SECTION 2C

Outpatient dialysis services

RECOMMENDATION

The Congress should maintain current law and update the composite rate in calendar year 2010 by 1 percent.

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

SECTION 2C

Outpatient dialysis services

Section summary

Each year, the Commission makes a payment update recommendation for outpatient dialysis services for the coming year. The Congress has charged the Commission to judge whether payments for the current year (2009) are adequate to cover the costs efficient dialysis providers incur and how much Medicare's payments should change in the coming year (2010).

Most of our indicators of payment adequacy are positive. The growth in the number of dialysis facilities and treatment stations has kept pace with the growth in the number of dialysis patients, suggesting continued access to care for most dialysis beneficiaries. The growth in the number of dialysis treatments—one indicator of the volume of services—has kept pace with patient growth between 2006 and 2007. The total volume of most dialysis drugs administered grew between 2004 and 2007 but more slowly than in the past because of statutory and regulatory changes that lowered the payment rate for most of them.

Some measures of quality of care are improving. Use of the recommended type of vascular access—the site on the patient's body

In this section

where blood is removed and returned during hemodialysis—has improved since 2000. More patients receive adequate dialysis and have their anemia under control. However, improvements in quality are still needed. For example, the proportion of dialysis patients registered for the kidney transplant waiting list does not meet the goal set forth by the Centers for Disease Control and Prevention Healthy People 2010.

Recent evidence about trends in the increase in the number of dialysis facilities suggests that providers have sufficient access to capital. Both the large dialysis organizations and smaller chains have obtained private capital to fund acquisitions.

The Medicare margin for composite rate services and dialysis drugs for freestanding dialysis facilities was 4.8 percent in 2007. The two largest dialysis chains realized a higher Medicare margin than other freestanding providers (6.9 percent vs. 0.2 percent). We project the overall Medicare margin for freestanding dialysis facilities will be 1.2 percent in 2009. This estimate reflects the update to the composite rate effective January 1, 2009, and the update to the add-on payment in 2008.

In summary, most of our payment adequacy indicators are positive—sufficient provider capacity, volume growth keeping pace with dialysis enrollment growth, some quality improvements, and sufficient provider access to capital. This evidence suggests that a moderate update of the composite rate is in order and that dialysis providers can achieve an efficiency gain similar to the economy at large, which is 1.3 percent. Therefore, the Commission recommends that the Congress maintain current law and update the composite rate by 1 percent for calendar year 2010. ■

Recommendation 2C

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

The Congress should maintain current law and update the composite rate in calendar year 2010 by 1 percent.

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 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 all ESRD patients undergo dialysis. Patients receive additional items and services related to their dialysis treatments, including dialysis drugs to treat conditions such as anemia and low blood calcium resulting from the loss of kidney function. The different types of dialysis available to patients are summarized (see text box, pp. 134–135).

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 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 beneficiaries.

For patients 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 patients 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. We estimate that there were about 113,000 new dialysis patients in 2007.[2]

If an employer group health plan (EGHP) covers a patient at the time of ESRD diagnosis, the EGHP is the primary payer for the first 33 months of care. Medicare is the secondary payer during this period. EGHPs include health plans that patients 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 2007, the more than 330,000 dialysis beneficiaries covered by the Medicare program received care at about 4,900 dialysis facilities.[3] About one-quarter of newly diagnosed ESRD patients were entitled to Medicaid benefits and about one-quarter were covered by an EGHP (USRDS 2008). For both freestanding and hospital-based facilities, Medicare spending for dialysis and dialysis drugs totaled about $8.6 billion in 2007, an increase of 2 percent compared with 2006. Medicare expenditures for composite rate services and dialysis drugs averaged about $26,000 per patient in 2007.

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 services that are 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. In 2007, payment for composite rate services averaged about $155 per treatment while the payment for drugs averaged about $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_08_dialysis.pdf).

Providers of outpatient dialysis services

During the past five years, an increasing proportion of dialysis providers are freestanding, bigger (as measured by the number of hemodialysis stations), owned by publicly traded companies, operated by a chain, and for profit (Table 2C-2, p. 136, and Figure 2C-1, p. 137). 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 chains merged into two chains. These two for-profit chains (Fresenius and DaVita) together account for about 60 percent of all facilities and about 70 percent of freestanding facilities (Figure 2C-1). In 2008, consolidation continued, with the merger of two smaller chains (Renal Advantage Inc. and National Renal Alliance) that served about 10,500 patients in 136 dialysis centers in 18 states (Ward 2008). These trends in the profit status, size, and consolidation of dialysis providers suggest that the dialysis industry is an attractive business to for-profit providers and that potential exists for efficiencies and economies of scale in providing dialysis care.

Since 2003, freestanding facilities have increased by 4 percent annually and currently account for 88 percent of all facilities. For-profit facilities have increased at a similar rate during this period and account for 81 percent

Dialysis treatment choices

A healthy human kidney continuously removes waste products and excess water from the blood. Chronic kidney disease is a slow, progressive loss of kidney function caused by inherited disorders; medical conditions, such as diabetes and hypertension; or the long-term use of certain drugs. When both kidneys fail, harmful wastes build up in the bloodstream along with excess fluid. A person's life can be sustained only through kidney transplantation or dialysis. Because of the shortage of donor kidneys, most patients rely on dialysis.

Dialysis is a treatment to replace the filtering function of the kidneys when they reach end-stage renal disease. The two types of dialysis—peritoneal dialysis and hemodialysis—remove wastes from a patient's bloodstream differently. Peritoneal dialysis uses the lining of the patient's abdomen as a filter to clear wastes and extra fluid and is usually performed in the patient's home. Hemodialysis uses an artificial membrane called a dialyzer to clean the patient's blood. Although hemodialysis is usually provided in dialysis facilities, it can also be done in the patient's home. As summarized in Table 2C-1, each dialysis type has advantages and disadvantages—no one type of dialysis is best for everyone. Patients choose one type of dialysis over another for many reasons, including quality of life, patient satisfaction, physician expertise, and patient education. Some patients switch from one dialysis type to another when their needs or condition changes.

Peritoneal dialysis

During peritoneal dialysis, a cleansing liquid, called dialysis solution, is drained from a bag into the patient's abdomen. Fluids and wastes flow through the lining of the cavity and remain "trapped" in the dialysis solution. The solution is then drained from the abdomen, removing the extra fluids and wastes from the body. Peritoneal dialysis is usually performed in the patient's home. To perform peritoneal dialysis, a physician places a catheter in the patient's abdomen to allow the dialysis fluid to enter and drain. On average, newly diagnosed patients choosing peritoneal dialysis tend to be younger than those selecting hemodialysis (USRDS 2008).

The two types of peritoneal dialysis are:

- Continuous ambulatory peritoneal dialysis, which does not use a machine and can be done at home or work. Most people change the dialysis solution at least four times a day and sleep with solution in their abdomen at night.

- Continuous cycler-assisted peritoneal dialysis, which uses a machine called a cycler to fill and empty the abdomen three to five times while the patient sleeps.

The most common problem with peritoneal dialysis is peritonitis, a serious abdominal infection. This infection can occur if the opening where the catheter enters the patient's body becomes infected or if contamination occurs as the catheter is connected or disconnected.

Hemodialysis

During hemodialysis, a machine removes wastes from the bloodstream. Hemodialysis is most often given in a dialysis facility (in-center) three times per week for three to four hours per treatment. This treatment is often referred to as conventional hemodialysis. To perform hemodialysis, a physician creates a vascular access to get the blood from the body to the dialyzer and back to the body. As we discuss later (p. 143), there are three vascular access types: arteriovenous (AV) fistula, AV graft, and central venous catheter.

Because of studies showing improved outcomes and quality of life, interest in more frequent hemodialysis regimens has grown substantially during the past decade. The two types of frequent hemodialysis are short daily hemodialysis, which is performed five to seven times per week for two to three hours per treatment; and nocturnal dialysis, which is performed three to six times per week while the patient sleeps. Short daily and nocturnal hemodialysis are typically performed in a patient's home. However, some dialysis providers are beginning to offer nocturnal hemodialysis in their facility.

(continued next page)

Dialysis treatment choices (cont.)

Muscle cramps and a sudden drop in blood pressure are two common side effects of conventional hemodialysis. Vascular access problems—including infection, blockage, and poor blood flow, are the most frequent reason that hemodialysis patients are hospitalized. ■

TABLE 2C–1

A comparison of the different dialysis types

Dialysis type and setting	Advantages	Disadvantages
Peritoneal dialysis performed at home	• Patient's diet and fluids are much closer to normal than with conventional hemodialysis. • Patients have the freedom to perform dialysis at home or at work. It is easier for someone to work, attend school, or travel. • Patients have a sense of independence and control over their schedule and treatment.	• Because the dialysis solution is composed of a sugar, there might be some weight gain and problems with glucose control. • This dialysis type is not an option if the patient has had previous abdominal surgery. • This dialysis type requires space in the patient's home for storing the machine and supplies.

Conventional hemodialysis provided in a dialysis facility three times per week	• Medical personnel are with the patient during dialysis.
	• A patient can interact with other patients.
		• Dialysis treatments are scheduled by the facility and are relatively fixed.
		• Patients must travel to the facility for treatment three times per week.
		• Compared to other dialysis types:
		  • This treatment has the strictest diet and fluid limits.
		  • Patients receive more dialysis drugs.

More frequent hemodialysis: short daily hemodialysis and nocturnal hemodialysis, which is often performed in a patient's home	• Patient's diet and fluids are much closer to normal than with conventional hemodialysis. • Patients have the freedom to perform dialysis at home. • Patients have a sense of independence and control over their treatment.	• Patients must have a partner to assist during the dialysis treatment. • This dialysis type requires space in the patient's home for storing the machine and supplies.

Source: Summarized from information obtained from National Institute of Diabetes and Digestive and Kidney Diseases 2008a and DaVita 2008.

of all facilities (Table 2C-2, p. 136). The number of hospital-based facilities decreased from 660 to 589 during this time. Most freestanding facilities (91 percent) are for profit; by contrast, most hospital-based facilities (94 percent) are nonprofit (data not shown). In terms of size, freestanding facilities are, on average, larger than hospital-based facilities. In 2008, freestanding facilities had 18 hemodialysis stations, on average, while hospital-based facilities had an average of 14 stations.

Most freestanding dialysis facilities (87 percent) are affiliated with a chain, whereas most hospital-based

TABLE 2C–2

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

	2008	Average annual percent change 2003–2008
Total number of dialysis facilities	4,957	3.2%
Number of hemodialysis stations		
Total	86,744	3.7
Mean	17.5	0.6
Percent of total facilities		
Nonchain	21%	–3.5
Affiliated with any chain	79	5.5
Affiliated with largest 2 chains	59	4.1
Rural	25	3.0
Urban	75	3.2
Freestanding	88	4.1
Hospital based	12	–2.3
For profit	81	4.4
Nonprofit	19	–1.2

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

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

facilities (79 percent) are not operated by a chain. The two largest chains together account for about 60 percent of all facilities; the third largest chain (Dialysis Clinic Inc.) operates 4 percent. Facilities not operated by these three chains are:

- 60 percent for-profit and 40 percent nonprofit facilities
- 68 percent freestanding and 32 percent hospital based
- 43 percent chain affiliated and 57 percent not affiliated with a chain

About one-quarter of dialysis facilities are located in a rural area. Rural and urban facilities have grown at similar rates during the past five years. The two largest dialysis chains, which together operate in 48 states, account for about 60 percent of all facilities in rural areas.

Recent regulatory and legislative changes to the outpatient dialysis payment method

During the past decade, the Commission has repeatedly called for the Congress to modernize the dialysis payment method in order to improve efficiency and quality. Specifically, we have recommended broadening the dialysis payment bundle to include composite rate services, dialysis drugs, and other services needed to treat ESRD and linking payment to the quality of care providers furnish. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) began to refine the payment method by reducing the profitability of separately billable drugs but kept the two-part structure in place. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) mandates substantial changes to the outpatient dialysis payment method. The new law refines the current payment method by equalizing payment rates between hospital-based and freestanding facilities and updates the base composite rate for 2009 and 2010. It also modernizes the payment method by expanding the payment bundle to include drugs, laboratory services, and other commonly furnished items that providers currently bill separately and by linking payment to quality. Table 2C-3 (p. 138) summarizes recent statutory and regulatory changes to the outpatient dialysis payment method.

Refinements to the outpatient dialysis method in 2005

The dialysis payment method remained relatively unchanged until the MMA, which increased the payment rate for dialysis treatments and decreased the payment rate for dialysis drugs that Medicare pays separately. The MMA mandated paying providers an add-on payment to the composite rate in 2005. The law funded 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 mandating that these changes occur in a budget-neutral manner.

The MMA also lowered the payment rate for most separately billable dialysis drugs to a rate closer to the prices providers paid. Beginning in 2005, CMS paid dialysis providers their acquisition cost—based on a survey of prices providers paid for the top dialysis drugs—for most (but not all) dialysis drugs.[4] In 2006, CMS revised this policy by paying average sales price (ASP) plus 6 percent for all dialysis drugs. These changes have resulted in Medicare's drug payment no longer being as profitable for most providers as it was before

2005, when the program paid either average wholesale price, reasonable cost, or a set (statutory) rate. A recent study by the Office of Inspector General (OIG) concluded that dialysis drugs remained profitable for most dialysis facilities in 2006 (OIG 2007).

However, the MMA did not change the two-part structure of the outpatient dialysis payment system. Providers still receive the composite rate for each dialysis treatment provided in dialysis facilities (in-center) or in patients' homes and separate payment for certain dialysis drugs and laboratory tests that were not available when Medicare implemented the composite rate.

Modernizing the outpatient dialysis payment method will begin in 2011

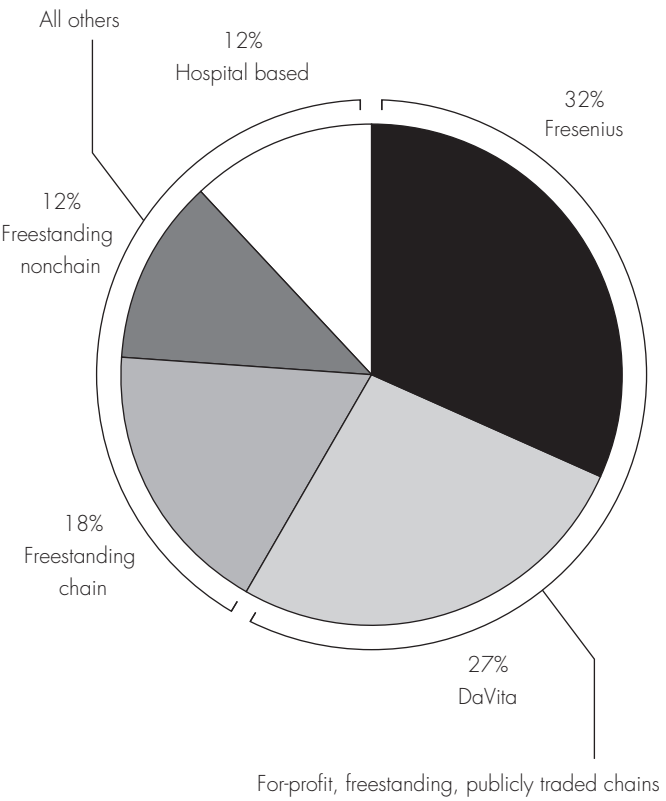
MIPPA modernizes the dialysis payment method by broadening the payment bundle and implementing a pay-for-performance program, improvements the Commission has long recommended (MedPAC 2004, MedPAC 2001). Beginning in 2011, the Secretary must implement a bundled payment system that includes:

- services included in the composite rate as of 2010,
- injectable biologicals used to treat anemia—erythropoiesis-stimulating agents—that are paid for separately under Part B and any oral form of such agents,
- other medications that are furnished to dialysis beneficiaries and paid for separately under Part B and any oral equivalent to such medications, and
- laboratory tests and other items and services that are furnished to beneficiaries for the treatment of ESRD.

The new payment bundle will not be implemented in a budget-neutral manner. Rather, MIPPA instructs the Secretary to ensure that the estimated total amount of payments in 2011 equal 98 percent of the estimated total amount of payments had the broader bundle not been implemented. Estimated total payments in 2011 will be based on the lowest per patient utilization of ESRD services between 2007 and 2009. MIPPA mandates that the new payment system be implemented over a four-year period. However, facilities can be paid fully under the new bundled system as early as 2011 (the first year of the phase in). Beginning in 2012, MIPPA also requires that the Secretary update the bundled payment rate by the market basket minus 1 percent. There is no provision under current law for the Secretary to change the composite rate.

FIGURE 2C–1

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



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

Source: Compiled by MedPAC from the 2008 Dialysis Compare database from CMS.

The bundled payment rate will include adjustments for patient case mix (e.g., patient weight, body mass index, comorbidities, and other patient characteristics), high-cost patients, and low-volume facilities that incur high costs. In addition, the Secretary can include adjustments for geographic factors, pediatric facilities, and facilities located in rural areas.

The new law links dialysis facilities' payment to the quality of care they furnish. Beginning in 2012, the bundled payment rate will be reduced by up to 2 percent for facilities that do not achieve or make progress toward specified quality measures. Quality measures will include anemia management, dialysis adequacy, and—to the extent feasible—patient satisfaction, iron management,

TABLE 2C–3 **Legislative and regulatory changes to the outpatient dialysis payment method**

Legislation or regulation	Change in composite rate payment	Change in payment for separately billable drugs
Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)	*In 2005:* Increased the base composite rate by 1.6 percent.[a] Created the add-on payment to the composite rate to account for the reduction in drug payment rate. Required CMS to adjust composite rate for case mix. *In 2006:* Required CMS to annually increase the add-on updated due to increased use and prices in separately billable drugs. Gave authority to CMS to update the wage index.	*In 2005:* Reduced payment for separately billable drugs by requiring that Medicare set payment based on providers' acquisition cost.
Deficit Reduction Act of 2005	*In 2006:* Increased the base composite rate by 1.6 percent.	
Tax Relief and Health Care Act of 2006	*Effective April 1, 2007:* Increased the base composite rate by 1.6 percent.	
Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)	*In 2009 and 2010:* Increased the base composite rate by 1.0 percent. *In 2009:* Lowered the base composite rate for hospital-based facilities to equal the rate for freestanding facilities. *In 2011:* Expands the dialysis payment bundle to include: composite rate services, dialysis drugs, laboratory services, and other services furnished to treat end-stage renal disease. *In 2012:* Links payment to the quality of care providers furnish. *In 2012:* Requires that the Secretary annually update the payment rate for the expanded bundle by the market basket minus 1 percent.	*In 2011:* Adds separately billable drugs into the dialysis payment bundle.
CMS regulation	*In 2005:* Set the add-on payment at 8.7 percent of the composite rate. Adjusted payment based on age and two measures of body mass.	Payment based on average acquisition payment, which was based on an Office of Inspector General–sponsored survey of providers' average acquisition cost.
	In 2006: Updated the add-on payment by 1.4 percent, thus increasing the add-on payment to 14.5 percent of the composite rate.[b] Began phasing in an updated wage index.	Payment set at average sales price plus 6 percent. Eliminated differences in drug payment between freestanding and hospital-based facilities.
	In 2007: Updated the add-on payment by 0.5 percent, thus increasing the add-on payment to 14.9 percent. Continued to phase in changes to wage index.	No change.
	In 2008: Updated the add-on payment by 0.5 percent, thus increasing the add-on payment to 15.5 percent. Continued to phase in changes to wage index.	No change.
	In 2009: No change to the add-on payment based on a projected price decline of 1.8 percent for dialysis drugs and a projected zero growth in per patient utilization. Add-on payment is 15.2 percent of the composite rate.[c] Completes four-year transition to a wage index based on core-based statistical areas.	No change.

Note: a. The base composite rate in 2005 was $128.35 for freestanding facilities and $132.41 for hospital-based facilities.
b. In addition, CMS moved to an average sales price–based payment method in 2006, which lowered the payment rate for dialysis drugs and required CMS to shift more drug profits to the add-on payment to maintain budget neutrality.
c. The MMA required that CMS implement the add-on payment in a budget-neutral manner. Because MIPPA increased the composite rate by 1 percent in 2009, CMS had to decrease the add-on payment to the composite rate from 15.5 percent in 2008 to 15.2 percent in 2009.

Source: MedPAC review of federal legislation and CMS regulations.

bone mineral metabolism, and maximizing the placement of the recommended type of vascular access (arteriovenous fistula). Each facility's performance scores will be reported online and posted at each facility.

MIPPA also modifies the current dialysis payment method by updating the prospective payment that covers the costs of services associated with a dialysis treatment—the composite rate—by 1 percent in 2009 and in 2010. In addition, beginning in 2009, it eliminates the difference in the base composite rate payment between hospital-based and freestanding facilities, which is consistent with the Commission's recommendation (MedPAC 2005).

At the end of this chapter, we discuss some of the issues policymakers will need to consider when implementing the new payment method.

Are Medicare payments adequate in 2009?

Each year, MedPAC makes a payment update recommendation for outpatient dialysis services for the coming year. In our framework, we address whether payments for the current year (2009) are adequate to cover the costs efficient dialysis providers incur and how much efficient providers' costs should change in the coming year (2010). Information we look at to assess payment adequacy includes beneficiaries' access to care, changes in the volume of services, and the relationship between Medicare's payments and providers' costs. In addition, the MMA requires that we consider the efficient provision of services in recommending updates.

Most of our indicators of payment adequacy are positive:

- Access to care appears to be good. Providers have sufficient capacity to meet demand.
- The growth in the number of dialysis treatments generally kept pace with the growth in the number of dialysis patients during the past decade.
- Since 2004, spending on dialysis drugs grew more slowly than in the past because of statutory and regulatory changes that lowered the payment rate for most dialysis drugs. The decline in the per treatment use of erythropoietin, the leading dialysis drug, may also be linked to a warning by the Food and Drug Administration (FDA) and recent studies reporting side effects with the use of this drug class.
- Quality is improving for some measures; for example, high proportions of patients are receiving adequate dialysis and have their anemia under control. Other measures suggest that quality improvements are needed, such as the proportion of dialysis patients who are registered on the kidney transplant waiting list.
- Providers' access to capital is good. The number of facilities—particularly for profit—continues to increase.
- The Medicare margin for composite rate services and dialysis drugs was 4.8 percent in 2007. We project the Medicare margin for composite rate services and dialysis drugs will be 1.2 percent in 2009.

Beneficiaries' access to care continues to be favorable

To assess beneficiaries' access to care, we look at:

- The capacity of providers to meet patient demand by assessing the growth rates of the dialysis population, dialysis facilities, and hemodialysis treatment stations.
- Changes in patients' ability to obtain different types of dialysis methods. Clinical factors, such as the patients' health problems, and nonclinical factors, such as training of physicians and patients' preferences, can affect the choice of dialysis. In addition, Medicare's payment policies might also affect the use of home dialysis. The Commission's 2006 and 2007 March reports provide a more complete discussion of this topic.
- Whether certain beneficiary groups face systematic problems in obtaining care. From this analysis, we assess whether certain types of patients, such as African Americans and dual-eligible patients, are having problems obtaining care.

Providers' capacity has kept pace with patient demand

Our analysis of the growth in the number of hemodialysis patients, stations, and facilities suggests that the growth in capacity appears to have kept up with the demand for care during the past decade. Since 2003, the total number of dialysis facilities and hemodialysis stations grew at annual rates of 3 percent and 4 percent, respectively, keeping up with the 4 percent per year growth in the number of dialysis patients.

Another indicator that suggests providers are able to meet the demand for care is "same-store growth"—the change in the number of hemodialysis treatments provided in consecutive years by a given provider. Facilities can increase the number of treatments they furnish by treating more patients, by providing more treatments to existing patients, and by increasing the number of shifts per day that they dialyze patients.[5] Between 2004 and 2005, facilities increased the total number of hemodialysis treatments they furnished by 4.0 percent. Since 2000, annual same-store growth has ranged from 3.8 percent to 4.8 percent.

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

Access to specific types of dialysis shows little change over time according to data from CMS. Between 1998 and 2008, at least 96 percent of all facilities offered in-center hemodialysis and 46 percent offered some type of peritoneal dialysis—continuous cycler-assisted peritoneal dialysis or continuous ambulatory peritoneal dialysis. Between 2003 and 2008, the proportion of facilities offering home hemodialysis increased from 12 percent to 18 percent of facilities. In addition, industry data suggest that dialysis facilities are beginning to offer patients the opportunity to receive in-center nocturnal hemodialysis. For example, DaVita operates 75 facilities (representing about 5 percent of all its facilities) with in-center nocturnal programs (Mathews 2008).

Most patients receive dialysis in dialysis facilities. In 2006 (the most current year for which data are available), 92 percent of all dialysis patients received hemodialysis in a facility, while 7 percent received peritoneal dialysis (at home) and 1 percent received home hemodialysis (USRDS 2008). Between 1995 and 2006, the number of patients receiving hemodialysis in a facility increased by 6 percent per year, while the number of patients treated at home declined by 2 percent per year. However, since 2002, the number of home dialysis patients has modestly increased. Between 2002 and 2006, use of peritoneal dialysis increased from 25,355 patients to 26,114 patients, while use of home hemodialysis increased from 1,756 patients to 2,455 patients.

Despite this modest increase in home dialysis, fewer patients overall dialyzed at home in 2006 than in the mid-1990s. Home dialysis offers several advantages related to quality of life and satisfaction to those patients who are able to dialyze at home. Compared with in-center hemodialysis, home dialysis is more convenient for patients because they can dialyze on their own schedules.

During the past few years, the use of more frequent hemodialysis (furnished either at home or in center) has also modestly increased. As mentioned in the text box (pp. 134–135), interest in more frequent hemodialysis regimens has grown substantially during the past decade because of studies showing improved outcomes and quality of life. According to CMS's facility survey, between 2004 and 2006, the number of patients receiving more frequent hemodialysis doubled to about 1,000 patients.

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

As shown in Table 2C-2 (p. 136), the supply of dialysis facilities and total hemodialysis stations is increasing. But, as in prior years, we wanted to see whether the types of patients using new, continuing, and closed facilities suggest some differences in access to treatment. Specifically, we compared the characteristics of patients treated by facilities that were open in 2006 and 2007, that newly opened in 2006, and that closed in 2006.

Some of our findings are consistent with long-term trends in supply (as shown in Table 2C-2, p. 136). Compared with facilities that remained open, facilities that closed in 2006 were more likely to be:

- hospital based
- nonprofit
- less profitable than facilities that remained open as measured by the Medicare margin.

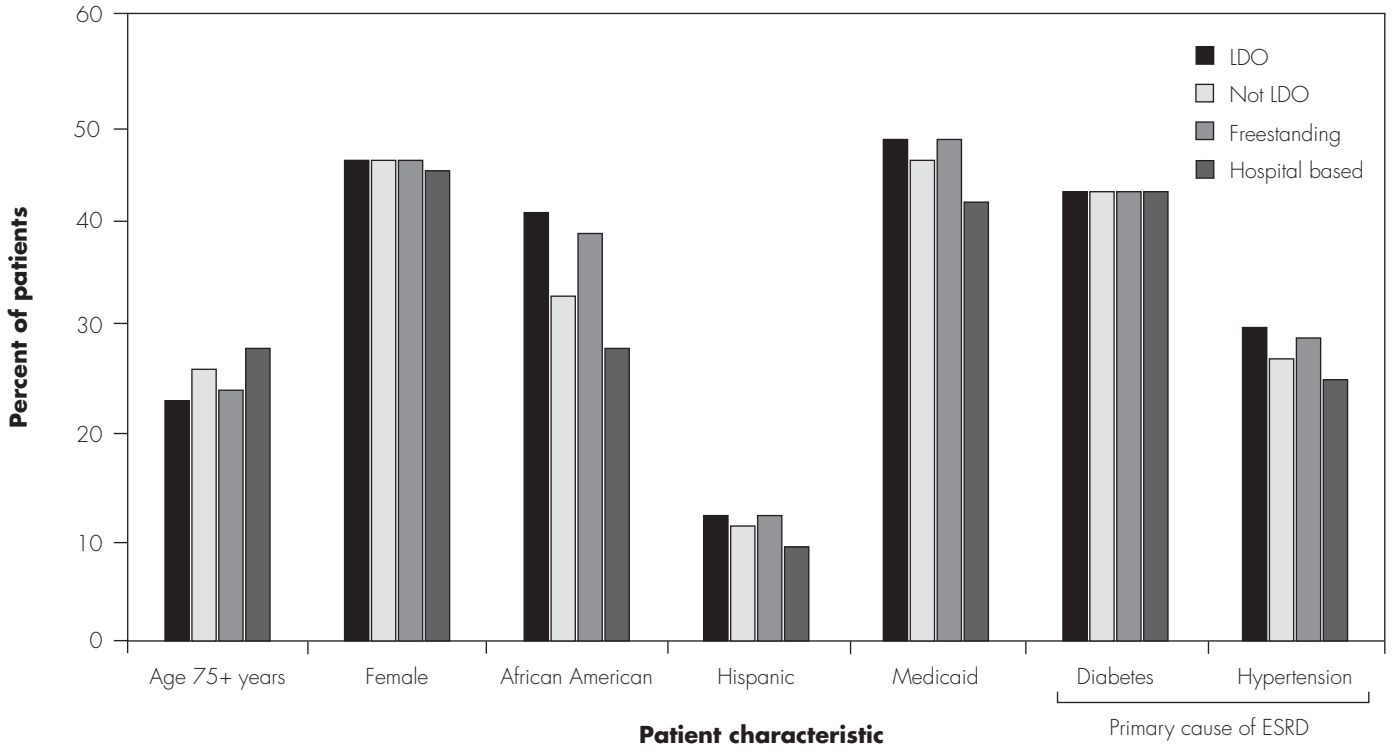
In addition, facilities that closed had less capacity than those that remained open (averaging 13 hemodialysis stations compared with 18 hemodialysis stations).

About 30 percent of facilities that closed were in rural areas, compared with 25 percent of those that stayed open in 2006 and 2007 and 25 percent of those that opened in 2007. Facility closures in rural areas do not appear to limit providers' capacity. Between 2006 and 2007, the number of hemodialysis stations grew in rural areas by 6 percent, from about 15,800 stations to 16,800 stations.

In contrast to previous years, facilities that closed in 2006 did not have a higher share of African American and dual-eligible patients than facilities that remained open. Compared with facilities that remained in business, facilities that closed treated a smaller proportion of African

FIGURE 2C–2

Characteristics of dialysis patients, by type of facility, 2007



Note: LDO (large dialysis organization), ESRD (end-stage renal disease). The facility types are not mutually exclusive (see text).

Source: MedPAC analysis of dialysis claims files, denominator files, Renal Management Information System files, and Dialysis Compare files from CMS.

American patients (23 percent compared with 38 percent) and dual-eligible patients (44 percent compared with 47 percent). We found no substantial differences in the mix of patients by age, sex, or disease severity (measured by the Charlson index and primary cause of ESRD) among provider types.

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 patient groups, such as African Americans and dual eligibles. In the future, we intend to examine access-to-care issues for rural dialysis patients, such as whether the distances they travel to obtain dialysis care have changed over time. Longer travel times might disproportionately affect beneficiaries living in rural areas. Researchers have reported that in patients with longer travel times, a problem with transportation was a significantly more frequent reason to skip or to shorten a dialysis session (Moist et al. 2008).

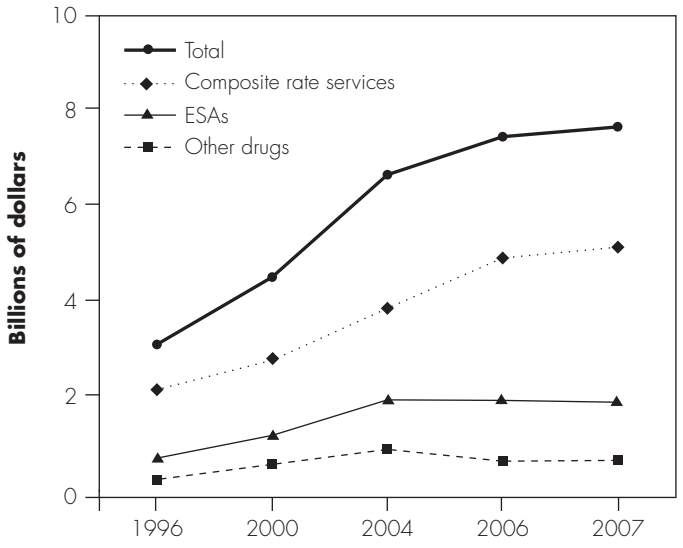
The mix of patients by provider type changed little in 2006 and 2007

We examined whether providers stopped treating certain types of patients by comparing the demographic and clinical characteristics of beneficiaries. Our analysis focused on certain groups, such as the elderly and 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 national chains, not affiliated with the two largest chains, freestanding, and hospital based. As shown later in this section, some of these groups overlap; for example, the two largest chains operate about 70 percent of all freestanding facilities.

Figure 2C-2 presents, for each type of provider, the proportion of patients in 2007 who were age 75 or older, female, African American, Hispanic, and dually eligible for Medicaid. Across the different provider types, the proportion of patients with these characteristics did not

FIGURE 2C–3

Statute and regulations changed trends in expenditures to freestanding dialysis facilities beginning in 2005



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

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

differ by more than 1 percentage point between 2006 and 2007 (data not shown for 2006). This analysis suggests that providers—including the two largest chains, which account for about 60 percent of all facilities—did not change the mix of patients they cared for in 2006 and 2007.

This analysis also shows that, in 2006 and 2007, freestanding facilities, which account for more than 85 percent of all dialysis facilities, were more likely than hospital-based facilities to treat African Americans and dual eligibles.

Volume of services

Between 1996 and 2007, the growth in the number of in-center hemodialysis treatments generally kept pace with the growth in the number of dialysis patients. The number of dialysis treatments increased, on average, by 6 percent annually; in comparison, the number of dialysis patients increased, on average, by about 5 percent.

Freestanding facilities treat most dialysis patients and account for nearly 90 percent of spending (about $7.7 billion in 2007) for composite rate services and dialysis drugs (Figure 2C-3). Since 2004, total payments to freestanding dialysis providers grew more slowly than in the past because spending on dialysis drugs decreased. Aggregate expenditures increased by about 10 percent per year between 1996 and 2004 but then slowed to a 5 percent increase between 2004 and 2007. Specifically:

- Drug expenditures by freestanding dialysis providers declined by 3 percent per year (from $2.8 billion to $2.5 billion) between 2004 and 2007. By contrast, between 1996 and 2004, dialysis drug expenditures grew by 15 percent per year, from $951 million to $2.8 billion.
- Expenditures for composite rate services increased by 10 percent between 2004 and 2007, while expenditures for these services increased 8 percent annually between 1996 and 2004.

The decline in spending on dialysis drugs is partly due to provisions in the MMA that increased Medicare's payment rate for composite rate services but lowered the rate for dialysis drugs beginning in 2005. 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. The MMA required that CMS base payment amounts for all dialysis drugs on providers' acquisition costs. In 2007, the agency paid 106 percent of the ASP for dialysis drugs. Thus, between 2004 and 2007, Medicare's payment rate for erythropoietin (the leading dialysis drug based on payments) dropped by 8 percent. We computed the percentage by which the 2007 payment rate was below the pre-MMA payment amounts for the leading dialysis drugs available in 2004 and 2007. When weighted by the 2007 payments to freestanding facilities for each drug, overall payment rates for the leading dialysis drugs declined by about 16 percent during this period.[6]

Despite the decrease in the payment rate, the total volume of most dialysis drugs increased between 2004 and 2007. 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 in 2004. We found that between 2004 and 2007, the total volume of dialysis drugs increased by 4 percent per year, an annual rate of growth that was slower than in the year that preceded the change in payment method.

The total volume of three injectable drugs—sodium ferric gluconate, calcitriol, and levocarnitine—has declined since 2004. Providers replaced sodium ferric gluconate and calcitriol with other injectable drugs that treat the same

comorbidities (iron deficiency and low blood calcium, respectively). Providers might be replacing injectable levocarnitine, which Part B covers, with oral levocarnitine, which Part D covers. In the future, the Commission intends to study the use of drugs covered under Part D by dialysis patients.

In addition to the MMA payment policy changes, two other factors may have contributed to a slowdown in Medicare spending for erythropoiesis-stimulating agents (ESAs)—erythropoietin and darbepoetin alfa:

- In March 2007, the 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 measures a patient's anemia status, expressed as a percentage of red blood cells in the bloodstream. 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 chronic kidney disease patients (who are not on dialysis) and 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 of a patient with a hemoglobin or hematocrit that exceeds 13 grams per deciliter (g/dL). 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 (NKF 2008).

Although the total volume of erythropoietin used by dialysis patients increased between 2004 and 2007, the number of units per treatment declined during this period. We found that the units per treatment increased by 7 percent per year in the year preceding the payment change—between 2003 and 2004. By contrast, between 2004 and 2007, units per treatment declined by about 2 percent. As discussed below, patients' anemia status, as measured by CMS, has improved between 2001 and 2006 (the most current year for which data are available).

Quality of dialysis care is improving for some measures

CMS data show that some aspects of dialysis care have improved. Between 2001 and 2006, the proportion of hemodialysis patients receiving adequate dialysis (a measure of how effectively dialysis removes waste products from the body) has increased (Table 2C-4, p. 144). The proportion of patients receiving adequate dialysis declined for one type of peritoneal dialysis (continuous cycler-assisted peritoneal dialysis). Increasing proportions of both hemodialysis and peritoneal patients have their anemia under control.

Patients' anemia status is related to the dose of ESAs they receive. As mentioned above, recent studies have shown that targeting higher hemoglobin values and high doses of ESAs was associated with increased mortality and morbidity for chronic kidney disease patients (who are not on dialysis) and cancer patients.

In addition, use of the recommended type of vascular access—AV fistula—has improved since 2001. 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.[7] For most patients, clinical guidelines consider an AV fistula a better type of vascular access than an AV graft or a catheter. AV fistulas last a long time and have fewer complications, such as infections and clotting, than other types of vascular access (NIDDK 2008b). CMS is leading a national quality initiative—Fistula First—to increase the use of fistulas. CMS's current goal is to have fistulas placed in at least half of new hemodialysis patients and to have a minimum of 66 percent of patients who continue dialysis using a fistula.

Other measures suggest that improvements in dialysis quality are still needed. Between 2001 and 2006, the proportion of dialysis patients who were registered on the kidney transplant waiting list increased from 13 percent to 16 percent of all dialysis patients, but the number fell far short of the Centers for Disease Control and Prevention Healthy People 2010 target of 30 percent. Registration for transplant is an important quality measure because most experts agree that kidney transplantation is the best treatment option for ESRD. National data are unavailable for another transplant-related quality measure—the proportion of all ESRD patients who were educated that transplantation is one of the treatment options for

TABLE 2C–4 **Dialysis outcomes continue to improve for some measures**

Outcome measure	2001	2002	2003	2004	2005	2006
Percent of in-center hemodialysis patients:						
Receiving adequate dialysis	92%	92%	94%	95%	94%	93%
With anemia under control	75	78	81	80	80	82
Dialyzed with an AV fistula	31	33	35	39	44	45
At lower risk for being malnourished	82	81	81	82	80	81
Percent of peritoneal dialysis patients:						
Receiving adequate CAPD	68	71	70	73	72	75
Receiving adequate CCPD	70	66	65	59	59	64
With anemia under control	76	81	83	82	83	85
At lower risk for being malnourished	56	60	63	62	62	63
Percent of prevalent dialysis patients wait-listed for a kidney	13	14	15	15	16	16
Annual mortality rate per 1,000 patient years	220	217	214	210	206	201
First-year mortality rate per 1,000 patient years	256	256	253	250	244	N/A
Total admissions per patient per year	2.06	2.05	2.04	2.06	2.06	1.97
Hospital days per patient per year	14.7	14.7	14.6	14.8	14.7	13.7

Note: AV (arteriovenous), CAPD (continuous ambulatory peritoneal dialysis), CCPD (continuous cycler-assisted peritoneal dialysis), N/A (not available). 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 2001–2007 Annual Reports for ESRD Clinical Performance Measures Project from CMS and USRDS 2008.

ESRD and evaluated for appropriate referral. The text box (pp. 146–147) summarizes some of the issues about access to kidney transplantation and Medicare payment for persons undergoing the procedure. The Commission intends to continue to study issues related to access to transplantation.

Other quality indicators have changed little in recent years. The proportion of dialysis patients with low albumin levels 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 have remained steady at about two admissions per year. Overall mortality and first-year adjusted mortality rates among dialysis patients have decreased during this time. By race, one-year mortality is lower among African American dialysis patients than among whites (226 vs. 259 per 1,000 patient years, respectively) (USRDS 2008).

Finally, two significant events occurred that affected the quality of dialysis care in 2008. First, updated conditions for coverage—the health and safety rules that all Medicare and Medicaid participating dialysis providers must meet—went into effect in October 2008. The new standard modernizes Medicare's standards for delivering safe, high-quality care to dialysis patients that the agency originally published in 1976. CMS anticipates that the new standard will promote higher quality of care for dialysis patients. It focuses on the importance of patients' rights, safety, and participation in the development of their own plan of care, and it includes a framework to incorporate performance measures that the medical community associates with dialysis quality. Importantly, the new standard requires that all dialysis facilities electronically submit their patients' clinical information to CMS via a web-based software application (CROWNWeb).

Second, in 2008, the use of heparin, a blood-thinning drug that was manufactured in China, resulted in reported instances of serious injuries and deaths. Heparin is commonly used by patients before they begin dialysis as well as by patients before certain types of surgery, including coronary artery bypass graft surgery. In February

2008, a manufacturer (Baxter International, Inc.) recalled its version of heparin because of reports of harmful side effects (FDA 2008). The adverse events included allergic or hypersensitivity-type reactions, with symptoms such as low blood pressure, angioedema, shortness of breath, nausea, vomiting, diarrhea, and abdominal pain. The FDA later reported that the heparin was contaminated. The FDA linked 149 patient deaths to one or more of the allergic symptoms associated with the contaminated heparin since January 2008 (FDA 2008). The FDA announced that, as of June 2008, all supplies of heparin sold in the United States were safe.

Access to capital is adequate

Providers need access to capital to improve their equipment and open new facilities to accommodate the growing number of patients requiring dialysis. Both small and large chains appear to have adequate access to capital, as demonstrated by their ability to make large purchases and the willingness of private investors to fund their acquisitions. For example:

- Fresenius has advanced its vertical integration by purchasing one pharmaceutical manufacturer and entering into a long-term licensing agreement with another. In 2008, Fresenius's subsidiary purchased a pharmaceutical company—APP Pharmaceuticals, Inc.—for $3.7 billion plus the assumption of $940 million in outstanding debt. APP manufactures injectable drugs, including heparin, that dialysis patients use. To finance the purchase of APP, Fresenius secured a $2.4 billion credit from Deutsche Bank, Credit Suisse, and JP Morgan (Reuters 2008). In addition to the APP purchase, Fresenius obtained an exclusive sublicense for 10 years to distribute, manufacture, and sell a type of injectable iron (Venofer) that dialysis patients use.[8]

- During the first 9 months of 2008, DaVita acquired six dialysis facilities, opened 22 new centers, merged 2 centers, and divested 1 center. In addition, DaVita repurchased 3,461,353 shares of its common stock for $169.7 million (globeinvestor.com 2008). Both actions suggest that DaVita has good access to capital. In addition, DaVita was added to Standard & Poor's 500 Index.

- In October 2008, Renal CarePartners announced a $10 million equity investment by a leading venture capital firm. Renal CarePartners intends to use the funds from this investment to continue to expand its growing network of dialysis facilities (RenalWEB News Service 2008).

- In November 2008, Dialysis Corporation of America amended its secured revolving credit facility with KeyBank to provide for up to $25,000,000 in financing. This three-year agreement is intended to support the company's growth and general business purposes (StreetInsider.com 2008a).

- In May 2008, Ambulatory Services of America received a $75 million investment from Lindsay Goldberg (Nephrology News & Issues 2008). The company intends to use the funds to acquire facilities and to enable its growth strategy.

- In late 2007, a new company, Reliant Renal Care, Inc., formed with the initial placement of $50 million in private equity (Reliant Renal Care, Inc. 2007). By the end of 2008, this new company operated eight facilities.

Home dialysis is an area that also appears to be attractive to investors. For example, Home Dialysis Plus, Ltd.—a developer of devices and products for dialysis—and Hewlett-Packard announced a licensing agreement. Home Dialysis Plus, Ltd., intends to adapt Hewlett-Packard's inkjet technology for use in its home dialysis machine to mix the correct amount of water and concentrated dialysate in real time and pump the dialysis solution into the dialyzer (Business Wire 2008). NxStage, a manufacturer of home hemodialysis equipment, announced a $43 million private placement of its common stock (StreetInsider.com 2008b). In November 2008, NxStage announced that it ranked 14th on Deloitte's 2008 Technology Fast 500, a ranking of the 500 fastest growing technology, media, telecommunications, and life sciences companies in North America (Bio-Medicine 2008).

As mentioned earlier, an increasing proportion of dialysis providers are freestanding, bigger, owned by publicly traded companies, operated by a chain, and for profit. These trends in the profit status, size, and consolidation of dialysis providers suggest that the dialysis industry is an attractive business to for-profit providers and that potential exists for efficiencies and economies of scale in providing dialysis care.

Between 2007 and 2008, the large dialysis chains and small chains showed similar growth rates, which suggests

Kidney transplantation as a treatment option for end-stage renal disease

It is widely believed that kidney transplantation is the best treatment option for individuals with end-stage renal disease (ESRD). Transplantation reduces mortality and improves patients' quality of life (Eggers 1988, Kasiske et al. 2000, Laupacis et al. 1996, Ojo et al. 1994). In large part, the small percentage of ESRD patients receiving a transplant is due to the shortage of organs. The Organ Procurement and Transplantation Network (OPTN), a public–private partnership mandated by the Congress in 1984, coordinates the process of matching and placing organs for every transplantation in the United States. OPTN's primary goals are to increase the available supply of organs for transplantation and to improve the efficiency and equity of organ allocation (OPTN 2003).[9] Notwithstanding organ shortages, the number of kidney transplants performed annually in the United States has nearly doubled since 1991, reaching more than 18,000 in 2006 (USRDS 2008).

Like dialysis, the cost of kidney transplantation is covered by Medicare for any ESRD patient who is eligible for Social Security benefits, even those under age 65 years. Initially, the 1972 amendments to the Social Security Act extended full Medicare benefits to kidney transplantation patients for one year. Current law mandates that all individuals receiving a Medicare-covered transplant are eligible for full Medicare benefits—including the immunosuppressive drug benefit—for 36 months after a transplant. Some observers have questioned whether the 36-month eligibility period affects patient outcomes. Little evidence in the peer-reviewed literature connects Medicare coverage to patients' adherence to their immunosuppressive drug regimen (which is crucial for the success of a kidney transplant). However, some peer-reviewed research reports that the higher rate of kidney graft failure for lower income patients (compared with higher income patients) decreased after the Congress extended the post-transplantation Medicare eligibility period for the immunosuppressive drug benefit from one year to three years (Woodward et al. 2008, Woodward et al. 2001, Yen et al. 2004).

The percentage of ESRD patients wait-listed for a kidney transplant has steadily increased over the past two decades. In 2006, 70,000 individuals (or roughly 16 percent of all dialysis patients) were on the waiting list (USRDS 2008).[10] Patients aged 50–64 represent 42 percent of the waiting list. More wait-listed patients were male (58 percent) than female (42 percent). About two-thirds of patients received a kidney from a deceased donor while one-third received a kidney from a live donor.

(continued next page)

that both small and large providers have adequate access to capital. During this period, the number of hemodialysis stations operated by Fresenius and DaVita grew by 4 percent. The smaller chains, which currently operate between 29 and 205 units, grew, in terms of number of hemodialysis stations, by an average of 3 percent between 2007 and 2008. These smaller chains include Dialysis Clinic, Inc.; National Renal Institutes; American Renal Associates; Renal Research Institute; Dialysis Corporation of America; Satellite Healthcare; and Renal Advantage and National Renal Alliance, which recently merged.

The two largest national chains have enjoyed mostly positive ratings from financial analysts in 2008. Investor analysts generally viewed dialysis providers' fundamentals—including the aging of the U.S. population, the higher incidence of diabetes, and recurring demand—as favorable from an economic perspective. According to Wachovia, "the dialysis sector [is] a safe haven for investors, with minimal risk of downward earnings revisions on financing pressure." In addition, Wachovia noted that "[the] volume growth is consistent and not subject to economic pressure" (Wachovia 2008). These investor analysts concluded that the reimbursement outlook is positive, with Medicare's payment set through 2010 with 1 percent updates for both 2009 and 2010 and the statutory update beginning in 2012.

Kidney transplantation as a treatment option for end-stage renal disease (cont.)

Access to kidney transplantation is not distributed uniformly across the ESRD population. In 2006, the incident rate of ESRD was 3.6 times higher for African American patients than for white patients, yet African Americans received 24 percent of total kidney transplants, compared with the 66 percent of transplants that went to white ESRD patients (USRDS 2008). Similarly, African Americans represented 35 percent of the transplant waiting list while more than half the wait-listed patients were white (USRDS 2008). Researchers have found that African American patients are less likely than white patients to be deemed appropriate candidates for a kidney transplant. They are also less likely than white patients to be referred for evaluation, much less receive a complete evaluation (Epstein et al. 2000). Even African Americans who are referred to the transplant waiting list are likely to spend more time on dialysis than white patients, a factor that decreases the probability of a successful transplant (Cass et al. 2003, USRDS 2008). The Commission intends to continue to monitor access to transplantation.

Access to transplantation also varies by insurance status. The uninsured population is far more likely to donate a kidney than to receive a transplant, as a recent study shows. While roughly 18 percent of kidney donors are uninsured, few kidney recipients are uninsured (Herring et al. 2008). This finding is associated with the availability of Medicare benefits to most people with ESRD. Research also suggests that Medicaid ESRD patients may be less likely to be placed on the transplant waiting list than their dually eligible Medicare/Medicaid or Medicare counterparts (Thamer et al. 1999).

Finally, residence in a rural area decreases the likelihood of obtaining a new kidney. Researchers found that residents of isolated rural areas and micropolitan regions were significantly less likely to obtain a kidney transplant. However, rural patients on the waiting list for a new kidney did not wait longer than their urban counterparts and there were no significant differences in post-transplantation outcomes between geographic areas (Axelrod et al. 2008).

An additional factor that might affect whether an ESRD patient is wait-listed for a kidney transplant is ownership of the dialysis facility. While the research is almost 10 years old, researchers found that for-profit ownership of dialysis facilities, compared with not-for-profit ownership, correlated with decreased rates of placement on the kidney waiting list (Garg et al. 1999). By implementing education of pre-ESRD patients about the different treatment options, including transplantation, the Medicare Improvements for Patients and Providers Act of 2008 may narrow the gap between waiting list placement rates by facility. ■

At the same time, investor analysts have pointed out that dialysis providers face potential pressures from private payers. Although Medicare is the primary payer for about 80 percent of these chains' patients, the proportion of revenues from Medicare is about 60 percent. Revenues from commercial payers account for about 40 percent of the chains' revenues.

The recent economy-wide turmoil in the capital markets does not appear to have significantly impaired access to capital for the publicly traded dialysis facilities. For example, a representative from Fresenius announced that the company is seeing little impact from the circumstances (Forbes.com 2008).

Investigations by the federal and state governments could affect a company's ability to gain access to capital. The OIG is reviewing the appropriateness of claims submitted by dialysis facilities for erythropoietin and other dialysis drugs. The OIG intends to determine whether facilities supported and billed the claims in accordance with Medicare requirements. In December 2008, DaVita received a subpoena from the OIG for documents related to Medicare claims for several dialysis drugs including erythropoietin. The OIG is also beginning to look into whether the dosing guidelines used by dialysis facilities for ESAs adhere to FDA labeling guidelines. The FDA modified ESAs' labeling in 2007 because of the health

TABLE 2C–5 **Medicare margin in 2007 varies by type of freestanding provider**

Provider type	Percent of spending by freestanding facilities	Medicare margin
All	100%	4.8%
Largest two chains	68	6.9
All others	32	0.2
Urban	82	5.1
Rural	18	3.1

Source: Compiled by MedPAC from 2007 cost reports and 2006 outpatient claims submitted by facilities to CMS.

risks associated with high doses of these biologics. The OIG's review will address concerns that some facilities may be using guidelines, standards, and protocols that are not consistent with FDA's revised labeling recommendations.

Payments and costs for 2007

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 would spend on delivering high-quality care. The latest and most complete data available on freestanding providers' costs are from 2007.[11]

When considering whether payments in the current year are adequate, we account for policy changes (other than the update) that are scheduled to take effect in the policy year under current law. In 2007 and 2008, CMS paid providers ASP plus 6 percent for all dialysis drugs. The MMA required that CMS, beginning in 2006, annually increase the add-on payment based on the estimated growth in drug spending from the previous year. The 2008 add-on payment of 15.5 percent also included an update of 0.5 percent. CMS did not change the add-on payment for 2009 because the agency concluded that per patient utilization of dialysis drugs would not grow between 2008 and 2009. However, because MIPPA increased the composite rate payment by 1 percent in 2009, CMS is required by law to adjust the add-on payment to maintain budget neutrality. Thus, the add-on payment is 15.2 percent of the composite rate in 2009.

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 2000 and 2007, the cost per treatment for composite rate services and drugs rose by 3.3 percent per year. The variation in cost growth across freestanding dialysis facilities shows that some facilities are able to hold their cost growth well below others'. For example, per treatment costs increased by 2.0 percent per year for facilities in the 25th percentile of cost growth, compared with 4.7 percent for facilities in the 75th percentile.

The growth in the cost per treatment during that period partly stems from rising general and administrative costs, which increased by 9 percent per year and accounted for about 30 percent of the total cost per treatment in 2007. 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, capital and labor costs (associated with direct patient care) increased by 2 percent per year while other direct medical costs decreased by 2 percent per year between 2000 and 2007. Capital, labor, and other direct medical costs accounted for 19 percent, 41 percent, and 11 percent, respectively, of the total cost per treatment in 2007.

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 freestanding providers' costs are from 2007.

For 2007, we estimate that the aggregate Medicare margin for composite rate services and dialysis drugs was 4.8 percent (Table 2C-5). The distribution of margins in 2007 shows wide variation in performance among freestanding dialysis facilities as well as variation by other facility groupings. One-quarter of freestanding facilities had margins at or below –2.2 percent, but half of the facilities had Medicare margins of at least 6.2 percent, and one-

quarter of the facilities had Medicare margins of at least 14.1 percent.

As in earlier years, facilities affiliated with the largest two chains tended to have higher margins than other freestanding facilities (6.9 percent vs. 0.2 percent). In addition, between 2006 and 2007, the difference in the margin for the largest two chains and other freestanding facilities widened. Last year we reported that the 2006 aggregate margin was 7.6 percent for the two largest dialysis chains and 2.0 percent for other freestanding facilities (MedPAC 2008). The difference in margins between the largest two chains and other freestanding facilities stems from differences in the composite rate cost per treatment and drug payment per treatment. Compared with their counterparts, facilities affiliated with the two largest chains had lower composite rate costs per treatment and higher drug payments per treatment. The latter finding stems from differences in the provision of dialysis drugs; the two largest chains furnish, on average, a higher volume of dialysis drugs than other freestanding facilities.[12] In addition, dialysis drugs are more profitable for the two large dialysis chains than for other freestanding facilities (OIG 2007).

Margins also varied based on the location of a facility. Consistent with our past findings, urban facilities had a greater Medicare margin than rural facilities. This finding partly stems from differences in the provision of dialysis drugs: on average, urban facilities furnish a greater volume of dialysis drugs than rural facilities.

The aggregate 2007 margin dropped by about 1 percentage point from the 2005 and 2006 margins, which we estimated to be 5.8 percent and 5.9 percent, respectively (MedPAC 2008, MedPAC 2007). Changes in per treatment payment and costs can explain this direction. Medicare's payment per treatment for dialysis drugs, which accounts for about one-third of the total per treatment payment, dropped slightly between 2006 and 2007 because the per treatment dose of erythropoietin fell. (This drug accounts for about 70 percent of the dialysis drug payment.) This decline is linked to changes in providers' practice patterns in furnishing dialysis drugs. As mentioned above, recent studies have shown that some patients experience excess mortality and morbidity when given high doses of erythropoietin. In addition, CMS's payment policy was modified in 2006; the policy change reduces payment for ESAs if providers do not reduce the dosage of a patient with a hemoglobin or hematocrit that exceeds 13 g/dL. In addition, between 2005 and 2007, the cost per treatment for composite rate services grew by 4.9 percent per year while the legislated increase in the composite rate was 1.6 percent in both 2005 and 2006 and was 1.6 percent beginning in April 2007.

On the basis of 2007 payment and cost data, we estimate that the 2009 aggregate margin is 1.2 percent. This estimate reflects the 1 percent composite rate update in MIPPA, effective January 1, 2009. This estimate also reflects the 0.5 percent updates to the composite rate's add-on payment in 2008. (In 2009, CMS did not update the add-on payment.)

How should Medicare's payments change in 2010?

CMS measures price inflation for the goods and services associated with the composite rate. CMS's latest forecast of this index for calendar year 2010 is 2.5 percent. In assessing projected increases in providers' costs, 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' historical 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 maintain current law and update the composite rate by 1 percent for calendar year 2010. By comparison, an update based on the current forecast of the ESRD market basket (2.5 percent) less the Commission's adjustment for productivity growth would have yielded an update

of 1.2 percent, which closely approximates current law. (Note that CMS revises its market basket projections on a quarterly basis.)

RECOMMENDATION 2C

The Congress should maintain current law and update the composite rate in calendar year 2010 by 1 percent.

RATIONALE 2C

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 Medicare margin decreased by about 1 percentage point between 2006 and 2007.

IMPLICATIONS 2C

Spending

- Because there is a provision in current law to update the composite rate in 2010, this recommendation would not increase federal program spending.

Beneficiary and provider

- This recommendation does not increase beneficiary cost sharing relative to current law. 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. Any increase to the composite rate will increase beneficiary cost sharing. Some dialysis providers help financially needy patients by paying the premiums of Part B and medigap policies through a fund administered by the American Kidney Fund. In addition, Medicare reimburses dialysis providers for bad debt incurred from furnishing composite rate services.

The Commission has a long-standing recommendation to link payment to the quality of care that facilities and physicians furnish to patients. In 2004, we first recommended implementing a payment incentive program. MIPPA mandates that, beginning in 2012, the Secretary link Medicare's payment (under a bundled payment system) to the quality providers furnish.

Modernizing the dialysis payment method: Issues to consider

MIPPA mandates substantial changes to the outpatient dialysis payment method. The new law modernizes the payment method by expanding the payment bundle to include drugs, laboratory services, and other commonly furnished items that providers currently bill separately and by linking payment to quality. The Commission has examined some of the issues that policymakers will need to consider in implementing the new law.

Defining the payment bundle

The broader payment bundle will include injectable ESRD drugs and laboratory services for which facilities currently receive separate payment under Part B. It will also include the oral equivalents to the injectable drugs. The Commission, Government Accountability Office (2006), and others have supported expanding the composite rate bundle to create incentives for providers to furnish services more efficiently and to improve the quality of dialysis care.

The new law gives the Secretary the discretion to include other items and services that are furnished to dialysis beneficiaries for the treatment of ESRD. The Commission previously noted that including other services needed by most dialysis patients, like nutritional services (e.g., oral supplements) and Medicare-covered preventive services, might control total spending and lower the high level of morbidity among this population (MedPAC 2008, MedPAC 2005). Part D drugs used to treat ESRD-related comorbidities may be another candidate for the expanded bundle. Their inclusion might help ensure that beneficiaries receive appropriate care and that providers do not substitute Part D drugs for drugs that are covered under the broader dialysis bundle.

Unit of payment

The Secretary has discretion over the unit of payment for ESRD services, which is currently a single dialysis session. Changing the unit of payment to either a week or a month might give providers more flexibility in furnishing care. In addition, a weekly or monthly unit of payment is more consistent with the provision of peritoneal dialysis and short daily or nocturnal hemodialysis administered five to seven times per week. However, a weekly or monthly unit of payment may be administratively more difficult for CMS to administer. Expanding the unit of payment to a week or a month would require the agency to adjust the rate for patients who do not receive dialysis when they are hospitalized, are traveling, or do not show up for their scheduled dialysis treatment (i.e., not adhering to their prescribed treatment regimen). As noted earlier, dialysis patients are hospitalized for more than 13 days per year on average.

TABLE 2C–6

The broader payment bundle will be adjusted for patient case mix, high-cost cases, facilities with low volume, and other factors

Adjustment	MIPPA	Current law
Case mix*	Factors will include—among others—patient weight, body mass index, comorbidities, number of years that a beneficiary has received dialysis, age, race, and ethnicity.	The composite rate is adjusted for patients' age and two body measurement variables. There is no adjustment to Medicare's payment for dialysis drugs separately paid for under Part B.
High-cost patients*	This factor will adjust for unusual variations in the type or amount of necessary care, such as variations in the amount of erythropoiesis-stimulating agents that treat anemia.	There is no adjustment for high-cost patients under the composite rate. Facilities bill on a per unit basis for Part B dialysis drugs not included in the composite rate. Thus, facilities are paid for the higher doses of drugs they furnish (as long as the drugs are medically reasonable and necessary).
Low-volume facilities*	This factor will adjust for the higher costs incurred by low-volume facilities. The adjustment will not be less than 10 percent during the phase in of the broader payment bundle (2011–2013). The new law gives the Secretary discretion in defining low-volume facilities.	There is no such adjustment under current law. However, facilities are reimbursed for their bad debt associated with composite rate services.
Pediatric patients**	The Secretary may include a payment adjustment for pediatric facilities.	Medicare provides for an exception to the composite rate for a facility with at least 50 percent of its patients under the age of 18.
Geographic factors**	The Secretary may include a payment adjustment for geographic factors.	CMS adjusts the composite rate for differences in local input prices by using the Office of Management and Budget's Core-Based Statistical Areas. The agency uses the acute care hospital wage and employment data for fiscal year 2004 to calculate the ESRD wage indexes in 2008. The labor-related portion of the composite rate is 53.7 percent for both provider types.
Rural facilities**	The Secretary may include a payment adjustment for rural facilities.	There is no such adjustment under current law.

Note: MIPPA (Medicare Improvements for Patients and Providers Act of 2008), ESRD (end-stage renal disease).
*The Secretary is required to adjust payment for this factor.
**The Secretary has the option to adjust payment for this factor.

Adjusting the payment rate for patient case mix, high-cost cases, and other factors

The new law mandates that the Secretary adjust the expanded bundle for (1) high-cost outliers, (2) facilities with low volume, and (3) patient case mix. The Secretary has the discretion to maintain an adjustment for geographic factors and create new adjustments for facilities that treat a high proportion of pediatric patients and facilities located in rural areas. Table 2C-6 compares the adjustments to the payment rate under MIPPA with the adjustments under current law.

Several issues exist for policymakers to consider when implementing these adjustments. For example, one adjustment involves increasing the payment rate for low-volume facilities with higher than average costs. MIPPA requires that the adjustment not be less than 10 percent during the phase-in of the broader payment bundle between 2011 and 2013. At issue is whether such an

adjustment is necessary for low-volume high-cost facilities that are close to other facilities. Adjusting the payment rate for such facilities, regardless of their proximity to other facilities, does not seem consistent with the notion of promoting provider efficiency. The new law gives the Secretary discretion in defining low-volume facilities.

The Commission's analysis of 2007 cost reports suggests that about one-quarter of low-volume high-cost facilities are located within two miles of another facility. In that analysis, we defined low-volume facilities as those with less volume than facilities in the 90th percentile of in-center hemodialysis treatments and high-cost facilities as those whose cost per hemodialysis treatment was greater than that for facilities in the 90th percentile of costs. Our preliminary analysis suggests that about 120 facilities met this definition of low volume and high cost. The average distance to the closest dialysis facility—13.4 miles—masks differences at the extremes: One-quarter of facilities were within about 2 miles of another facility while another one-quarter of facilities were more than 21 miles from the closest facility. Policymakers will need to consider whether payment adjustments should be made to facilities in close proximity to another facility.

Another issue warranting further examination is the overlap or duplication among payment adjustments. For example, the adjustments for geographic factors, facilities located in rural areas, and low volume would together affect the payment rate based on the facility's geographic location.

Payment for different types of dialysis

Another key issue to consider under the broader payment bundle is whether Medicare should continue to pay the same rate for all types of dialysis. Currently, CMS pays the same composite rate for the various dialysis methods. The Congress called for the same rate when this payment system was created in 1981 to encourage the use of home dialysis.

Under a broader bundle, the Secretary could set the same rate for all dialysis methods, which would give some incentive for providers to furnish lower cost treatments. Providers' costs to furnish peritoneal dialysis are lower, on average, than their costs to furnish in-center hemodialysis. Between 2000 and 2007, the cost per treatment for composite rate services was 3 percent to 15 percent lower for peritoneal dialysis than for in-center hemodialysis. In addition, peritoneal dialysis patients on average use less dialysis drugs per treatment than in-center hemodialysis patients. Commission and USRDS data both show that per capita drug payments are, on average, lower for peritoneal dialysis than for in-center hemodialysis.[13] Alternatively, the Secretary could set different payment rates for each method based on the resources each method requires.

Implementing a pay-for-performance program in 2012

The new law takes several steps to ensure that facilities continue to provide high-quality care under the new payment method. The Secretary must develop measures assessing each facility's anemia management and dialysis adequacy and, to the extent possible, indicators of patient satisfaction, iron management, bone mineral metabolism, and vascular access.

In general, the Secretary must select measures endorsed by a consensus entity with a contract under section 1890(a).[14] The Secretary has the authority to use a measure not endorsed by the consensus entity as long as due consideration is given to measures endorsed by the consensus entity. The Secretary is required to establish a process for updating the measures.

In addition to the measures specified in the law, there may be other measures the Secretary could explore using the pay-for-performance program. For example, serum albumin level is a potential measure not mentioned in MIPPA. It is a marker for patients being at increased risk for malnutrition; patients with comparatively lower serum albumin levels have a higher risk for malnutrition, hospitalization, and mortality (Lacson et al. 2009). Also, protein energy malnutrition, which is common among dialysis patients, is one of the strongest predictors of hospitalization and mortality. Surveys suggest that up to 70 percent of dialysis patients have protein energy malnutrition (NKF 2008). The Secretary could explore these and other clinical measures that assess patients' nutritional status.[15]

Linking payment to nutritional status would give providers an incentive to improve patients' quality of care. Under a broader bundle, providers would have the flexibility of improving patients' nutritional status as they see fit. For example, dietitians could provide additional counseling to patients on eating healthier diets. In addition, providers could furnish oral supplements to those patients who would benefit from the treatment. In 2007, the Commission convened an expert panel of physicians who treat dialysis patients (MedPAC 2008). The panel noted that, although eating healthier diets is ideal, the constraints

many patients face led most panel members to suggest the use of oral supplements, which they estimated would benefit more than half of all dialysis patients.

The Secretary could also consider whether to rely primarily on intermediate outcomes that measure clinical outcomes, such as dialysis adequacy and anemia management, or to include measures that assess rates of morbidity, such as admissions to inpatient hospitals, use of emergency departments, and mortality. Researchers have found that in patients receiving long-term hemodialysis, meeting multiple clinical measure targets (dialysis adequacy, anemia management, use of AV fistula for vascular access, and serum albumin as a proxy for nutritional status) is associated with a decrease in hospitalization and mortality rates (Rocco et al. 2006). Specifically, there was a progressive increase in the risk for one-year mortality and hospitalization rates for each clinical measure that was not met. At issue is whether morbidity and mortality measures together might be a more holistic way to capture improvements in a patient's clinical condition than individual intermediate outcomes.

To assess each facility's performance, the Secretary will calculate a performance score for each quality measure. In addition, the Secretary will develop a total performance score calculated by weighting the individual performance measures to reflect the priorities for quality improvement. The individual and total performance scores will be publicly available online and posted at each facility.

Each year, the Secretary will develop a performance standard for assessing facilities' quality of care. Specifically, the new law requires that the Secretary:

- develop a performance standard based on levels of achievement and improvement using the selected quality measures.
- set a one-year performance period.
- establish the performance standard before the beginning of the performance period under assessment.

Providers may meet performance standards by demonstrating improvement or high levels of achievement. The law permits the Secretary to reduce the bundled payment rate by a maximum of 2 percent for facilities that do not achieve or make progress toward the performance standard. Facilities achieving the lowest total performance scores will receive the largest reduction in payments.

The new law specifies the initial performance standard. Each facility's performance on anemia management and dialysis adequacy will be measured against the lesser of its performance between 2007 and 2009 or the national performance rate. ■

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 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 According to CMS's facility survey, 5 percent of all dialysis patients were not enrolled in the Medicare program in 2004 and 2005.

4 In 2005, Medicare used three different ways to pay for dialysis drugs: (1) For the top 10 dialysis drugs that accounted for the greatest payment in 2004, Medicare paid freestanding providers by using a method called the average acquisition payment. To calculate this rate, CMS used the acquisition costs the Office of Inspector General collected in a 2003 survey of freestanding providers. (2) For all other dialysis drugs furnished by freestanding providers, CMS used a different method—average sales price. This method uses the prices manufacturers report to the agency each quarter. CMS set the 2005 rates for these drugs at average sales price plus 6 percent. (3) Unlike freestanding providers, CMS paid hospitals their reasonable costs for all dialysis drugs except erythropoietin. CMS paid the same average acquisition payment rate as freestanding providers.

5 Facilities can increase the number of treatments provided to a given patient by: (1) improving patients' compliance in attending their thrice weekly hemodialysis treatments, and (2) reducing the number of days that patients are hospitalized. CMS pays for three hemodialysis treatments per week.

6 Leading drugs available in 2004 and 2007 included in this analysis are erythropoietin, calcitriol, doxercalciferol, iron sucrose, levocarnitine, paricalcitol, sodium ferric gluconate, darbepoetin alfa, alteplase, and vancomycin.

7 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.

8 The Federal Trade Commission's (FTC's) review of the agreement between the two companies raised concerns that Fresenius's vertical integration could increase Medicare's payment rate (average sales price) for Venofer. Therefore, the FTC issued a consent order that is preventing Fresenius from reporting an intracompany transfer price to CMS for Venofer higher than the level determined in the consent order, which was determined from current market prices.

9 In the 1984 National Organ Transplantation Act, the Congress created the Organ Procurement and Transplantation Network (OPTN). OPTN is a public–private partnership, administered by the United Network for Organ Sharing (UNOS). Since 1986, UNOS has collected and managed data on every organ transplant occurring in the United States and facilitated the organ matching and placement processes (UNOS 2009, OPTN 2003).

10 However, the USRDS reports that only 46,000 wait-listed patients were considered active.

11 We do not include hospital-based providers in the margin analysis, because cost data for dialysis drugs are missing from the cost reports for most of these providers.

12 Other researchers have also reported that, on average, the largest two chains provide a greater volume of dialysis drugs (on a monthly basis) than their counterparts (USRDS 2008).

13 A previous Commission analysis reported that Medicare's payment for dialysis drugs averaged $90 per treatment for in-center hemodialysis patients compared with $31 per treatment for peritoneal dialysis patients in 2003 (MedPAC 2006). More current USRDS analyses also show differences in per capita drug payments between the dialysis types (USRDS 2008).

14 Section 1890(a) of MIPPA requires that the Secretary contract with a consensus-based entity, such as the National Quality Forum, as soon as practicable for a four-year period.

15 No single measure provides a comprehensive indication of protein energy nutritional status. Although researchers and clinicians use serum albumin as an indicator of nutritional status, other conditions, such as acute or chronic inflammation, can affect a patient's albumin level. The Commission's expert panel of physicians who treat dialysis patients suggested several potential measures including serum albumin concentrations, C-reactive protein levels, and some measure of weight loss (e.g., a 5 percent to 10 percent weight loss) over time (MedPAC 2008).

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