

SECTION
2C

Outpatient dialysis services

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

The Congress should update the composite rate in calendar year 2009 by the projected rate of increase in the end-stage renal disease market basket index less the Commission's adjustment for productivity growth. The Commission reiterates its recommendation that the Congress implement a quality incentive program for physicians and facilities that treat dialysis patients.

COMMISSIONER VOTES: YES 16 • NO 0 • NOT VOTING 0 • ABSENT 1

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 (2008) are adequate to cover the costs efficient dialysis providers incur and how much Medicare’s payments should change in the coming year (2009).

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 2005 and 2006. The volume of most dialysis drugs administered grew between 2004 and 2006 but more slowly than in the past because of statutory and regulatory changes that lowered the payment rate for most of them.

In this section

- Recent regulatory and legislative changes to dialysis payment policies
- Are Medicare payments adequate in 2008 and how should they change in 2009?
- Update recommendation
- Creating incentives to improve dialysis quality and providers’ efficiency

Some measures of quality of care are improving. Use of the recommended type of vascular access—the site on the patient’s body where blood is removed and returned during hemodialysis—has improved since 2000. More patients receive adequate dialysis and have their anemia under control. Some researchers have raised concerns about the health risks associated with the overuse of erythropoietin, the drug used to treat anemia. A payment bundle that includes all dialysis drugs, a policy that the Commission has recommended, might encourage more efficient drug use.

Other measures suggest that improvements in dialysis quality are still needed. Patients’ nutritional status has not improved during the past five years. At the end of this chapter, we discuss potential ways to improve nutritional status and vascular access care.

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 was 5.9 percent in 2006. The two largest dialysis organizations realized a higher Medicare margin than all other providers (7.6 percent vs. 2.0 percent). We project the overall Medicare margin will be 2.6 percent in 2008. This estimate reflects the update to the composite rate effective April 1, 2007, and the add-on payment in 2007 and 2008.

In summary, most of our payment adequacy indicators are positive. Providers have sufficient capacity to furnish care, growth in the volume of dialysis treatments is keeping pace with the growth in the number of beneficiaries, the quality of care is improving for some measures, and providers have sufficient access to capital. Therefore, the recommendation is to update the composite rate in 2009 by the projected rate of increase in the end-stage renal disease (ESRD) market basket less the Commission’s adjustment for productivity growth. We base our productivity adjustment on the 10-year

moving average of multifactor productivity in the economy as a whole, which is 1.5 percent for our 2009 deliberations. Under the current forecast of the ESRD market basket (2.5 percent), the Commission's recommendation would update the composite rate by 1.0 percent in 2009. CMS revises the input cost projections on a quarterly basis, so the actual update percentage may change as a result of those revisions.

Concomitant with the update recommendation, the Commission is reiterating its recommendation to link Medicare payment for providers treating dialysis patients to the quality of care they furnish (MedPAC 2004a). The outpatient dialysis sector is a ready environment for linking payment to quality. Credible measures are available that are broadly understood and accepted. Obtaining information to measure quality will not pose an excessive burden and measures can be adjusted for case mix so providers are not discouraged from taking more complex patients. ■

The Congress should update the composite rate in calendar year 2009 by the projected rate of increase in the end-stage renal disease market basket index less the Commission's adjustment for productivity growth. The Commission reiterates its recommendation that the Congress implement a quality incentive program for physicians and facilities that treat dialysis patients.

Recommendation 2C

COMMISSIONER VOTES:
YES 16 • NO 0 • NOT VOTING 0 • ABSENT 1

Background

End-stage renal disease (ESRD) is a chronic illness characterized by permanent kidney failure. ESRD patients include those who are treated with dialysis—a process that removes wastes and fluid from the body—and those who have undergone kidney transplantation and have a functioning kidney transplant.¹ Because of the limited number of kidneys available for transplantation, 70 percent of all ESRD patients undergo dialysis. Patients receive additional items and services during their dialysis treatments, including drugs to treat conditions resulting from the loss of kidney function (e.g., anemia and renal-related bone disease).

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. This disease-specific entitlement is unique in Medicare. Beneficiaries entitled to Medicare due to ESRD alone (i.e., people under age 65 and not disabled) have the same benefits as other Medicare beneficiaries.

Medicare coverage does not begin until the fourth month after the start of dialysis for patients entitled to benefits due to ESRD alone. Exceptions to this statutory provision are patients who have undergone a kidney transplant or who receive training to perform dialysis at home. In 2006, there were about 109,000 new dialysis patients. About half of all new ESRD patients are under age 65 and thus are entitled to Medicare only because they have chronic renal failure.

If an employer group health plan (EGHP) covers a patient at the time of ESRD diagnosis, then the EGHP is the primary payer for the first 33 months of care.² Medicare is the secondary payer during this time. EGHPs include health plans that patients were enrolled in through their own employment or through a spouse's or parent's employment before they became eligible for Medicare due to ESRD.

In 2006, Medicare covered more than 325,000 dialysis patients. About one-quarter of all newly diagnosed ESRD patients were entitled to Medicaid benefits and about one-quarter were covered by an EGHP (USRDS 2007). For both freestanding and hospital-based dialysis facilities, Medicare spending for dialysis and dialysis-related drugs totaled \$8.4 billion in 2006, an increase of 6 percent compared with 2005. Medicare expenditures for composite rate services and separately billable dialysis drugs averaged about \$26,000 per patient in 2006.

Recent regulatory and legislative changes to dialysis payment policies

Since 1983, Medicare has paid dialysis facilities a predetermined payment for each dialysis treatment. Under the prospective payment—the composite rate—Medicare pays for services that are associated with 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. MedPAC's Payment Basics provides more information about Medicare's method for paying for outpatient dialysis services (http://www.medpac.gov/documents/MedPAC_Payment_Basics_07_dialysis.pdf).

These payment policies remained relatively unchanged until the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), which increased the payment rate for dialysis treatments and decreased the payment rate for separately billable dialysis drugs. First, the MMA mandated paying providers an add-on payment in addition 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 and mandated that these changes occur in a budget-neutral manner.

Second, the MMA lowered the payment rate for most dialysis drugs to a rate closer to the prices providers paid. In 2005, CMS paid dialysis providers their acquisition cost—set at the average acquisition payment—for most (but not all) dialysis drugs.³ 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. As we discuss later, a recent study by the Office of Inspector General (OIG) concludes 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 payment system. Providers still receive the composite rate for each dialysis treatment and separate payment for certain dialysis drugs, such as erythropoiesis-stimulating agents (ESAs), which include erythropoietin and darbepoetin alpha, iron, and vitamin D analogs, and

**TABLE
2C-1**

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	<ul style="list-style-type: none"> • Increased the base composite rate by 1.6 percent in 2005.* • Created the add-on payment to the composite rate to account for the reduction in drug payment rate in 2005. • Required CMS to annually increase the add-on updated due to increased use and prices in separately billable drugs beginning in 2006. • Required CMS to adjust composite rate for case mix in 2005. • Gave authority to CMS to update the wage index. 	Reduced payment for separately billable drugs in 2005 by requiring that Medicare set payment based on providers' acquisition cost.
Deficit Reduction Act of 2005	Increased the base composite rate by 1.6 percent in 2006.	
Tax Relief and Health Care Act of 2006	Increased the base composite rate by 1.6 percent effective April 1, 2007.	
CMS regulation	<p><i>In 2005:</i> Set the add-on payment at 8.7 percent of the composite rate. Adjusted payment based on age and two measures of body mass.</p> <p><i>In 2006:</i> Updated the add-on payment by 1.4 percent, thus increasing the add-on payment to 14.5 percent of the composite rate.** Began phasing in an updated wage index.</p> <p><i>In 2007:</i> 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.</p> <p><i>In 2008:</i> 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.</p>	<p>Payment based on average acquisition payment, which was based on a survey—sponsored by the Office of Inspector General—of providers' average acquisition cost.</p> <p>Payment set at average sales price plus six percent. Eliminated differences in drug payment between freestanding and hospital-based facilities.</p> <p>No change.</p> <p>No change.</p>

Note: *The base composite rate in 2005 was \$128.35 for freestanding facilities and \$132.41 for hospital-based facilities.
 **In addition, CMS moved to a payment method based on average sales price in 2006, which lowered the payment rate for dialysis drugs and required CMS to shift more drug profits, thereby increasing the add-on payment.

Source: MedPAC review of federal legislation and CMS regulations.

laboratory tests that were not available when Medicare implemented the composite rate.

As intended by policy, the composite rate increased from about \$126 per treatment in 2004 to \$151 per treatment in 2006. At the same time, the drug payment per treatment declined from about \$92 per treatment to \$79

per treatment between 2004 and 2006. Per legislative and regulatory actions outlined in Table 2C-1, the composite rate (including the add-on payment) increased to about \$152 per treatment in 2007.

Are Medicare payments adequate in 2008 and how should they change in 2009?

Each year, the Commission makes a payment update recommendation for outpatient dialysis services for the coming year. In our framework, we address whether payments for composite rate services and dialysis drugs in the current year (2008) are adequate to cover the costs of efficient dialysis providers and how much efficient providers' costs should change in the coming year (2009). Information we examine 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 for composite rate services and dialysis drugs. 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:

- The proportion of providers furnishing the different types of dialysis remains unchanged between 1997 and 2007.
- Providers have sufficient capacity to meet demand.
- The number of facilities—particularly for profit—continues to increase.
- The growth in the number of dialysis treatments generally kept pace with the growth in the number of dialysis patients during the past decade.
- Spending on dialysis drugs grew between 2004 and 2006 but more slowly than in the past because of statutory and regulatory changes that lowered the payment rate for most dialysis drugs. The use of dialysis drugs continued to increase after 2004 but at a slower rate than in previous years.
- Quality is improving for some but not all measures.
- Providers' access to capital is good.
- The Medicare margin for composite rate services and dialysis drugs was 5.9 percent in 2006. We project the Medicare margin for composite rate services and dialysis services will be 2.6 percent in 2008.

Beneficiaries' access to care

To assess beneficiaries' access to care, we monitor changes in patients' ability to obtain different types of

dialysis methods and examine whether certain beneficiary groups face systematic problems in accessing care.

Access to the different types of dialysis

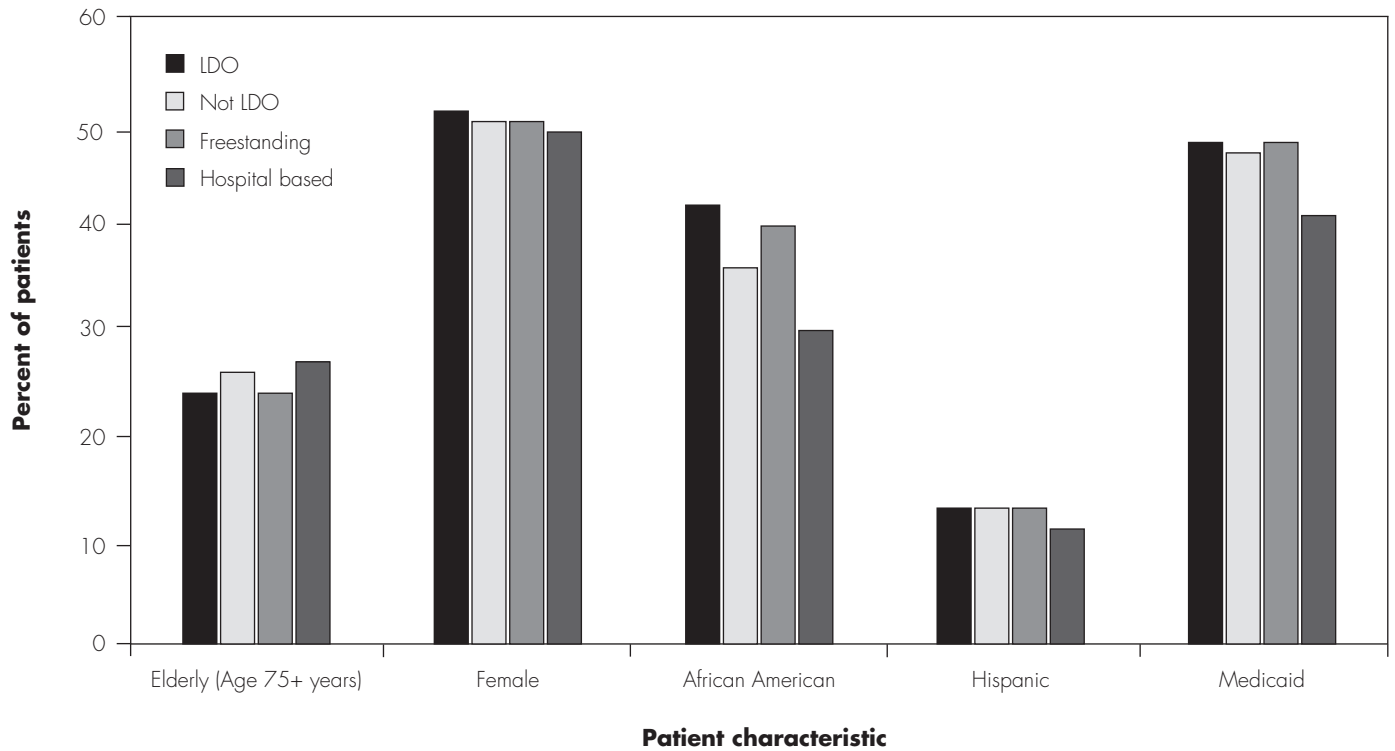
Access to specific types of dialysis—in-center hemodialysis, peritoneal dialysis (usually done in patients' homes), and home hemodialysis—shows little change over time. Between 1997 and 2007, at least 96 percent of all facilities offered in-center hemodialysis and 45 percent offered some type of peritoneal dialysis—continuous cycle peritoneal dialysis or continuous ambulatory peritoneal dialysis. The proportion of facilities offering home hemodialysis increased between 2006 and 2007. In 2003 and 2006, about 12 percent of facilities offered home hemodialysis (these data are not available before 2003); in 2007, 16 percent of facilities offered this type of dialysis.

Fewer patients overall are receiving dialysis in their homes. Most recent data from the United States Renal Data System (USRDS) show that, between 1996 and 2005, the number of patients receiving hemodialysis in facilities increased by 6 percent per year. By contrast, the number of patients treated at home (using peritoneal dialysis) declined by 1 percent per year.⁴ In 2005, most dialysis patients (91 percent) received hemodialysis in a facility, while 8 percent received peritoneal dialysis and 1 percent received home hemodialysis. 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 schedule. MedPAC's 2006 and 2007 March reports to the Congress discuss this topic more completely.

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 affect the use of home dialysis. In particular, the profitability of dialysis drugs before 2005 may have given some providers an incentive to furnish in-center dialysis instead of home dialysis. In-center patients on average use more dialysis drugs per treatment (as measured by payments) than home patients. The Commission will continue to monitor the use of home dialysis.

Did providers change the mix of patients they treated between 2005 and 2006?

We examined whether providers stopped treating certain types of patients by comparing the demographic and clinical characteristics of beneficiaries. This analysis

**FIGURE
2C-1****Characteristics of patients, by type of facility, 2006**

Note: LDO (largest dialysis organization).

Source: MedPAC analysis of dialysis claims files, denominator files from CMS.

focuses 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, which we refer to as the largest dialysis organizations (LDOs); not affiliated with the LDOs; freestanding; and hospital based. As shown later in this chapter, some of these groups overlap; for example, the LDOs operate about 70 percent of all freestanding facilities.

Figure 2C-1 presents, for each type of provider, the proportion of patients in 2006 who were elderly, female, African American, Hispanic, and dually eligible for Medicaid. Across the different provider types, the proportion of patients with these characteristics does not differ by more than 1 percentage point between 2005 and 2006 (data not shown for 2005). This analysis suggests that providers, including the LDOs, which account for

about 60 percent of all facilities, did not change the mix of patients they cared for in 2005 and 2006.

This analysis also shows that in 2005 and 2006, freestanding facilities were more likely than hospital-based facilities to treat African Americans and dual eligibles. As mentioned later in the section, freestanding facilities account for more than 85 percent of all dialysis facilities.

Do certain beneficiary groups face systematic problems in accessing care?

In general, the supply of facilities is increasing: In 2006, providers' capacity to furnish care improved with a net increase of 201 hemodialysis stations. But as in prior years, we wanted to see whether the types of patients using new, continuing, and closed facilities suggest some access differences. Specifically, we compared the characteristics of patients treated by facilities that were open in 2005 and 2006, that newly opened in 2006, and that closed in 2005.

Some of our findings are consistent with long-term trends we have seen in supply. Compared with facilities that remained open, facilities that closed in 2005 were more likely to:

- have less capacity (averaging 13 stations vs. 18 hemodialysis stations),
- be hospital based,
- be nonprofit, and
- be less profitable than facilities that remained open as measured by the Medicare margin.

Even though we see that closed facilities had a higher share of African-American and dual-eligible patients, we find that facilities that remained open also served many of these patients. Compared with facilities that opened in 2006, closed facilities treated a larger proportion of African Americans (54 percent vs. 30 percent) and dual eligibles (43 percent vs. 40 percent). At the same time, however, these groups have good access to facilities that remained open in both years. The proportion of African Americans and dual eligibles treated in facilities that remained open in 2005 and 2006 closely matches the share of these groups among all dialysis patients. Facility closures may not necessarily result in access problems as long as other facilities are available to treat patients.

We found no substantial differences in the mix of patients by age, sex, or disease severity (measured by a comorbidity scale, the Charlson index) among provider types. Closures do not disproportionately affect rural patients; 13 percent of closed facilities were in rural areas, compared with 25 percent of those that stayed open in 2005 and 2006.

Together, these findings suggest that most beneficiaries do not face systematic problems in obtaining care. Nonetheless, we will continue to monitor beneficiaries' access to care among different provider types. We are particularly interested in tracking whether facility closures may disproportionately affect certain patient groups, such as African Americans and dual eligibles.

What types of providers furnish dialysis care?

During the past 15 years, an increasing proportion of dialysis providers are freestanding, are bigger, are owned by publicly traded companies, are operated by a chain, and

operate for profit (Table 2C-2 (p. 118) and Figure 2C-2 (p. 119)). Moreover, the dialysis sector has evolved into an oligopoly, in which a small number of firms furnish most of the care. 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 all freestanding facilities (Figure 2C-2). 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 with the potential for efficiencies and economies of scale in providing dialysis care.

Between 1997 and 2007, freestanding facilities increased from 77 percent to 87 percent of all facilities, while for-profit facilities increased from 71 percent to 80 percent of all facilities (Table 2C-2). The absolute number of hospital-based facilities decreased (from 731 to 601, respectively) during this time. Most (91 percent) freestanding facilities are for profit. Most (94 percent) hospital-based facilities are nonprofit (data not shown).

Dialysis facilities are bigger in 2007 than in 1997; the average number of treatment stations increased from 15.5 stations to 17.5 stations during the past decade. This trend is consistent with the findings that freestanding facilities are bigger than hospital-based facilities (18.1 stations vs. 13.5 stations in 2007) and chain-affiliated facilities are bigger than facilities not operated by a chain (18.0 stations vs. 15.2 stations in 2007 (data not shown)).

Most freestanding dialysis facilities (87 percent) are affiliated with a chain; most hospital-based facilities (81 percent) are not. As mentioned earlier, the two largest chains account for about 60 percent of all facilities. The next largest chain (Dialysis Clinic Inc.) operates 4 percent of all facilities. Facilities not operated by these chains are:

- 58 percent for-profit and 42 percent nonprofit facilities,
- 67 percent freestanding and 33 percent hospital based, and
- 44 percent chain affiliated and 56 percent not affiliated with a chain.

The 3 largest chains operate facilities in 26 to 45 states. Most of the other 89 chains operate in fewer than 5 states. Five chains operate in up to 21 states.

**TABLE
2C-2**

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

	2007	Average annual percent change	
		1997-2007	2003-2007
Total number of dialysis facilities	4,798	4.2%	3.1%
Total number of hemodialysis stations	83,918	5.5	3.8
Mean number of hemodialysis stations per center	17.5	1.2	0.7
Percent of total, by type of facility			
Nonchain	21	N/A	-5.0
Affiliated with any chain	79	N/A	6.0
Affiliated with largest 2 chains	58	N/A	4.1
Rural	25	4.5	3.0
Urban	75	4.2	3.1
Freestanding	87	5.6	4.1
Hospital based	13	-1.9	-2.3
For profit	80	5.5	4.5
Nonprofit	20	0.5	-1.5

Note: N/A (not applicable). Nonprofit includes those designated as either nonprofit or government.

Source: Compiled by MedPAC from the 1997 Facility Survey file from CMS and from the 2003 and 2007 Dialysis Compare database from CMS.

Do providers have the capacity to meet patient demand?

Our analysis of the growth in the number of hemodialysis treatments, facilities, and patients suggests that the growth in capacity appears to have kept up with the demand for care during the past decade. Between 1997 and 2007, the total number of dialysis facilities and hemodialysis stations grew at annual rates of 4.2 percent and 5.5 percent, respectively, keeping up with the 5 percent per year growth in the number of dialysis patients (Table 2C-2).

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.

Volume of services

Between 1996 and 2006, 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 6.5 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 \$7.5 billion in 2006) for composite rate services and dialysis drugs (Table 2C-3, p. 120). Recently, total payments to freestanding dialysis providers grew more slowly than in the past. Aggregate expenditures increased by about 10 percent per year between 1996 and 2004 but then slowed to a 6 percent increase between 2004 and 2006.

Between 2004 and 2006, total payments increased but at a slower rate than in the past because drug spending fell. As a result of changes due to law and regulations:

- Drug payments to freestanding dialysis providers declined by 5 percent per year (from \$2.8 billion to \$2.6 billion) between 2004 and 2006. By contrast,

between 1996 and 2004, dialysis drug expenditures grew by 15 percent per year, from \$951 million to \$2.8 billion.

- Payments for composite rate services increased by 13 percent between 2004 and 2006, while spending for these services increased 8 percent annually between 1996 and 2004.

The decline in spending on dialysis drugs is due to the change in policy that lowered Medicare’s payment rate for these drugs. As mentioned earlier, Medicare paid freestanding facilities either 95 percent of the average wholesale price or a statutory rate for dialysis drugs in 2004. The MMA required that CMS base drug payment amounts on providers’ acquisition costs and, in 2006, the agency paid 106 percent of the ASP for dialysis drugs. Between 2004 and 2006, Medicare’s payment rate for erythropoietin (the leading dialysis drug based on payments) dropped by 5 percent. We computed the percentage by which the 2006 payment rate is below the pre-MMA payment amounts for the leading dialysis drugs available in 2004 and 2006. When weighted by the 2006 payments to freestanding facilities for each drug, overall payment rates for the leading dialysis drugs declined by about 14 percent during this period.⁶

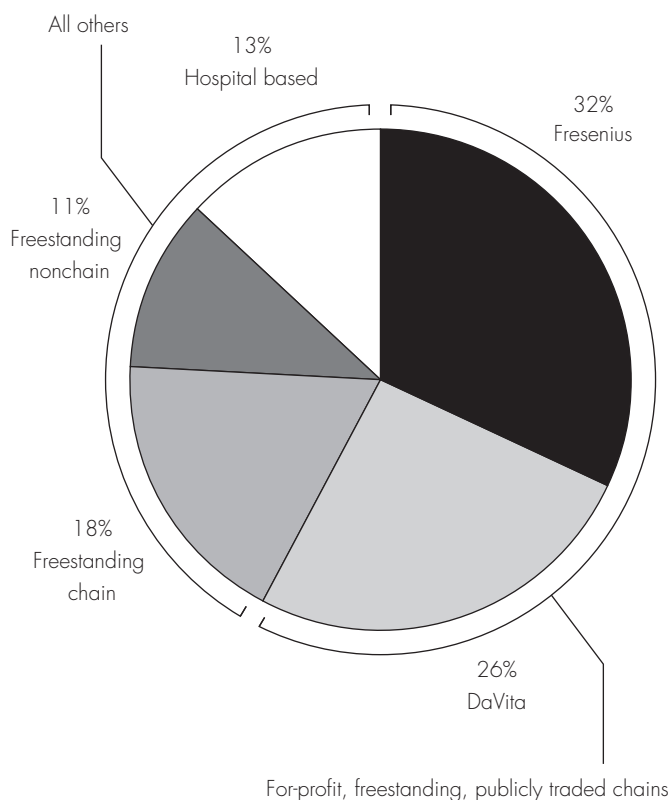
Despite the decrease in the payment rate, the volume of most dialysis drugs increased during this period. We assessed changes in the volume of the leading dialysis drugs by holding the drug payment rate constant and looking at the dollar change in the total volume of services for the top 11 dialysis drugs in 2004. We found that the volume of dialysis drugs increased by 5 percent per year between 2004 and 2006, an annual rate of growth that is slower than in the year that preceded the change in the payment method.

The volume of three injectable drugs—sodium ferric gluconate, calcitriol, and levocarnitine—declined between 2005 and 2006. 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. Part D data are not available to confirm oral levocarnitine use among dialysis patients (we call for release of these data in Chapter 4). Using oral levocarnitine for dialysis patients is inconsistent with the product’s Food and Drug Administration (FDA) label. The

FIGURE 2C-2

The dialysis industry is composed primarily of freestanding, for-profit facilities affiliated with a chain in 2007



Source: Compiled by MedPAC from the 2007 Dialysis Compare database from CMS.

FDA has approved only the injectable form for dialysis patients, not the oral form.⁷ We also checked whether the injectable form of levocarnitine is profitable. Like most other dialysis drugs, Medicare’s payment rate for injectable levocarnitine declined between 2005 and 2006 (from \$13.63 per gram in 2005 to an average of \$9.65 per gram in 2006); the OIG reports that freestanding facilities were able to purchase levocarnitine for an average of 23 percent below Medicare’s payment rate in the third quarter of 2006 (OIG 2007).⁸

To detect changes in erythropoietin volume, we also looked at the number of units administered per treatment between 2003 and 2006. We found that the units per treatment increased by 7 percent per year between 2003 and 2004 and remained relatively constant between 2004

**TABLE
2C-3**

The statute and regulations changed trends in payments to freestanding dialysis facilities beginning in 2005

	Payments (in millions)					Annual change in spending	
	1996	2000	2004	2005	2006	1996-2004	2004-2006
Total	\$3,090	\$4,506	\$6,658	\$6,935	\$7,457	10%	6%
Composite rate services	2,139	2,758	3,850	4,405	4,907	8	13
Dialysis drugs	951	1,747	2,808	2,531	2,550	15	-5
ESAs	700	1,178	1,925	1,922	1,914	13	-0.3
Other drugs	251	569	884	609	636	17	-15

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

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

and 2005 (declining slightly by 0.6 percent). Between 2005 and 2006, units per treatment increased by 2 percent.

Finally, to assess the impact on beneficiaries' outcomes, we looked at the proportion of beneficiaries receiving adequate dialysis and with their anemia under control between 2003 and 2006. For this analysis, we used data on dialysis adequacy and anemia status that providers are required to report on their dialysis and erythropoietin claims, respectively. The proportion of patients receiving adequate dialysis (i.e., patients who had a urea reduction ratio greater than 65 percent) has remained relatively constant since 2003 (94 percent in 2003, 95 percent in 2004 and 2005, and 94 percent in 2006). The proportion of patients whose anemia was under control (defined as patients with a hemoglobin concentration greater than 11 grams per deciliter (g/dL)) increased from 86 percent in 2003 to 89 percent in 2004, 90 percent in 2005, and 89 percent in 2006. As we discuss later (p. 123), the current FDA label recommends that patients' hemoglobin levels range from 10 g/dL to 12 g/dL.

Clinical effectiveness and payment method explain increasing use of dialysis drugs

The volume of dialysis drugs has grown partly because they are new and effective. Researchers have shown that these new drugs have benefited patients. However, the financial incentives of the current dialysis payment method have also contributed to the use of dialysis drugs; overuse of services can have negative clinical consequences. For example, Singh and colleagues (2006) reported that cardiovascular events (congestive heart failure, myocardial infarction, and stroke) were more frequent among patients

with chronic kidney disease maintained on higher doses of erythropoietin. Thus, the Medicare program needs to balance the tension between providing patients access to new and effective drugs and services and setting the payment rates so that providers do not overfurnish them, which could lead to negative clinical effects.

The FDA approved many of the drugs—including erythropoietin, vitamin D agents, and iron injectables—beginning in the late 1980s. Since then, the National Kidney Foundation (NKF) has advocated using them in its clinical guidelines. These medications have enhanced the quality of care furnished to dialysis beneficiaries. For example, erythropoietin has reduced the proportion of dialysis patients with anemia, which contributes to morbidity if not treated effectively. Medicare's coverage decisions also affect the use of these drugs. For example, CMS made a national coverage decision to cover injections of levocarnitine for patients with ESRD beginning January 1, 2003.⁹

Second, paying according to the number of units administered gives providers greater profits from larger doses than from smaller doses (as long as Medicare's payment rate exceeds providers' costs). The profitability of certain dialysis drugs under the old (pre-MMA) payment method gave providers the incentive to use more of them. As intended by the statute, CMS lowered the drug payment rate in 2005 and 2006, but this change did not eliminate the profitability of drugs (as mentioned previously).

In 2006, CMS began paying all dialysis facilities 106 percent of the ASP for all dialysis drugs. CMS calculates ASP based on actual transaction prices from data drug manufacturers submit quarterly. Paying based on ASP lowered the payment rate for all but one of the leading dialysis drugs in 2006. Although the payment rate dropped for most dialysis drugs, a recent OIG report concluded that dialysis drugs are profitable for most providers as of the third quarter of 2006 (OIG 2007). For freestanding facilities, the OIG reported that:

- Overall drug acquisition costs were, on average, 10 percent below the Medicare payment rate in the third quarter of 2006.
- Freestanding facilities could purchase 9 of the 11 leading dialysis drugs below the Medicare payment rate. For the remaining two drugs (alteplase and iron dextran, 50 milligrams), average acquisition costs ranged from 3 percent to 9 percent above the Medicare payment rate.
- Freestanding chain facilities purchased 8 of the 11 dialysis drugs at rates lower than freestanding facilities not operated by a chain.

Some policymakers are concerned about the use of ASP to pay for sole source drugs and biologics (sole source means that one manufacturer produces the drug). The text box (p. 122) summarizes the issues about using ASP for sole source drugs and biologics.

Historical trends in the use of erythropoietin demonstrate the concerns with paying for profitable services on a per unit basis. After CMS changed its method for paying for erythropoietin—from a relatively fixed payment per dose between 1989 and 1991 to a per unit basis after 1991—per patient use of the drug escalated 8 percent annually between 1991 and 2004 (from 7,100 units per week to 20,100 units per week) (USRDS 2007).¹⁰ Before 1991, providers received \$40 per dose for doses under 10,000 units and \$70 per dose for doses over 10,000. Under the pre-1991 payment method, the dose of erythropoietin (about 2,700 units per treatment) was much lower than on a per unit basis (Greer et al. 1999). CMS has tried to address the increasing per patient use of erythropoietin through a monitoring payment policy for ESAs (see text box, p. 124).

Paying on a per unit basis promotes use of the intravenous form of erythropoietin rather than the subcutaneous form, which requires higher average doses or units to achieve

target hemoglobin levels. Most hemodialysis patients (95 percent) in the United States receive erythropoietin intravenously (CMS 2005). Nonetheless, certain populations receive it subcutaneously. For example, approximately 70 percent of patients treated at facilities operated by the Department of Veterans Affairs receive erythropoietin subcutaneously (VA 2002). Thamer and colleagues (2006) reported greater use of subcutaneous erythropoietin therapy among patients in the Midwest and West, in facilities not affiliated with chains, and in hospital-based and nonprofit freestanding facilities. The NKF anemia guideline (recently updated in 2007) states that convenience favors the intravenous route for hemodialysis patients. The original NKF guideline published in 1997 stated that the preferred route of administration is subcutaneous in hemodialysis patients.¹¹ Some international guidelines recommend subcutaneous administration for hemodialysis patients, such as the European Best Practice Guideline.

Medicare could better achieve its objectives of providing incentives for controlling costs and promoting access to quality services if all dialysis-related services, including drugs, were bundled under a single payment. The Commission previously recommended that the Congress broaden the dialysis payment bundle and implement pay for performance for both physicians and facilities who treat dialysis patients (MedPAC 2004a, 2003, 2001). These steps should improve the efficiency of the payment system, better align incentives for providing cost-effective care, and reward providers for furnishing high-quality care.

ESA use varies considerably across providers and the FDA addressed some safety issues in 2007

Some researchers have suggested that providers could provide erythropoietin more efficiently and that appropriate use of intravenous iron could reduce erythropoietin dose requirements. Fishbane (2006) analyzed existing clinical trials and estimated that the erythropoietin dose could be lowered by 27 percent to 75 percent of the current average dosage with appropriate iron management. Pizzi and colleagues (2006) estimated a net savings to Medicare of \$257 per patient per month if providers followed the NKF anemia guideline. Data from the USRDS show some variation in spending for erythropoietin and intravenous iron among providers. Spending varied from \$522 to \$698 per patient per month for erythropoietin and from \$54 to \$92 for intravenous iron across the freestanding chains and hospital-based facilities (USRDS 2007). Among patients with similar hemoglobin levels, erythropoietin use varies considerably across

Concerns about the method Medicare uses to set payments for single source dialysis drugs and biologics

Paying according to the average sales price (ASP) has improved the accuracy of Medicare's method for paying for dialysis drugs by reducing the difference between Medicare's payment rate and providers' acquisition costs. Nonetheless, concerns remain that ASP may not appropriately pay for single source drugs and biologics without clinical alternatives (GAO 2006). The ASP method relies on market forces to achieve a favorable payment rate for Medicare—that is, one that is sufficient to maintain beneficiary access but not overly generous for providers and therefore wasteful for taxpayers. In principle, under ASP when two or more clinically similar products exist in a market, market forces could bring prices down, as each manufacturer competes for its own product's market share. In contrast, when a product is available through only one manufacturer and no clinically similar product exists, Medicare's rate may lack the moderating influence of competition.

For this reason, ASP may not be appropriate to set the payment for biologics and sole source drugs without clinical alternatives. The two erythropoiesis-stimulating agents (ESAs)—erythropoietin and darbepoetin—prescribed to dialysis patients are manufactured by the same company and have no competitor products in the dialysis market.¹² ESA spending by Medicare for dialysis patients in 2006 was substantial—\$2.1 billion—with erythropoietin spending, which totaled about \$1.9 billion, accounting for nearly all of it.

By contrast, in the European Union, a competitive market exists, with the availability of ESAs manufactured by more than one company. Some countries in Europe have national contracting for ESA products, which puts pressure on ESA suppliers to offer competitive pricing (Macdougall 2007).

A recent change to the alphanumeric code assigned to erythropoietin has lowered Medicare's payment rate for this biologic. Before July 2007, CMS used two codes to pay for erythropoietin—one for dialysis use and another

for nondialysis use. Historically, the payment rate for erythropoietin has been higher for dialysis use than for nondialysis use. (The nondialysis erythropoietin market is more competitive than the dialysis market because two companies market it.) Beginning in July 2007, CMS changed the coding of erythropoietin and began using one payment code (Healthcare Common Procedures Codes) for erythropoietin for both dialysis and nondialysis use. Since the coding change, the payment rate for erythropoietin for dialysis patients has decreased—from \$9.58 per 1,000 units before the coding change (in the second quarter of 2007) to \$9.10 per 1,000 units and \$9.06 per 1,000 units after the coding change (in the third and fourth quarters of 2007, respectively).

The dialysis ESA market may become competitive if follow-on (generic) products become available in 2012, when the manufacturer's patents on erythropoietin expire.¹³ One issue that may impede the availability of follow-on (generic) biologics, including erythropoietin, is the lack of an abbreviated process by the Food and Drug Administration (FDA) to approve them. Unlike drugs, manufacturers of follow-on biologics have to conduct clinical trials to show safety and efficacy. By contrast, manufacturers of generic drugs have to demonstrate only that their drug is equivalent to the sole source drug that they are copying. In 1984, the Hatch-Waxman Act created a process for the FDA to approve generic drugs after a sole source drug loses its patent protection. A statutory change would enable the FDA to create a biogenerics-approval pathway. The European Union is ahead of the United States in dealing with these issues; a follow-on erythropoietin will be available in 2008 (Macdougall 2007). Having an abbreviated biogenerics approval process is urgently needed because many of the most innovative and costly products entering the market are biologics. The availability of follow-on biologics will lead to increased competition, which in turn will improve the accuracy of Medicare's payment method and the value of Medicare spending. ■

providers. The USRDS reported that, among patients with hemoglobin levels of 12 g/dL, the average weekly erythropoietin dose ranged from 22,463 units to 34,046 units in 2005 (USRDS 2007). Even after adjustment for differences in case mix, the weekly erythropoietin dose varied among providers (Thamer et al. 2007).

A recent clinical trial reported more adverse health events among patients who received higher erythropoietin doses to achieve higher hemoglobin levels. Singh and colleagues (2006) reported that a higher target hemoglobin value (13.5 g/dL compared with 11.3 g/dL) was associated with increased risk of death, myocardial infarction, congestive heart failure, and stroke among patients with chronic kidney disease. Improvements in patients' quality of life were similar in both groups. On the basis of these results, the researchers recommended using a lower target hemoglobin level because of the increased risk, likely increased cost, and lack of quality-of-life benefit from maintaining a higher target hemoglobin level.

In 2007, the FDA reviewed the safety of ESAs and dosage instructions for treating anemia among patients with chronic renal failure, patients with cancer, and patients with human immunodeficiency virus undergoing zidovudine therapy. In March 2007, the FDA issued warnings for clinicians to prescribe ESAs more carefully. Specifically, the FDA included a new "black box" warning on the product's label and modified the dosing instructions. The new warning advised clinicians to monitor patients' levels of red blood cells and to use the lowest possible ESA dose to avoid the need for blood transfusions. The FDA previously revised the product labeling for ESAs in 1997, 2004, and 2005 to reflect new safety information.

In November 2007, the agency again revised the boxed warnings and made other safety-related product labeling changes. The revised label incorporated advice from the FDA advisory committees and expanded on labeling changes made in March 2007. For patients with chronic renal failure, the boxed warning states that ESAs should maintain a hemoglobin level between 10 g/dL and 12 g/dL. The boxed warning states that maintaining higher hemoglobin levels increases the risk for death and for serious cardiovascular effects such as stroke, heart attack, and heart failure. The new labeling provides instructions for dosage adjustments and hemoglobin monitoring for patients with chronic kidney failure who do not respond to ESA treatment with an adequate increase in their hemoglobin levels.

More evidence may be needed for providers to achieve optimal outcomes in the most efficient way

Some of the variability we see in the use of ESAs may reflect the lack of clinical evidence about their use. Notwithstanding the randomized comparative trials on ESA use among predialysis and dialysis patients, some clinicians contend that there are limited data on how best to achieve hemoglobin targets (Kasiske 2007). Lazarus and Hakim (2007) assert that there is no scientific evidence that a hemoglobin value of 12 g/dL is the threshold level above which there is significant health risk in dialysis patients. Weiner and Levey (2007) argue that the current clinical guidelines are unable to offer more than a loose framework of opinion-based guidance for erythropoietin administration and utilization. The latest NKF clinical guideline, updated in 2007, recommends that the target hemoglobin level should generally range from 11 g/dL to 12 g/dL and that it should not exceed 13 g/dL. This recommendation differs from the FDA label that advises ESA dosing in patients with renal failure to achieve and maintain hemoglobin levels within the range of 10 g/dL to 12 g/dL.

The many unanswered questions concerning the use of ESAs suggest the need for more evidence from randomized comparative-effectiveness trials. Cotter and colleagues (2006) recommended public sponsorship of clinical trials that would elucidate both physiological and clinical responses to erythropoietin administered at different dosages. Such trials could address not only outcomes but also how to achieve outcomes more cost effectively (Kasiske 2007). The Secretary might consider sponsoring the trials since Medicare is the largest purchaser of erythropoietin in the United States—total Medicare spending in 2006 included \$2 billion for dialysis patients and \$850 million for other patients, primarily cancer patients undergoing chemotherapy treatments. Medicare expenditures for ESAs account for the highest percentage of Medicare Part B drug spending. A federal government role may be warranted because several researchers have shown that industry-sponsored studies were significantly more likely to reach conclusions favorable to the sponsor than non-industry-sponsored studies (Bekelman et al. 2003). The Commission recommended that the Congress should charge an independent entity to sponsor credible research on comparative effectiveness of health care services and disseminate this information to patients, providers, and public and private payers (MedPAC 2007a). Finally,

The erythropoiesis-stimulating agent monitoring payment policy

CMS has developed a number of policies for paying for erythropoiesis-stimulating agents (ESAs) since it began to cover erythropoietin in 1989. CMS has based its policies on the hematocrit or hemoglobin level reported on erythropoietin claims. Both measures assess a patient's anemia status by determining the percentage of red blood cells in the bloodstream. Higher hematocrit and hemoglobin values suggest that a patient's anemia is under control.

Initially, CMS used the hemoglobin target range of 10 grams per deciliter (g/dL) to 11 g/dL, recommended by the Food and Drug Administration (FDA) as its cutoff for payment. In 1994, CMS adjusted its payment policy to reflect the FDA-approved labeled indication that broadened its recommended hemoglobin target range to 10 g/dL to 12 g/dL. Between 1991 and 1997, payments for erythropoietin grew from \$246 million to \$735 million. This rise in spending was related to increased use of erythropoietin and not to a price effect. During this time, providers increased the mean dose per administration and furnished erythropoietin to a larger proportion of patients (Greer et al. 1999). In 1994, Medicare's payment rate decreased from \$11 to \$10 per 1,000 units.

To address the rapid growth in erythropoietin use, CMS implemented a payment policy in August 1997

that did not pay providers for the last month's dosage of the drug if a patient's hemoglobin exceeded about 12.2 g/dL for a three-month average. The agency also eliminated physicians' ability to make exceptions to its hematocrit guidelines. During the next few months, the average patient hematocrit level stopped rising, and the average patient erythropoietin dose leveled off. CMS then increased the upper limit to 12.5 g/dL in 1998, and the average patient dose began to rise again.

Between 1997 and 2005, Medicare spending for erythropoietin increased from \$735 million to nearly \$1.9 billion. In April 2006, CMS implemented a new monitoring policy and revised it in October 2006 and July 2007. CMS made these changes partly in response to concerns about the risks to patients from receiving large doses of ESAs (CMS 2007a). In the latest revision, CMS will reduce payments (by 50 percent) if the facility reports that the beneficiary's hemoglobin has exceeded 13 g/dL for three consecutive months including the current billed month. Under the revised policy Medicare will not pay for dosages of erythropoietin that exceed 400,000 units per month or darbepoetin alpha in excess of 1,200 micrograms per month. Dosages at these levels are unlikely and are generally the result of typographical errors rather than accurate dosage reports. ■

improving the availability of information about the clinical and cost effectiveness of medical services may lead to more efficient use of Medicare's resources and address the long-term sustainability of the program.

The need for more clinical evidence in treating dialysis patients may not be limited to the use of ESAs. A recently published systematic review of randomized controlled trials of vitamin D compounds in patients with chronic kidney disease reported that these compounds have unclear benefits and potential harms (Palmer et al. 2007). The researchers reported that, although some vitamin D agents affected biochemical markers (e.g., the parathyroid hormone level), vitamin D agents did not reduce the risk of death and bone pain. The authors also noted that few studies have looked at patient-level outcomes and the

lack of studies comparing newer vitamin D agents with older ones. Medicare spent \$392 million on vitamin D compounds in 2006.

Quality of dialysis care

CMS data show that some aspects of dialysis care have improved. Between 2000 and 2005, the proportion of in-center hemodialysis patients receiving adequate dialysis (a measure of how effectively dialysis removes waste products from the body) increased (Table 2C-4). The proportion of patients receiving adequate dialysis declined for one type of peritoneal dialysis. Increasing proportions of both hemodialysis and peritoneal dialysis patients have their anemia under control.

**TABLE
2C-4**

Dialysis outcomes continue to improve for some measures

Outcome measure	2000	2001	2002	2003	2004	2005
Percent of in-center hemodialysis patients:						
Receiving adequate dialysis	91%	92%	92%	94%	95%	94%
With anemia under control	71	75	78	81	80	80
Dialyzed with an AV fistula	30	31	33	35	39	44
With low serum albumin (greater risk of being malnourished)	20	18	19	19	18	20
Percent of peritoneal dialysis patients:						
Receiving adequate CAPD	69	68	71	70	73	72
Receiving adequate CCPD	62	70	66	65	59	59
With anemia under control	75	76	81	83	82	83
With low serum albumin (greater risk of being malnourished)	44	39	40	37	38	38
Annual mortality rate per 1,000 patient years	213	213	211	208	204	200
First-year mortality rate per 1,000 patient years	242	238	238	235	232	N/A
Total admissions per patient year	2.02	2.05	2.04	2.04	2.05	2.01
Hospital days per patient year	14.4	14.6	14.6	14.5	14.7	14.3

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 2000–2005 Annual Reports for ESRD Clinical Performance Measures Project from CMS and USRDS 2007.

In addition, use of the recommended type of vascular access—an arteriovenous fistula—has improved since 2000. All hemodialysis patients require vascular access—the site on the patient’s body where blood is removed and returned during dialysis. 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 all new hemodialysis patients and to have a minimum of 66 percent of all patients who continue dialysis using a fistula.

Other measures suggest that improvements in dialysis quality are still needed. The proportion of dialysis patients with low serum albumin levels has remained unchanged. Patients with low serum albumin levels, a measure of increased risk of malnutrition, are at increased mortality risk. Since 1995, overall rates of hospitalization have remained steady at about two admissions per patient year. Although overall mortality rates have decreased (from 213 deaths per 1,000 patients to 200 deaths per 1,000 patients), first-year adjusted mortality rates among dialysis patients have remained relatively unchanged during this time. About one-quarter of all patients died during the first year of hemodialysis (USRDS 2007). At the end of this

section, we discuss potential ways to improve the quality of nutritional and vascular access care.

As the Commission has recommended in the past, linking payment to the quality of care provided by physicians and facilities treating dialysis patients is one way to improve dialysis quality (MedPAC 2004a). A Medicare program that rewards quality would send the strong message that it values the care beneficiaries receive and encourages investments in improving care. The dialysis sector is ready for pay for performance: Evidence-based measures are available, providers can improve on these measures, data are available to risk-adjust the measures, and systems are available to collect the information. CMS already collects some clinical information—dialysis adequacy and anemia status—on providers’ claims. CMS is developing additional data infrastructure that will permit the agency to collect information about quality of care from all facilities.

Access to capital

Recent financial information and evidence about trends in the increase in the number and capacity of dialysis facilities suggest that providers have sufficient access to capital, which they need to improve their equipment and to

open new facilities to accommodate the growing number of patients requiring dialysis.

Both small and large for-profit chains appear to have adequate access to capital, as demonstrated by the willingness of private investors to fund their acquisitions. For example:

- Fresenius's third-quarter 2007 profits exceeded analysts' predictions by increasing 30 percent compared with 2006 levels. A senior executive did not foresee problems in obtaining access to capital, stating that "[T]he banks have already signaled readiness to lend us money to finance acquisitions" (Reuters 2007). Fresenius had sufficient access to capital to acquire Renal Solutions, Inc., a medical device company with a technology for tap water purification for home dialysis.
- DaVita purchased a large amount of its stock, which suggests that it has good access to capital. In addition, DaVita acquired a majority stake in HomeChoice Partners Inc., a company that provides infusion therapy services, for approximately \$65 million in cash. Finally, DaVita entered into a multiyear agreement with NxStage Medical to expand the availability of home hemodialysis in the United States. Under the agreement, DaVita purchased \$20 million (7 percent) of NxStage stock.
- Dialysis Corporation of America announced its listing on the NASDAQ global market.
- DSI Holding Company received private equity to purchase 105 facilities, 3 home dialysis programs, and 1 renal acute program for approximately \$511 million from Fresenius and Renal Care Group. Centre Partners, a leading private equity firm, is backing DSI.
- National Renal Alliance received a commitment of \$100 million in private equity, which it will use to finance capital needs for acquisitions, to finance new facilities, and to provide working capital. National Renal Alliance doubled in size in each of the past two years.
- Renal Advantage, the fourth largest dialysis chain, purchased a clinical laboratory, RenaLab, from Fresenius.

Another indicator of adequate access to capital is growth in the number of dialysis facilities. Among the top 10 chains, the number of facilities grew by 7 percent between

2006 and 2007. Based on our analysis of CMS Dialysis Facility Compare data, these top 10 chains accounted for 70 percent of all dialysis facilities. Nearly all the growth has come from the smaller chains rather than from the two largest ones. These smaller chains, which currently operate between 26 and 198 units, grew by 46 percent between 2006 and 2007. One of the chains, National Renal Alliance, was named one of the 500 fastest-growing private companies in the United States (Inc. 2007).

The two largest national chains have, in large part, enjoyed positive ratings from financial analysts in 2007. Investor analysts note that the sector benefits from recurring revenues from dialysis treatments. Between 2000 and 2006, total revenues of dialysis facilities grew faster than revenues for the entire health care and social assistance services sector (11 percent vs. 7 percent per year, respectively) (Census Bureau 2007).

Investor analysts have also pointed out that the earnings of dialysis providers are sensitive to the coverage and payment policies of both private payers and Medicare. Although about three-quarters of these chains' patients are insured by Medicare as the primary payer, the proportion of revenues from Medicare represents about 55 percent of revenues for these chains. Revenues from commercial payers represent about 35 percent of revenues for these chains.

Payments and costs for 2006

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. We also consider the accuracy of the data freestanding providers include in their cost reports. We first examine two indicators of the appropriateness of current costs:

- trends in the growth of cost per treatment for composite rate services and dialysis drugs, and
- differences in cost per treatment for composite rate services between audited and unaudited cost reports for the same facilities.

We then present our calendar year 2008 projection of the Medicare margin for composite rate services and dialysis drugs for freestanding providers. The latest and most complete data available on freestanding providers' costs are from 2006.¹⁴

In modeling 2008 payments, we incorporate policy changes that went into effect between 2006 (the year of our most recent data) and 2009. In 2007 and 2008, CMS pays providers ASP plus 6 percent for all dialysis drugs. The MMA requires that CMS, beginning in 2006, annually increase the add-on payment based on the estimated growth in drug spending from the previous year. The 2007 add-on payment of 14.9 percent of the composite rate includes an update of 0.5 percent. The 2008 add-on payment of 15.5 percent also includes an update of 0.5 percent. Finally, we also incorporated the increase in the composite rate in 2007. For the first quarter of 2007, the composite rate payment remained at the 2006 level. Beginning in April 2007, CMS updated the composite rate by 1.6 percent, as mandated by the Tax Relief and Health Care Act of 2006.

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 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 2006, the cost per treatment for composite rate services and drugs rose by 2.7 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 1.3 percent per year for facilities in the 25th percentile of cost growth and by 4.2 percent for facilities in the 75th percentile.

The growth in the cost per treatment between 2000 and 2006 partly stems from rising general and administrative costs, which increased by 10 percent per year and accounted for about 30 percent of the total cost per treatment in 2006. By contrast, capital and labor costs increased by 2 percent per year while other direct costs decreased by 2 percent per year between 2000 and 2006. Capital, labor, and other direct costs accounted for 19 percent, 40 percent, and 11 percent, respectively, of the total cost per treatment in 2006.

We looked at whether facility-level characteristics and the mix of patients that facilities treat affect their costs. We estimated a cost function (using ordinary least-squares

regression) to examine the determinants of costs at the level of the dialysis facility.¹⁵

Providers' costs were significantly associated with economies of scale. The LDOs and facilities that provided more dialysis treatments exhibited lower costs relative to their counterparts. A number of patient case-mix variables were significantly associated with facility costs. An increasing proportion of diabetic patients lowered a facility's costs. Higher facility costs were associated with an increasing proportion of the number of days patients were hospitalized. The number of inpatient days may be a proxy for patients' severity of illness. In addition, facilities with a higher total number of inpatient days probably incur, on average, greater costs per treatment because they have to spread their fixed costs across fewer total treatments (Medicare's payment to the hospital covers the dialysis provided to hospitalized patients).

Auditing dialysis cost reports

For dialysis providers, the Commission has corrected providers' costs based on CMS's auditing efforts. For last year's report, we used 2001 audited cost report data and calculated the ratio of allowable costs to reported costs for the same facilities—94.5 percent for the cost per dialysis treatment. We then applied this correction to the costs of composite rate services for facilities for which CMS had not yet settled their cost reports in last year's analysis (MedPAC 2007b).

We made this correction because MedPAC's analysis of current costs uses only Medicare-allowable costs. In addition, audited cost reports are available for this sector. In the Balanced Budget Act of 1997, the Congress mandated that the Secretary audit cost reports of dialysis providers once every three years. The Commission's predecessor—the Prospective Payment Assessment Commission (ProPAC)—raised concerns about the reliability of dialysis cost reports and the need to have an accurate measure of the cost of providing dialysis services (ProPAC 1997).

This year, we updated our analysis by assessing the effect—that is, the difference between reported and allowed costs—of CMS's most recent auditing efforts of 2004 and 2005 cost reports. For the same facilities, we calculated the cost per treatment before and after CMS audited their cost reports in 2004.¹⁶ We then replicated this analysis using 2005 data.

**TABLE
2C-5****Medicare margin in 2006 varies
by type of freestanding provider**

Provider type	Percent of spending by freestanding facilities	Medicare margin
All	100%	5.9%
Largest two chains	69	7.6
All others	31	2.0
Urban	82	6.2
Rural	18	4.5

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

We find that the difference between reported and allowed costs has narrowed between 2001 and 2005. We calculated that the ratio of allowable cost to reported cost per dialysis treatment for facilities with audited cost reports was 94.5 percent in 2001, 97.8 percent in 2004, and 99.8 percent in 2005.

Because the difference between reported and allowable costs narrowed between 2001 and 2005, we will not correct providers' costs in this year's analysis based on CMS's auditing efforts. Next year, we will re-evaluate whether to correct for the audit by updating this analysis if CMS audits 2006 cost reports.¹⁷

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 2006.

For 2006, we estimate that the aggregate Medicare margin for composite rate services and dialysis drugs is 5.9 percent (Table 2C-5). The distribution of margins in 2006 shows wide variation in performance among freestanding dialysis facilities as well as variation by groups. One-quarter of all facilities had margins at or below -0.9 percent, but half of all facilities had Medicare margins of at least 6.9 percent, and one-quarter of facilities had Medicare margins of at least 14.6 percent. As in earlier years, we continue to see higher margins for facilities affiliated with the largest two chains. This finding stems

from differences in the composite rate cost per treatment and drug payment per treatment. Compared with their counterparts, the composite rate cost per treatment was lower and the drug payment per treatment was higher for the two largest chains.

In addition, margins vary based on the location of a facility. Consistent with our past findings, urban facilities have a greater Medicare margin than rural facilities. Although urban facilities have higher costs per treatment than rural facilities, urban facilities have higher payments per treatment than rural facilities.

Based on 2006 payment and cost data, we estimate that the 2008 aggregate margin is 2.6 percent. This estimate reflects the 1.6 percent composite rate update, effective April 1, 2007, legislated in the Tax Relief and Health Care Act of 2006. This estimate also reflects the 0.5 percent updates to the composite rate's add-on payment in 2007 and in 2008.

Update recommendation

On the basis of our review of payment adequacy for outpatient dialysis services and expected cost changes in the coming year, the Commission recommends that the Congress update the composite rate in 2009 by the ESRD market basket index less the Commission's adjustment for productivity growth (1.5 percent). Based on the current projection of the ESRD market basket (2.5 percent), this recommendation would update the composite rate by 1.0 percent.

RECOMMENDATION 2C

The Congress should update the composite rate in calendar year 2009 by the projected rate of increase in the end-stage renal disease market basket index less the Commission's adjustment for productivity growth. The Commission reiterates its recommendation that the Congress implement a quality incentive program for physicians and facilities that treat dialysis patients.

RATIONALE 2C

Most of our indicators of payment adequacy are positive, including beneficiaries' access to care, volume of services, and access to capital. The Medicare margin trended upward between 2000 and 2006. The Commission previously recommended linking the payment to physicians and facilities treating dialysis patients to the

quality of care they furnish. The dialysis sector is ready for pay for performance: evidence-based measures are available, providers can improve on these measures, data are available to risk-adjust the measures, and systems are available to collect the information.

IMPLICATIONS 2C

Spending

- Because there is no provision in current law to change the composite rate in 2009, this recommendation will increase federal program spending relative to current law by between \$50 million and \$250 million for calendar year 2009 and by less than \$1 billion over five years.

Beneficiary and provider

- This recommendation increases beneficiary cost sharing but will ensure access to care. Although beneficiary cost sharing will increase under this recommendation, we do not anticipate any negative effects on beneficiary access to care. This recommendation is not expected to affect providers' willingness and ability to provide quality care to beneficiaries. A payment incentive program should improve quality for beneficiaries and result in some providers receiving higher payments or lower payments.

Some dialysis providers help financially needy patients pay for Part B premiums 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.

Creating incentives to improve dialysis quality and providers' efficiency

Dialysis quality has improved for some measures. Other measures suggest that improvements in dialysis quality are still needed. The focus of this section is to begin to explore ways to improve quality and providers' efficiency. Specifically, we discuss the potential for selected services—nutritional care and vascular access care—to improve dialysis quality and providers' efficiency.

In addition to reviewing the literature, we convened an expert panel composed of 10 providers (facilities and physicians) who treat dialysis patients. We asked them to discuss the effectiveness of different strategies to improve

patients' nutritional standing and options for decreasing the frequency of vascular access complications.

Improving nutritional care

Protein energy malnutrition is common among dialysis patients and is one of the strongest predictors of hospitalizations and mortality. Surveys suggest that up to 70 percent of dialysis patients have protein energy malnutrition (NKF 2007). Serum albumin level is a marker for patients being at increased risk for malnutrition; patients with a lower serum albumin level have a higher risk for malnutrition than patients with a higher serum albumin level. The mean serum albumin level of hemodialysis patients remained unchanged in 1997 and 2005 (averaging 3.8 g/dL in both years). The NKF practice guideline recommends a serum albumin of 4.0 g/dL. About two-thirds of hemodialysis patients had a serum albumin level lower than 4.0 g/dL in 2005 (CMS 2007b).

The etiology of malnutrition is complex and may include many factors (NKF 2000), such as inadequate food intake, loss of nutrients during the dialysis process, inadequate dialysis, dietary restrictions, anorexia, loss of blood due to gastrointestinal bleeding and frequent blood sampling, and conditions associated with chronic renal failure that may induce a chronic inflammatory state. Many factors may cause poor food intake such as anorexia and nausea and vomiting due to uremic toxicity. In addition, some patients do not eat enough because they have limited means to purchase food recommended by their practitioners or they have difficulty preparing their meals because of post-dialysis fatigue or disability.

Researchers have shown that patients with lower serum albumin values have increased risk of hospitalization and mortality. In a study of 12,000 hemodialysis patients, the adjusted risk ratio for mortality increased progressively as serum albumin level decreased (Lowrie and Lew 1990). Patients with serum albumin levels at or lower than 3.5 g/dL have a three- to sixfold higher risk of mortality than patients with albumin levels of 4.0 g/dL or more (Owen et al. 1993). The strongest predictor of hospitalization rates was a lower serum albumin level, and the mean number of hospitalized days increased as serum albumin levels decreased (Rocco et al. 1996).

Dialysis patients can prevent malnutrition by eating healthy diets, getting dietary counseling, and receiving an adequate dose of dialysis (Kopple 1999). Treatment options discussed by the panel to improve patients' nutritional status included consuming oral supplements

**TABLE
2C-6****Summary of coverage policies for nutritional services and issues raised in literature**

Nutritional service	Part B	Part D	Issues
Dietitian	Providing dietetic services is required under Medicare's condition for coverage.	N/A	Three most frequently reported reasons why renal dietitians did not implement the NKF's nutrition guidelines are: 1) lack of tools (e.g., food models, calipers, and computers); 2) lack of time (low dietitian to patient ratio); and 3) lack of support in the dialysis unit.
Food and oral supplements	Not covered. OIG antikickback provisions limit providers' ability to furnish service free or at reduced cost.	Not covered.	Some concern that patients may aspirate food eaten during dialysis. Some patients tire of the supplements and will not continue. If providers send patients home with supplements, some concern that patients may give supplements to needy family member.
Intradialytic parenteral nutrition	Coverage is limited to patients with permanent dysfunction of the digestive tract.	Covered by some plans when dietary counseling and oral supplements do not improve patients' nutritional status	It may not provide sufficient calories and protein to support long-term daily needs because it is administered during dialysis three times a week; it does not change patients' food behavior or encourage them to eat more healthy meals; and it is more costly than oral supplements.

Note: N/A (not applicable), NKF (National Kidney Foundation), OIG (Office of Inspector General).

Source: Burrowes et al. 2005 and <http://www.cms.hhs.gov/NationalMedicareTrainingProgram/Downloads/RxCoverageDeskAid.pdf>

and administering intradialytic parenteral nutrition (IDPN)—a solution of amino acids, dextrose, and, if needed, lipids, that providers administer directly into the bloodstream during dialysis. Table 2C-6 summarizes Medicare's coverage policies and issues associated with each option.

According to the panel, eating healthier diets would clearly benefit dialysis patients, but many patients have limited financial resources and state policies for food assistance are complex. Using Medicaid as a proxy for having a lower household income, we find that dialysis patients are more likely to be dually eligible for Medicaid than the general Medicare population (36 percent vs. 17 percent in 2004, respectively, based on data from CMS's denominator file for dialysis patients and the Medicare Current Beneficiary Survey for all patients).

Medicare requires that the attending physician and a dietitian evaluate patients' nutritional needs. The dietitian is responsible for assessing the nutritional and dietetic needs of each patient, recommending therapeutic diets, counseling patients and their families on prescribed diets, and monitoring adherence and response to diets. In a

national survey of 951 renal dietitians, respondents most frequently cited the following obstacles in carrying out their responsibilities: 1) lack of tools (e.g., food models, calipers, and computers); 2) lack of time (low dietitian to patient ratio); and 3) lack of support from the medical director or corporate office (Burrowes et al. 2005). On average, each full-time dietitian was responsible for about 105 patients and almost 20 percent of dietitians were responsible for more than 150 patients. Dietitians who worked in for-profit and freestanding facilities had significantly more patients than those who worked in nonprofit and hospital-based facilities. On average, dietitians spent about 15 minutes per patient per week providing nutrition services, including developing and implementing treatment plans and counseling patients.

Although the panel believed that 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. Medicare does not cover oral supplements and antikickback provisions in the statute limit the ability of providers to furnish patients with nutritional supplements at no cost or at reduced prices. The retail cost of oral

supplements is about \$600 per year, assuming patients received a supplement during dialysis administered three times per week (Amazon 2007). A recent study used clinical data from severely malnourished patients—those with a serum albumin level of 3.5 g/dL or lower—treated by the largest dialysis provider to estimate the impact on outcomes and Medicare spending by improving nutritional status for all dialysis patients. The authors modeled that improving the nutritional status for the U.S. dialysis population (who are severely malnourished) would save about 1,400 lives, avert 6,300 hospitalizations, and reduce Medicare spending by \$36.3 million due to averted hospitalizations (Lacson et al. 2007).¹⁸

Including oral supplements in a broader dialysis payment bundle that includes separately billable dialysis drugs might improve dialysis quality. Under a broader bundle, the cost of including oral supplements might be offset by the more efficient administration of dialysis drugs by providers.

The panel thought that a negligible proportion (1 percent to 2 percent) of dialysis patients would benefit from IDPN. Coverage of IDPN is severely restricted under Part B but some Part D plans pay for it. The panel believed that more dialysis patients are getting IDPN than need it.

Evidence about the use of nutritional treatments

The NKF has published practice guidelines on nutritional care based on a structured review of the medical literature and, where insufficient evidence exists, on expert opinion (NKF 2000). Because there are no large-scale randomized prospective clinical trials evaluating the effects of nutrition support in dialysis patients, the NKF based its recommendations on the experience of nonrenal patients as well as current information about nutrition and metabolism of dialysis patients. Most of the studies of nutritional therapies have been small and observational.

The NKF guideline recommends that all dialysis patients receive intensive nutritional counseling based on an individualized plan of care that is developed before or at the time of starting dialysis, modified frequently based on the patient's medical and social conditions, and updated every three months to four months. Patients should receive nutritional counseling at the start of dialysis and thereafter every one month to two months, or more frequently if inadequate nutrient intake or malnutrition is present. These recommendations were based on expert opinion.

The guideline recommends that dialysis patients who are unable to meet their protein and energy requirements with food intake for about two weeks should receive nutrition support. The guideline recommends fortifying patients' diet with oral nutrition (i.e., energy and protein supplements). If oral nutrition is not adequate, the guideline recommends either tube feeding (if medically appropriate), or, if enteral tube feedings are not used, IDPN for hemodialysis patients or intraperitoneal amino acids (IPAA) for peritoneal dialysis patients. IDPN and IPAA involve administering nutrients (amino acids, glucose, and lipids) during dialysis. If the combination of these interventions does not meet a patient's protein and energy requirements, the guideline suggests that providers consider parenteral nutrition.

Finally, the NKF highlighted the need for randomized clinical trials that compare oral nutritional supplements, tube feeding, and IDPN in malnourished dialysis patients. Such trials should measure survival, hospitalization rates, and patients' quality of life.

Measures to monitor nutritional status of patients

CMS does not measure nutritional status at either the facility level or the physician level. Instead, the agency has monitored national trends in patients' nutritional status in an annual survey beginning in 1993. As a part of this survey, the agency obtains serum albumin levels from the medical records of a sample of dialysis patients. The sample size of this survey does not permit facility-level measurement. (The sample of patients from each facility is too small to assess facility-level care.)

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. Consequently, the panel suggested that providers could use several clinical measures to identify patients with malnutrition who might benefit from oral supplements. These measures include 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.¹⁹ Patients with low C-reactive protein and albumin levels could be candidates for oral nutritional supplements. Routinely assessing patients' nutritional and inflammatory status using the malnutrition inflammation score is another option to consider. Researchers have shown that the malnutrition inflammation score is associated with malnutrition and inflammation among dialysis patients and

is predictive of hospitalization and mortality (Kalantar-Zadeh et al. 2001). The score assesses patients' weight, dietary intake, gastrointestinal symptoms, functional capacity, comorbidities, fat stores, muscle wasting, body mass index, serum albumin, and serum total iron binding capacity.

Examples of other programs that covered oral nutrition therapies

Between 1998 and 2001, CMS's ESRD managed care demonstration enrolled dialysis patients to assess whether an integrated system of care was feasible and efficient and able to produce outcomes comparable to the fee-for-service system. The two participating plans furnished nutritional supplements (along with other additional benefits) to meet the demonstration's requirement of providing 5 percent extra benefits above Medicare's fee-for-service program.

Beneficiaries in the demonstration reported significantly more satisfaction with their ability to obtain nutritional supplements than a matched fee-for-service population. The plans' cost of providing the nutritional supplements ranged from \$7 per member per month to \$11 per member per month between 1998 and 2000 (Dykstra et al. 2003). The evaluation of the demonstration did not specifically analyze nutritional outcomes but it did show that:

- Compared with the statewide (control) population, the adjusted mortality rate was significantly lower at one of the sites (Kaiser in California) and not statistically different at the other site (Health Options Inc. in Florida).
- Relative to comparison patients in California and Florida, adjusted hospitalization rates were not statistically different for either demonstration site (Lewin Group 2002).

Medicare's current ESRD management demonstration offers an opportunity to assess the effectiveness of providing oral nutritional supplements to enrolled patients. As part of the demonstration, Fresenius Medical Care health plan is providing oral protein supplements to enrollees who meet the clinical criterion (a serum albumin level of less than 3.8 g/dL and a physician order).

Some states have implemented programs specific to chronic renal disease and at least two of them (Pennsylvania and Delaware) cover nutritional supplements. For example, Pennsylvania's Chronic Renal Disease Program, which assists qualifying ESRD

patients with the costs of dialysis services, medications, and transportation, covers nutritional supplements for patients who meet specific clinical criteria. Specifically, physicians submit an exception form indicating the need for nutritional supplements along with laboratory results that verify that the patient's albumin level has been 3.5 g/dL or lower for two months. Approved patients receive a prescription for specific supplements and are required to cover the \$9 copayment for a month's supply from a pharmacy. Patients must be reapproved every six months to continue nutritional therapy.²⁰ No data are available to measure patients' clinical outcome and satisfaction with care.

Improving vascular access care

All hemodialysis patients need a vascular access—the site on the patient's body where blood is removed and returned during dialysis. Vascular access care is a clinical area in which substantial improvements in quality are needed. Vascular access complications accounted for about 15 percent of dialysis patients' hospital admissions in 2005 (USRDS 2007). Using data from CMS and USRDS, we estimate that Medicare spending for vascular access services was \$1.5 billion in 2005 (which represents about 8 percent of total dialysis spending). For most patients, clinical guidelines consider an arteriovenous (AV) fistula a better type of vascular access than an AV graft or a catheter. AV fistulas last a long time and have a lower complication rate than other types of vascular access (NIDDK 2007). As a result, annual Medicare spending for patients with an AV fistula (\$58,000) was lower than spending for patients maintained on a catheter (\$75,000) or a graft (\$67,000) (USRDS 2007).

According to CMS, the use of AV fistulas has increased during this decade. About 54 percent of all new patients used a fistula in 2005 compared with 27 percent in 2000. Use of catheters has remained about the same (about 36 percent in each year), while graft use has decreased during this time (CMS 2007b).

In 2004, CMS announced the "Fistula First" quality initiative. The goal of this initiative is to increase the use of AV fistulas. CMS, collaborating with other groups including the 18 ESRD networks, providers, and beneficiary groups, is promoting the use of fistulas by providing training resources on fistula placement to clinicians, training health care professionals in the appropriate use and care of fistulas, and educating patients about the value of fistulas.

Panelists and the literature generally agreed that:

- Reducing the number of patients with a catheter is key to reducing vascular access complications. CMS reported that in 2005 about 36 percent of new patients and 27 percent of all patients used a catheter (CMS 2007b). Reducing catheter use could be accomplished by switching most patients to an AV fistula within the first 90 days of dialysis and by increasing the proportion of patients with an AV fistula when they start dialysis. The panel raised an access to care issue. Some patients under age 65 with chronic renal failure have no insurance before they start dialysis and may have difficulty obtaining needed health care. Medicare coverage does not begin until the 91st day after starting dialysis for these patients.
- Better coordination of vascular access care might decrease urgent events such as procedures to remove a clot (thrombectomies). Some panelists thought that having a vascular access coordinator would improve care. Key responsibilities of a coordinator include providing ongoing patient support, oversight, and education related to vascular access; assessing vascular access needs for each patient; collaborating with dialysis staff in developing strategies to prevent complications; coordinating services for the patient in the dialysis facility, outpatient clinic, and inpatient setting; and facilitating communication among nephrologists, surgeons, interventional radiologists, hospitals, and dialysis facilities. CMS does not require facilities to employ a vascular access coordinator in either its current or proposed conditions for coverage.
- Early identification of vascular access complications may reduce the morbidity and costs of repairing or replacing vascular accesses and improve patient outcomes (McCarley et al. 2001). In 2005, about one-third of patients with a graft or fistula did not have their accesses routinely monitored for vascular access problems—stenosis (narrowing in the width of a blood vessel) and thrombosis (clotting of a blood vessel) (CMS 2007b). An important component of care is training dialysis technicians to physically evaluate the vascular access site. In addition to physical examination, regular use of tests that gauge how well vascular accesses are working and can detect problems—such as those that measure access blood flow and venous pressures—may be associated with improved patient outcomes. Patients treated at facilities that used a variety of tests to monitor

vascular accesses weekly or more often had lower rates of all-cause hospitalization than patients treated at facilities that monitored vascular accesses less frequently or never (Plantinga et al. 2006). Plantinga and colleagues also found that patients treated at facilities with more frequent monitoring were more likely to undergo procedures to repair an access problem (stenosis or thrombosis), suggesting that access dysfunctions may be detected more often when monitoring is performed more frequently.

Measures to assess vascular access care at the nephrologist and facility level include the proportion of patients with a catheter 90 days after starting dialysis, the rate of thrombectomies, and the rate of vascular-access-related hospitalizations. CMS reports national trends on the proportion of patients with a catheter at 90 days or later but does not report this information by facility.

The panel was split about holding dialysis facilities and nephrologists accountable for vascular access outcomes. Some panelists thought that a pay-for-performance program should hold both physicians and facilities equally accountable. Others thought that physicians should be more accountable than facilities. They argued that facilities have less influence over the placement of AV fistulas than physicians.

Still other panelists thought that providers other than nephrologists and facilities have a greater bearing on vascular access care. They argued that:

- Surgeons have more influence than nephrologists and dialysis facilities in determining the type of vascular access created for a patient.
- Some patients do not see a nephrologist until they require dialysis. These patients are more likely to start dialysis using a catheter than a fistula because fistulas require more time to be ready for use than catheters. A MedPAC-sponsored analysis showed that 28 percent of dialysis patients did not see a nephrologist until they started dialysis and 17 percent saw one less than 4 months before they started dialysis (MedPAC 2004b). ■

Endnotes

- 1 The two types of dialysis—hemodialysis and peritoneal dialysis—remove wastes from a patient’s bloodstream differently. During hemodialysis, a machine removes wastes from the bloodstream; it is usually performed in a dialysis facility. By contrast, 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.
- 2 EGHPs are usually the primary payer for 33 months—the 3-month waiting period plus the 30-month coordination period.
- 3 In 2005, Medicare used three different ways to pay for dialysis drugs: 1) For the top 10 dialysis drugs, which accounted for the greatest payment in 2004, Medicare paid freestanding providers 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 that of freestanding providers.
- 4 USRDS reports that the number of in-center hemodialysis patients increased from 190,090 in 1996 to 312,057 in 2005. By contrast, the number of peritoneal dialysis patients decreased from 29,647 in 1996 to 25,932 in 2005.
- 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 2006 and included in this analysis are erythropoietin, calcitriol, doxercalciferol, iron sucrose, levocarnitine, paricalcitol, sodium ferric gluconate, darbepoetin alfa, alteplase, and vancomycin.
- 7 In addition, the product’s FDA label warns about safety concerns with the prolonged use of high doses of the oral form in dialysis patients.
- 8 Freestanding nonchains were able to purchase levocarnitine at a rate lower than freestanding chains (\$5.40 per unit vs. \$7.14 per unit, respectively).
- 9 Levocarnitine supplements the loss of carnitine, a naturally occurring body substance that helps transport long-chain fatty acids for energy production by the body. Patients on hemodialysis can have carnitine deficiencies from dialytic loss, reduced renal synthesis, and reduced dietary intake. Patients must show improvement from the levocarnitine treatment within six months of initiation of treatment for Medicare to continue to pay for the treatment.
- 10 The FDA approved erythropoietin in 1989. A typical starting dose of erythropoietin is 50 to 100 units per kilogram of body weight. A patient weighing 150 pounds (about 68 kilograms) might receive a dose between 3,400 units and 6,800 units three times a week. Physicians titrate the dose based on the patient’s response to therapy.
- 11 Some providers contend that erythropoietin is predominantly furnished intravenously because patients experience less discomfort than when it is furnished subcutaneously. In addition, the development of red cell aplasia has been principally associated with subcutaneous administration in Europe.
- 12 A third ESA exists but is not marketed for dialysis because of a comarketing agreement between the respective companies.
- 13 At least one company (Hospira) announced its intent to launch an anemia follow-on (generic) biologic in the United States in 2012 (Kelly 2007).
- 14 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.
- 15 The dependent variable was the natural log of total Medicare composite rate and dialysis drug costs.
- 16 Each cost report includes an indicator reporting its status: as submitted, settled without an audit, settled with an audit, or reopened.
- 17 CMS audited about 20 percent of 2001 cost reports and 10 percent of 2004 and 2005 cost reports. It does not appear that CMS has begun auditing 2006 audits, as the agency has audited less than 1 percent of them.
- 18 The authors based this projection on the assumption that 50 percent of severely malnourished patients responded to a serum albumin increase of 0.2 g/dL. The authors also modeled other scenarios that assumed different response rates (25 percent and 75 percent) and different improvements in serum albumin (0.1 g/dL and 0.3 g/dL).

- 19 C-reactive protein is not a nutritional parameter but may be used to identify the presence of inflammation in individuals with a low serum albumin level.
- 20 Similarly, Delaware's Chronic Renal Disease Program covers nutritional supplements if a physician or a certified nurse practitioner certifies that they are necessary. Certification must be done upon initial referral and at least every six months. The program requires lab values and other information related to the patient's nutritional status to determine initial and ongoing eligibility.

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