SECTION 2C

Outpatient dialysis services

RECOMMENDATION

The Congress should update the composite rate in calendar year 2008 by the projected rate of increase in the end-stage renal disease market basket index less the Commission's expectation for productivity growth.

COMMISSIONER VOTES: YES 14 • NO 0 • NOT VOTING 0 • ABSENT 3

SECTION 2C

Outpatient dialysis services

Section summary

Each year, MedPAC makes a payment update recommendation for outpatient dialysis services for the coming year. We first judge whether payments for the current year (calendar year 2007) are adequate by considering beneficiaries' access to care, changes in providers' capacity, changes in the volume of services, changes in the quality of care, providers' access to capital, and Medicare's payments and costs for 2007.

Most of our indicators of payment adequacy are positive. Beneficiaries' access to dialysis care is generally good; there was a net increase of 79 facilities between 2004 and 2005. Providers, including the two largest dialysis organizations, did not change the mix of patients they treated between 2004 and 2005. However, facilities that closed in 2005 were more likely to treat African Americans and beneficiaries also receiving Medicaid benefits than those that opened. Although this phenomenon does not appear to affect overall access to care, the Commission is concerned about the continuity of care for African Americans and dual eligibles. The Commission will continue to track access to care by patients' demographic and clinical characteristics for the different provider types.

In this section

The growth in the number of dialysis treatments—one indicator of the volume of services—kept pace with patient growth between 2004 and 2005. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) changed the way Medicare pays for dialysis drugs. As intended by policy, the payment rate for most dialysis drugs decreased while the prospective payment (the composite rate) that CMS pays for each dialysis treatment increased. The use of dialysis drugs continued to increase between 2004 and 2005 but at a slower rate than in previous years.

Quality of care is improving for some measures. More patients are receiving adequate dialysis and have their anemia under control. Some researchers have raised concerns about the potential overuse of erythropoietin, a drug used to treat anemia. A payment bundle that includes all dialysis drugs might encourage providers to use drugs more efficiently. One quality measure—patients' nutritional status—has not improved during the past five years. The Commission intends to study different ways to improve dialysis patients' nutritional status.

Recent evidence about trends in the increase in dialysis facilities and capacity suggests that providers have sufficient access to capital. The largest dialysis organizations and smaller chains have obtained private capital to fund acquisitions.

Between 2004 and 2005, the cost per treatment for composite rate services and dialysis drugs fell by 5 percent. The Medicare margin for composite rate services and dialysis drugs was 8.4 percent in 2005. The Medicare margin varies by provider type: The two largest dialysis organizations realized a higher Medicare margin than all other providers (10.7 percent vs. 2.6 percent). We project the Medicare margin will be 4.1 percent in 2007. This estimate reflects the update to the composite rate and the add-on payment in 2006 and 2007.

In summary, most of our payment adequacy indicators are positive. Therefore, the recommendation is to update the composite rate in 2008 by

the projected rate of increase in the end-stage renal disease (ESRD) market basket less the Commission's expectation for productivity growth. We base our productivity objective on the 10-year moving average of multifactor productivity in the economy as a whole, which is 1.3 percent for 2006. Under the current forecast of the ESRD market basket, the Commission's recommendation would update the composite rate by 1.2 percent in 2008.

The Congress should update the composite rate in calendar year 2008 by the projected rate of increase in the end-stage renal disease market basket index less the Commission's expectation for productivity growth.

Recommendation 2C

COMMISSIONER VOTES:
YES 14 • NO 0 • NOT VOTING 0 • ABSENT 3

The Commission remains concerned that Medicare continues to pay separately for drugs and laboratory tests that providers commonly furnish to dialysis patients. 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 and laboratory tests, were bundled under a single payment. In addition to broadening the payment bundle, the Secretary should continue efforts to improve dialysis quality. The Commission has recommended that Medicare base a portion of payments on the quality of care furnished by facilities and physicians who treat dialysis patients (MedPAC 2004a). The Secretary also needs to continue to develop quality measures and to monitor and improve dialysis care. Together, 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.

We conclude the chapter by noting that the recent payment changes mandated by the MMA have not increased the use of home dialysis. In the future, we may address issues about paying for home and in-center dialysis under a broader payment bundle and the benefits and costs of programs that counsel patients about the different dialysis methods before they require dialysis. ■

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 excess fluids 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, nearly three-quarters of ESRD patients undergo dialysis. Patients also receive items and services related to their dialysis treatments, including dialysis drugs to treat conditions that result from the loss of kidney function, such as anemia and bone disease.

The 1972 amendments to the Social Security Act extended Medicare benefits to people with ESRD who are eligible for Social Security benefits. This disease-specific entitlement is unique to Medicare. ESRD patients entitled to Medicare due to ESRD alone have the same benefits as other Medicare beneficiaries.

Medicare entitlement begins for most beneficiaries in the fourth month after the start of maintenance dialysis except for patients who have undergone a kidney transplant or who receive training to perform dialysis at home. If an employer group health plan (EGHP) covers a patient at the time of ESRD diagnosis, then the EGHP is the primary payer for up to 33 months of care.[2] Medicare is the secondary payer during this time. EGHPs include the 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. During the first three months of dialysis, also known as the waiting period, the patient, state Medicaid program, insurer (usually an EGHP), or state renal program is responsible for payment.

In 2005, the Medicare program covered more than 320,000 dialysis patients. About one-quarter of newly diagnosed ESRD patients were entitled to Medicaid benefits and about one-quarter were covered by an EGHP (USRDS 2006). Medicare expenditures for dialysis and dialysis-related drugs totaled $7.9 billion for both freestanding and hospital-based facilities. Medicare expenditures for composite rate services and dialysis drugs averaged about $25,000 per patient in 2005.

Medicare changed how it pays for outpatient dialysis services in 2005

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) changed the way Medicare pays for dialysis treatments and dialysis drugs (as described in the text box, p. 130). The law increased the payment rate for dialysis treatments and decreased the payment rate for dialysis drugs.

However, the MMA did not change the two-part structure of the outpatient dialysis payment system. One part is a prospective payment called the composite rate that covers the bundle of services routinely required for dialysis treatment; the other part includes separate payments for certain dialysis drugs, such as erythropoietin, iron, and vitamin D analogs that were not available when Medicare implemented the composite rate. Providers receive the composite rate for each dialysis treatment provided in dialysis facilities (in-center) or in patients' homes.

As intended by policy, the composite rate increased from $127 per treatment in 2004 to $142 per treatment in 2005 through an add-on payment. The law funded this add-on payment by shifting some of the "profits" previously associated with payments for dialysis drugs and mandated that these changes occur in a budget-neutral manner. At the same time, the drug payment rate declined from $93 per treatment to $82 per treatment between 2004 and 2005.[3]

Are Medicare payments adequate in 2007?

Most indicators of payment adequacy are positive. Most beneficiaries have good access to care. There was a net increase in the number of dialysis providers in 2005, and the growth in the number of dialysis treatments generally kept pace with the growth in the number of patients. Dialysis drug spending and use grew more slowly between 2004 and 2005 than in previous years because the Congress lowered the payment rate for most dialysis drugs. Quality is improving for some (but not all) measures, and providers' access to capital is good. Between 2003 and 2005, the Medicare margin for composite rate services and dialysis drugs increased from 2.0 percent to 8.4 percent. We project that the Medicare margin will be 4.1 percent in 2007. This estimate incorporates the updates to the composite rate and the add-on payment in 2006 and 2007.

The outpatient dialysis payment system changed in 2005

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) significantly changed the payment method for composite rate services and dialysis drugs. First, the MMA mandated paying providers an add-on payment in addition to the composite rate in 2005. CMS set the add-on payment at 8.7 percent of the composite rate in 2005 and 14.5 percent of the composite rate in 2006. The add-on payment increased in 2006 because CMS updated it by 1.4 percent. The MMA mandated that CMS update the add-on payment based on the growth in drug expenditures beginning in 2006. In addition, in 2006, CMS moved to a payment method based on average sales price (ASP), which lowered the payment rate for dialysis drugs and required CMS to shift more drug profits to the add-on payment.[4]

Second, the MMA lowered the payment rates for most dialysis drugs closer to the prices providers paid. Beginning in 2005, CMS paid dialysis providers their acquisition cost—set at the average acquisition payment—for most (but not all) dialysis drugs.[6] In 2006, CMS revised this policy by paying ASP plus 6 percent for all dialysis drugs. These changes have resulted in Medicare's drug payment no longer being as profitable as it was before 2005, when the program paid average wholesale price, reasonable cost, or a set (statutory) rate.

Lastly, the MMA and regulations that CMS issued to implement the new law adjusted the composite rate and the add-on payment for case mix and updated the wage index and the definitions used to define labor market areas. ■

The Congress updated the composite rate by 1.6 percent in 2006. The Tax Relief and Health Care Act of 2006 updates the composite rate by 1.6 percent beginning in April 2007. CMS updated the add-on payment by 1.4 percent and 0.5 percent in 2006 and 2007, respectively.

Beneficiaries' access to care

To assess beneficiaries' access to care, we monitor changes in patients' ability to obtain different types of dialysis and examine whether certain beneficiary groups face systematic problems in accessing care.

Access to different types of dialysis

Access to specific types of dialysis—in-center hemodialysis, peritoneal dialysis (usually performed in patients' homes), and home hemodialysis—shows little change over time.[5] Between 1998 and 2006, at least 97 percent of all facilities offered in-center hemodialysis and 45 percent offered some type of peritoneal dialysis—continuous cycler-assisted peritoneal dialysis or continuous ambulatory peritoneal dialysis. In 2003 and 2006, about 12 percent of facilities offered home hemodialysis (these data are not available before 2003).

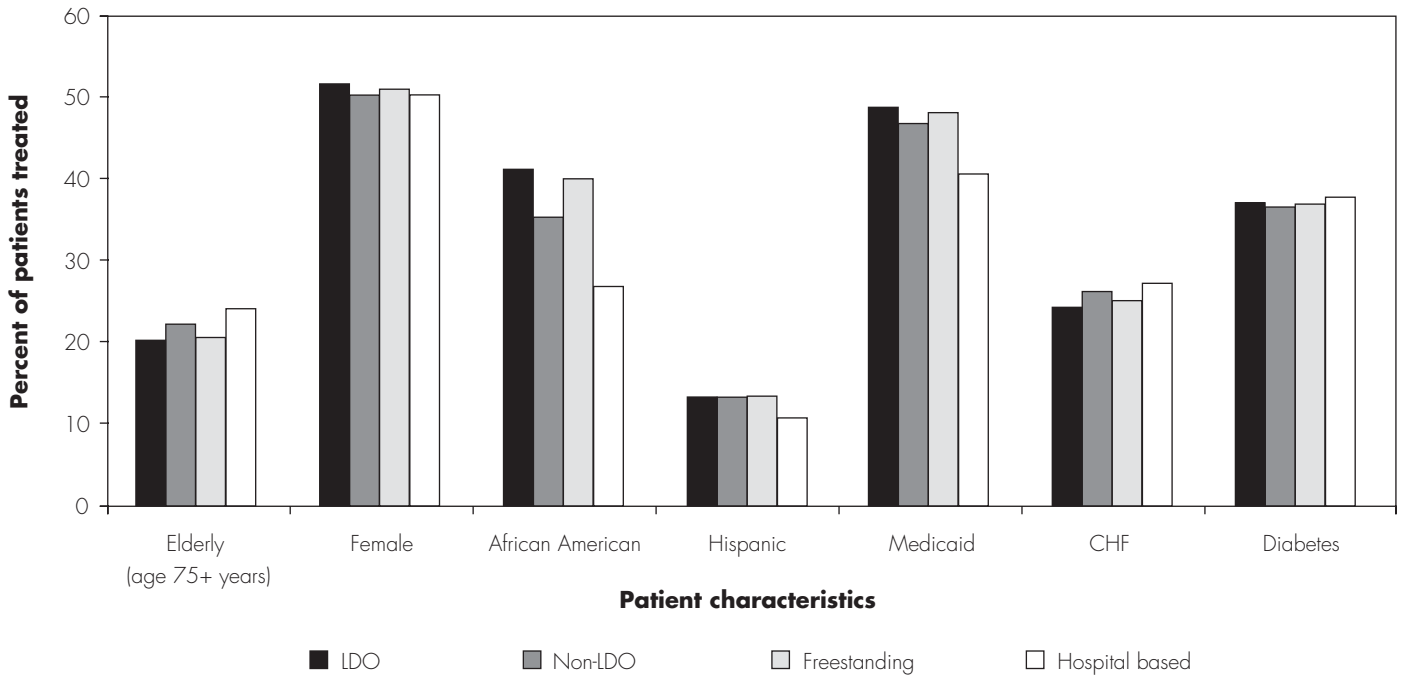
Nonetheless, fewer patients overall are receiving dialysis in their homes. Most recent data from the United States Renal Data System (USRDS) show that, between 1996 and 2004, the number of patients receiving hemodialysis in facilities increased by 6 percent per year; by contrast, the number of patients treated at home (using peritoneal dialysis) declined by 2 percent per year. USRDS reports that the number of in-center hemodialysis patients increased from about 194,000 in 1996 to 307,000 in 2004. By contrast, the number of peritoneal dialysis patients decreased from about 30,000 in 1996 to 26,000 in 2004 (USRDS 2006). Fewer than 2,000 patients undergo hemodialysis in their homes. At the end of this chapter, we discuss some factors that may affect the use of home dialysis, such as a patient's care before dialysis, physicians' characteristics, and Medicare's payment and coverage policies.

Did providers change the mix of patients they treated between 2004 and 2005?

We examined whether providers stopped treating certain types of patients by comparing the demographic and clinical characteristics of beneficiaries they treated in the years before and after the payment method changed. Our analysis included the following provider types: affiliated with the two large national chains, which we refer to as the large dialysis organizations (LDOs); not affiliated with the LDOs; freestanding; and hospital based. As

FIGURE 2C–1

Characteristics of patients, by type of facility, 2005



Note: LDO (large dialysis organization), CHF (congestive heart failure).

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

shown later in this chapter, some of these groups overlap; for example, 70 percent of all freestanding facilities are affiliated with the LDOs.

Figure 2C-1 presents, for each type of provider, the proportion of patients in 2005 who are elderly, female, African American, Hispanic, dually eligible for Medicaid, who have congestive heart failure, and who have diabetes. Across the different provider types, the proportion of patients with these characteristics does not differ by more than 1 percentage point between 2004 and 2005 (data not shown for 2004). This analysis suggests that providers have not changed the mix of patients they cared for in 2004 and 2005, including the LDOs, which account for 60 percent of all facilities.

This analysis also shows that, in 2004 and 2005, freestanding facilities were more likely than hospital-based facilities to treat African Americans and dual eligibles. As mentioned later in the chapter, freestanding facilities account for more than 85 percent of all dialysis facilities.

Do certain beneficiary groups face systematic problems in accessing care?

We updated our analysis to ascertain whether specific groups of patients have systematic problems accessing care. We compared the characteristics of patients treated by facilities that were open in 2004 and 2005, that newly opened in 2005, and that closed in 2004. In 2005, providers' capacity to furnish care improved with a net increase of 79 facilities and 1,104 hemodialysis stations.

Some of our findings are intuitive. Compared with facilities that remained open, facilities that closed in 2004 were more likely to:

- have less capacity (averaging 15 hemodialysis stations vs. 18 hemodialysis stations),
- be hospital based (67 percent vs. 12 percent),
- be nonprofit (65 percent vs. 20 percent), and

TABLE 2C–1

Number of dialysis facilities is growing and share of for-profit and freestanding dialysis providers is increasing

	1995	2006	Average annual percent change
Total number of:			
Dialysis facilities	2,721	4,594	5%
Hemodialysis stations	40,578	80,383	6
Mean number of hemodialysis stations	15	17	1
Percent of all facilities:			
Nonchain	N/A	23%	N/A
Affiliated with any chain	N/A	77	N/A
Affiliated with largest two chains	N/A	60	N/A
Hospital based	26%	13	–2
Freestanding	74	87	6
Rural	23	25	6
Urban	77	75	5
For profit	65	79	7
Nonprofit	35	21	<1

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

Source: Compiled by MedPAC from the 1995 Facility Survey file from CMS and the 2006 Dialysis Compare database from CMS.

- be less profitable than facilities that remained opened as measured by the Medicare margin (–13.7 percent vs. 3.9 percent).

However, the closed facilities provided a greater share of treatments paid for by Medicare than facilities that remained in business (83 percent vs. 70 percent). This finding may be due to the payment rate of commercial payers, which generally exceeds that of Medicare and Medicaid. Some dialysis providers have informed the Commission that they prefer to be located in areas where employer insurance covers more people.

We also found differences in the mix of patients treated by these provider types. Compared with facilities that opened in 2005, closed facilities treated a greater proportion of African Americans (48 percent vs. 29 percent) and dual eligibles (45 percent vs. 40 percent). By contrast, fewer Hispanics received care in closed facilities than in new facilities (8 percent vs. 17 percent). These findings may be partly linked to facility locations. A greater share of closed facilities were located in the New England and mid-Atlantic regions, while a greater share of new facilities were located in the south and west—Texas, Florida, and California.

Importantly, these three groups have good access to facilities that remained open in both years. The proportion of African Americans, dual eligibles, and Hispanics treated in facilities that remained open in 2004 and 2005 closely match the share of these groups among all dialysis patients.

We found no substantial differences in the mix of patients by age, sex, or disease severity (measured by the Charlson index and the share of patients with diabetes and congestive heart failure) among the provider types. Closures do not disproportionately affect rural patients; 26 percent of closed facilities were in rural areas, compared with 24 percent of those that stayed open and 22 percent that opened in 2005.

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 certain patient groups, such as African Americans, may be disproportionately affected by facility closures.

What types of providers furnish dialysis care?

An increasing proportion of dialysis providers are freestanding, have more capacity, are owned by publicly traded companies, and operate for profit (Table 2C-1 and Figure 2C-2). These trends in the profit status, size, and consolidation of dialysis providers suggest that the dialysis business is attractive to for-profit entities and that there are efficiencies and economies of scale in providing dialysis care.

Between 1995 and 2006, freestanding facilities increased from 74 percent to 87 percent of all facilities, while for-profit facilities increased from 65 percent to 79 percent of all facilities (Table 2C-1). The absolute number of hospital-based facilities decreased (from 708 to 611) during this time. Most (90 percent) freestanding facilities are for profit; by contrast, most (93 percent) hospital-based facilities are nonprofit (data not shown).

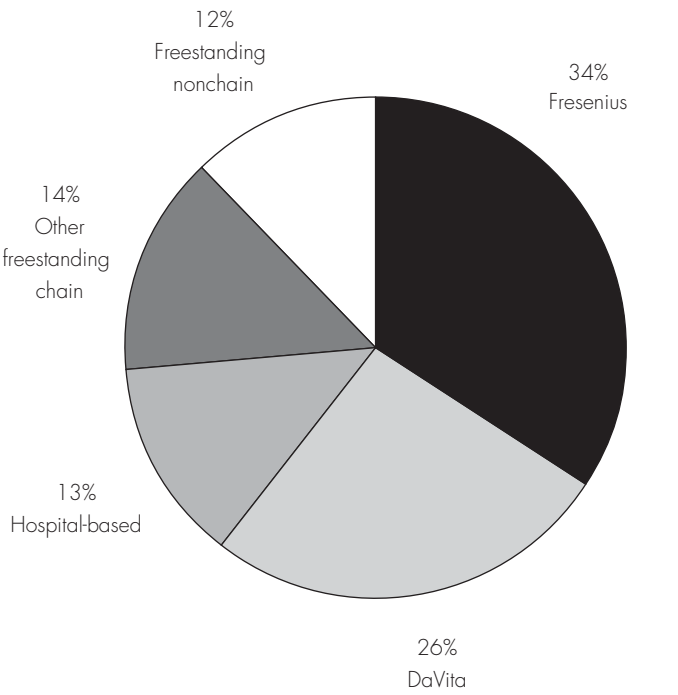
Between 1995 and 2006, dialysis facilities increased the number of hemodialysis stations, a trend consistent with the findings that freestanding facilities have more capacity than hospital-based facilities (18 stations vs. 14 stations, respectively) and chain-affiliated facilities have more capacity than those not affiliated with a chain (18 stations vs. 15 stations, respectively (data not shown)).

The dialysis industry rapidly consolidated over the past decade.[7] More consolidation occurred in 2005 and 2006, when the four largest chains merged into two chains. Specifically, the merger of the second- and third-largest chains (DaVita and Gambro) became final in October 2005 and the merger of the first- and fourth-largest chains (Fresenius and Renal Care Group) became final in 2006. These two for-profit freestanding providers together account for 60 percent of all facilities and 70 percent of all freestanding facilities (Figure 2C-2). The consolidation resulted in at least one new for-profit chain (Renal Advantage). To merge with Gambro, the Federal Trade Commission required that DaVita divest 70 facilities, which Renal Advantage acquired.

In addition to these three chains, a nonprofit chain operates 4 percent of all facilities. Facilities not owned by these chains are:

FIGURE 2C–2

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



Note: Fresenius and DaVita are the two largest freestanding chains. Total may not sum to 100 percent due to rounding.

Source: Compiled by MedPAC from the 2006 Dialysis Compare database from CMS.

- 53 percent for profit and 47 percent nonprofit,
- 63 percent freestanding and 37 percent hospital based, and
- 36 percent affiliated with a small chain and 64 percent not affiliated with a chain.

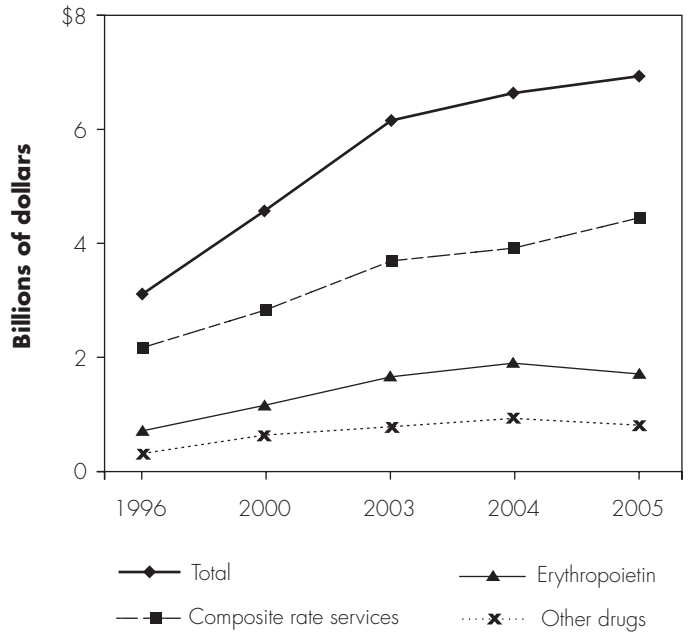
Only the LDOs and the nonprofit chain operate facilities nationally (up to 45 states). The other chains operate in no more than 12 states and most operate in only 1 to 3 states.

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 1995 and

FIGURE 2C–3

Medicare's payments to freestanding dialysis facilities have increased steadily



Note: In 2005, payments for composite rate services include composite rate and add-on payments.

Source: MedPAC analysis of 1996, 2000, and 2003–2005 outpatient dialysis claims from CMS.

2006, the number of dialysis facilities and hemodialysis stations grew at annual rates of 5 percent and 6 percent, respectively, keeping up with the 6 percent per year growth in the number of in-center hemodialysis patients (Table 2C-1, p. 132).

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 and by providing more treatments to existing patients.[8] Our analysis of CMS's facility surveys shows that between 2003 and 2004, providers increased the total number of hemodialysis treatments they furnished by 4 percent.

Volume of services

Between 1996 and 2005, 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 7 percent annually; the number of dialysis patients increased, on average, by about 6 percent annually.

Freestanding facilities treat most dialysis patients and therefore account for nearly 90 percent ($6.9 billion in 2005) of spending for composite rate services and dialysis drugs (Figure 2C-3). Total payments to freestanding dialysis providers grew more slowly than historical trends would indicate. Aggregate expenditures increased by about 10 percent per year between 1996 and 2004 but then slowed to a 4 percent increase between 2004 and 2005 due to the MMA (Figure 2C-4).

The growth in total payments slowed because drug spending fell. As a result of the MMA's changes:

- Payments for composite rate services increased by 14 percent between 2004 and 2005, while payments for these services increased 8 percent annually between 1996 and 2004.
- Drug payments to freestanding dialysis providers declined by about 10 percent (from $2.8 billion to $2.5 billion) between 2004 and 2005. By contrast, between 1996 and 2004, dialysis drug payments grew by about 15 percent per year, from $951 million to $2.8 billion.

The growth in composite rate payments between 2004 and 2005 is due to the add-on payment, mandated by the MMA and implemented by CMS in 2005. The decline in drug payments is also due to the MMA, which lowered the payment rate for most dialysis drugs at this time.

Although payments for dialysis drugs declined between 2004 and 2005, at issue is whether the volume of drugs declined and if the payment change affected patients' outcomes. To analyze this question, we conducted three analyses.

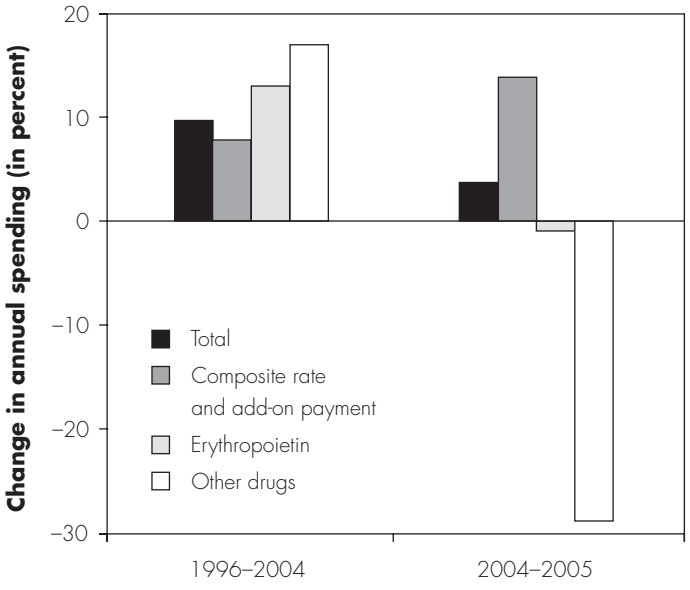
First, we held the drug payment rate constant and looked at the dollar change in the total volume of services for the top 10 dialysis drugs in 2004. Applying the 2004 payment rate to 2005 volume suggests that erythropoietin volume increased by 2 percent and the volume of the other leading drugs increased by 7 percent in 2005. The volume of only two drugs—iron dextran and calcitriol—declined between 2004 and 2005 because providers replaced them with other drugs that treat the same comorbidities (iron deficiency and bone disease, respectively).

Second, we looked at the number of units of erythropoietin administered per treatment between 2003 and 2005. The units per treatment increased by 7 percent per year between 2003 and 2004 and remained relatively constant between 2004 and 2005 (declining by 0.6 percent). Other researchers have also shown that the mean amount of erythropoietin administered remained relatively flat between 2004 and 2005.[9]

Finally, we used available data on quality that providers report on their Medicare claims to assess whether the change in the drug payment method affected patients' outcomes. We looked at whether the proportion of patients who received adequate dialysis and have their anemia under control declined between 2003 and 2005. Dialysis adequacy, which measures the effectiveness of the dialysis treatment, is not affected by any one dialysis drug. Many factors—including the patient's age, body weight, and length of dialysis treatment—affect dialysis adequacy. Anemia is a common condition among dialysis patients. Researchers have linked higher doses of erythropoietin during the past decade to more patients having their anemia under control. The proportion of patients receiving adequate dialysis (i.e., with a urea reduction ratio greater than 65 percent) remained the same for the three years (94 percent in 2003 and 95 percent in 2004 and 2005). The proportion of patients whose anemia was under control increased from 86 percent in 2003 to 89 percent in 2004 and 90 percent in 2005.

FIGURE 2C–4

The MMA increased spending for composite rate services and decreased spending for dialysis drugs



Note: MMA (Medicare Prescription Drug, Improvement, and Modernization Act of 2003). The MMA's changes to drug payment rates began on January 1, 2005.

Source: MedPAC analysis of 1996, 2000, and 2003–2005 outpatient dialysis claims from CMS.

Why did providers increase the volume of dialysis drugs and is all of the growth in volume appropriate?

Use of dialysis drugs has grown for two reasons. First, there are new and effective drugs. Many of them—including erythropoietin and iron supplements—were approved by the Food and Drug Administration in the late 1980s. Since then, the National Kidney Foundation (NKF) has advocated use of certain drugs in its clinical guidelines. The use of many of these medications has enhanced the quality of care furnished to dialysis beneficiaries. For example, the increased use of erythropoietin has reduced the proportion of dialysis patients with anemia, which contributes to morbidity if not treated effectively. Medicare's coverage decisions also affect use of these drugs. For example, CMS decided to cover injections of levocarnitine for patients with ESRD beginning January 1, 2003.[10]

Second, paying according to the number of units given to patients means that providers derive greater profits from larger doses than from smaller ones (as long as Medicare's payment exceeds their costs). In addition, the profitability of certain dialysis drugs under the old (pre-MMA) payment method gave providers an incentive to use more of them. In 2005, the new drug payment method (i.e., paying facilities the average acquisition payment rate for most drugs) reduced but did not eliminate the profitability of drugs. Medicare's payment rate for the top dialysis drugs exceeded the average transaction price—as measured by the average sales price (ASP)—in 2005.[11] CMS calculates ASP based on actual transaction prices submitted quarterly by drug manufacturers. As shown in Table 2C-2 (p. 136), Medicare's payment rate in 2005 (for the leading five dialysis drugs, which accounted for 93 percent of drug spending) was greater than the average transaction price as measured by ASP. For example, Medicare's payment rate for erythropoietin was $9.76 per 1,000 units in 2005 while the drug's average transaction price was $8.77 in 2005.

TABLE 2C–2 **AAP exceeded ASP in 2005**

Drug	AAP	ASP
Erythropoietin	$9.76	$8.77
Doxercalciferol	2.60	2.07
Iron sucrose	0.37	0.34
Paricalcitol	4.00	3.70
Sodium ferric gluconate complex	4.95	4.47

Note: AAP (average acquisition payment), ASP (average sales price). These five drugs together accounted for 93 percent of drug expenditures for freestanding dialysis facilities in 2005. Beginning in 2005, CMS paid dialysis providers AAP for most dialysis drugs. In 2006, CMS revised this policy by paying ASP plus 6 percent for all dialysis drugs. We calculated ASP values by averaging four quarters of 2005 ASP data obtained from CMS.

Source: MedPAC analysis of 2005 ASP Drug Pricing files from CMS.

Historical trends in the use of erythropoietin demonstrate the concerns about paying for profitable services on a per unit basis. After CMS changed its method of 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 substantially escalated—8 percent annually between 1991 and 2004 (from 7,100 units per week to 20,100 units per week) (USRDS 2006).[12] Before 1991, providers received $40 per dose of less than 10,000 units and $70 per dose of more than 10,000 units. Under the pre-1991 payment method, the average dose of erythropoietin (about 2,700 units per treatment) was much lower than under a per unit basis (Greer et al. 1999). CMS has tried to address the increasing per patient use of erythropoietin through a series of payment policies (as described in the text box).

Some researchers have questioned whether providers could furnish erythropoietin more efficiently and have suggested that appropriate use of intravenous iron could reduce erythropoietin dose requirements. Fishbane analyzed existing clinical trials and estimated that erythropoietin dose could be lowered by 27 percent to 75 percent with appropriate iron management (Fishbane 2006). Pizzi and colleagues estimated a net savings to Medicare of $257 per patient per month if providers followed the NKF's anemia guideline (Pizzi et al. 2006). Data from the USRDS show some variation in spending for erythropoietin and intravenous iron across the different providers. Per patient per month spending varied from $449 to $568 for erythropoietin and from $88 to $112 for intravenous iron across the large for-profit chains and hospital-based facilities (USRDS 2005). Some of this variation may be related to case mix, as measured by patients' characteristics.

As we discuss later in this chapter, broadening the payment bundle and including drugs and other commonly furnished services that providers currently bill separately might create more incentives for providers to furnish these services more efficiently. The Commission is interested in exploring the advantages and disadvantages of Medicare creating a dialysis drug payment bundle as an interim step until CMS bundles both composite rate services, dialysis drugs, laboratory tests, and other services dialysis patients need. Providers might be encouraged to use drugs more efficiently under a dialysis drug bundle than under the current payment method.

Another question is the extent to which patients benefit clinically from the increasing use of erythropoietin and a higher target hematocrit range. Researchers have reached conflicting conclusions. Some researchers have shown that the higher dose and target hematocrit range may be linked to poorer outcomes among some patients. Zhang and colleagues used administrative claims data to examine the association between erythropoietin dose and hematocrit and mortality in nearly 95,000 hemodialysis patients (Zhang et al. 2004). After adjusting for differences in disease severity, they found a significant relationship between increasing erythropoietin dose and mortality.

In a recent clinical trial, a higher target hematocrit value (40.5 percent vs. 33.9 percent) was associated with increased risk of death, myocardial infarction, hospitalization for congestive heart failure, and stroke among patients with chronic kidney disease (who were not on dialysis) (Singh et al. 2006). Improvements in quality of life were similar in both groups of patients. On the basis of these results, the researchers concluded that the use of a high target hemoglobin level provides no benefit for patients or payers. Other small clinical comparative trials have also looked at the effectiveness of maintaining higher hematocrit levels among patients with anemia (Besarab et al. 1998, Parfrey et al. 2005).

By contrast, other researchers have found that the risks of death and hospitalization are inversely associated with patients' hematocrit levels. For example, Ofsthun and colleagues reported that patients with lower hematocrit levels (less than 27 percent) had an adjusted relative risk of death of 2.1 compared with patients with higher

The erythropoietin monitoring payment policy

CMS has developed numerous policies to pay for erythropoietin since it began to cover the drug in 1989. CMS has based its policies on the hematocrit or hemoglobin level that providers report on their erythropoietin claims. Both measures assess a patient's anemia status by determining the percentage of red blood cells in the bloodstream.[13] Higher hematocrit and hemoglobin values suggest that a patient's anemia is under control.

Initially, CMS used the Food and Drug Administration's (FDA's) recommended hematocrit target range of 30 percent to 33 percent as its cutoff for payment. In 1994, CMS adjusted its payment policy to reflect the FDA labeled indication that increased the upper limit to 36 percent. Between 1991 and 1997, payments for erythropoietin grew from $246 million to $735 million.

To address the rapid growth in the use of erythropoietin, CMS implemented a payment policy (the hematocrit management audit policy) in August 1997 that did not pay providers for the last month's dosage of the drug if a patient's hematocrit exceeded 36.5 percent 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 stopped rising, and the average patient dose of erythropoietin leveled off. CMS increased the upper limit to 37.5 percent in 1998, and average patient doses began to rise again.

Beginning in April 2006, CMS implemented a policy that requires providers to reduce erythropoietin dosage by 25 percent if the hematocrit level exceeds 39 percent. If providers fail to reduce the patient's dose, and there is no documentation to support the higher dose, CMS reduces that month's payment by 25 percent. In addition, CMS does not pay providers for monthly doses that exceed 500,000 units per patient. Typically, monthly doses per patient are less than 500,000 units; CMS data show that in 2004 the patient dose per month averaged about 77,000 units for patients weighing 150 pounds.

Beginning in October 2006, CMS refined the erythropoietin monitoring policy by eliminating the reference to a minimum dose reduction of 25 percent and by requiring providers to indicate whether they reduced the erythropoietin dose in response to the patient's hematocrit level. CMS expects providers to reduce the erythropoietin dose as the hematocrit level approaches 36 percent and to maintain hematocrit levels between 30 percent and 36 percent (CMS 2006). ■

hematocrit levels (between 33 percent and 36 percent) (Ofsthun et al. 2003). The authors also reported that both the number of hospitalizations and the length of stay decreased as patients' hematocrit levels increased. Similarly, Wolfe and colleagues reported that standardized mortality ratios were lower for facilities with a larger proportion of patients who had their anemia under control (hematocrit level greater than or equal to 33 percent) (Wolfe et al. 2005).

More research may be needed to assess whether a higher erythropoietin dose and target hematocrit range significantly improve survival in dialysis patients (Cotter et al. 2006). Volkova and Arab concluded that published trials provide little evidence about the relationship between hematocrit level and mortality (Volkova and Arab 2006). A comparative (practical) clinical trial might offer an opportunity to evaluate the costs and benefits of different strategies for treating anemia in real-world settings (Tunis et al. 2003). The Secretary might consider sponsoring such studies since Medicare is the largest purchaser of erythropoietin in the United States; total spending in 2005 included $2 billion for dialysis patients and $1 billion for other patients, primarily cancer patients undergoing chemotherapy treatments. Medicare expenditures for erythroid growth factors (erythropoietin and darbepoetin alpha, which is used primarily by nondialysis patients) account for the highest percentage of Medicare Part B drug spending. A federal government role may be warranted. In a systematic review of published clinical trials (which included a variety of drug classes), researchers showed that industry-sponsored studies were significantly more likely to reach conclusions that were

favorable to the sponsor than non-industry-sponsored studies (Bekelman et al. 2003). Finally, improving the availability of information about the clinical and cost effectiveness of medical services may lead to more efficient use of Medicare's resources.

Quality of dialysis care

CMS data show that the quality of dialysis care improved for some measures (Table 2C-3). Between 2000 and 2004, the proportion of hemodialysis patients receiving adequate dialysis increased. The trend in the adequacy of peritoneal dialysis is mixed. The proportion of patients receiving adequate dialysis increased for one peritoneal dialysis method (continuous ambulatory peritoneal dialysis) and declined for another method (continuous cycler-assisted peritoneal dialysis). Increasing proportions of both hemodialysis and peritoneal dialysis patients have their anemia under control.

We previously showed few differences in dialysis adequacy and anemia status by type of facility (e.g., rural vs. urban; freestanding vs. hospital based) (MedPAC 2005). For each provider type, more than 90 percent of patients received adequate dialysis and more than 87 percent of patients had their anemia under control.

Patients' anemia status is related to the dose of erythropoietin they receive. Some researchers have raised concerns about the increasing use of erythropoietin and higher hematocrit ranges, as discussed in the preceding section.

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. Use of arteriovenous (AV) fistulas, considered the best type of vascular access, is improving, from 30 percent to 39 percent of hemodialysis patients between 2000 and 2004. Clinical guidelines recommend that at least 40 percent of all hemodialysis patients have an AV fistula. CMS is leading a national quality initiative—Fistula First—to increase the use of fistulas. The 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. CMS aims to improve rates of fistula use to levels seen in Europe and Asia, which average 70 percent and 80 percent, respectively.

Nutritional care is another clinical area that needs substantial improvements. The proportion of dialysis patients who are malnourished has remained relatively constant during the past decade. Researchers have shown that poor nutritional status increases rates of hospitalization and mortality of dialysis patients. Several factors may affect the nutritional status of patients, including physiological responses to ESRD, the dialysis process itself, presence of anemia, endocrine factors, and inadequate food intake secondary to certain conditions (e.g., anorexia and emotional distress).

Nutritional counseling is included in the bundle of services currently covered by the composite rate. Medicare's current conditions for coverage require that a dietician assess the nutritional and dietetic needs of patients, recommend therapeutic diets, and monitor adherence and response to diets. In CMS's proposal to update the current conditions for coverage, providers would also be required to monitor a nutritional measure—the serum albumin level—on a monthly basis. Providers would also be required to include nutritional status in their quality assessment and performance improvement program.

Augmenting dietary counseling with nutritional therapy might be one way to improve patients' nutritional status. The NKF has developed a clinical guideline for managing nutrition in dialysis patients that includes recommendations for supplementing dialysis patients' diet with nutritional supplements. Medicare does not cover oral nutritional supplements, and coverage policies for the other treatments, such as enteral tube feeding, intradialytic parenteral nutrition, and total parenteral nutrition are restrictive. Anti-kickback provisions in the statute limit the ability of providers to furnish patients with nutritional supplements at no cost or at reduced prices.

The Commission will consider recommending options to improve the nutritional status of dialysis patients in the near future. Our research agenda will include examining different alternatives to encourage the appropriate use of nutritional supplements by dialysis patients. One option is to include nutritional supplements in an expanded dialysis payment bundle that includes commonly furnished services under a single rate. As we discuss later in this chapter, broadening the dialysis payment bundle would modernize this payment system. A bundled approach would encourage providers to operate efficiently, as they retain the difference if Medicare's payment exceeds their costs. Separate payment for nutritional supplements could result in their overuse by providers (if Medicare's payment exceeded providers' costs). We have seen that providers do react to a service's profitability; the pre-MMA drug

TABLE 2C–3 **Dialysis outcomes continue to improve for some measures**

Outcome measure	2000	2001	2002	2003	2004
Percentage of in-center hemodialysis patients:					
Receiving adequate dialysis	91%	92%	92%	94%	95%
With anemia under control	74	76	79	80	83
Dialyzed with an AV fistula	30	31	33	35	39
Not malnourished	80	82	81	81	82
Percent of all peritoneal dialysis patients:					
Receiving adequate CAPD	69	68	71	70	73
Receiving adequate CCPD	62	70	66	65	59
With anemia under control	73	76	80	82	82
Not malnourished	56	61	60	63	62

Note: AV (arteriovenous), CAPD (continuous ambulatory peritoneal dialysis), CCPD (continuous cycler-assisted peritoneal dialysis). Data on dialysis adequacy and use of fistulas represent percent of patients meeting CMS's clinical performance criteria. Patients with anemia under control include those with hemoglobin ≥ 11 g/dL. Not malnourished includes patients with serum albumin ≥ 3.5/dL.

Source: MedPAC analysis of 2000–2005 Annual Reports for ESRD Clinical Performance Measures Project from CMS.

payment method gave some providers an incentive to overuse certain drugs. Part of this work will consider the financial impact of including nutritional supplements in a broader bundle. We may also explore the legal issues surrounding providers furnishing oral supplements.

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

In addition to providing nutritional supplements, monitoring nutritional outcomes—such as serum albumin level—for all patients might lead to quality improvements. CMS could require providers to report nutritional outcomes on their dialysis claims. Currently, CMS collects this information for a sample of patients. There is precedent for collecting dialysis outcome information for all patients. CMS requires providers to report two outcomes—dialysis adequacy and anemia status—on their claims. Collecting nutritional information for all patients might give providers more incentive to improve upon the nutritional counseling services they furnish. The availability of information for all patients would enable CMS to calculate and post facility-level nutritional outcomes on its website. Patients could then compare the quality of nutritional care different facilities furnish. CMS posts facility-level information about dialysis adequacy, anemia status, and survival on its website. Collecting nutritional outcomes for all patients would be especially important if Medicare were to include nutritional supplements in a broader bundle.

Access to capital

Recent financial information and evidence about trends in the increase in 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:

- The mergers of Fresenius–Renal Care Group and DaVita–Gambro were financed through bonds and bank debt. Fresenius acquired 425 dialysis facilities and paid $4.5 billion, or $115,131 per patient. DaVita acquired 565 facilities and paid $3.05 billion, or $70,601 per patient.

- In 2006, Fresenius acquired the rights to sell an oral drug used to reduce phosphorus absorption in dialysis patients. Under this agreement, analysts anticipate that Fresenius will pay up to $150 million over 10 years to Nabi Biopharmaceuticals.
- A private equity investor group funded the acquisition in 2005 of 70 facilities (divested by DaVita due to the merger with Gambro) by a newly created company, Renal Advantage. By 2007, Renal Advantage has grown to 80 facilities and acquired a clinical laboratory (Pack 2007).

Investor analysts note that the sector benefits from recurring revenues from dialysis treatments. But they also have pointed out that dialysis providers face potential pressures from 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 ranges from 48 percent to about 58 percent. Revenues from commercial payers account for 30 percent to 42 percent of revenues for these chains.

The two largest national chains enjoyed positive ratings from financial analysts in 2006. As expected, the mergers of the four largest chains resulted in a downgrade in the credit ratings. Standard & Poor's analysts lowered Fresenius's and DaVita's ratings because of the increased debt burden the companies incurred to finance the mergers.

Factors other than Medicare's payments may affect access to the capital markets for the largest chains, because each chain operates other lines of business. The largest chains operate clinical laboratories and one of the chains also manufactures dialysis equipment and supplies and provides dialysis services internationally.

Payments and costs for 2007

We assess freestanding providers' costs and the relationship between Medicare's payments and freestanding providers' costs by considering whether current costs approximate what efficient providers are expected to 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 2001 cost reports for the same facilities.

We then present our calendar year 2007 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 2005.[14]

In modeling 2007 payments, we incorporate policy changes that went into effect between the year of our most recent data, 2005, and our target year, 2007. In 2006 and 2007, CMS paid providers ASP plus 6 percent for all dialysis drugs. The MMA requires that CMS annually increase the add-on payment based on the estimated growth in drug spending from the previous year beginning in 2006. The 2006 add-on payment of 14.5 percent includes an update of 1.4 percent. The 2007 add-on payment of 15.1 percent includes an update of 0.5 percent. Finally, we also incorporated the increase in the composite rate in 2006 (by 1.6 percent) and 2007. For the first quarter of 2007, the composite rate payment remains at the 2006 level. Beginning April 1, 2007, CMS will update the composite rate by 1.6 percent, as mandated by the Tax Relief and Health Care Act of 2006. To ensure that total add-on payments remain constant (required by the MMA), CMS will lower the adjustment to the add-on payment to 14.9 percent (from 15.1 percent) when the composite rate increase takes effect on April 1, 2007.

Appropriateness of current costs

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

Average cost per treatment for composite rate services and dialysis drugs increased between 2003 and 2004 and declined in 2005 We see no clear trend in providers' costs per treatment for composite rate services and dialysis drugs between 2003 and 2005. Overall, total cost per treatment decreased by 1.1 percent per year. Total cost per treatment rose by 3 percent between 2003 and 2004 and fell by 5 percent between 2004 and 2005. These changes primarily stem from the drug cost per treatment rising

between 2003 and 2004 and then falling between 2004 and 2005. The MMA changes to drug payment rates in 2005 slowed the growth in the aggregate volume of drugs providers furnished.

Cost growth varies across freestanding dialysis facilities, indicating that some facilities are able to hold their growth in cost well below others'. For example, between 2003 and 2005, per treatment costs fell annually by 4 percent for facilities in the 25th percentile of cost growth and rose by 3 percent for facilities in the 75th percentile.

This year, we also 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. The dependent variable was the natural log of total Medicare composite rate and dialysis drug costs. Independent variables included:

- facility-level variables such as affiliation with the LDOs, number of hemodialysis stations, total number of dialysis treatments, and location (rural vs. urban areas); and
- patient case-mix variables such as the proportion of each facility's patients who are elderly dual eligibles; the presence of congestive heart failure and diabetes; and the patient's average severity (Charlson) index, inpatient days, and body size measured by body mass index (BMI) and body surface area (BSA).

Providers' costs were significantly associated with economies of scale and location. The LDOs and facilities that had more hemodialysis stations and that provided more dialysis treatments exhibited significant cost savings relative to their counterparts. Facilities in urban areas had higher costs per treatment than rural facilities.

A number of patient case-mix variables were significantly associated with facility costs. An increasing proportion of diabetics lowered a facility's costs. Providers' costs are linked to patients' body size: Higher BSA values or low BMI values raised costs. Higher facility costs were also 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).

Hirth et al. (1999) also found that composite rate costs were significantly lower for facilities affiliated with the largest chains. They reported that higher costs were associated with certain dialysis practices (using a synthetic dialysis membrane, not reusing dialyzers, and longer treatments) and with hospital-based facilities. Finally, the researchers reported only two demographic variables associated with costs; an increasing proportion of Hispanic patients decreased costs while an increase in patients' bilirubin levels (an indicator of liver disease) increased costs.

Auditing cost reports lowered average dialysis cost per treatment in 2001 For dialysis providers, MedPAC has looked at the effect of using audited cost reports when examining the appropriateness of current costs. We do so because MedPAC's analysis of 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).

Correcting costs to reflect the findings from these auditing efforts is not new. ProPAC corrected dialysis costs using the findings of the Health Care Financing Administration's (HCFA's) 1988 and 1991 audits (ProPAC 1997, 1993). MedPAC corrected dialysis costs using the findings from HCFA's 1996 audit, and the Government Accountability Office (GAO) adopted this correction in its analysis of dialysis payments and costs (GAO 2004, MedPAC 2003a).

We do not correct the costs of other providers—hospitals, skilled nursing facilities, and home health agencies—because this information is not generally available. There is no statutory requirement that CMS regularly audit the cost reports of other providers who submit cost reports to the agency. CMS rarely audits the cost reports of these other providers for accuracy, and the few audits the agency does conduct tend to focus on variables that are unrelated to our cost analysis. If sufficient audited cost report data were available for these other providers, however, we would assess the effect of the audit and make a similar correction.

TABLE 2C–4 **Medicare margin in 2005 varies by type of freestanding provider**

Provider type	Percent of spending by freestanding facilities	Medicare margin
All	100%	8.4%
LDOs	72	10.7
Non-LDOs	28	2.6
Urban	83	8.5
Rural	17	7.9

Note: LDO (large dialysis organization).

Source: Compiled by MedPAC from 2001 and 2005 cost reports and 2005 outpatient claims submitted by facilities to CMS.

We used the most recent audited data that are available—2001—to examine the potential effect of CMS's audit. We compared the cost per treatment calculated from audited and unaudited 2001 cost reports from the same providers.[15] Each cost report includes an indicator giving its status: as submitted, settled without an audit, settled with an audit, reopened. The proportion of 2001 cost reports that CMS settled with an audit has increased from 1 percent to 20 percent since 2003. By contrast, CMS has audited fewer than 1 percent of 2005 cost reports.

For the same facilities, the cost per treatment from their audited cost reports differed from the cost per treatment before CMS audited their reports. The audit primarily affects the cost per treatment for composite rate services, not the drug cost per treatment. For facilities whose cost reports were settled by an audit, the cost per treatment for composite rate services decreased by about $7 (from $144.41 to $136.51). By contrast, their drug cost per treatment did not change. We expected this finding because the audits primarily target those cost fields that can affect the Medicare payments a facility receives. CMS considers the costs reported for dialysis, not drug costs, when determining whether the agency will reimburse providers for bad debt. Looking at the components of composite rate costs—capital, labor, other direct, and administrative—the audit correction is greater for administrative costs than for the other components.

Based on these results, we determine payment margins using the results of the 2001 audit. For facilities with audited cost reports, we calculated the ratio of allowable costs to reported costs in 2001—94.5 percent for the cost per dialysis treatment. We then apply this correction to the costs of composite rate services for facilities for which CMS has not yet settled their cost reports (about 80 percent of facilities in 2005).

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. As mentioned earlier, the latest and most complete data available on freestanding providers' costs are from 2005.

For 2005, we estimate that the aggregate Medicare margin for composite rate services and injectable drugs is 5.5 percent without the audit correction (data not shown) and 8.4 percent after correcting for the audit (Table 2C-4). Aggregate margins vary based on a facility's affiliation with the LDOs. This finding stems from differences in the cost per treatment. Our regression analysis indicates that total cost per treatment was 6 percent lower for the LDOs than their counterparts after adjusting for patient case mix and other facility-level characteristics.

Urban facilities have a slightly greater Medicare margin than rural facilities. Although urban facilities have greater costs per treatment than rural facilities (as mentioned earlier), urban facilities have greater payments per treatment than rural facilities. Aggregate margins vary less based on the location because a similar share of the LDOs and the non-LDOs are located in rural areas.

Since 2003, aggregate margins for composite rate services and dialysis drugs have trended upward (from 2 percent in 2003 to 4 percent in 2004). Changes in total payment and cost per treatment can explain this direction. Between 2003 and 2005, the total payment per treatment grew by 4 percent each year because of increasing drug use and the legislated increase in the composite rate by 1.6 percent in 2005. At the same time, the total cost per treatment rose by 3 percent between 2003 and 2004 but fell by 5 percent in 2005.

Based on 2005 payment and cost data, we estimate that the 2007 aggregate margin is 4.1 percent. This estimate reflects the Congress's update of the composite rate in 2006 (by 1.6 percent) and in 2007. For the first quarter of 2007, the composite rate payment is held at the 2006 level. Beginning April 1, 2007, the Tax Relief and Health Care

Act of 2006 updates the composite rate by 1.6 percent. This estimate also reflects the update of the add-on payment in 2006 and 2007 (by 1.4 percent and 0.5 percent, respectively).

How should Medicare payments change in 2008?

CMS's market basket index for composite rate services projects that costs will increase by 2.5 percent between 2007 and 2008. This forecast may change because the agency updates it quarterly.

MedPAC's update framework reflects the expectation that, in the aggregate, providers should be able to reduce the quantity of inputs required to produce a unit of service while maintaining service quality. Prospective payment is designed to promote efficiency and providers should be expected to increase productivity. To estimate productivity increases, MedPAC uses the 10-year moving average of multifactor productivity in the economy as a whole, which is 1.3 percent for 2006.

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 2008 by the ESRD market basket index (2.5 percent) less the Commission's expectation for productivity growth (1.3 percent). This recommendation would update the composite rate by 1.2 percent.

RECOMMENDATION 2C

The Congress should update the composite rate in calendar year 2008 by the projected rate of increase in the end-stage renal disease market basket index less the Commission's expectation for productivity growth.

RATIONALE 2C

Most of our indicators of payment adequacy are positive, including beneficiaries' access to care, volume of services, quality of care, and access to capital. The Medicare margin has trended upward between 2003 and 2005.

IMPLICATIONS 2C

Spending

- Because there is no provision in current law to change the composite rate in 2008, this recommendation will increase federal program spending relative to current law by between $50 million and $250 million for calendar year 2008 and less than $1 billion over five years.

Beneficiary and provider

- This recommendation increases beneficiary cost sharing but would maintain current levels of beneficiary access to dialysis care. No negative effects on beneficiary access to care are anticipated because of the increase in beneficiary cost sharing. This recommendation is not expected to affect providers' willingness and ability to provide quality care to Medicare beneficiaries.

Note that 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.

Modernizing the outpatient dialysis payment system

The Commission has recommended that the Congress broaden the payment bundle to modernize the outpatient dialysis payment system (MedPAC 2003b). Medicare could provide incentives for controlling costs and promoting quality care by broadening the payment bundle to include drugs, laboratory services, and other commonly furnished items that providers currently bill separately and by linking payment to quality.

A bundled rate would create incentives for providers to furnish services more efficiently. For example, a bundled rate would remove the financial incentive for facilities to overuse separately billable drugs under the current payment method. In addition to an expanded bundle, changing the unit of payment to a week or a month might give providers more flexibility in furnishing care and better enable Medicare to include services that patients do not receive during each dialysis treatment.

A bundled rate would also simplify the outpatient dialysis system. The MMA created the add-on payment to the

composite rate from some of the profits that Medicare paid providers under the pre-MMA drug payment method. The MMA requires that CMS update the add-on payment based on the previous year's increase in drug expenditures. Under a bundled rate, it would no longer be necessary for CMS to separately update the add-on payment to the composite rate.

It would be necessary to adjust payment for factors affecting providers' costs under a broader bundle. Otherwise, facilities may be underpaid for treating medically complex patients. Another issue to consider is whether the payment rate should vary by provider type. The Commission has previously recommended that the Congress eliminate differences in paying for composite rate services between hospital-based and freestanding facilities and that the Secretary use the same payment method to pay for all dialysis drugs provided by both facility types (MedPAC 2005).

GAO recently released a study that supported bundling Medicare's payment for composite rate services and dialysis drugs (GAO 2006). As mandated by the MMA, CMS is exploring the creation of a broader payment bundle. The MMA also required that CMS conduct a three-year demonstration to test the design of a bundled ESRD payment method.

The Commission also has recommended pay for performance in the outpatient dialysis setting (MedPAC 2004a). Linking payment to quality would send a strong message to dialysis providers that Medicare values the care beneficiaries receive and encourages investments in quality. Outpatient dialysis care is ready for pay for performance:

- Well-accepted measures are available.
- Systems are in place to collect data.
- Data are available to risk-adjust measures.
- Providers can improve upon measures.

CMS has yet to implement pay for performance for dialysis providers, although the agency included it in the recently implemented ESRD disease management demonstrations (CMS 2005).

A broader bundle might give some providers an incentive to stint on care. The Secretary will need to continue efforts to monitor, report on, and improve the quality of dialysis care in order to promote the delivery of clinically appropriate care. The Secretary should also develop new measures to monitor the use of services in an expanded bundle. Currently, CMS collects dialysis adequacy and anemia status for all patients. It will be important to develop measures for other aspects of dialysis care, such as nutritional outcomes (as mentioned previously).

The use of home dialysis is declining

Most dialysis patients (91 percent) undergo hemodialysis in a facility three times per week. (We also refer to this method as "conventional" dialysis.) The proportion of all dialysis patients receiving other types of dialysis declined during the past decade. Use of peritoneal dialysis, the most common home method, declined from 14 percent to 8 percent of all dialysis patients between 1990 and 2004 (USRDS 2006). Only 7 percent of the 102,000 new patients chose peritoneal dialysis in 2004, compared with 14 percent of the nearly 50,000 new patients in 1990. No more than 1 percent of new patients chose home hemodialysis in 1990 and 2004. Home hemodialysis patients usually dialyze five to seven times per week either during the day or while they sleep.

There is no "best" dialysis method. Each method—in-center hemodialysis, home hemodialysis, and peritoneal dialysis—offers advantages and disadvantages to patients. Patients dialyzing at home do not have to visit a dialysis facility as often as in-center patients. But home patients must maintain their own dialysis equipment and, after proper training, perform their own treatment alone or with the assistance of a helper.

Optimizing patients' outcomes should be the major driver in the choice of a dialysis method. Ideally, patients should be informed about the tradeoffs and actively participate in choosing a dialysis method.

Advantages of home dialysis

Home dialysis should remain a viable option because it offers several advantages to those patients who are able to dialyze at home. First, home patients are more satisfied with their care than in-center patients. Patients receiving peritoneal dialysis rated their care higher than those receiving hemodialysis. About 85 percent of peritoneal dialysis patients rated their overall care as excellent compared with 56 percent of hemodialysis patients (Rubin et al. 2004). Adjustment for patient age, race, education, health status, marital status, employment status, distance from the dialysis facility, and time since starting dialysis

did not reduce the differences between peritoneal dialysis and hemodialysis patients. After adjusting for these factors, peritoneal dialysis patients were 1.5 times more likely than hemodialysis patients to give an excellent rating (95 percent confidence interval 1.3 to 1.6).

Second, among individuals who prioritize working and traveling, home dialysis may lead to higher health-related quality of life than in-center dialysis. At the end of one year on dialysis, peritoneal dialysis patients reported better quality of life in areas specific to dialysis, such as significantly greater ability to travel and fewer dietary restrictions (Wu et al. 2004). By contrast, hemodialysis patients reported higher levels of sexual functioning than peritoneal dialysis patients.

Third, peritoneal dialysis offers a survival advantage for most patients compared with conventional dialysis during the first two to three years after starting dialysis. USRDS data show that 71 percent of peritoneal dialysis patients are alive two years after they start dialysis, compared with 65 percent of conventional hemodialysis patients. After three years of dialysis, 57 percent of peritoneal dialysis patients are alive compared with 54 percent of conventional hemodialysis patients. After five years, peritoneal dialysis loses its survival advantage. As mentioned earlier, peritoneal dialysis may not be appropriate for all patients. The relative advantage of peritoneal dialysis appears to be lower for patients with diabetes than for those without diabetes.

Lastly, total Medicare payments are on average lower for peritoneal dialysis patients than for hemodialysis patients. For example, among patients older than 75 years, total Medicare payments averaged $47,000 for peritoneal dialysis patients and $63,000 for hemodialysis patients (USRDS 2004). Payments for inpatient hospital services and dialysis drugs are substantially lower (by 27 percent and 67 percent, respectively) for peritoneal dialysis patients than for hemodialysis patients. Some of this difference stems from differences in socioeconomic characteristics of the patients. New peritoneal dialysis patients are healthier, achieved higher education levels, are more likely to be working, and had significantly better health-related quality of life than those who started hemodialysis.

Future issues to consider

The Commission's March 2006 report to the Congress discussed some clinical and nonclinical factors that may influence a patient selecting in-center hemodialysis versus home dialysis. Our review of the literature suggested that patients' other health problems and the care patients receive before dialysis may influence the dialysis method they choose. In addition, we also found studies suggesting that the length of time physicians have practiced and their training may affect their patients' use of home dialysis.[16] Finally, we reviewed Medicare's policies that might affect payment for home dialysis services.

The Commission will continue to monitor the use of home dialysis post-MMA. Preliminary analysis of 2003 through 2005 claims suggests that the number of peritoneal dialysis patients has remained relatively constant (21,051 patients in 2003, 21,669 in 2004, and 21,959 in 2005). We are also interested in exploring the effect of Medicare's payment and coverage policies and nonclinical factors on the use of home dialysis.

One question concerns how Medicare would pay for dialysis services under a bundled payment method. The MMA mandated that CMS conduct a demonstration that would bundle dialysis services, including composite rate services, dialysis drugs, and other services dialysis patients need. A key issue to consider is whether, under a broader payment bundle, Medicare should continue to pay the same rate for all types of dialysis. Currently, CMS pays the same composite rate for the various dialysis methods. The Congress called for the same rate when this payment system was created in 1981 to encourage the use of home dialysis.

Under a broader bundle, the Secretary could set the same rate for all dialysis methods, which would give some incentive for providers to furnish lower cost treatments. In 2003, Medicare's total payment per treatment for peritoneal dialysis patients (composite rate services and drugs) was much lower than the per treatment payment for in-center hemodialysis (about $160 vs. $220 per treatment, respectively). Alternatively, the Secretary could set different payment rates for each method based on the resources each method requires.

Pay for performance might be one way to give an incentive to providers who increase the number of home dialysis patients they treat or who care for more home patients than other providers. To link the use of home dialysis to payment, it may be necessary to identify those patients who are not appropriate candidates for home dialysis because of the presence of certain clinical morbidities. Thus, the calculation of the pay-for-performance measure might need to account for such patients.

Another question to explore is the potential benefits and costs of counseling Medicare beneficiaries about the different treatment methods before they require dialysis. Some evidence suggests that early referral to kidney specialists and patient counseling before starting dialysis are determinants of choosing peritoneal dialysis (Lameire and Van Biesen 1999, Little et al. 2001, Stack 2002). Although Medicare covers physician visits for patients with chronic kidney disease (who are not yet on dialysis), some physicians may not inform their patients about all the options for treating ESRD. Only one-quarter of new patients who selected hemodialysis reported that medical professionals informed them about peritoneal dialysis (USRDS 1997).

Currently, Medicare covers counseling about nutritional issues for beneficiaries with chronic kidney disease who have not yet started dialysis. One option is to expand this service to include counseling about the different treatment options (home dialysis, conventional hemodialysis, and transplantation) and other important aspects of dialysis care such as the different types of vascular access interventions.

Of course, pre-ESRD counseling will benefit only those patients whom physicians identify as having chronic kidney disease. Some research suggests that primary care physicians do not diagnose and refer patients with chronic kidney disease to renal specialists. Only 59 percent of family physicians and 78 percent of general internal medicine physicians fully recognized the signs and symptoms of chronic kidney disease (Boulware et al. 2006). These physicians referred 76 percent to 81 percent of patients with chronic kidney disease to kidney specialists.

Identifying patients at the earliest stage of chronic renal failure and referring them to a renal team may lead to better outcomes. One commercial insurer reported that a program to identify patients with chronic kidney disease and educate them about vascular access interventions improved the use of AV fistulas, the recommended type of access for hemodialysis patients (Glazer et al. 2006). The risk of death was significantly greater among patients referred to a renal team late (less than 4 months before the start of dialysis) than among patients referred early (more than 12 months before the start of dialysis) (Kinchen et al. 2002). Previous MedPAC analysis showed that patients referred to a renal team late had higher inpatient spending in the year before dialysis than early referral patients (MedPAC 2004b). ■

Endnotes

1 The two types of dialysis—hemodialysis and peritoneal dialysis—remove wastes and fluids from a patient's bloodstream differently. During hemodialysis, a machine removes wastes from the bloodstream; the procedure 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; it is usually performed by patients at home.

2 EGHPs are usually the primary payer for 33 months—the 3-month waiting period plus the 30-month coordination period.

3 CMS estimated that drug payment amounts would drop by 13 percent between 2004 and 2005 (CMS 2005).

4 CMS adjusts the composite rate and add-on payment for age (<18, 18 to 44, 45 to 59, 60 to 69, 70 to 79, ≥80 years) and two body measurement variables—body surface area and body mass index.

5 Patients who dialyze at home learn to perform either peritoneal dialysis or home hemodialysis. Facilities provide the necessary equipment and supplies for patients to perform dialysis at home.

6 In 2005, Medicare used three different ways to pay for dialysis drugs. (1) For the top 10 dialysis drugs that accounted for the greatest share of payments 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 (OIG 2004). (2) For all other dialysis drugs furnished by freestanding providers, CMS used a different method—ASP. This method uses the prices manufacturers report to the agency each quarter. CMS set the 2005 rates for these drugs at ASP 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 for erythropoietin as that of freestanding providers.

7 For example, in May 1997, Gambro acquired the 262 facilities of Vivra Renal Care. In November 1997, Total Renal Care acquired the 358 facilities of Renal Treatment Centers. In February 2002, Renal Care Group acquired the 87 facilities of National Nephrology Associates.

8 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.

9 USRDS data show that the mean units of erythropoietin administered monthly remained relatively constant between 2004 and 2005 (declining by 0.02 percent) (USRDS 2006).

10 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 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 it. Applying the 2003 payment rate to 2004 and 2005 volume suggests that the total volume of levocarnitine increased by 29 percent between 2003 and 2005.

11 ASP represents the amount drug manufacturers receive for their product. CMS calculates ASP using data submitted quarterly by pharmaceutical manufacturers and is net of rebates and discounts offered to purchasers by the manufacturers. Some prices are excluded from calculation of ASP, including prices paid by the Department of Veterans Affairs and other federal purchasers.

12 The Food and Drug Administration 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 might receive 3,400 to 6,800 units 3 times a week. Physicians titrate the dose based on the patient's response to therapy.

13 To convert hemoglobin units to hematocrit units, multiply by 10.

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 Audited 2001 cost reports refer to those obtained from CMS in September 2005; 20 percent of these cost reports were settled by an audit. Unaudited 2001 cost reports refer to those obtained from CMS in September 2003; only 1 percent of these cost reports were settled by an audit.

16 Mehrotra and others concluded that many training programs do not allocate enough time to ensure appropriate training in providing care for peritoneal dialysis patients. These researchers found that U.S. training programs provided care to significantly fewer patients undergoing dialysis than those in Canada (Mehrotra et al. 2002).

References

Bekelman, J. E., Y. Li, and C. P. Gross. 2003. Scope and impact of financial conflicts of interest in biomedical research. A systematic review. *Journal of the American Medical Association* 289, no. 4 (January 22/29): 454–465.

Besarab, A., W. K. Bolton, J. K. Browne, et al. 1998. The effects of normal as compared with low hematocrit values in patients with cardiac disease who are receiving hemodialysis and epoetin. *New England Journal of Medicine* 339, no. 9 (August 27): 584–590.

Boulware, L. E., M. U. Troll, B. G. Jaar, et al. 2006. Identification and referral of patients with progressive CKD: A national study. *American Journal of Kidney Diseases* 48, no. 2 (August): 192–204.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2006. Revision to the EPO/aranesp monitoring policy. http://www.cms.hhs.gov/Transmittals/Downloads/R1043CP.pdf.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2005. CMS announces demonstration sites for beneficiaries with end-stage renal disease. http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1703.

Cotter, D. J., M. Thamer, K. Narasimhan, et al. 2006. Translating epoetin research into practice: The role of government and the use of scientific evidence. *Health Affairs* 25, no. 5 (September/October): 1249–1259.

Fishbane S. 2006. How can erythropoietin requirements be reduced in dialysis patients? *Seminars in Dialysis* 19, no. 5 (September–October): 365–366.

Government Accountability Office. 2006. *End-stage renal disease: Bundling Medicare's payment for drugs with payment for all ESRD services would promote efficiency and clinical flexibility.* Washington, DC: GAO.

Government Accountability Office. 2004. *Medicare dialysis facilities: Beneficiary access stable and problems in payment system being addressed.* Washington, DC: GAO.

Glazer, S., J. Diesto, P. Crooks, et al. 2006. Going beyond the kidney disease outcomes quality initiative: Hemodialysis access experience at Kaiser Permanente Southern California. *Annals of Vascular Surgery* 20, no. 1 (January): 75–82.

Greer, J. W., R. A. Milam, and P. W. Eggers. 1999. Trends in use, cost, and outcomes of human recombinant erythropoietin, 1989–98. *Health Care Financing Review* 20, no. 3 (Spring): 55–62.

Hirth, R. A., P. J. Held, S. M. Orzol, et al. 1999. Practice patterns, case mix, Medicare payment policy, and dialysis facility costs. *Health Services Research* 33, no. 6 (February): 1567–1592.

Kinchen, K. S., J. Sadler, N. Fink, et al. 2002. The timing of specialist evaluation in chronic kidney disease and mortality. *Annals of Internal Medicine* 137, no. 6 (September): 2351–2357.

Lameire, N., and W. Van Biesen. 1999. The pattern of referral of patients with end-stage renal disease to the nephrologist—A European survey. *Nephrology Dialysis Transplantation* 14 (Suppl. 6): 16–23.

Little, J., A. Irwon, H. Rayner, et al. 2001. Predicting a patient's choice of dialysis modality: Experience in a United Kingdom renal department. *American Journal of Kidney Diseases* 37, no. 5 (May): 981–986.

Medicare Payment Advisory Commission. 2005. *Issues in a modernized Medicare program.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2004a. *Medicare payment policy.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2004b. *New approaches in Medicare.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2003a. *Medicare payment policy.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2003b. *Modernizing the outpatient dialysis payment system.* Washington, DC: MedPAC.

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

Office of Inspector General, Department of Health and Human Services. 2004. *Medicare reimbursement for existing end-stage renal disease drugs.* Washington, DC: OIG.

Ofsthun, N., J. Labrecque, E. Lacson, et al. 2003. The effects of higher hemoglobin levels on mortality and hospitalization in hemodialysis patients. *Kidney International* 63, no. 5 (May): 1908–1914.

Pack, T. 2007. Renal Advantage buys RenaLab. *Tennessean*. January 3. http://tennessean.com.

Parfrey, P. S., R. N. Foley, B. H. Wittreich, et al. 2005. Double-blind comparison of full and partial anemia correction in incident hemodialysis patients without symptomatic heart disease. *Journal of the American Society of Nephrology* 16, no. 7 (July): 2180–2189.

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

Prospective Payment Assessment Commission. 1997. *Report and recommendations to the Congress.* Washington, DC: ProPAC.

Prospective Payment Assessment Commission. 1993. *Report and recommendations to the Congress.* Washington, DC: ProPAC.

Rubin, H. R., N. E. Fink, L. C. Plantinga, et al. 2004. Patient ratings of dialysis care with peritoneal dialysis vs. hemodialysis. *Journal of the American Medical Association* 291, no. 6 (February 11): 697–703.

Singh, A. K., L. Szczech, K. L. Tang, et al. 2006. Correction in anemia with epoetin alfa in chronic kidney disease. *New England Journal of Medicine* 355, no. 20 (November 16): 2085–2098.

Stack, A. G. 2002. Determinants of modality selection among incident US dialysis patients: Results from a national study. *Journal of the American Society of Nephrology* 13, no. 5 (May): 1279–1287.

Tunis, S. R., D. B. Stryer, and C. M. Clancy. 2003. Practical clinical trials. *Journal of the American Medical Association* 290, no. 12 (September 24): 1624–1632.

United States Renal Data System, National Institute of Diabetes and Digestive and Kidney Diseases. 2006. *USRDS 2006 annual data report*. Bethesda, MD: NIDDK.

United States Renal Data System, National Institute of Diabetes and Digestive and Kidney Diseases. 2005. *USRDS 2005 annual data report*. Bethesda, MD: NIDDK.

United States Renal Data System, National Institute of Diabetes and Digestive and Kidney Diseases. 2004. *USRDS 2004 annual data report*. Bethesda, MD: NIDDK.

United States Renal Data System, National Institute of Diabetes and Digestive and Kidney Diseases. 1997. *USRDS 1997 annual data report*. Bethesda, MD: NIDDK.

Volkova, N., and L. Arab. 2006. Evidence-based systematic literature review of hemoglobin/hematocrit and all-cause mortality in dialysis patients. *American Journal of Kidney Diseases* 47, no. 1 (January): 24–36.

Wolfe, R. A., T. E. Hulbert-Shearon, V. B. Ashby, et al. 2005. Improvements in dialysis patient mortality are associated with improvements in urea reduction ratio and hematocrit, 1999 to 2002. *American Journal of Kidney Diseases* 45, no. 1 (January): 127–135.

Wu, A. W., N. E. Fink, J. V. R. Marsh-Manzi, et al. 2004. Changes in quality of life during hemodialysis and peritoneal dialysis treatment: Generic and disease specific measures. *Journal of the American Society of Nephrology* 15, no. 3 (March): 743–753.

Zhang Y., M. Thamer, K. Stefanik, et al. 2004. Epoetin requirements predict mortality in hemodialysis patients. *American Journal of Kidney Diseases* 44, no. 5 (November): 866–876.