bone and mineral disorders, a frequent comorbidity of kidney failure, suggest some improvement between 2003 and 2010. About 47 percent of hemodialysis and peritoneal dialysis patients achieved the recommended range for phosphorus and calcium levels. Since 2007, the percentage of dialysis patients achieving the recommended range for these two measures has remained constant.

Finally, because data from our traditional sources (Elab Project, USRDS) end in 2009 or 2010, we used DOPPS, an industry-sponsored effort that samples, since 2010, representative facilities to obtain clinical outcome data on adequacy of dialysis, management of anemia, and management of bone disease.[11]

According to DOPPS, between January and April 2011:

- Across all patients, dialysis adequacy was unchanged after implementation of the new payment bundle. This finding held when the data were analyzed by race.
- Across all patients, mean hemoglobin measures (an assessment of anemia status) trended slightly down from 11.43 g/dL to 11.39 g/dL. By race, the proportion of patients with hemoglobin levels between 10.0 g/dL and 12.0 g/dL remained steady at between 75 percent and 79 percent for African Americans and at 79 percent for non-African Americans.[12] Among patients who have hemoglobin levels outside of this range, a greater proportion of them have higher levels (greater than 12.0 g/dL) versus lower levels (less than 10.0 g/dL).
- Overall, mean serum calcium values, a measure of bone disease, decreased from 9.07 mg/dL to 9.04 mg/dL. Mean serum calcium values trended down for both African Americans and whites from January through March 2011 and then increased slightly in April 2011.

Trends in outcomes for dialysis patients

In general, trends in outcomes—including mortality, hospitalization, and access to kidney transplantation—suggest that improvements in dialysis quality are still needed.

Between 2003 and 2009, overall adjusted mortality rates decreased but remained high among dialysis patients. By race, dialysis patients included in the "other" category (which includes Asian Americans and Native Americans) had the lowest adjusted mortality rate; this finding is a function of the lower mortality rate among Asian Americans. In contrast to the pattern seen in the general population, adjusted mortality was lower among African American dialysis patients than among white dialysis patients (16.0 vs. 19.6 per 100 patient years, respectively, in 2009) (United States Renal Data System 2011). However, new research has demonstrated an age-based effect in the racial differences in mortality. Kucirka and colleagues found that among patients new to dialysis, African Americans under age 50 years had significantly higher mortality than their white counterparts (Kucirka et al. 2011). The authors suggest that several factors, including the differential access to kidney transplantation and socioeconomic factors, may contribute to the higher mortality rates among young, but not old, African Americans compared with whites.

Mortality rates for dialysis patients increase with age, from 14.5 per 100 patient years at risk for patients between 45 and 64 years to 37.0 per 100 patient years at risk for patients 75 years or older. Similarly, one-year survival decreases with increasing age.

Overall rates of hospitalization remained steady at about two admissions per dialysis patient per year. With the exception of lower rates for Asian Americans, hospitalization rates do not vary substantially by age and race. Between 2003 and 2009, conditions related to ESRD—cardiovascular conditions, infections, and vascular access complications—accounted for the majority of inpatient admissions for dialysis patients. In 2009, among hemodialysis patients: cardiovascular conditions accounted for about 29 percent of admissions, infections accounted for 25 percent, and vascular access complications accounted for 12 percent (United States Renal Data System 2011). According to USRDS, 30-day rates of rehospitalization for dialysis patients remained high and unchanged. For example, between 2003 and 2009, hospital stays with a primary diagnosis of infection had a 30-day rehospitalization rate of about 34 percent.

Trends in kidney transplantation

Kidney transplantation is a lifesaving medical procedure for which the demand far exceeds the transplantable organ supply. Transplantation improves clinical outcomes compared with dialysis. When no living kidney donor is available, end-stage renal disease (ESRD) patients must rely on the limited supply of cadaveric donor organs.

Multiple factors affect access to kidney transplantation: (1) a kidney allocation policy that uses immunologic factors to match kidneys to potential recipients; (2) the rate of kidney transplants from living donors; (3) patients' attitudes and preferences, clinical characteristics, and socioeconomic status; (4) patients' education and referral to a transplant center by the physicians and dialysis facilities who treat dialysis and predialysis patients; and (5) the criteria used by transplant centers that determine placement on the kidney waiting list (such as physical health, mental health, social support, insurance status, and financial support).

Although the principle of equity is emphasized in the distribution of this limited resource, several studies document that kidney transplantation rates differ by patients' demographic and socioeconomic characteristics.

For example, access to kidney transplantation and organ donation rates vary by race. Data from the United States Renal Data System show that in 2009:

- White ESRD patients accounted for 61 percent of ESRD patients and received 64 percent of transplants.
- African Americans accounted for 32 percent of ESRD patients and received 25 percent of transplants.
- Asian Americans and Native Americans together accounted for 7 percent of the ESRD population and accounted for 11 percent of transplant recipients.

Researchers also find differences in access to kidney transplantation based on patients' sex and income. Compared with whites, men, and higher income patients, African Americans, women, and lower income patients were less likely to complete the pretransplant workup (Alexander and Sehgal 1998).

From the patient's perspective, the transplantation process involves a series of steps that include: (1) being educated about transplantation, (2) being interested in transplantation and referred to a transplant center, (3) completing the transplant center's workup and being placed on at least one kidney waiting list, and (4) moving up the waiting list and receiving a transplant. The factors affecting this process are complex. Unequal transplantation rates reflect (1) the matching process that considers the immunologic compatibility of donor kidneys with potential recipients; (2) patient-level factors, including patients' knowledge of renal

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We looked at several measures that examine access to kidney transplantation, because it is widely considered the best treatment option for ESRD patients. Transplantation reduces mortality and improves patients' quality of life (Eggers 1988, Kasiske et al. 2000, Laupacis et al. 1996, Ojo et al. 1994). The proportion of dialysis patients accepted on the kidney transplant waiting list showed little change over time, increasing from 17.0 percent of dialysis patients in 2008 to 17.3 percent in 2009 (Table 6-6, p. 156).

We also examined rates of kidney transplantation from 2003 to 2009. In 2009, the USRDS reported that 17,736 individuals underwent transplantation, which represents about 25 percent of the ESRD patients wait-listed for a kidney in that year. Between 2003 and 2006, rates of kidney transplantation remained relatively steady (Table 6-6) (United States Renal Data System 2011). However, between 2006 and 2009, the rate of kidney transplantation and the total number of procedures declined. Between 2006 and 2009, African Americans and whites experienced a decrease in the rate of kidney transplantation while

Trends in kidney transplantation (cont.)

treatment options, their preferences, and their clinical characteristics; and (3) provider-level factors, including the process by which nephrologists and dialysis facilities educate patients about different treatment opportunities and the evaluation process that transplant centers use to place patients on the kidney waiting list.

Lower rates of renal transplantation, particularly among African Americans, partly reflect the immunologic (including blood type and antibodies in the blood) matching process of donors to recipients. Reducing the number of biological mismatches improves the outcomes of kidney transplantation; as a result, the matching process gives priority to candidates who have fewer mismatches. Researchers report that because of racial and ethnic differences in the frequency of alleles (any one of two or more genes) at a given site on a chromosome, whites are more likely than people in other racial and ethnic groups to find a good match in the cadaver kidney pool (Roberts et al. 2004). This difference, coupled with the matching process, increases the transplantation rate among white candidates and reduces access for candidates with less common blood types and antibodies in the blood, including those who are members of minority groups (Roberts et al. 2004).

A recent study shows the importance of these immunologic factors on access to kidney transplantation. According to Hall and colleagues, a change in the relative priority given to tissue matching in 2003 significantly decreased, but did not eliminate, racial disparity in access to transplantation for individuals on the kidney waiting list (Hall et al. 2011). In 2003, the United Network for Organ Sharing, the private nonprofit organization that manages the U.S. organ transplant system, eliminated giving priority to a specific immunologic factor (HLA-B antigen) in the process that matches cadaver kidneys to potential recipients. These researchers estimate a 23 percent reduction in the disparity for wait-listed African Americans and whites after the policy change in 2003.

Differences in access may also stem from differences in transplants from live donors, which, in 2009, accounted for about 36 percent of all transplant procedures (United States Renal Data System 2011). By race, whites accounted for 73 percent of live donor procedures, compared with 13 percent for African Americans, 11 percent for Asian Americans, and 2 percent for Native Americans. Researchers note that there are fewer living donors among African Americans, increasing the dependence of African American patients on cadaver organs (Young and Gaston 2000). According to some researchers, interventions that attempt to reduce transplant disparities should prioritize the improvement of live donation rates for African Americans (Hall et al. 2011).

Differences in kidney transplantation rates may also reflect patient factors, such as lack of knowledge about transplantation, concerns about surgery and adverse

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Native Americans and Asian Americans experienced a rate increase. During that period, kidney transplants from living donors declined by 4 percent, while transplants from deceased donors declined by 1 percent. The text box summarizes issues related to the distribution of kidney transplantation across the ESRD population.

Dialysis quality varies by type of organization in 2009

According to USRDS, dialysis quality, as measured by standardized hospitalization and mortality ratios, varies across types of dialysis organizations, including large dialysis chains, smaller dialysis chains, independent facilities, and hospital-based facilities (Table 6-7, p. 161).

In 2009, for all patients, small dialysis chains had slightly lower standardized hospitalization and mortality ratios than large dialysis chains; independent (i.e., freestanding nonchain) facilities had higher standardized hospitalization ratios. Although hospital-based facilities had lower hospitalization ratios, they had the highest standardized mortality ratios among the different facility types.

Outcomes by race varied between and within organizations. Some organizations had lower

Trends in kidney transplantation (cont.)

effects of medication, and mistrust of the medical system. In addition, some patients are not able to receive a transplant because of the presence of medical contraindications, such as a recent history of substance abuse, cancer, a serious infection (including from dental disease), and significant cardiovascular disease.

Provider-level factors can also affect access to kidney transplantation. Dialysis facilities and physicians who treat dialysis patients have an important role in educating patients about renal treatment options, including transplantation and home dialysis, and referring patients to a transplant center. The literature on the relationship between the role of the dialysis facility and access to transplantation is mixed. Some researchers have found that patients treated at for-profit facilities are less likely to undergo transplantation, while other researchers have not reached this conclusion. Some dialysis providers contend that the decision about whether patients are included on the transplant wait list and ultimately undergo transplantation is the responsibility of the transplant center. Because these factors are outside of their purview, dialysis providers argue that these measures should not be used to assess their quality.

The process used by transplant centers plays an important role in determining which candidates are placed on the kidney waiting list. For most transplant centers, the process for placing individuals on the waiting list includes evaluating the patient's physical and mental health (American Society of Transplantation 2006, National Institute of Diabetes and Digestive and Kidney Diseases 2008). Other factors that transplant centers consider are the patient's ability to carry out necessary posttransplant treatment plans, patient's education, and patient's financial resources, including insurance covering the transplant procedure and the anti-rejection medicines needed after transplantation (Volk et al. 2011).[13] According to experts in the field, transplant centers' selection committees rule out patients with psychosocial barriers, including lack of or inadequate social support (no spouse, family, or friends).

In the coming year, the Commission intends to review quality improvement initiatives sponsored by the Secretary of Health and Human Services that have focused on reducing racial disparities in kidney transplantation. For example, the Centers for Disease Control and Prevention's Healthy People 2020 initiative includes objectives to increase the proportion of dialysis patients on the kidney wait list (by 10 percent to 18.8 percent) and to increase the proportion of patients with treated chronic kidney disease who receive a kidney transplant (Department of Health and Human Services 2011a). Nonetheless, neither this initiative nor the recent initiative by the Secretary to address racial disparities in minority health includes activities specific to reducing racial disparities in transplantation (Department of Health and Human Services 2011b). The Commission also intends to assess the literature on the effectiveness of public and private campaigns to reduce racial disparities in transplantation. To increase kidney transplantation rates, quality improvement efforts must be multifaceted to address the varied provider and patient factors that affect access. Recently, some researchers concluded that little is known about effective strategies for improving patients' and families' early consideration of live kidney transplantation. ■

hospitalization and mortality ratios for African Americans and higher ones for whites. By contrast, in hospital units, standardized hospitalization ratios were lower for whites and higher for African Americans. In 2009, the largest freestanding nonprofit dialysis chain, DCI, had the lowest standardized hospitalization and mortality ratios for all patients as well as separately for whites and African Americans. These data show the opportunity for quality improvement across different facility types and the role of the QIP in ensuring dialysis quality.

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. Between 2010 and 2011, the large and small dialysis chains showed similar growth rates, which suggests that both small and large providers have adequate access to capital. During this period, the number

TABLE 6–7 **Standardized hospitalization and mortality ratios for 2009 vary by provider type**

	All patients		Whites		African Americans	
Provider	**Hospitalization**	**Mortality**	**Hospitalization**	**Mortality**	**Hospitalization**	**Mortality**
Fresenius	0.99	1.00	1.02	1.00	0.96	0.98
DaVita	1.01	0.97	1.02	0.99	1.01	0.97
DCI	0.91	0.96	0.93	0.97	0.88	0.91
Other freestanding chains	0.99	0.98	1.00	1.00	1.00	0.96
Independent freestanding facilities	1.02	1.00	0.97	0.98	1.07	1.01
Hospital-based facilities	1.01	1.08	0.95	1.04	1.09	1.15

Note: The standardized hospitalization (or mortality) ratio compares the actual number of hospital admissions (or deaths) for the provider and the number of admissions that would be expected if patients under the care of that provider experienced admissions (or deaths) at the national rate for patients with similar characteristics (age, gender, race, and number of years on dialysis). A value of less than 1.0 indicates that a provider's total number of events was less than expected, based on national rates; whereas a value of greater than 1.0 indicates that a provider had a rate of total events higher than the national average. The reference cohorts are all 2009 Medicare hemodialysis patients for the standardized hospitalization ratio and all 2009 hemodialysis patients (Medicare and non-Medicare) for the standardized mortality ratio.

Source: United States Renal Data System 2011.

of hemodialysis stations grew by 5 percent—both for stations operated by the two largest organizations (Fresenius Medical Care North America and DaVita) and for those operated by smaller freestanding chains.

The two largest dialysis organizations as well as other renal companies appeared to have adequate access to capital in 2010 and 2011. For example:

- In September 2011, DaVita completed its acquisition of DSI, a midsized, for-profit, freestanding chain operating 106 clinics in 23 states for roughly $690 million.
- In 2011, DaVita purchased a company that owns two dialysis centers in Germany and manages two others.
- In December 2010, two midsized, for-profit, freestanding chains (Liberty Dialysis and Renal Advantage) merged to create the third largest dialysis chain (with 260 clinics in 32 states). Subsequently, in 2011, Fresenius purchased Liberty Dialysis for $1.7 billion.
- Fresenius purchased American Access Care Holdings, which operates outpatient clinics for procedures such as fistulas and grafts, for $385 million.
- The former chairman of a midsized chain, which was acquired by another midsized chain in 2010, announced that he is partnering with a private equity firm to create a new dialysis company that will acquire and build centers nationally (Nephrology News & Issues 2011).
- In December 2011, Ambulatory Services of America acquired Renal CarePartners. Once the acquisition is complete, Ambulatory Services of America will operate 62 facilities.

In addition to these mergers, a small chain was created as a consequence of DaVita's acquisition of DSI. To preserve competition and proceed with its acquisition of DSI, the Federal Trade Commission required DaVita to sell 30 facilities. Frazier Healthcare and New Enterprise Associates purchased the 30 facilities for $91 million and plans to operate them as one company called DSI.

These current trends in the profit status and consolidation among dialysis providers suggest that the dialysis industry is an attractive business 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).

TABLE 6–8 **Medicare margin in 2010 varies by type of freestanding provider**

Provider type	Percent of spending	Medicare margin
All	100%	2.3%
Affiliated with one of the two largest dialysis organizations	69	3.4
All others	31	0.1
Urban	85	3.4
Rural	15	–3.7
More than 10,000 treatments	54	7.7
Less than or equal to 10,000 treatments	46	–2.3

Source: Compiled by MedPAC from 2010 cost report and outpatient claims submitted by facilities to CMS.

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. The latest and most complete data available on freestanding providers' costs are from 2010.

For most facilities, 2010 is the last year that Medicare paid a prospective payment for each dialysis treatment furnished and separate payments for furnishing certain drugs during dialysis. In 2011, nearly 90 percent of all facilities were paid under a new PPS that includes dialysis drugs for which facilities previously received separate payments.

Appropriateness of current costs

Between 2005 and 2010, the cost per treatment for services paid for under the former payment system using the composite rate rose by an average 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.

Differences exist in cost growth trends and adjusted cost per treatment (adjusted for differences in labor costs and patient case mix) between the two largest dialysis organizations and all other freestanding facilities. Between 2005 and 2010, cost per treatment increased by 2.6 percent per year for facilities affiliated with the two largest chains and by 2.0 percent for all other freestanding facilities. In 2010, the cost per treatment for composite rate services standardized for differences in labor costs and patient case mix for the two largest dialysis organizations was 1 percent lower than for all other freestanding facilities.

The growth in cost per treatment between 2005 and 2010 partly stemmed from rising general and administrative costs, which increased by 4 percent per year and accounted for about 27 percent of the total cost per treatment in 2010. General and administrative costs include expenses associated with legal and accounting services, record-keeping and data-processing tasks, telephone and other utilities, home office costs, and malpractice premiums. By contrast, between 2005 and 2010, capital and labor costs (associated with direct patient care) increased by 3 percent and 2 percent per year, respectively; other direct medical costs increased by 0.5 percent per year. In 2010, capital, labor, and other direct medical costs accounted for 22 percent, 40 percent, and 11 percent, respectively, of the total cost per treatment. Cost report data do not permit us to assess which cost elements contributed to the high rate of cost growth within the general and administrative cost category.

Medicare margin for freestanding providers

For 2010, the Commission assessed payments and costs for dialysis services for freestanding dialysis facilities by comparing Medicare's payments for composite rate services and dialysis drugs with providers' Medicare-allowable costs.

For 2010, we estimate that the aggregate Medicare margin for composite rate services and dialysis drugs was 2.3 percent (Table 6-8). The distribution of margins in 2010 shows 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.

In 2008 and 2009, the aggregate Medicare margins were 3.2 percent and 3.1 percent, respectively. The modest decline in the Medicare margin in 2010 is explained by the change in drug payment and cost per treatment. Between 2009 and 2010: (1) drug payment per treatment dropped by about 5 percent and (2) drug cost per treatment declined by 3.5 percent. During this period, the volume of

ESAs and vitamin D analogs declined. As in earlier years, urban facilities had higher margins than rural facilities (3.4 percent and –3.7 percent, respectively), and facilities affiliated with the two largest dialysis organizations tended to have higher margins than other freestanding facilities (3.4 percent and 0.1 percent, respectively). The number of treatments a facility furnishes also affects the Medicare margin; in 2010, the margin for higher volume facilities was 7.7 percent, compared with –2.3 percent for lower volume facilities.

The Commission is concerned that the gap in the Medicare margin widened between urban and rural facilities between 2009 and 2010 (Medicare Payment Advisory Commission 2010). We will continue to monitor the adequacy of Medicare's payments for rural and urban facilities in the coming years. The low-volume adjuster in the new payment method should disproportionately benefit rural facilities. Our analysis of 2007–2009 cost reports finds that while 22 percent of all facilities are rural, 44 percent of facilities meeting CMS's definition of low volume are rural. We are also analyzing changes that would better target the low-volume adjuster to facilities that are both isolated and low volume, which would also benefit rural facilities.

On the basis of 2010 payment and cost data, we project that the 2012 aggregate margin will be 2.7 percent. This estimate reflects:

- the 2 percent reduction in total spending that MIPPA mandated to begin in 2011,
- the 3.1 percent budget-neutrality adjustment in 2011 that CMS applied between January and April 2011,
- the 2011 payment update of 2.5 percent and the 2012 payment update of 2.1 percent,
- the reduction of 0.2 percent of payments due to implementation of the QIP in 2012, and
- a conservative behavioral offset to account for efficiencies anticipated under the new payment method.

The conservative behavioral offset included in the 2011 margin projection is based on industry data that providers have become more efficient in the delivery of drugs under the new payment method (Dialysis Outcomes and Practice Patterns Study 2011). The high rate of facilities opting into the new payment method (nearly 90 percent) suggests that most can operate within the provisions of the new payment method. Published studies also suggest that providers can decrease costs while maintaining quality (Hasegawa et al. 2010, Kaufman et al. 1998, Pizzi et al. 2006). Charytan summarized the following selected strategies to maximize efficiencies in the management of anemia: switching from intravenous to subcutaneous routes, lowering hemoglobin targets and doses in hyporesponsive patients, increasing administration of intravenous iron, increasing use of home dialysis, and optimizing ESA dosing intervals (Charytan 2010).

TABLE 6–9 **Estimated impact of the quality incentive program, 2012–2014**

Estimated reduction in payments due to QIP	2012	2013	2014
Total impact	–0.19%	–0.29%	–0.27%
Percent of facilities, by estimated reduction			
0%	74	82	70
0.5% to 1%	21	5	23
1.5%	4	6	4
2%	1	7	3

Note: QIP (quality improvement program).

Source: CMS 2011 final rules.

How should Medicare payments change in 2013?

The effect of the QIP in 2013 on Medicare's payments to dialysis facilities is not modeled in the Commission's projection of the 2012 aggregate Medicare margin. In 2013, the year of the Commission's update recommendation, CMS predicted that the impact of the QIP would decrease total payments by 0.29 percent (Table 6-9). CMS estimated that reductions would be greater in 2013 and 2014 compared with 2012. In addition, the full impact of the QIP—a reduction of up to 2 percent—will affect more facilities in 2013 than in 2012 and 2014.

Update recommendation

The evidence on payment adequacy suggests that a moderate update of the outpatient dialysis payment rate is in order to ensure continued beneficiary access to outpatient dialysis services. Therefore, the Commission recommends that the Congress update the outpatient dialysis payment rate by 1 percent for calendar year 2013.

RECOMMENDATION 6

The Congress should update the outpatient dialysis payment rate by 1 percent for calendar year 2013.

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. The Medicare margin in 2010 was 2.3 percent, and we project that it will be 2.7 percent in 2012.

IMPLICATIONS 6

Spending

- Under current law, if current projections were used, the payment rate would be updated by the ESRD market basket less a productivity adjustment, an update of 1.9 percent. This recommendation would decrease federal program spending relative to current law by between $50 million and $250 million in 2013 and by less than $1 billion over five years. The spending implication of this recommendation is based on Medicare spending projections that were made prior to a sequester, as the recommendation was developed and voted on before the sequester was triggered and became current law. If a Medicare sequester does occur, it will change the spending implication of the recommendation.

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. ■

Endnotes

1 To be eligible for Medicare ESRD benefits: (1) the individual must file an application for Medicare with Social Security; (2) a physician must certify that the individual requires chronic dialysis or a kidney transplant to maintain life; and (3) the individual must be entitled to a monthly benefit under Social Security, be fully or currently insured under Social Security, or be the spouse or dependent child of a person meeting these Social Security requirements. Individuals qualify for Social Security by earning Social Security credits when employed in a job that pays Social Security taxes. Generally, individuals are fully insured under Social Security if they have 40 credits of covered employment. Individuals are currently insured under Social Security if they have a minimum of 6 credits of covered employment in the three years before ESRD diagnosis (http://www.ssa.gov/pubs/10072.html). Individuals who are not eligible for Social Security have not earned a minimum of credits toward retirement under Social Security.

2 New dialysis patients include those who are not eligible for Medicare either because they do not meet the eligibility criteria (explained in Endnote 1) or because they have not yet applied for Medicare coverage.

3 The proportion of all dialysis patients and FFS patients with Medicare as the secondary payer may be underestimated because of the extent to which Medicare's enrollment databases do not identify patients with private insurance.

4 Beneficiaries with ESRD on dialysis cannot join an MA plan unless they developed ESRD while already enrolled in an MA plan. Enrollment in an ESRD special needs plan or the ESRD demonstration program are exceptions to this statutory provision.

5 The base prospective payment under the former payment method of $162 per treatment is inclusive of the drug add-on payment of about $20 per treatment.

6 Some observers are concerned that CMS's proposed approach for updating the base rate per dialysis treatment (by dividing the sum of Part D payments in 2007 by total treatments) may not reflect their cost of furnishing these drugs. They contend that the agency's proposed approach will not cover their costs because the Part D spending data do not reflect the drug use of dialysis FFS patients who are not enrolled in a Part D plan.

7 CMS requires that dialysis facilities provide documentation in the patient's medical record to support any diagnosis recognized for a payment adjustment (Centers for Medicare & Medicaid Services 2010).

8 Medicare pays for a maximum of six kidney disease education sessions for beneficiaries with stage IV chronic kidney disease, the precursor to kidney failure. The statute permits only qualified persons to furnish such education services, such as physicians, physician assistants, nurse practitioners, and clinical nurse specialists. In addition, providers of services (e.g., hospitals, critical access hospitals) in rural areas can furnish kidney disease services. The statute precludes dialysis facilities from providing kidney disease education sessions regardless of the provider's geographic location (Centers for Medicare & Medicaid Services 2009).

9 For 2010, the Elab Project collected laboratory data (for the fourth calendar quarter) from 5,472 facilities for about 97 percent of all dialysis patients in the United States. Facilities submit the first laboratory value of the month for October, November, and December of each year (Renal Network of the Upper Midwest 2011).

10 Physicians 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. Physicians 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.

11 DOPPS is based on a sample of about 145 facilities and is designed to provide results representative nationally and by dialysis organization size, location of facility (rural versus urban), and facility type (freestanding versus hospital based). Laboratory data (e.g., hemoglobin levels) are generally based on a monthly value reported by sampled facilities (Robinson et al. 2011).

12 Since 2011, the FDA no longer recommends a target hemoglobin range for dialysis patients with ESAs. According to the FDA, providers should initiate ESA therapy when a patient's hemoglobin level is less than 10.0 g/dL and reduce or interrupt the ESA dose when a patient's hemoglobin level approaches or exceeds 11.0 g/dL. By contrast, the National Kidney Foundation recommends a target hemoglobin range of 11.0 g/dL to 12.0 g/dL.

13 Medicare covers anti-rejection medicines. However, for beneficiaries under age 65 entitled to Medicare because of ESRD alone, their Medicare entitlement ends 36 months after the month of the transplant.

References

Alexander, G. C., and A. R. Sehgal. 1998. Barriers to cadaveric renal transplantation among blacks, women, and the poor. *Journal of the American Medical Association* 280, no. 13 (October 7): 1148–1152.

American Association of Kidney Patients. 2011. *Understanding your hemodialysis access options*. Tampa, FL: AAKP.

American Renal Holdings. 2011. *Form 10-K for the fiscal year ended December 31, 2010*. Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Commission file number 333–170376. http://www.sec.gov/Archives/edgar/data/1504735/000119312511084560/d10k.htm

American Society of Transplantation. 2006. *Getting a kidney: Facts about kidney transplants*. Mount Laurel, NJ: AST. http://www.a-s-t.org/files/pdf/patient_education/english/AST-EdBroNEWKIDNEY-ENG.pdf.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2009. Coverage of kidney disease patient education services. Change request 6557. Pub 100–04 Medicare claims processing. CMS manual system. December 18. http://www.cms.gov/transmittals/downloads/R1876CP.pdf.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2010. Medicare program; end stage renal disease prospective payment system. Final rule. *Federal Register* 75, no. 155 (August 12): 49029–49214.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2011a. *Medicare benefit policy manual: Chapter 11—End stage renal disease (ESRD)*. Rev. 136, 01–28–11. Baltimore, MD: CMS.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2011b. Medicare programs: Changes to the end-stage renal disease prospective payment system transition budget-neutrality adjustment. Interim final rule. *Federal Register* 76, no. 66 (April 6): 18930–18934.

Charytan, C. 2010. Bundled-rate legislation for Medicare reimbursement for dialysis services: implications for anemia management with ESAs. *Clinical Journal of the American Society of Nephrology* 5, no. 12 (December): 2355–2362.

Culleton, B. F., M. Walsh, S. W. Klarenbach, et al. 2007. Effect of frequent nocturnal hemodialysis vs conventional hemodialysis on left ventricular mass and quality of life: A randomized controlled trial. *Journal of the American Medical Association* 298, no. 11 (September 19): 1291–1299.

DaVita Inc. 2010. *Form 10–K for the fiscal year ended December 31, 2009*. Commission file number 1–14106. Annual report pursuant to section 13 and 15(d) of the Securities and Exchange Act of 1934.

Department of Health and Human Services. 2011a. Healthy people 2020. http://healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=6.

Department of Health and Human Services. 2011b. *HHS action plan to reduce racial and ethnic health disparities*. Washington, DC: HHS. http://www.minorityhealth.hhs.gov/npa/files/Plans/HHS/HHS_Plan_complete.pdf.

Dialysis Outcomes and Practice Patterns Study. 2011. DOPPS practice monitor. http://www.dopps.org/DPM/.

Eggers, P. W. 1988. Effect of transplantation on the Medicare end-stage renal disease program. *New England Journal of Medicine* 318, no. 4 (January 28): 223–229.

Food and Drug Administration. 2011. Prescribing information for Epogen® (epoetin alfa). http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/103234Orig1s5166_103234Orig1s5266lbl.pdf.

Fresenius Medical Care AG & Co. KGaA. 2006. Fresenius Medical Care completes the acquisition of the phosphate binder business from Nabi Biopharmaceuticals. http://www.fmc-ag.com/640.htm.

Fresenius Medical Care AG & Co. KGaA. 2010. *Form 20-F*. Annual report for the fiscal year ended December 31, 2010 pursuant to section 13 and 15(d) of the Securities and Exchange Act of 1934. http://www.fmc-ag.com/files/20F_2010.pdf.

Golper, T. A., A. B. Saxena, B. Piraino, et al. 2011. Systematic barriers to the effective delivery of home dialysis in the United States: A report from the Public Policy/Advocacy Committee of the North American Chapter of the International Society for Peritoneal Dialysis. *American Journal of Kidney Diseases* 58, no. 6 (December): 879–885.

Hall, E. C., A. B. Massie, N. T. James, et al. 2011. Effect of eliminating priority points for HLA-B matching on racial disparities in kidney transplant rates. *American Journal of Kidney Diseases* 58, no. 5 (November): 813–816.

Hasegawa, T., J. L. Bragg-Gresham, R. L. Pisoni, et al. 2010. Changes in anemia management and hemoglobin levels following revision of a bundling policy to incorporate recombinant human erythropoietin. *Kidney International* (October 20): Epub ahead of print.

Home Dialysis Central. 2011. Growth in home dialysis. http://www.homedialysis.org/growth/.

Kasiske, B. L., D. Cohen, M. R. Lucey, et al. 2000. Payment for immunosuppression after organ transplantation. American Society of Transplantation. *Journal of the American Medical Association* 283, no. 18 (May 10): 2445–2450.

Kaufman, J. S., D. J. Reda, C. L. Fye, et al. 1998. Subcutaneous compared with intravenous epoetin in patients receiving hemodialysis. Department of Veterans Affairs Cooperative Study Group on Erythropoietin in Hemodialysis Patients. *New England Journal of Medicine* 339, no. 9 (August 27): 578–583.

Kucirka, L. M., M. E. Grams, J. Lessler, et al. 2011. Association of race and age with survival among patients undergoing dialysis. *Journal of the American Medical Association* 306, no. 6 (August 10): 620–626.

Laupacis, A., P. Keown, N. Pus, et al. 1996. A study of the quality of life and cost-utility of renal transplantation. *Kidney International* 50, no. 1 (July): 235–242.

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

Medicare Payment Advisory Commission. 2010. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

Mehrotra, R., P. Blake, N. Berman, et al. 2002. An analysis of dialysis training in the United States and Canada. *American Journal of Kidney Diseases* 40, no. 1 (July): 152–160.

National Institute of Diabetes and Digestive and Kidney Diseases. 2008. *Vascular access for hemodialysis*. Bethesda, MD: NIDDK. http://kidney.niddk.nih.gov/kudiseases/pubs/vascularaccess/index.htm.

National Institutes of Health. 2010. More frequent dialysis improves health of kidney patients. NIH Research Matters. December 6. http://www.nih.gov/researchmatters/december2010/12062010dialysis.htm.

Nephrology News & Issues. 2011. Former Dialysis Corporation of America chairman to start new dialysis company. http://www.nephrologynews.com/print.aspx?articleid=6207.

Ojo, A. O., F. K. Port, R. A. Wolfe, et al. 1994. Comparative mortality risks of chronic dialysis and cadaveric transplantation in black end-stage renal disease patients. *American Journal of Kidney Diseases* 24, no. 1 (July): 59–64.

Pizzi, L. T., N. M. Patel, V. M. Maio, et al. 2006. Economic implications of non-adherence to treatment recommendations for hemodialysis patients with anemia. *Dialysis & Transplantation* 35, no. 11: 660–671.

Renal Network of the Upper Midwest. 2011. *National 2010 and trends: Elab report.* St. Paul, MN: Renal Network of the Upper Midwest/End Stage Renal Disease Network 11. http://www.esrdnet11.org/Elab/elab_national_2010_and_trends_report.pdf.

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

Roberts, J. P., R. A. Wolfe, J. L. Bragg-Gresham, et al. 2004. Effect of changing the priority for HLA matching on the rates and outcomes of kidney transplantation in minority groups. *New England Journal of Medicine* 350, no. 6 (February 5): 545–551.

Robinson, B., D. Fuller, D. Zinsser, et al. 2011. The Dialysis Outcomes and Practice Patterns Study (DOPPS) Practice Monitor: Rationale and methods for an initiative to monitor the new US bundled dialysis payment system. *American Journal of Kidney Diseases* 57, no. 6 (June): 822–831.

Rocco, M. V., R. S. Lockridge, Jr., G. J. Beck, et al. 2011. The effects of frequent nocturnal home hemodialysis: The Frequent Hemodialysis Network Nocturnal Trial. *Kidney International* 80, no. 10 (November): 1080–1091.

United States Renal Data System, National Institute of Diabetes and Digestive and Kidney Diseases. 2010. *USRDS 2010 annual data report*. Bethesda, MD: NIDDK.

United States Renal Data System, National Institute of Diabetes and Digestive and Kidney Diseases. 2011. *USRDS 2011 annual data report*. Bethesda, MD: NIDDK.

Volk, M. L., S. W. Biggins, M. A. Huang, et al. 2011. Decision making in liver transplant selection committees: A multicenter study. *Annals of Internal Medicine* 155, no. 8 (October 18): 503–508.

Xi, W., L. Harwood, M. J. Diamant, et al. 2011. Patient attitudes towards the arteriovenous fistula: A qualitative study on vascular access decision making. *Nephrology Dialysis Transplantation* 26, no. 10 (October): 3302–3308.

Young, C. J., and R. S. Gaston. 2000. Renal transplantation in black Americans. *New England Journal of Medicine* 343, no. 21 (November 23): 1545–1552.