

SECTION
2D

Outpatient dialysis services

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

- 2D** The Congress should update the composite rate by the projected rate of increase in the end-stage renal disease market basket less the adjustment for productivity growth for calendar year 2011.

COMMISSIONER VOTES: YES 15 • NO 0 • NOT VOTING 1 • ABSENT 1

Outpatient dialysis services

Section summary

Outpatient dialysis services are used to treat individuals with end-stage renal disease (ESRD). In 2008, about 330,000 beneficiaries were covered by Medicare and received dialysis from nearly 5,000 ESRD facilities. In that year, Medicare expenditures for outpatient dialysis services, including separately billable drugs administered during dialysis, were \$8.6 billion.

Assessment of payment adequacy

Our payment adequacy indicators for outpatient dialysis services are generally positive. Our analysis suggests that a moderate update of the composite rate is in order and that dialysis providers can achieve efficiency gains similar to those in the economy at large. Therefore, the Commission recommends updating the composite rate for calendar year 2011 by the projected rate of increase in the ESRD market basket less the adjustment for productivity growth. Based on CMS’s latest forecast of the market basket, this recommendation would yield an update of 0.7 percent.

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.

- **Capacity and supply of provider**—Dialysis facilities appear to have the capacity to meet beneficiaries’ demand. Growth in the number of dialysis

In this section

- Are Medicare payments adequate in 2010?
- How should Medicare payments change in 2011?

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

- ***Beneficiaries' ability to obtain care***—The number of ESRD facilities continues to increase. The few facility closures do not appear to disproportionately affect African Americans or beneficiaries dually eligible for Medicare and Medicaid. Freestanding facilities, which treat most dialysis beneficiaries, did not change the proportion of African American, dual eligibles, or elderly treated between 2007 and 2008.
- ***Volume of services***—Since 1996, the number of dialysis treatments grew at an average annual rate that kept pace with growth in the number of beneficiaries. Statutory and regulatory changes that CMS implemented beginning in 2005 reversed spending trends for dialysis drugs. Although spending on dialysis drugs decreased since 2004, our analysis suggests that the volume of drugs increased but at a slower rate than in previous years.

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 dialysis. Other measures suggest that improvements in quality are still needed. In particular, the proportion of all dialysis patients accepted for the registry on the kidney transplant waiting list remains low and rates of hospitalization and mortality remain high.

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

Medicare payments and providers' costs—In 2008, the Medicare margin for composite rate services and dialysis drugs for freestanding facilities was 3.2 percent. We project the Medicare margin for freestanding dialysis facilities will be 2.5 percent in 2010. This projection reflects the 1 percent update to the composite rate effective in 2009 and 2010, which is less than CMS's forecast of the increases in providers' costs during this period. This projection does not take into account the 2 percent reduction in total spending that the Medicare Improvements for Patients and Providers Act of 2008 mandated to begin in 2011 under the new dialysis payment method because: (1) the regulatory provisions to implement the new payment method are not finalized and (2) providers' response to the new payment method is unknown. Including drugs and services in the payment bundle that Medicare now separately pays for may lead to improvements in the efficiency of care. ■

Dialysis treatment choices

Dialysis is a treatment to replace 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. 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. Each dialysis method (modality) 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, personal preference, physician recommendation, and awareness of different treatment methods. Some patients switch from one dialysis method to another when their needs or condition changes. The advantages and disadvantages of the different dialysis methods are summarized in Table 2D-A1 in the online appendix to this chapter. ■

Background

End-stage renal disease (ESRD) is a chronic illness characterized by permanent 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 undergone kidney transplantation and have a functioning kidney transplant. Because of the limited number of kidneys available for transplantation, 70 percent of ESRD patients undergo dialysis. The text box summarizes the two 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, even those under age 65. 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 beneficiaries.

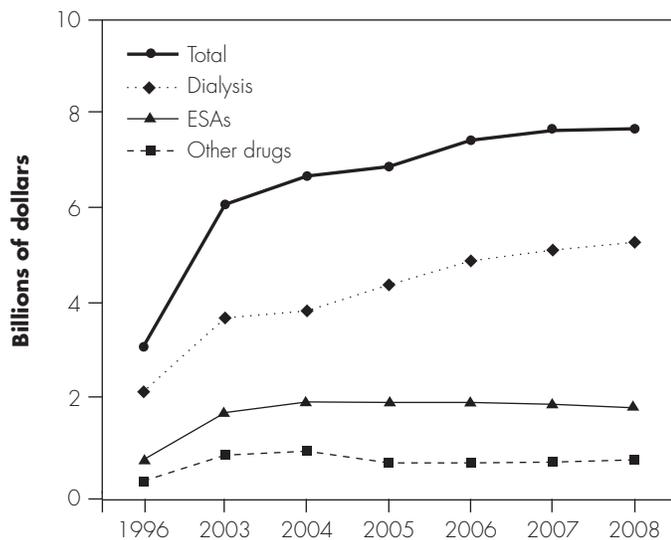
For beneficiaries entitled to benefits due to ESRD alone, Medicare coverage does not begin until the fourth month after the start of dialysis. Exceptions to this statutory provision are beneficiaries who have undergone a kidney transplant or who are trained to perform dialysis at home.

About half of new ESRD patients are under age 65 and thus are entitled to Medicare because they have chronic renal failure. In 2008, there were an estimated 110,000 new dialysis patients.²

If an employer group health plan (EGHP) covers a beneficiary at the time of ESRD diagnosis, it is the primary payer for the first 33 months of care. Medicare is the secondary payer during this period. 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.

In 2008, about 330,000 dialysis beneficiaries were covered by the Medicare program.³ Compared with all Medicare beneficiaries, dialysis beneficiaries are disproportionately younger and African American. A substantial number of dialysis patients are dually eligible for Medicare and Medicaid benefits: about one-quarter of newly diagnosed ESRD patients and 45 percent of current ESRD patients. About one-quarter of newly diagnosed patients were covered by an EGHP (United States Renal Data System 2009).

Most dialysis beneficiaries receive care in freestanding dialysis facilities. Such facilities account for 89 percent of all facilities and treat about 90 percent of dialysis beneficiaries. The two largest dialysis organizations supply the major portion of this industry’s output; in 2008, they operated 60 percent of all facilities and treated about 65 percent of dialysis beneficiaries.

**FIGURE
2D-1****Statute and regulations changed trends in payments to freestanding dialysis facilities beginning in 2005**

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

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

Since 1983, Medicare pays dialysis facilities a predetermined payment for each dialysis treatment they furnish. Under the prospective payment—the composite rate—Medicare covers the cost of some (but not all) services associated with a single dialysis treatment, including nursing, dietary counseling and other clinical services, dialysis equipment and supplies, social services, and certain laboratory tests and drugs. In addition, Medicare pays separately for certain drugs and laboratory tests that have become a routine part of care since 1983. Since 2005, Medicare has paid providers an add-on payment to the composite rate. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) created this add-on payment by shifting some of the payments previously associated with separately billable dialysis drugs to the composite rate (via the add-on payment) and mandated that these changes occur in a budget-neutral manner.

In 2008, payment for composite rate services (including the add-on payment) averaged about \$158 per treatment, while the payment for drugs used to treat conditions resulting from the loss of kidney function (referred to in this chapter as dialysis drugs) averaged nearly \$75 per

treatment. The Commission's Payment Basics provides more information about Medicare's method for paying for outpatient dialysis services (available at http://www.medpac.gov/documents/MedPAC_Payment_Basics_09_dialysis.pdf).

Medicare spending on outpatient dialysis services

For both freestanding and hospital-based facilities, Medicare spending for dialysis services, including separately billable drugs administered during dialysis, totaled about \$8.6 billion in 2008, an increase of 0.3 percent compared with 2007. Medicare expenditures for composite rate services and dialysis drugs averaged about \$26,000 per beneficiary in 2008.

Freestanding facilities treat most dialysis beneficiaries and account for nearly 90 percent of spending (about \$7.8 billion in 2008) for composite rate services and dialysis drugs. Since 2004, total payments to dialysis facilities grew more slowly than in the past because spending on dialysis drugs decreased (Figure 2D-1). Between 1996 and 2004, expenditures for composite rate services and dialysis drugs increased by about 10 percent per year but then slowed between 2004 and 2008 to a 4 percent average annual increase. Specifically:

- Since 2005, drug expenditures to freestanding dialysis providers declined by 3 percent per year (from \$2.8 billion to \$2.5 billion). By contrast, between 1996 and 2004, dialysis drug expenditures grew by 15 percent per year, from \$951 million to \$2.8 billion.
- Before and after 2005, expenditures for composite rate services increased at about the same annual rate—8 percent.

The decline in spending on dialysis drugs is partly due to provisions in the MMA that, beginning in 2005, increased Medicare's payment rate for composite rate services but lowered the rate for dialysis drugs. The MMA required that CMS base payment amounts for all dialysis drugs on providers' acquisition costs, which has resulted in a lower payment rate for most dialysis drugs.⁴ Since 2006, the agency pays 106 percent of the average sales price for dialysis drugs.

Despite the decrease in the payment rate, the total volume of dialysis drugs increased between 2004 and 2007. Between 2007 and 2008, the volume of most dialysis drugs continued to increase with one notable exception. The volume of erythropoiesis-stimulating

agents (ESAs) declined during this period. ESAs are drugs (erythropoietin and darbepoetin alpha) used to treat anemia, a common condition among dialysis patients, and account for nearly 70 percent of spending on dialysis drugs. The recent decline in ESA volume is linked to: (1) changes in CMS's payment policies for ESAs and (2) new clinical evidence about the appropriate use of ESAs. We discuss these two changes in more detail later in the chapter.

A new dialysis prospective payment method is planned to begin in 2011

While the MMA decreased the profitability of most dialysis drugs, the law did not change the two-part structure of the outpatient dialysis payment method. However, the Congress recently passed a law—the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)—that will modernize the payment method by including dialysis drugs in the payment bundle beginning in 2011. MIPPA calls for CMS to implement a new dialysis prospective payment system (PPS) that would broaden the dialysis payment bundle beginning in 2011 and initiate a quality incentive program beginning 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 have repeatedly said that Medicare could provide incentives for controlling costs and promoting quality care by broadening the bundle to include drugs, laboratory services, and other commonly furnished items that providers currently bill separately and by linking payment to quality. A bundled rate would create incentives for facilities to furnish services more efficiently. For example, a bundled rate would reduce incentives inherent in the current payment method to overutilize drugs.

CMS issued a proposed rule in September 2009 that, if finalized, would enact MIPPA's provisions by making three key changes to the outpatient dialysis payment method. Table 2D-1 (p. 122) compares the proposed provisions with the current payment method. The first change to the payment method concerns definition of the payment bundle. Beginning in 2011, the proposed dialysis payment bundle would include:

- composite rate services,
- Part B separately billable drugs furnished by the facility,

- separately billable laboratory tests ordered by the facility and separately billable laboratory tests (performed by independent laboratories) ordered by physicians who are paid the monthly capitation payment amount,
- Part B separately billable equipment and supplies furnished by the facility,
- selected ESRD-related Part D drugs, and
- self-dialysis training services.

Second, CMS's proposal would increase the number of beneficiary-level and facility-level payment adjusters. MIPPA gave the Secretary the authority to adjust the payment rate by appropriate factors that affect providers' costs. The agency proposed augmenting the current beneficiary-level adjusters used for adults—age and body mass—by including beneficiaries' sex, the presence of selected comorbidities, and onset of dialysis (for the first four months of dialysis treatment).⁵ For adults, CMS's proposal would maintain the same payment rate for the different types of dialysis methods. For pediatric beneficiaries, CMS proposed adjusting payment by age, the presence of selected comorbidities, and dialysis method.⁶ Under the current payment method, beneficiary-level adjusters are not used for pediatric beneficiaries.

MIPAA required a facility-level adjustment for low-volume facilities. CMS's proposal defines a low-volume facility as one that furnished 3,000 or fewer treatments annually in the three years before the payment year. Included in the facility's treatment total would be treatments provided by facilities owned by the same organization that are located within 25 miles of the facility in question. The new payment method would continue to use the same wage index that is used under the current payment method (the acute care hospital wage index).

Although MIPPA gave the Secretary the authority to change the unit of payment, CMS's proposal maintains the current unit of payment as a single dialysis treatment. The new payment method will be phased in over three years; facilities may elect to bypass the transition (by notifying CMS 60 days before January 1, 2011).

A third change is proposed for calendar year 2012 with implementation of a quality incentive program, which MIPPA mandated. CMS is proposing a pay-for-performance initiative using two measures that assess anemia management and one measure that assesses

**TABLE
2D-1**

Key features of the current dialysis payment method and the proposed prospective payment method that is expected to begin in 2011

Payment method feature	Current payment method	Proposed new payment method
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.	<ul style="list-style-type: none"> • Composite rate services • Separately billable (Part B) injectable dialysis drugs and their oral equivalents • ESRD-related laboratory tests • Selected ESRD Part D drugs • Self-dialysis training services
Unit of payment	Single dialysis treatment	Single dialysis treatment
Add-on payment to the composite rate	Yes	None
Self-dialysis training services adjustment	Yes	None
Beneficiary-level adjustments	<ul style="list-style-type: none"> • For adults: age and body mass • For pediatric beneficiaries: none 	<ul style="list-style-type: none"> • For adults: age, sex, dialysis onset, body mass, 11 comorbidities • For pediatric patients: age, presence of four comorbidities, dialysis method
Facility-level adjustments	Wage index	<ul style="list-style-type: none"> • Wage index • Low-volume adjustment
Outlier policy	None	Applies to the portion of the broader payment bundle composed of the drugs and services that are currently separately billable
Quality incentive program	None	Begins in 2012

Note: ESRD (end-stage renal disease).

Source: MedPAC analysis of CMS 2009 proposed ESRD rule.

dialysis adequacy. This information would be obtained from claims submitted by ESRD facilities. Facilities that do not meet the performance standard could receive up to a 2 percent reduction in their payment rate.

As CMS phases in the new PPS, the Commission intends to continue its annual assessment of payment adequacy by examining beneficiaries' access to care, changes in dialysis quality of care and providers' access to capital, and the relationship between Medicare's payments and providers' costs. In addition, the Commission is developing new beneficiary quality measures, including rates of rehospitalization.

Providers of outpatient dialysis services

During the past six years, an increasing proportion of dialysis facilities are freestanding, owned by publicly

traded companies, operated by a chain (i.e., multifacility enterprises), and for profit (Table 2D-2 and Figure 2D-2, p. 124). By chain, we mean facilities operated under common ownership; CMS's Dialysis Facility Compare database indicates "whether or not the facility is owned or managed by a chain organization." Recently, the dialysis sector has evolved into an oligopoly, in which a small number of firms supply the major portion of an industry's output. In 2005 and 2006, the four largest dialysis organizations merged into two for-profit organizations. Together the two largest dialysis organizations (Fresenius Medical Care North America and DaVita) account for about 60 percent of all facilities and about 70 percent of freestanding facilities (Figure 2D-2). The recent trends in the profit status and consolidation among dialysis providers suggest that the dialysis industry is an attractive business to for-profit

**TABLE
2D-2****The total number of dialysis facilities is growing; for-profit and freestanding dialysis providers are a larger share over time**

	2009	Average annual percent change	
		2003-2009	2008-2009
Total number of dialysis facilities	5,211	3.5%	5.1%
Number of dialysis stations			
Total	91,465	4.0	5.4
Mean (per facility)	17.6	0.5	0.3
	Percent of facilities	Average annual percent change in number of facilities	
Nonchain	21%	-2.3%	3.6%
Affiliated with any chain	79	5.5	5.5
Affiliated with one of the two large dialysis organizations	60	4.5	6.8
Rural	25	3.2	4.2
Urban	75	3.6	5.8
Freestanding	89	4.4	5.9
Hospital based	11	-2.5	-3.9
For profit	81	4.7	5.9
Nonprofit	19	-0.7	1.9

Note: Nonprofit includes those designated as either nonprofit or government.

Source: Compiled by MedPAC from the 2003, 2008, and 2009 Dialysis Facility Compare database from CMS.

providers and that there are efficiencies and economies of scale in providing dialysis care.

Since 2003, freestanding facilities have increased by more than 4 percent annually and currently account for 89 percent of all facilities (Table 2D-2). During this period, for-profit facilities have increased at 4.7 percent per year and account for 81 percent of all facilities. The number of hospital-based facilities decreased from 660 to 566 during this time (data not shown). Most freestanding facilities (91 percent) are for profit; by contrast, most hospital-based facilities (94 percent) are nonprofit (data not shown). Most freestanding dialysis facilities (87 percent) are affiliated with a chain, whereas most hospital-based facilities (79 percent) are not operated by a chain (data not shown). In terms of size, as measured by the number of dialysis treatment stations (i.e., the equipment used to provide dialysis to a patient), freestanding facilities are, on average, larger than hospital-based facilities (data not

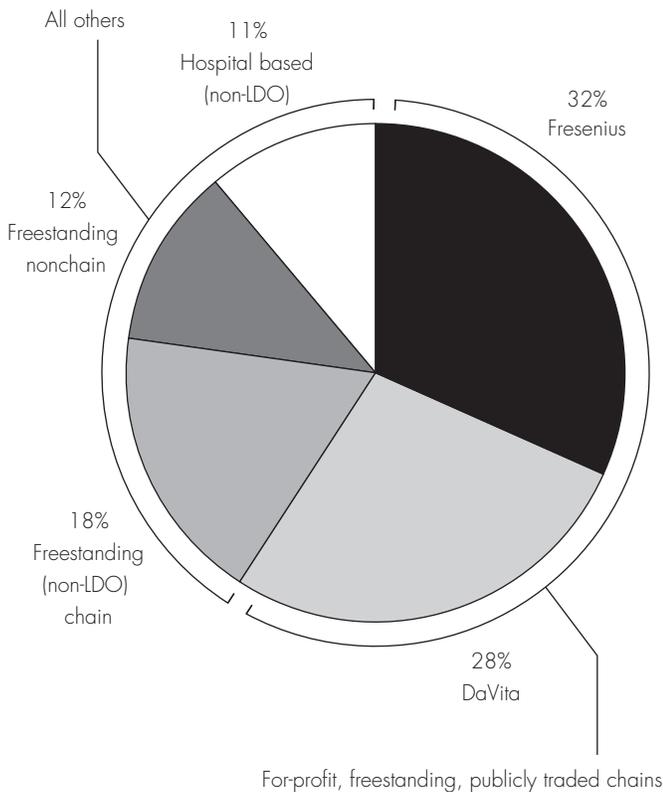
shown). In 2009, freestanding facilities had 18 dialysis stations, on average, while hospital-based facilities averaged 14 stations (data not shown).

About one-quarter of dialysis facilities are located in rural areas. Rural and urban facilities have grown at similar rates during the past five years. However, between 2008 and 2009, urban facilities grew at a higher rate than rural facilities (5.8 percent vs. 4.2 percent, respectively). Freestanding facilities account for 85 percent of all facilities in rural areas, while hospital-based facilities account for the remainder. The two largest dialysis organizations, which together operate in 48 states, account for about 60 percent of all facilities in rural areas.

Medicare is the principal payer for most dialysis facilities. Our analysis of cost reports submitted by freestanding dialysis facilities indicates that Medicare accounts for about three-quarters of treatments furnished by freestanding facilities.

**FIGURE
2D-2**

The dialysis industry is composed primarily of freestanding, for-profit facilities affiliated with a chain, 2009



Note: LDO (two largest dialysis organizations). Fresenius Medical Care North America and DaVita are the two LDOs. The LDOs operate freestanding facilities. Facilities included in the "freestanding chain" category are freestanding facilities that are operated by a chain other than the LDOs. Total may not sum to 100 percent due to rounding.

Source: Compiled by MedPAC from the 2009 Dialysis Facility Compare database from CMS.

Are Medicare payments adequate in 2010?

To address whether payments for the current year (2010) are adequate to cover the costs that efficient providers incur and how much providers' costs should change in the coming year (2011), we examine several indicators of payment adequacy. Specifically, we assess beneficiaries' access to care by examining the capacity and supply 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:

sufficient provider capacity, volume growth keeping pace with beneficiary growth, some quality improvements, and sufficient provider access to capital. The Medicare margin for composite rate services and dialysis drugs was 3.2 percent in 2008. We project the Medicare margin for composite rate services and dialysis drugs will be 2.5 percent in 2010.

Beneficiaries' access to care: Indicators continue to be favorable

Our analysis of access indicators shows that beneficiary access to care remains favorable. These indicators include the capacity of providers to meet beneficiary demand, changes in patients' ability to obtain different types of dialysis, whether certain beneficiary groups face problems in obtaining care, and the change in the volume of services furnished to beneficiaries.

Capacity and supply of providers: Capacity has kept pace with beneficiary demand

Growth in the number of dialysis stations and dialysis beneficiaries suggests that provider capacity has kept up with the demand for care during the past decade. Between 1996 and 2008, the number of dialysis beneficiaries and the number of dialysis treatment stations each grew by 5 percent annually (Figure 2D-3).

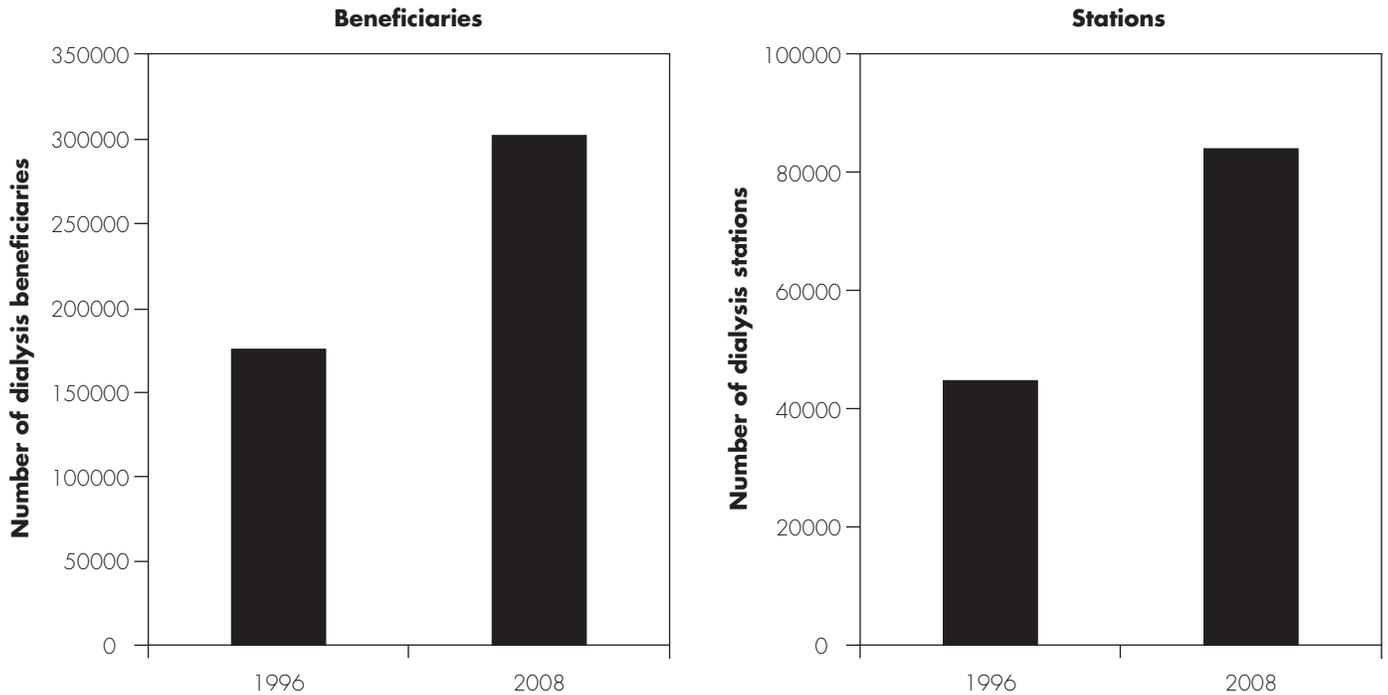
Access to the different types of dialysis has changed little over time

Access to types of dialysis shows little change over time according to data from CMS. Between 1998 and 2009, at least 96 percent of facilities offered in-center hemodialysis and 46 percent offered some type of peritoneal dialysis—continuous cycle peritoneal dialysis or continuous ambulatory peritoneal dialysis. Between 2003 and 2009, the proportion of facilities offering home hemodialysis increased from 12 percent to 21 percent. In addition, industry data suggest that dialysis facilities are beginning to offer in-center nocturnal hemodialysis. For example, across 29 states, DaVita operated 75 facilities with in-center nocturnal programs in 2008 and 114 facilities in 2009 (representing about 8 percent of all its facilities) (DaVita 2009, Mathews 2008).

Most patients receive dialysis in outpatient dialysis facilities. In 2007 (the most current 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 2009).

**FIGURE
2D-3**

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



Source: MedPAC analysis of CMS's 2003 and 2008 Dialysis Facility Compare files and claims files.

Between 1997 and 2007, the number of patients receiving hemodialysis in a facility increased by 5 percent per year, while the number of patients treated at home declined by 1 percent per year. However, since 2002, the number of home dialysis patients has increased by 2 percent per year.⁷

Fewer patients overall were dialyzed at home in 2007 than in the mid-1990s. Home dialysis offers several advantages related to quality of life and satisfaction. Compared with in-center hemodialysis, home dialysis is more convenient for patients because they can dialyze on their own schedule. The Commission will continue to monitor the use of home dialysis and is interested in exploring the effect of Medicare's payment and coverage policies on the use of home dialysis. Policy options to consider include using pay for performance to encourage people to dialyze at home. In addition, we intend to monitor the use and effect of educating pre-ESRD beneficiaries about kidney disease, a service that Medicare began to cover in 2010. Predialysis education can help beneficiaries better understand their illness and dialysis modality options and may help delay the need for dialysis.

During the past few years, the use of more frequent hemodialysis (furnished either at home or in center five to seven times per week compared with the typical three times a week regimen) has also modestly increased. Interest in more frequent hemodialysis regimens has grown during the past decade because of studies showing improved outcomes and quality of life. According to CMS's facility survey, between 2004 and 2007, the number of patients receiving more frequent hemodialysis more than tripled to about 1,700 patients.

Most beneficiaries do not face problems in obtaining care when dialysis facilities close

In addition to aggregate supply of dialysis facilities and hemodialysis stations, we also examine whether the types of beneficiaries using new, existing, and recently closed facilities suggest some differences in access to treatment. Specifically, we compared the characteristics of dialysis beneficiaries treated by facilities that were open in 2007 and 2008, that newly opened in 2008, and that closed in 2008.

Compared with facilities that remained open, facilities that closed in 2008 were more likely to be hospital based and nonprofit, which is consistent with long-term trends in supply (as shown in Table 2D-2, p. 123). In addition, facilities that closed had less capacity than those that remained open (averaging 12 dialysis stations compared with 17 dialysis stations). Facility closures in rural areas did not appear to limit providers' capacity. Between 2007 and 2008, the number of dialysis stations increased in rural areas by about 4 percent from about 16,800 stations to 17,400 stations.

Facility closures in 2007 did not appear to have adversely affected beneficiaries who are African American, dually eligible for Medicare and Medicaid, or elderly (beneficiaries 75 years or older). Compared with facilities that remained in business, facilities that closed treated similar proportions of African American beneficiaries (35 percent compared with 38 percent) and dual-eligible beneficiaries (47 percent compared with 48 percent). Facilities that closed and that remained in business had a similar share (24 percent) of elderly beneficiaries. Area-level data from the Bureau of the Census suggest that facility closures are not disproportionately occurring in lower income areas.

Together, these findings suggest that most beneficiaries do not face systematic problems in obtaining care. We will continue to track whether facility closures may disproportionately affect certain beneficiary groups, such as African Americans and dual eligibles.

The mix of beneficiaries by provider type changed little in 2007 and 2008

We examined whether providers stopped treating certain types of beneficiaries by comparing the demographic and clinical characteristics of beneficiaries. Our analysis focused on certain groups, such as African Americans, who are disproportionately affected by renal disease. Our analysis looked at the differences by the following provider types: affiliated with the two largest dialysis organizations, not affiliated with the two largest dialysis organizations, freestanding, and hospital based.

By provider type, the proportion of dialysis beneficiaries in 2008 who were elderly, female, African American, Hispanic, dually eligible for Medicare and Medicaid, or had diabetes or hypertension as the primary cause of ESRD did not vary by more than 1 percentage point between 2007 and 2008. The findings from this analysis

are shown in Figure 2D-A1 in the online appendix to this chapter, available at <http://www.medpac.gov>. For example, in 2008, we found that:

- The proportion of dialysis beneficiaries who were elderly ranged from 23 percent for the two largest dialysis organizations to 28 percent for hospital-based facilities.
- The proportion of dialysis beneficiaries who were female was about 46 percent across all provider types.
- The proportion of dialysis beneficiaries who were African American ranged from 28 percent for hospital-based facilities to 41 percent for the two largest dialysis organizations.

This analysis suggests that providers did not change the mix of patients they cared for in 2007 and 2008.

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. For this analysis, we focused on the volume of services furnished by freestanding facilities, as they treat most dialysis beneficiaries. As mentioned earlier, freestanding facilities furnished care to about 90 percent of all dialysis beneficiaries in 2008.

Between 1996 and 2008, dialysis treatments grew at an average annual rate that kept pace with the growth in the number of dialysis beneficiaries. During this time period, the number of dialysis treatments furnished by freestanding facilities grew by 6 percent per year, while the number of dialysis beneficiaries grew by 5 percent per year. These two measures should parallel one another because ESRD beneficiaries require maintenance dialysis to live unless they receive a kidney transplant.

To assess changes in drug volume, we held the drug payment rate constant and looked at the dollar change in the total volume of services for the top 11 dialysis drugs since 2004, when statutory and regulatory provisions changed Medicare's payment for these drugs. We found that, between 2004 and 2008, the total volume of dialysis drugs increased by 3 percent per year, an annual rate of growth slower than in the period that preceded the change in payment method.

In the most recent period (2007–2008), changes in volume varied across the different drugs. During this period,

the aggregate volume of ESAs declined by 4 percent, while the aggregate volume of all other dialysis drugs grew by 6 percent. Consistent with the slowdown in the aggregate use in the 2007–2008 period, the volume of ESAs furnished per treatment also declined. We found, using claims submitted by dialysis facilities, that the dose per treatment of erythropoietin (which accounts for most of the ESA use among dialysis beneficiaries) declined by about 5 percent between 2007 and 2008.

In addition to the MMA payment policy changes, two other factors have contributed to a slowdown in the use of ESAs since 2006:

- In March 2007, the Food and Drug Administration (FDA) included a “black box warning” on ESA drug labels to advise physicians about ESA dosage adjustments: They should maintain the lowest hemoglobin level needed to avoid a blood transfusion. Hemoglobin indicates a patient’s anemia status, measured as grams of hemoglobin per deciliter of blood (g/dL). The FDA added the warning based on evidence from recent studies showing that higher target hemoglobin values were associated with increased mortality and morbidity for patients with chronic kidney disease (who are not on dialysis) and for cancer patients.
- In April 2006, CMS changed its national payment policy for ESAs to promote the efficient use of these drugs. In 2008, the agency modified the 2006 policy based on the recent studies and the FDA warning about the risks associated with large doses of ESA and high hemoglobin levels. The policy change reduces payment for ESAs if providers do not reduce the dosage for a patient whose hemoglobin level exceeds 13 g/dL.⁸

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

CMS data show that the quality of some aspects of dialysis care has remained high. Between 2002 and 2006, the proportion of hemodialysis patients receiving adequate dialysis (a measure of the effectiveness of the dialysis treatment in removing waste products from the body) remained high (Table 2D-3, p. 128). During this period, increasing proportions of both hemodialysis and peritoneal patients had their anemia under control. Nearly all dialysis patients have anemia because diseased kidneys often do not produce sufficient amounts of a hormone

that stimulates red blood cell production, leading to the development of anemia. Providers furnish ESAs to treat anemia, which is a common comorbidity among dialysis patients.

This year, we examined the variation in dialysis adequacy and anemia management across providers using 2007 data from CMS’s Dialysis Facility Compare file. Adequacy of hemodialysis did not vary substantially among facilities. In 2007, the proportion of beneficiaries receiving adequate dialysis ranged from 89 percent for facilities in the 10th percentile to 100 percent for facilities in the 90th percentile.

By contrast, facilities’ anemia management strategies varied, particularly the proportion of beneficiaries maintained at high hemoglobin levels (greater than 12 g/dL). In 2007, the percentage of beneficiaries with high hemoglobin levels ranged from 17 percent for facilities in the 10th percentile to 72 percent for facilities in the 90th percentile. Recent clinical trials have shown that patients with chronic kidney disease who have high hemoglobin levels are at greater risk for death and serious cardiovascular events (Singh et al. 2006). Clinical guidelines recommend that the hemoglobin target should generally be in the range of 11 g/dL to 12 g/dL and that the target should not be greater than 13 g/dL (National Kidney Foundation 2009). There was much less variation in the percentage of beneficiaries whose hemoglobin levels were low (less than 10 g/dL). In 2007, the percentage of beneficiaries with low hemoglobin levels ranged from 1 percent for facilities in the 50th percentile to 5 percent of beneficiaries for facilities in the 90th percentile. Low values of hemoglobin have also been linked to increased risk of morbidity and mortality (Ishani et al. 2008). Our finding about more variation in the proportion of beneficiaries maintained at high hemoglobin levels rather than low levels is not surprising. Under the current payment method, providers have little incentive to control utilization of separately billable dialysis drugs because Medicare pays providers according to the number of units of the drug administered.

Use of the recommended type of vascular access—arteriovenous (AV) fistula—improved between 2002 and 2006. All 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.⁹ For most patients, clinical guidelines consider an AV fistula a better

**TABLE
2D-3****Dialysis outcomes continue to improve for some measures**

Outcome measure	2002	2003	2004	2005	2006	2007
Percent of in-center hemodialysis patients:						
Receiving adequate dialysis	92%	94%	95%	94%	93%	N/A
With anemia under control	78	81	80	80	82	N/A
Dialyzed with an AV fistula	33	35	39	44	45	N/A
Not malnourished (indicated by albumin levels)	81	81	82	80	81	N/A
Percent of peritoneal dialysis patients:						
Receiving adequate CAPD	71%	70%	73%	72%	75%	N/A
Receiving adequate CCPD	66	65	59	59	64	N/A
With anemia under control	81	83	82	83	85	N/A
Not malnourished	60	63	62	62	63	N/A
Percent of prevalent dialysis patients wait-listed for a kidney:						
All	14%	15%	15%	16%	16%	17%
White	13	14	15	15	15	16
African American	15	16	16	16	17	17
Asian American	23	24	25	25	25	25
Native American	13	14	13	14	14	15
Renal transplant rate per 100 dialysis patient years:						
All	4.9	4.8	4.8	4.8	4.8	4.4
White	6.2	5.9	5.8	5.7	5.5	5.0
African American	3.1	3.1	3.1	3.2	3.2	3.0
Asian American	5.1	5.3	5.5	5.5	6.7	7.7
Native American	3.2	3.3	3.7	3.4	4.5	4.4
Annual mortality rate per 100 dialysis patient years:						
All	21.7	21.4	21.0	20.6	20.1	19.3
White	23.6	23.2	22.7	22.2	21.7	20.9
African American	19.2	19.2	19.0	18.7	18.1	17.3
Other	16.9	16.4	15.9	15.5	14.9	14.1
Inpatient admission rate per dialysis patient:						
All	2.0	2.0	2.0	2.0	2.0	1.9
White	2.0	2.0	2.1	2.1	2.0	1.9
African American	2.0	2.0	2.1	2.1	2.0	1.9
Asian American	1.5	1.4	1.4	1.5	1.4	1.4
Native American	2.0	2.0	2.0	1.9	1.9	1.8

Note: N/A (not available), AV (arteriovenous), CAPD (continuous ambulatory peritoneal dialysis), CCPD (continuous cycler-assisted peritoneal dialysis). 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 (ESRD).

Source: Compiled by MedPAC from 2003–2007 Annual Reports for ESRD Clinical Performance Measures Project from CMS and USRDS 2009.

type of vascular access than an AV graft or a catheter. Because they are native vessels, AV fistulas last longer and have fewer complications, such as infections and clotting, than other types of vascular access (National Institute of Diabetes and Digestive and Kidney Diseases 2008). CMS

is leading a national quality initiative—Fistula First—with a goal of having fistulas placed in at least half of new hemodialysis patients and having a minimum of 66 percent of patients who continue dialysis using a fistula.

In the 2002–2007 period, 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 whites (17.3 vs. 20.9 per 100 patient years, respectively in 2007) (United States Renal Data System 2009). The presence of cardiovascular disease, which is the leading cause of death in dialysis patients, may explain some of the paradoxical association of race with mortality in dialysis patients. Researchers have reported that, compared with African American dialysis patients, white dialysis patients are at increased risk of developing atherosclerotic cardiovascular disease (even after adjusting for traditional cardiovascular and dialysis-related risk factors) and that this increased risk may contribute to the higher risk of mortality in whites than in African Americans (Parekh et al. 2005).

Other measures suggest that improvements in dialysis quality are still needed. We looked at several measures that examine access to kidney transplantation because it is widely believed that kidney transplantation is the best treatment option for individuals with ESRD. 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 (Table 2D-3).

We also examined rates of kidney transplantation in the 2002–2007 period. Between 2002 and 2006, rates of kidney transplantation remained relatively steady (Table 2D-3) (United States Renal Data System 2009). However, between 2006 and 2007, the rate of kidney transplantation as well as the total number of procedures declined.¹⁰ Between 2006 and 2007, all racial groups except Asian Americans experienced a decrease in the rate of kidney transplantation. This recent one-year decline is partly due to a decrease in kidney donations from living donors. Between 2006 and 2007, kidney transplants from living donors declined by 6.1 percent, while transplants from deceased donors declined by 1.3 percent (Health Resources and Services Administration 2008). The decline in the number of transplant procedures may also be partly linked to a small drop in the incidence of ESRD. Between 2006 and 2007, ESRD incidence (adjusted for age, gender, race, ethnicity, and primary diagnosis) dropped from

361 to 354 per million population, the first decline in the incidence rate since 1995 (United States Renal Data System 2009). Some researchers have linked the decline in ESRD incidence to a decline in the incidence of ESRD among individuals with diabetes and have suggested that improved treatment and care may have contributed to this decline (Burrows et al. 2010). The text box (pp. 130–131) summarizes some issues about the distribution of kidney transplantation across the ESRD population that the Commission monitors.

Another measure that suggests that dialysis quality improvements are still needed is the proportion of dialysis patients with low albumin levels, which has remained unchanged over time. Patients with lower serum albumin levels, a measure of increased risk of malnutrition, are at increased mortality risk.

Overall rates of hospitalization remained steady at about two admissions per dialysis patient per year. By race, the hospitalization rate is lowest among Asian Americans (United States Renal Data System 2009). In addition to hospitalizations, we examined inpatient readmission rates for dialysis beneficiaries, which can be indicators of poor care or missed opportunities to better coordinate care (Medicare Payment Advisory Commission 2007). We found, using 2007 hospital claims data for dialysis beneficiaries, that a significant proportion (32 percent) of hospitalized dialysis beneficiaries were readmitted to a hospital within 30 days. This readmission rate did not vary substantially by race or sex. For example, 32 percent of whites and 33 percent of African Americans who were hospitalized were readmitted within 30 days. At 32 percent, the overall readmission rate for dialysis beneficiaries in 2007 remained virtually unimproved from 2005, when 33 percent of hospitalized dialysis beneficiaries were readmitted within 30 days.

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 2008 and 2009, the largest dialysis organizations and smaller chains showed similar growth rates, which suggests that both small and large providers have adequate access to capital. During this period, the number of dialysis stations operated by the two largest dialysis organizations (Fresenius Medical Care North America and DaVita) grew by 6 percent; in comparison, the number of dialysis stations operated by smaller

Distribution of kidney transplantation

This text box describes some of the trends and factors affecting access to kidney transplantation. Kidney transplantation is a life-saving medical procedure for which the demand far exceeds the supply of the resource (i.e., transplantable organs). Transplantation improves clinical outcomes compared with dialysis. When no living related kidney donor is available, many end-stage renal disease (ESRD) patients must rely on the limited supply of cadaveric donor organs. Although the principle of equity is emphasized in the distribution of this limited resource, several studies have documented that kidney transplantation rates differ by patients' demographic and socioeconomic characteristics.

Access to kidney transplantation varies by race. Data from the United States Renal Data System (USRDS) show that in 2007:

- White ESRD patients accounted for 62 percent of ESRD patients and received 66 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 6 percent of the ESRD population and accounted for 9 percent of transplants.

However, in the recent five-year period, there has been some change in transplantation rates across racial groups. Between 2002 and 2007, rates of transplantation increased for some minority groups—Asian Americans and Native Americans—while the rate for African Americans remained relatively constant (Table 2D-3, p. 128). During this period, the rates of transplantation for whites declined.

The factors affecting access to kidney transplantation are complex. Unequal transplantation rates result in part from differences in the clinical appropriateness of patients as candidates for transplantation. Some patients are not able to receive a transplant because of the presence of medical contraindications—such as a recent

(continued next page)

freestanding chains grew by an average of 4 percent between 2008 and 2009.

The two large dialysis organizations appear to have adequate access to capital despite the economic downturn that began in the fall of 2008, as demonstrated by their ability to make large purchases and the willingness of private investors to fund their acquisitions. For example, Fresenius Medical Care North America advanced its vertical integration by acquiring an information technology company that has developed a nephrology-specific electronic health record that links care furnished by the physician, dialysis facility, hospital, pharmacy, laboratory, and vascular access center. In 2009, this large dialysis organization opened a national retail pharmacy catering to renal patients. In addition, Fresenius Medical Care North America developed a system (KidneyTel[®]) that combines home telehealth monitoring services with

an integrated care management program tailored to renal patients. In 2009, DaVita repurchased 744,400 shares of common stock for \$32 million and announced a \$5 million investment in underserved communities across the country (PRNewswire 2009, TheStreet.com 2009). Smaller dialysis chains also appear to have adequate access to capital. For example, Renal Advantage, Inc., has teamed with Welsh, Carson, Anderson & Stowe for capital and guidance for new center development.

The fact that an increasing proportion of dialysis facilities are freestanding, owned by publicly traded companies, chain operated (i.e., operated under common ownership), and for profit suggests 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 two largest dialysis organizations have enjoyed mostly positive ratings from investor analysts

Distribution of kidney transplantation

history of substance abuse, the presence of cancer, a serious infection, or significant cardiovascular disease. Lower rates of renal transplantation, particularly among African American patients, also 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.

Differences in access may also stem from differences in transplants from live donors. In 2007, transplants from live donors accounted for about 37 percent of procedures, while kidney transplants from deceased donors accounted for 63 percent of procedures (Health Resources and Services Administration 2008). By race, whites accounted for 75 percent of live donor procedures compared with 14 percent for African Americans and 12 percent for Asian Americans and Native Americans (United States Renal Data System 2009). Researchers have noted that there are fewer living donors among African Americans, increasing their dependence on cadaver organs (Young and Gaston 2000).

Differences in kidney transplantation rates may also reflect patient and provider factors. Possible

patient-level factors include lack of knowledge about transplantation and concerns about surgery and adverse effects of medication. Provider-level factors that may affect access to kidney transplantation include clinicians' subconscious bias and transplant center characteristics.

However, even after controlling for some of these demographic and clinical characteristics, differences in access to kidney transplantation persisted. Researchers have examined the sequential steps that lead to transplantation (a patient being medically suitable and possibly interested in a transplant, being definitely interested in transplantation, completing the pretransplant workup, and moving up the waiting list to eventual transplantation) and have found that access to cadaveric kidney transplantation is significantly related to patients' race, sex, and income. For example, 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). The Commission intends to continue to analyze the trends in kidney transplantation and research on access to this procedure. ■

in 2009, who have generally viewed dialysis providers' fundamentals—including the aging of the U.S. population, the higher incidence of diabetes, and recurring demand—and low sensitivity to economic cycles as favorable from an economic perspective. In addition, investor analysts remain favorable about the dialysis sector because of its record of solid growth rates and available “free cash flow,” the cash flow available for distribution among an organization's securities holders. Standard & Poor's recently upgraded DaVita's stock ranking to “buy” from “hold” based on the stock's potential for future performance. Concerning DaVita's prospects, Deutsche Bank is “very comfortable with the fundamental outlook into 2010, as we think DaVita has strong visibility into volume and pricing growth, while underlying cost trends remain under control” (Deutsche Bank 2009). Fresenius's chief financial officer noted that the company “secures the lowest cost of total capital including equity” (Burger 2009).

Outside capital investment might be discouraged if investor analysts are uncertain about the impact of a new payment method on a sector's financial outlook. Since the release of the CMS proposed rule, investor analysts remain positive about the long-term economic prospects for the dialysis sector. For example, Standard & Poor's views the proposed bundled dialysis payment rates (included in the proposed rule) “as manageable and removing some anxiety surrounding the [dialysis] group” (Standard & Poor's 2009). Wells Fargo Securities generally views the “transition to a bundled payment scheme as a long term positive for the industry” (Wells Fargo Securities 2009).

Medicare payments and providers' costs

Each year, we assess freestanding providers' costs and the relationship between Medicare's payments and freestanding providers' costs by considering whether current costs approximate what efficient providers

are expected to spend on delivering high-quality care. Two indicators of the appropriateness of current costs are: (1) trends in the growth of cost per treatment for composite rate services between 2003 and 2008 and (2) the distribution of facilities' per treatment costs in 2008, adjusted for a facility's wage index and average case-mix index. Medicare margins also illuminate the relationship between Medicare payments and providers' Medicare-allowable costs. We examined margins for freestanding facilities for 2008, the latest year for which cost reports and claims data are available. We also include our projection for the Medicare margin in 2010.

Appropriateness of current costs

Because the composite rate is set prospectively, providers have an incentive to restrain their costs for composite rate services. In contrast, because Medicare pays for dialysis drugs on a per unit basis, providers have an incentive to negotiate lower drug prices, but they have little incentive to restrain drug volume. At issue is whether aggregate dialysis costs provide a reasonable representation of costs that efficient providers would incur in furnishing high-quality care.

Between 2003 and 2008, the cost per treatment for composite rate services rose by 3.2 percent per year. The variation in cost growth across freestanding dialysis facilities shows that some facilities were able to hold their cost growth well below others. For example, per treatment costs increased by 1.6 percent per year for facilities in the 25th percentile of cost growth, compared with 5.1 percent for facilities in the 75th quartile.

The growth in cost per treatment during that period partly stems from rising general and administrative costs, which increased by 6 percent per year and accounted for about 30 percent of the total cost per treatment in 2008. General and administrative costs include expenses associated with legal and accounting services, recordkeeping and data-processing tasks, telephone and other utilities, and malpractice premiums. By contrast, between 2003 and 2008, capital and labor costs (associated with direct patient care) increased by 3 percent per year; other direct medical costs decreased by 1 percent per year. In 2008, capital, labor, and other direct medical costs accounted for 20 percent, 41 percent, and 11 percent, respectively, of the total cost per treatment.

The distribution of the cost per treatment in 2008, adjusted for each facility's wage index and average case mix,

suggests that some facilities are able to furnish care at a lower cost than others. While the average adjusted cost per treatment was \$161, cost per treatment varied for facilities in the 10th percentile, the 25th percentile, the 50th percentile (median), the 75th percentile, and the 90th percentile of costs at \$127, \$140, \$158, \$178, and \$200, respectively. Previous Commission research suggests that the two largest dialysis organizations and facilities that provided more dialysis treatments exhibited lower costs relative to their counterparts (Medicare Payment Advisory Commission 2008).

The Medicare margin for freestanding providers

The Commission assesses current 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. The latest and most complete data available on payments and costs are from 2008.

For 2008, we estimate that the aggregate Medicare margin for composite rate services and dialysis drugs was 3.2 percent. The distribution of margins in 2008 shows wide variation in performance among freestanding facilities. One-quarter of facilities had margins at or below -5.5 percent, but half the facilities had Medicare margins of at least 4.1 percent, and one-quarter of facilities had Medicare margins of at least 12.9 percent.

The aggregate 2008 margin dropped from the 2006 and 2007 margins, which we estimated to be 5.9 percent and 4.8 percent, respectively (Medicare Payment Advisory Commission 2009). Changes in per treatment cost and payment can partly explain this direction. Between 2007 and 2008, the cost per treatment for composite rate services was greater than the update to the composite rate. In 2008, CMS updated the add-on to the composite rate from 14.9 percent to 15.5 percent of the composite rate, which amounted to an increase of about 0.5 percent to the composite rate (from \$152.23 to \$153.03 per dialysis treatment). The decline in the volume of ESAs in 2008 has also affected the Medicare margin. In addition, CMS's payment policy was modified in 2006; the policy change reduces payment for ESAs if providers do not reduce the dosage for a patient with a hemoglobin level that exceeds 13 g/dL. Between 2007 and 2008, the decline in the average ESA payment per treatment was greater than the decline in the average ESA cost per treatment.

As in earlier years, urban facilities had higher margins than rural facilities (3.9 percent vs. -0.3 percent,

respectively), and facilities affiliated with the two largest dialysis organizations tended to have higher margins than other freestanding facilities (4.0 percent vs. 1.6 percent, respectively) (Table 2D-4). However, compared with 2007, the margin gap between urban and rural facilities widened, while the gap between the two largest dialysis organizations and their counterparts narrowed (data not shown).

The gap in the Medicare margin widened between urban and rural facilities between 2007 and 2008 in part because: (1) the wage index floor declined and (2) the volume of ESAs declined for the two largest dialysis organizations, which account for a greater proportion of facilities in rural areas than other freestanding facilities.¹¹

Between 2007 and 2008, although the add-on payment to the composite rate increased across all facilities (by 0.5 percent), the average composite rate payment per treatment increased more for urban facilities than for rural facilities. Changes to the ESRD wage index partly account for this finding. The ESRD wage index is developed from wage and employment data obtained from the Medicare hospital cost reports.¹² Beginning in calendar year 2006, CMS adopted geographic designations based on core-based statistical areas and began reducing the wage index floor. Before 2006, CMS used wage-adjusted designations based on metropolitan statistical areas. To mitigate the impact of these changes, CMS transitioned the changes as follows:

- In 2006, the first year of the transition, CMS implemented a 75/25 blend. The wage index floor was reduced from 0.9 to 0.85.
- In 2007, CMS implemented a 50/50 blend. The wage index floor was reduced to 0.80.
- In 2008, CMS implemented a 25/75 blend. The wage index floor was reduced to 0.75.

CMS estimated that the wage index changes between 2007 and 2008 would decrease total payments to rural facilities by -0.6 percent and increase total payments to urban facilities by 0.1 percent (Centers for Medicare & Medicaid Services 2007). Including the effect of the update to the add-on payment on the composite rate, CMS estimated total composite rate payments would not change for rural facilities and would increase by 0.7 percent for urban facilities in 2008.

**TABLE
2D-4**

Medicare margin in 2008 varies by type of freestanding provider

Provider type	Percent of spending	Medicare margin
All	100%	3.2%
Two largest dialysis organizations	68	4.0
All others	32	1.6
Urban	83	3.9
Rural	17	-0.3

Source: Compiled by MedPAC from 2008 cost report and outpatient claims submitted by facilities to CMS.

The Commission is concerned that the gap in the Medicare margin between urban and rural facilities widened between 2007 and 2008. We will continue to monitor the adequacy of Medicare’s payments for rural and urban facilities in the upcoming years. Some rural facilities are expected to benefit from the low-volume adjustment that will be included in the new ESRD PPS scheduled to begin in 2011.

On the basis of 2008 payment and cost data, we project that the 2010 aggregate margin will be 2.5 percent. This estimate reflects the 1 percent composite rate update in MIPPA, effective January 1, 2009, and January 1, 2010. This projection for 2010 does not take into account the 2 percent reduction in total spending that MIPPA mandated to begin in 2011 under the new dialysis payment method. We did not include the 2 percent reduction in our projection because CMS has not yet finalized the regulatory provisions to implement the new payment method. In addition, providers’ response to the new payment method is unknown. Including ESRD drugs now separately paid for under Part B in the new payment bundle may lead to better management of drug therapy, which may lead to improvements in the efficiency of care.

How should Medicare payments change in 2011?

CMS measures price inflation for the goods and services associated with the composite rate. CMS’s latest forecast of this index for calendar year 2011 is 2.0 percent. In considering an appropriate update for each sector, the Commission also takes into account improvements in

productivity. Competitive markets demand continual improvements in productivity from workers and firms. These workers and firms pay the taxes used to finance Medicare. Medicare's payment systems should exert the same pressure on providers of health services. The Commission begins its deliberations with the expectation that Medicare should benefit from productivity gains in the economy at large (the 10-year average of productivity gains in the general economy is currently 1.3 percent). This factor links Medicare's expectations for efficiency to the gains achieved by the firms and workers who pay taxes that fund Medicare. The Commission's assessment of dialysis providers' historic responsiveness to changes in payments, along with the other components of the update framework discussed above, suggests that it is reasonable to apply a productivity adjustment to the composite rate update to encourage dialysis providers to produce a unit of service as efficiently as possible while maintaining quality.

Update recommendation

The evidence on payment adequacy suggests that a moderate update of the composite rate is in order. Therefore, the Commission recommends that the Congress should update the composite rate by the projected rate of increase in the ESRD market basket less the adjustment for productivity growth for calendar year 2011. Under the current estimate of the ESRD market basket, this recommendation would increase the composite rate by 0.7 percent in 2011. (Note that CMS revises its market basket

projections on a quarterly basis.) By comparison, under current law, MIPPA mandates that the Secretary update the composite rate by the ESRD market basket less 1 percent.

RECOMMENDATION 2D

The Congress should update the composite rate by the projected rate of increase in the end-stage renal disease market basket less the adjustment for productivity growth for calendar year 2011.

RATIONALE 2D

Most of our indicators of payment adequacy are positive, including beneficiaries' access to care, volume of services, quality of care, and access to capital. The projected 2010 aggregate Medicare margin is 2.5 percent.

IMPLICATIONS 2D

Spending

- This recommendation would decrease federal program spending relative to current law by between \$50 million and \$250 million in 2011 and by less than \$1 billion over five years.

Beneficiary and provider

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

Endnotes

- 1 Individuals with a diagnosis of ESRD who are not eligible for Medicare coverage either do not qualify for fully or currently insured status under Social Security or have not filed an application to become eligible.
- 2 In addition to Medicare eligibles, 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 In this chapter we use the term “dialysis beneficiaries” to refer to those individuals who are covered under Medicare and “dialysis patients” to refer to all individuals requiring dialysis, including individuals covered under Medicare and individuals not covered under Medicare. In 2007, we found, using claims data, that about 330,000 dialysis beneficiaries were covered under Medicare. During the same year, according to data from CMS’s facility survey, dialysis facilities furnished care to 358,000 dialysis patients.
- 4 Before the MMA, Medicare paid freestanding facilities a statutory rate for erythropoietin and 95 percent of the average wholesale price or a statutory rate for all other dialysis drugs.
- 5 Comorbidities include: alcohol and drug dependence, cardiac arrest, pericarditis, human immunodeficiency virus–acquired immunodeficiency syndrome (HIV/AIDS), hepatitis B, specified infection (septicemia, bacterial pneumonia, and opportunistic infections), gastrointestinal tract bleeding, hereditary hemolytic or sickle cell anemia, cancer, myelodysplastic syndrome, and monoclonal gammopathy.
- 6 The comorbidity adjustment is based on the presence of HIV/AIDS, septicemia, diabetes, and cardiac arrest.
- 7 Between 2002 and 2007, use of peritoneal dialysis increased from 25,396 patients to 26,364 patients, while use of home hemodialysis increased from 1,758 patients to 2,999 patients.
- 8 The current FDA label recommends that patients’ hemoglobin levels range between 10 g/dL and 12 g/dL. National Kidney Foundation guidelines currently recommend that dialysis patients’ hemoglobin levels range between 11 g/dL and 12 g/dL (National Kidney Foundation 2009).
- 9 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, physicians implant AV grafts 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 within two to three weeks. Catheters placed in the patient’s neck, chest, or leg are used as a temporary access when a patient needs dialysis immediately and is waiting for an AV fistula or AV graft to mature. They are also used when an AV fistula or graft fails.
- 10 The number of kidney transplants declined from 18,056 in 2006 to 17,513 in 2007.
- 11 USRDS data show that the two largest dialysis organizations furnish, on average, a higher volume of dialysis drugs than other freestanding facilities (United States Renal Data System 2008).
- 12 The ESRD wage index values are calculated without regard to geographic reclassifications and utilize prefloor hospital data that are unadjusted for occupational mix.

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