

CHAPTER

6

**Quality of dialysis care
and providers' costs**

Quality of dialysis care and providers' costs

Certain freestanding dialysis facilities incur substantially lower costs per hemodialysis treatment than others. Of concern is whether the lower costs per treatment result in quality problems for beneficiaries. MedPAC's analysis shows that quality of care does not significantly differ between facilities with lower and higher costs for dialysis services included in the prospective payment bundle (the composite rate). Considering both the costs for furnishing dialysis and separately billable injectable drugs, we find that beneficiaries' outcomes are poorer for facilities with higher than average costs. One explanation for this finding is that certain facilities are less efficient at furnishing injectable drugs than other facilities and this inefficiency may in turn reflect less than optimal patient care. Another explanation is that higher drug costs may be a proxy for furnishing care to more medically complex patients. Previous MedPAC recommendations to refine the outpatient dialysis payment system would address either of these issues. These recommendations would broaden the payment bundle to include commonly used services currently excluded from it and account for differences known to affect providers' costs, such as patient case mix.

In this chapter

- Paying for outpatient dialysis services
 - Assessing the relationship between quality and dialysis providers' costs
 - Implications and next steps
-

Certain freestanding dialysis facilities incur substantially lower Medicare-allowable costs per in-center hemodialysis treatment than others.¹ Analysis of 2000 cost reports shows that facilities in the lowest quartile of costs incurred an average cost per hemodialysis treatment of about \$110 for services included in Medicare's prospective payment bundle (the composite rate).² By comparison, facilities in the highest quartile of costs incurred average treatment costs of nearly \$170 per treatment (Table 6-1). Lower-cost facilities are more likely to be:

- for-profit,
- affiliated with one of four national dialysis chains,
- located in rural and low-wage areas, and
- more productive.

Other investigators have shown that certain demographic, clinical, and functional characteristics of patients are also associated with providers' costs (Dor et al. 1992, Freund et al. 1998, Hirth et al. 1999, Sankarabaiyan and Holley 2000).

Of concern is whether the lower costs per treatment result in quality problems for beneficiaries. Dialysis is somewhat unique among Medicare services for both its availability of a core set of measures to assess key aspects of dialysis care, and that these measures are regularly collected and disseminated by CMS. The key measures of dialysis quality—adequacy (the dose of dialysis delivered) and anemia status—have steadily improved since the mid-1990s (CMS 2002). For instance, the proportion of in-center hemodialysis patients receiving adequate dialysis increased from 74 to 89 percent in 1996 and 2001, respectively (CMS 2002, HCFA 1997a). In addition, CMS data

TABLE 6-1

Characteristics of freestanding dialysis facilities, by quartile of average cost per hemodialysis treatment, 2000

Cost quartile	Cost per treatment	Average number of treatments	For profit	Major chain	Rural
Percent of all facilities					
Composite rate services only					
Quartile 1	\$110	9,483	94%	83%	26%
Quartile 2	125	8,264	91	73	17
Quartile 3	138	7,151	92	76	12
Quartile 4	167	5,221	88	65	11
Composite rate services and injectable drugs					
Quartile 1	\$162	9,024	93%	81%	23%
Quartile 2	181	7,657	90	77	20
Quartile 3	196	7,015	93	96	12
Quartile 4	229	5,752	88	63	10

Note: Lowest cost quartile is 1; highest is 4. Data are weighted by the number of in-center hemodialysis treatments.

Source: Analysis by Direct Research LLC of 2000 cost reports and claims submitted by freestanding dialysis facilities to CMS.

show that the variation in quality of care has also declined since the mid-1990s. For example, between 86 and 92 percent of in-center hemodialysis patients received adequate dialysis in 2001, whereas dialysis adequacy varied from 63 to 85 percent in 1996.

Other investigators have assessed the association between the facilities' profit status, a proxy for lower cost, and the quality of dialysis care (Table 6-2). Some of these investigators have hypothesized that, despite the overall improvements in key dialysis processes of care, the steady decline in the inflation-adjusted value of the composite rate has adversely affected dialysis quality.³ In particular, for-profit facilities may be under more pressure than nonprofit facilities to stint on the services and inputs used to produce care in order to generate income. Data from CMS's

annual facility survey show that an increasing proportion of patients are treated by for-profit facilities, from 60 percent in 1993 to nearly 80 percent in 2001.

Investigators assessing the relationship between facilities' profit status and quality of care report differing results. CMS investigators concluded that profit status was not associated with adequacy of dialysis and anemia and nutritional status (Frankenfield et al. 2000). A recent analysis by Port et al. (2001) concluded that the risk of mortality does not differ based on facilities' profit status. Others have found a correlation between facilities' profit status and rates of mortality and transplantation (Devereaux et al. 2002, Ebben et al. 2000, Garg et al. 1999, McClellan et al. 1998).

1 About 93 percent of all dialysis patients undergo hemodialysis three times per week in dialysis facilities. In hemodialysis, a patient's blood flows through a machine with a special filter to remove wastes and extra fluids. The remainder of patients undergoing peritoneal dialysis—cleaning a patient's blood with the lining of his or her abdomen as a filter—have it performed at home.

2 CMS designed the composite rate in 1983 to include all nursing services, supplies, equipment, and drugs associated with a single dialysis session.

3 Since 1983, per treatment payment has only increased on 3 occasions: by \$1 in 1991, by 1.2 percent in 2000, and by 2.4 percent in 2001.

**TABLE
6-2**

Recent studies examining the impact of providers' characteristics on quality of dialysis care

Author	Data and year(s) of study	Measures of outcome/quality	Main finding
Devereaux PJ et al. 2002	Meta analysis; 7 studies used data from 1990–1997; 1 study used data from 1973–1982.	Mortality	Death rate 8% higher among kidney failure patients receiving dialysis at for-profit centers than those treated at nonprofit facilities.
Port et al. 2001	Analysis of 12,791 hemodialysis patients treated in 1,394 dialysis facilities, 1994–1995.	Mortality	No statistical evidence that risk of mortality differed based on facilities' profit status.
Frankenfield et al. 2000	Analysis of 1997 data from HCFA's Core Indicator Project, facility survey, and HCFA's online survey, certification, and reporting system.	Adequacy of dialysis, anemia, and nutritional status	Facility profit status not associated with adequacy of dialysis, anemia and nutritional status. Larger facility size modestly associated with increased adequacy of hemodialysis, but neither anemia nor nutritional status.
Irvin RA 2000	Analysis of 1996 data for 180,913 hemodialysis patients.	Mortality	For-profit dialysis facilities had slightly higher mortality rates than nonprofit facilities, after controlling for patient case mix and market type.
Port and Wolfe 2000	Analysis of patients receiving dialysis between 1996–1997.	Mortality, transplantation	Adjusted rate of placement on a waiting list for a renal transplant was significantly lower in for-profit facilities than nonprofit facilities. Rate of transplantation did not differ based on facilities' profit status. Relative risk of death for patients treated in for-profit facilities was greater than nonprofit facilities.
Ebben et al. 2000	Analysis of 5 cohorts of hemodialysis beneficiaries surviving from July–December of entry year (1991–1995).	Mortality	Compared with nonprofit facilities, for-profit facilities had significantly greater risk of mortality, 1991–1993. In 1994 and 1995, providers' profit status was no longer a significant risk factor.
Garg et al. 1999	Analysis of 1990–1993 data collected by the USRDS.	Mortality, transplantation	For-profit dialysis facilities experienced increased mortality and decreased rates of placement on transplant waiting lists compared to nonprofits.
Fink et al. 1999	Analysis of 1996 data collected from facilities in Va. and Md.	Adequacy of dialysis	Patients dialyzing at for-profit dialysis facilities had a mean URR value 1.5% higher than those dialyzed at nonprofit facilities.
McClellan et al. 1998	Analysis of 1994 data collected from facilities in N.C., S.C., and Ga.	Mortality	Mortality rates of hemodialysis patients are significantly higher in for-profit facilities than nonprofit facilities.
Collins et al. 1998	Analysis of 13,926 patients in 1989–1990 and 20,422 patients in 1991–1993.	Mortality	Risk of mortality did not differ between freestanding and hospital-based facilities not reusing dialyzers in 1989–1990. In 1991–1993, freestanding for-profit units had a higher mortality risk than hospital-based nonprofit units, and hospital-based for-profit units had a lower mortality risk than hospital-based nonprofit units.

Note: HCFA (Health Care Financing Administration), URR (urea reduction ratio), USRDS (United States Renal Data System).

Source: MedPAC analysis of studies published between 1998 and 2003 assessing the relationship between selected outcomes of care (adequacy of dialysis, anemia and nutritional status, and rates of hospitalization, transplantation, and mortality) and characteristics of dialysis facilities (size and profit status).

No recent studies in the peer-reviewed literature examine the relationship between dialysis facilities' costs and quality of care. Therefore, in this chapter, we examine whether beneficiaries' outcomes (quality of care) are associated with the costs incurred by freestanding dialysis providers furnishing in-center hemodialysis in 2000. In the first section, we summarize how Medicare pays for outpatient dialysis services, highlighting important differences in the methods used to pay for dialysis treatments and certain injectable drugs. Next, we provide results from a study conducted by Direct Research LLC on behalf of MedPAC that finds that beneficiaries' outcomes do not significantly differ among facilities with lower and higher costs for composite rate services after controlling for other facility and beneficiary characteristics (Hogan 2003). When considering both the costs for furnishing dialysis and separately billable drugs, we find that beneficiaries' outcomes are poorer for facilities with higher than average costs. We have two interpretations of these findings. First, certain facilities may be less efficient at furnishing injectable drugs than others because of Medicare's payment methods for these drugs and their profitability. This inefficiency may in turn reflect less than optimal care. Second, higher drug costs may be a proxy for furnishing care to more medically complex patients whose characteristics we may not fully capture in the model. This chapter concludes with a discussion of the implications of these findings.

Paying for outpatient dialysis services

Medicare pays a prospective payment—the composite rate—for each dialysis treatment provided in dialysis facilities (in-center) or in patients' homes. The base payment rate was \$127 for freestanding facilities and \$131 for hospital-based

facilities in 2001. The payment rate does not vary with factors known to affect providers' costs, including dialysis dose, frequency of dialysis, differences in the resources used for different dialysis methods, and patient case mix.⁴ Rather, the payment rate is only adjusted to account for differences in local area wages.

By contrast, providers receive an additional, separate payment for furnishing certain injectable drugs during dialysis. The Congress has set the payment for erythropoietin, the costliest of these drugs in terms of spending by Medicare and beneficiaries, at \$10 per 1,000 units. Erythropoietin is the mainstay in the treatment of anemia, affecting nearly all dialysis patients. Providers receive 95 percent of the average wholesale price (AWP) for separately billable injectable medications other than erythropoietin administered during in-center dialysis. (Chapter 9 provides a detailed discussion of drugs paid for by Medicare and the AWP.) Since these injectable drugs are paid on a per dose basis, providers have the incentive to furnish as many of these drugs as the severity of the patient warrants.

Use of injectable dialysis drugs, as measured by Medicare's payments, has steadily increased since the mid-1990s. For freestanding dialysis providers, revenue from injectable medications relative to that from composite rate services has increased from about 33 percent of total payments in 1997 to 40 percent in 2001. The profitability of certain injectable medications has also provided incentives to administer them in certain ways (MedPAC 2003). For instance, Medicare pays \$10 per 1,000 units for erythropoietin administered either intravenously or subcutaneously (under the skin). Paying on a per unit basis promotes the use of the intravenous form of this medication, which requires higher average doses (more units) to achieve target hematocrit levels.⁵ The

predominant use of intravenous erythropoietin persists despite the publication of the National Kidney Foundation's (NKF's) Kidney Disease Outcomes Quality Initiative Clinical Practice Guideline for the treatment of anemia that advocated subcutaneous administration.

Assessing the relationship between quality and dialysis providers' costs

The key issue addressed in our analysis is whether quality differences exist between lower- and higher-cost freestanding dialysis facilities. The four measures of quality we used are:

- adequacy of hemodialysis,
- adequacy of anemia management,
- rate of death, and
- rate of kidney transplantation.

Researchers and providers generally agree that these measures reflect the quality of care furnished by dialysis providers and beneficiaries' outcomes (although these are not the only such measures, as discussed later). The text box beginning on page 95 provides information about each outcome measure.

Both dialysis adequacy and anemia management reflect dialysis facilities' processes of care. We used clinical guidelines developed by the NKF to assess adequacy of hemodialysis and anemia status (NKF 2003). The NKF used an evidence-based approach to develop their guidelines and CMS based its clinical performance measures for hemodialysis adequacy and anemia management on these guidelines. CMS's Clinical Performance Measurement Project, a national effort to improve dialysis patients' care and outcomes, has

4 The Commission previously recommended that the Congress should instruct the Secretary to revise the outpatient dialysis payment system to account for factors that affect providers' costs to deliver high-quality clinical care (MedPAC 2001).

5 Some providers contend that erythropoietin is predominately furnished intravenously rather than subcutaneously because patients experience less discomfort.

Measures used to assess quality of dialysis care and beneficiaries' outcomes

Among the services furnished by traditional Medicare, dialysis is rare in the availability of agreed-upon measures of dialysis quality and beneficiaries' outcomes. As noted earlier, the National Kidney Foundation (NKF) has developed clinical guidelines for several aspects of dialysis care—adequacy of dialysis, anemia management, vascular access management, and nutrition management. CMS and the United States Renal Data System regularly report on these processes of dialysis care.

Adequacy of dialysis. Adequacy of dialysis refers to the delivered dose of dialysis. The proportion of patients receiving adequate dialysis has improved, from 74 to 89 percent in 1996 and 2001, respectively (CMS 2002, HCFA 1999).

This analysis uses the urea reduction ratio (URR), which measures the extent to which the dialysis treatment removes urea from the blood, to assess adequacy of dialysis. Consistent with the NKF clinical guideline, this analysis uses a level of URR of 65 percent or greater as the standard of hemodialysis adequacy. Research has established that excess rates of complications and mortality occur below 65 percent. The delivered dose of dialysis is influenced by a number of patient-related factors (such as patient comorbidities, compliance, and weight) and technical factors (such as the duration of a dialysis treatment, the number of dialysis treatments per week, the type of vascular access and dialyzer membrane, and the blood and dialysate flow rate).

Anemia management. Anemia, mainly caused by erythropoietin deficiency in diseased kidneys, develops early in the course of renal failure, becomes prominent as the

disease progresses, and contributes substantially to morbidity. The anemia status of dialysis patients has shown steady improvements, with the proportion of anemic patients declining from 57 to 24 percent of all patients in 1997 and 2001, respectively (CMS 2002).

This analysis uses hematocrit, the fraction of blood that consists of red blood cells, to assess beneficiaries' anemia status. Consistent with the clinical guideline developed by the NKF, hematocrit levels above 33 percent are the standard of adequacy for anemia management. The NKF's clinical guideline for anemia management recommends a target hematocrit range of 33 to 36 percent and notes that a hematocrit greater than 30 percent has been associated with increased survival, decreased left ventricular hypertrophy, improved quality of life, and improved exercise capacity.

Transplantation. Kidney transplantation is the preferred treatment for renal failure. When successful, it restores patients more nearly to a normal and satisfactory quality of life than does dialysis. In addition, transplantation is more cost-effective than dialysis as a treatment for renal failure, as beneficiaries with functioning grafts are about one-third as costly as beneficiaries on dialysis (Eggers 1988).

The scarcity of organs limits the number of transplant procedures performed. The increase in the number of transplants—from 13,343 in 1998 to 14,287 in 2000—is due to growth in the number of living donor procedures. In addition, other clinical and nonclinical factors may be contraindications for transplant. These factors include advanced coronary artery disease, congestive heart failure

and cardiomyopathy, active infections such as tuberculosis, other advanced organ failures, history of malignancy, active substance abuse, and likely inability to comply with the follow-up treatment regimen.

Finally, patient preferences and financial burden may also play a role in the transplant decision. Socioeconomic factors influence referral for pretransplant medical evaluations and placement on kidney transplant waiting lists (Alexander and Sehgal 1998). The loss of Medicare eligibility 3 years after kidney transplantation for patients under age 65 may limit certain individuals from being considered for a transplant because of the patient's financial burden of maintaining the immunosuppressive regimen.

Unlike dialysis services, Medicare is not the predominant payer for kidney transplants. Younger patients more frequently undergo kidney transplantation and have private insurance as their primary payer than older patients. In 2000, incident end-stage renal disease (ESRD) patients 65 years and older accounted for only 6 percent of all kidney transplant patients but nearly half of all in-center hemodialysis patients (USRDS 2002). Data from the Agency for Healthcare Research and Quality show that Medicare was the primary payer for less than half of all cases.

Mortality rate. ESRD beneficiaries have a higher mortality rate compared with non-ESRD beneficiaries. The Medicare population as a whole has about 5.5 deaths per 100 persons per year; by comparison, the ESRD population has about 17 deaths per 100 persons per year. The leading causes of death are cardiac arrest, septicemia, and heart attack (USRDS 2002). ■

collected data annually since 1994 to assess these measures.⁶ Since 2001, the agency has reported information about hemodialysis adequacy and anemia status for individual facilities on its Dialysis Facility Compare website (CMS 2003).

By contrast, the other measures we use—death and transplantation—reflect processes of care that are also influenced by providers other than dialysis facilities. Although the risk of mortality increases with inadequate dialysis and poor anemia status, death can also be caused by factors not directly related to the dialysis process. As noted in the text box on page 95, patients' preferences and physicians' judgment about the suitability of a patient influence access to transplantation. The extent to which facilities influence access to this treatment is debatable. However, other investigators have used risk of mortality and access to transplantation to compare differences in the quality of care between dialysis facilities; CMS reports a measure of patient survival for individual facilities on its Dialysis Facility Compare website, so we included them in this study (Ebben et al. 2000; Garg et al. 1999; Irvin 2000; Port et al. 2001, 2000).

Our analysis focuses on the cost of in-center hemodialysis. This method treats the majority of dialysis patients, so estimating the average cost per in-center hemodialysis treatment on a facility-level basis is more reliable than for the other methods of dialysis—peritoneal dialysis and home hemodialysis—used by about 9 percent of all patients (USRDS 2002). Our analysis measures facilities' hemodialysis costs in two ways: (1) composite rate services only, and (2) both composite rate services and injectable drugs. Even though Medicare pays for injectable drugs separately, they are an integral part of the

care furnished to beneficiaries and, as mentioned earlier, their use has steadily increased since the mid-1990s.

Our analysis also focuses on the care furnished by freestanding—not hospital-based—facilities because their costs are easier to interpret. Unlike hospital-based facilities, the costs reported by freestanding facilities are not affected by hospitals' cost allocation decisions (MedPAC 2003). And, there is no current evidence showing differences in the costs incurred by freestanding and hospital-based facilities. Freestanding dialysis facilities are the predominant suppliers of dialysis care:

- In 2001, they treated about 80 percent of all dialysis patients and furnished a similar proportion of all in-center hemodialysis treatments.
- The proportion of all freestanding facilities has steadily increased throughout the 1990s, from 60 percent in 1993 to about 80 percent in 2001.

Although the main research question of the relationship between cost and quality is simple in theory, answering it in practice is a complex task. Many factors can affect average cost per treatment but have no particular link to the quality of care delivered. For instance, certain facilities may be able to furnish care at lower costs per treatment because they simply provide more services and can spread their fixed costs over more patients. Patient self-selection to certain providers also confounds any underlying relationship. Numerous attributes, including weight and comorbidities, make certain patients more difficult to dialyze. Such patients are more costly to dialyze as they require greater than average doses of dialysis, which, if not furnished, may result in poorer anemia status and

increased risk of mortality (HCFA 1997b).⁷ A facility with a higher than average share of these patients will have higher costs. For this reason, we control for many patient-level factors in our study.

To control simultaneously for both facility- and patient-level characteristics, we used multivariate ordinary least squares regression analyses to measure the association between cost per hemodialysis treatment and quality on a facility-level basis. We included several patient-level characteristics in the analysis:

- demographic characteristics,
- 16 clinical characteristics assessed at the onset of dialysis,
- weight (in pounds),
- number of years on dialysis,
- tobacco use, and
- 2 indicators of functional status (inability to ambulate and transfer).

We included several facility-level characteristics:

- profit status,⁸
- facility size as measured by the number of in-center hemodialysis treatments furnished in 2000,
- geographic location,
- hospital wage index, and
- the proportion of patients who are not Medicare-entitled.

The text box on page 97 provides additional information about the data sources used in this analysis and how we constructed the analytical file.

6 An evidence-based approach evaluates the use of a medical service while applying the best available scientific evidence according to the generally accepted hierarchy.

7 For example, the delivered dose of hemodialysis in large patients, as measured by the urea reduction ratio, is often less than adequate. Use of large surface area dialyzers, high blood flow rates, high dialysate flow rates, and increased dialysis time can increase the delivered dose of hemodialysis (Powers et al. 2000).

8 Our multivariate regression model includes facilities' profit status instead of chain affiliation because of the overlap between these two variables.

Data sources and constructing the analytical file

This study used 2000 data derived from the cost reports submitted by freestanding dialysis providers, the Renal Beneficiary Utilization System/Program Management and Medical Information System (REBUS/PMMIS) file, a database that integrates administrative and clinical data on end-stage renal disease (ESRD) patients, and institutional outpatient claims submitted by freestanding dialysis providers.

Cost reports. All dialysis facilities are required to submit cost reports to Medicare each year. We used information obtained from the cost reports to calculate:

- Medicare-allowable cost per treatment for furnishing composite rate services, and the aggregate cost per treatment for furnishing both composite rate services and separately billable drugs, including erythropoietin;
- facility size by volume of hemodialysis treatments furnished;
- number of staff furnishing care; and
- provider characteristics, including geographic location and profit status.

As noted in MedPAC's March 2003 report, CMS's contractors—fiscal intermediaries—have not yet audited the 2000 cost reports to ensure that the costs reported by providers are Medicare-allowable. The Balanced Budget Act of 1997 required the Secretary to audit the cost reports of each dialysis provider at least once every three years beginning in 1996. CMS's recent audit of the 1996 data resulted in reopening and auditing 62 percent of submitted cost reports. The

auditing of more recent cost reports is currently underway but not complete.¹

REBUS/PMMIS file. This data system collects and integrates clinical and administrative data on ESRD patients, including data gathered at ESRD entitlement, quarterly summaries of dialysis, transplantation records, inpatient utilization, and death. Information obtained from this file and used in our analysis includes:

- beneficiary demographics,
- patient weight,
- date of death,
- dialysis method of treatment (modality), and
- comorbidities at the most recent start of dialysis treatment, including: AIDS, alcoholism, cancer, cardiac arrest, heart failure, chronic obstructive pulmonary disease, stroke, diabetes, drug addiction, cardiac dysrhythmia, hypertension, ischemic heart disease, acute myocardial infarction, pericarditis, peripheral vascular disease, use of tobacco, inability to ambulate, and inability to transfer.

Institutional outpatient standard analytic file. Dialysis facilities bill Medicare on institutional outpatient claims. In addition to service and payment information, these claims code ongoing clinical information on adequacy of dialysis and anemia status. Anemia values, measured in terms of beneficiaries' hematocrit level, are coded in the value trailers on the records. The first Healthcare Common Procedure Coding System modifier on the revenue center trailer gives ranges for the urea reduction ratio (URR), a measure of dialysis adequacy for the dialysis session being billed.

Constructing the analytical file. The final analytical file is a facility-level file. Construction took several steps, adding data from each of the sources noted above.

For each beneficiary, we calculated mean URR and hematocrit. Next, we aggregated these data to the provider level. Since approximately 25 percent of beneficiaries used multiple facilities during the year, we calculated provider-level averages for dialysis adequacy and anemia status by proportionally attributing the value of these outcome measures to a given facility based on the length of time care was furnished to each beneficiary (based on the first date on the first bill and last date on the last dialysis bill). We calculated rates of transplant and death on a per-beneficiary basis and attributed them to the beneficiary's principal dialysis provider, defined as the provider accounting for the greatest span of time during the year.

We edited the cost report data in stages. First, we dropped providers reporting for a partial year, and providers whose calendar-year claims data and cost reports did not substantially overlap. These changes avoid mismatch between cost and volume numbers drawn from the claims and those reported on the cost reports. We also dropped outlier or grossly misreported data from the analysis. For the key variables (cost per treatment, cost including drugs, cost per dose of erythropoietin), we dropped records at the 1st and 99th percentiles of the distribution. Editing of the file resulted in dropping nearly one-third of facilities, and these were concentrated in nonchain facilities. We included a total of 1,921 facilities in our analysis. ■

¹ For example, the proportion of 1997 to 2001 reopened or audited cost reports range from 0.1 percent in 2001 to 11 percent in 1998. During fiscal year 2003, the fiscal intermediaries (FIs) will audit one-third of facilities with cost report years ending between January 1, 2001 and December 31, 2001. In fiscal years 2004 and 2005, the FIs will audit the remaining ESRD cost reports for this time period (CMS 2002).

Quality of care and costs for composite rate services

In a bivariate analysis, we find that both lower- and higher-cost facilities had similar proportions of beneficiaries receiving adequate dialysis (85 percent), not suffering from anemia (70 percent), and dying (17 percent). Only rate of transplantation was modestly greater for higher than lower-cost facilities (Table 6-3). The proportion of beneficiaries undergoing transplantation increased from 2.2 to 2.5 percent for lowest- and highest-cost facilities, respectively.

Once we move to multivariate regression analysis, we find that, after adjusting for facility and patient characteristics, average cost per treatment for composite rate services is unrelated to any of our measures of beneficiaries' outcomes (Table 6-4). Facilities' profit status is also not significantly related to either dialysis adequacy or anemia status, a finding consistent with Frankenfield et al. (2000).

Certain demographic and clinical characteristics are significantly related to outcomes and our findings are generally consistent with those of other investigators.⁹ On average, outcomes decline with greater proportions of beneficiaries who are more difficult to dialyze or sicker. For instance, negative predictors of dialysis adequacy include treating a greater proportion of beneficiaries who are male, minorities, heavier, or diagnosed with certain illnesses such as heart failure, hypertension, and chronic obstructive pulmonary disease. Dialysis adequacy is positively associated with increasing years on dialysis, which is consistent with evidence that the level of renal function is lower during the first year of dialysis.

Quality of care and costs for both composite rate services and injectable drugs

In our bivariate analysis looking at costs for composite rate services and injectable drugs together, the proportion of beneficiaries receiving adequate dialysis

TABLE 6-3

Quality of dialysis care and beneficiaries' outcomes, by quartile of average cost per hemodialysis treatment, 2000

Cost quartile	URR \geq 65%	HCT \geq 33%	Mortality rate	Transplant rate
Percent of all beneficiaries				
All facilities	85%	70%	17%	2.3%
Composite rate services only				
Quartile 1	85%	70%	16%	2.2%
Quartile 2	85	69	17	2.3
Quartile 3	85	70	17	2.4
Quartile 4	84	70	17	2.5
Composite rate services and injectable drugs				
Quartile 1	87%	70%	17%	2.1%
Quartile 2	85	70	16	2.4
Quartile 3	84	69	17	2.3
Quartile 4	83	69	17	2.5

Note: HCT (hematocrit), URR (urea reduction ratio). Lowest cost quartile is 1; highest cost quartile is 4. Data are weighted by the number of in-center hemodialysis treatments.

Source: Analysis by Direct Research LLC of 2000 cost reports and claims submitted by freestanding dialysis facilities to CMS.

declines with facilities' aggregate cost per treatment, from 87 percent for lowest-cost facilities to 83 percent for highest-cost facilities (Table 6-3). Rates of transplantation modestly increase as providers' costs increase, from 2.1 to 2.5 percent for lowest- and highest-cost facilities, respectively. Across all facilities, 70 percent of all beneficiaries achieved hematocrit levels greater than 33 percent and mortality rates ranged between 16 and 17 percent.

The multivariate regression analysis shows a negative association between facilities' costs and three of the four outcome measures: dialysis adequacy, anemia management, and mortality rate (Table 6-5, p. 100). On average, dialysis adequacy and anemia status are lower and mortality rates are greater for higher- than for lower-cost facilities. We again find no association between facilities' profit status

and outcomes. As expected based on our earlier findings, on average, facilities' outcomes decline with increasing proportions of beneficiaries who are more difficult to dialyze or sicker.

Implications and next steps

Our analysis shows that the quality of dialysis care is not linked to the cost per treatment for composite rate services. This finding suggests that providers are not stinting on furnishing composite rate services. The lack of a relationship between dialysis quality and composite rate costs also suggests that many dialysis providers have responded to the economic incentives created by Medicare's prospective payment system and reporting system by improving productivity without compromising quality. The opposite

⁹ Our lack of a significant negative relationship between diabetes and mortality differs from Port et al. (2001), but is consistent with others, such as McClellan et al. (1998).

**TABLE
6-4**

Multivariate regression analysis of facility-level cost per treatment for composite rate services and beneficiaries' outcomes, 2000

Variable	URR ≥ 65%	HCT ≥ 33%	Mortality rate	Transplant rate
Intercept	1.07803**	0.75203**	-0.07046	0.12733**
Facility characteristics				
Average cost	-0.00015	-0.00014	8.83E-05	1.94E-05
Hospital wage index	-0.03087**	0.00866	-0.02099*	-0.00193
Size squared	-4.72E-12	-5.20E-11**	-1.43E-11	1.13E-11*
Non-Medicare share	-0.01113	-0.0213	0.02824**	0.00807*
For profit	-0.00654	0.00439	0.00757	0.000954
Beneficiary characteristics				
Age	6.11E-06**	1.35E-06	1E-05**	-2.5E-06**
Male	-0.10698**	0.04634*	0.00176	0.00371
Minority	-0.04646**	-0.05092**	-0.03275**	-0.01622**
Weight (in pounds)	-0.00141**	-0.00054**	0.000416**	-0.00022**
Years on dialysis	0.00738**	0.00437	-0.00522**	7.14E-05
Heart failure	-0.0891**	-0.04189	0.03002	0.00358
COPD	-0.12619*	-0.14766**	0.15373**	-0.00891
Diabetes	0.07494**	0.03344*	-0.01866	-0.00315
Cardiac dysrhythmia	0.09208	0.08366	-0.10479*	-0.01058
Hypertension	-0.0563*	-0.0041	-0.02113	-0.00387
Peripheral vascular disease	0.09247**	0.08364**	-0.01051	0.00933
Unable to ambulate	-0.20177*	-0.19119*	0.06436	0.00262
R ²	0.14	0.08	0.19	0.05

Note: COPD (chronic obstructive pulmonary disease), HCT (hematocrit), URR (urea reduction ratio). Coefficients reported for: cost per treatment; profit status; and variables found to be significant at $p < 0.05$. See text box on page 97 for a list of all variables considered in this analysis and Hogan (2003) for complete results. Data are weighted by the number of in-center hemodialysis treatments.
 * Statistically significant at 5 percent level.
 ** Statistically significant at 1 percent level.

Source: Analysis by Direct Research LLC of 2000 cost reports and claims submitted by freestanding dialysis facilities to CMS.

interpretation—that all facilities are stinting on composite rate services—is less likely given the substantial and clinically significant improvement in hemodialysis adequacy and anemia status since 1993.

Considering both costs for furnishing dialysis and injectable drugs together, we find that beneficiaries' outcomes are poorer for facilities with higher than average costs. One interpretation is that, since these drugs are paid on a per dose basis, some providers may not furnish these drugs as efficiently as if they were

paid for prospectively. The profitability of injectable drugs subsidizes the lower margins under the composite rate and may provide incentives for their overuse, to the extent possible, by certain providers. Spending varies widely for injectable dialysis drugs by Medicare; for instance, in 2000, per patient per month spending for intravenous iron and vitamin D analogues varied by a factor of two between freestanding dialysis facilities based on their chain affiliation and profit status (USRDS 2002).

Alternatively, this finding may suggest that higher-cost facilities may be furnishing care to more medically complex beneficiaries. As noted earlier, providers have the incentive to furnish as many of these drugs as the severity of the patient warrants since these injectable drugs are paid on a per dose basis. Our model, however, adjusts outcomes for medical complexity by including information about beneficiaries' demographic characteristics, duration of dialysis, 16 comorbidities, and functional status. However, there may be some unresolved case-mix differences. Either interpretation supports previous MedPAC recommendations:

**TABLE
6-5**

Multivariate regression analysis of facility-level cost per treatment for both composite rate services and injectable drugs and beneficiaries' outcomes, 2000

Variable	URR ≥ 65%	HCT ≥ 33%	Mortality rate	Transplant rate
Intercept	1.1132**	0.75667**	-0.09058	0.12878**
Facility characteristics				
Average cost	-0.00041**	-0.00017*	0.000239**	7.29E-06
Hospital wage index	-0.02109*	0.00974	-0.02659**	-0.00148
Size squared	8.22E-12	-5.16E-11**	-2.17E-11	1.21E-11*
Non-Medicare share	-0.01134	-0.02222	0.02838**	0.00825*
For profit	-0.00727	0.00448	0.00799	0.000885
Beneficiary characteristics				
Age	6.26E-06**	1.4E-06	9.93E-06**	-2.5E-06**
Male	-0.10354**	0.0467*	-0.0002	0.00387
Minority	-0.04443**	-0.04973**	-0.03393**	-0.01632**
Weight (in pounds)	-0.0013**	-0.00049**	0.000352*	-0.00023**
Years on dialysis	0.00747**	0.00429	-0.00527**	9.41E-05
Heart failure	-0.0879**	-0.04068	0.0293	0.00341
COPD	-0.11988*	-0.14567**	0.1501**	0.00888
Diabetes	0.06834**	0.03071*	-0.01484	-0.00304
Cardiac dysrhythmia	0.08668	0.08236	-0.10169*	-0.01068
Hypertension	-0.05916**	-0.00458	-0.01949	-0.00397
Peripheral vascular disease	0.09524**	0.08454**	-0.01211	0.00933
Unable to ambulate	-0.2146*	-0.19473*	0.07174	0.00247
R ²	0.16	0.09	0.19	0.05

Note: COPD (chronic obstructive pulmonary disease), HCT (hematocrit), URR (urea reduction ratio). Coefficients reported for: cost per treatment; profit status; and variables found to be significant at $p < 0.05$. See text box on page 97 for a list of all variables considered in this analysis and Hogan (2003) for complete results. Data are weighted by the number of in-center hemodialysis treatments.
 * Statistically significant at 5 percent level.
 ** Statistically significant at 1 percent level.

Source: Analysis by Direct Research LLC of 2000 cost reports and claims submitted by freestanding dialysis facilities to CMS.

- The composite rate bundle should include commonly used services currently excluded from it (MedPAC 2001). This would offer providers an incentive to furnish injectable drugs more efficiently than paying on a per dose basis.
 - Payment for outpatient dialysis services should adjust for differences in patient case mix, as well as other factors known to affect providers' costs to deliver high-quality care (MedPAC 2001). The findings from this study show the importance of adjusting for patient case mix with an expanded payment bundle that includes injectable drugs.
- Assessing the link between quality and efficiency is critical when making judgments about the appropriateness of dialysis providers' costs and payment adequacy. Each year, MedPAC considers the adequacy of Medicare's dialysis payments and recommends to the Congress updates of the composite rate. The finding from this analysis—that lower costs do not appear to compromise quality of care—will be useful to the Commission's discussion of how we judge the appropriateness of dialysis providers' costs and how Medicare's payments compare relative to efficient providers' costs. As a next step, it may be useful to compare the margins for higher quality/lower cost providers to those of lower quality/higher cost providers.
- This link is also important for the other providers for which we make annual payment recommendations, including hospitals, skilled nursing facilities, and home health agencies. As reliable information becomes available on quality of care and providers' costs, MedPAC plans to replicate this research for these other providers.

As discussed in Chapter 7, the Commission believes it is important for Medicare to explore the use of nonfinancial and financial incentives to improve quality of care. To date, Medicare has only used nonfinancial incentives, particularly public disclosure of quality of care information, to improve quality in both the traditional Medicare program and Medicare+Choice. Currently, the payments providers receive for the higher-quality care they produce are no higher than they would be for lower-quality care.

Having a set of credible, broadly understood, and accepted measures of quality is a critical component of designing incentives. Based on these criteria, implementing both nonfinancial and financial incentives for dialysis providers is more feasible than for others. As mentioned earlier, CMS measures and publishes information on dialysis quality nationally and for individual facilities.

CMS accomplished the positive trend in improving dialysis adequacy and anemia status since the mid-1990s without the use of financial incentives by Medicare. Rather, quality improvement efforts undertaken by providers and the end-stage renal disease (ESRD) networks and CMS's efforts in measuring and reporting dialysis quality have influenced dialysis quality.¹⁰ Both nonfinancial and financial

incentives, however, might be useful tools to improve other processes of dialysis care.

One area increasingly recognized as a critical component of care is the management of hemodialysis patients' vascular access.¹¹ Vascular access care accounts for about 10 percent of Medicare spending for hemodialysis patients and is the second leading reason for hospitalization for these patients (USRDS 2002). In 1999, CMS began reporting on three measures of vascular access management in its Clinical Performance Measurement Project.¹² This quality measure, however, is not publically reported for individual facilities by the agency. CMS data show that opportunities exist to enhance beneficiaries' quality of care by modifying vascular access practice patterns. For instance, only 30 percent of hemodialysis patients had arteriovenous fistulas, the vascular access type recommended in the clinical guidelines developed by the NKF, compared with 46 percent of patients with arteriovenous grafts and 24 percent with catheters (CMS 2002). In addition, only 47 percent of patients with an arteriovenous graft had the graft routinely monitored for the presence of stenosis.

Dialysis facilities, nephrologists, vascular surgeons, and radiologists together make decisions about beneficiaries' vascular

access care. Publically reporting vascular access measures for individual facilities on CMS's Dialysis Facility Compare website may be one way to improve the quality of vascular access care.¹³ Financial incentives also should be considered if public disclosure alone does not result in improvement.

Finally, there are other measures of dialysis quality in addition to the four measures used in this analysis. The NKF has developed clinical guidelines for vascular access management, adequacy of peritoneal dialysis, and nutrition management. CMS nationally reports these measures in its Clinical Performance Measurement Project. This study did not include the measures of vascular access management and peritoneal dialysis adequacy because of data reliability and availability issues. We did not include the measures of nutrition management because Medicare's payment policies restrict the number of beneficiaries who qualify for nutritional interventions. We also did not assess the relationship between other outcomes of care—patient satisfaction and reasons for hospitalization—and providers' costs because of data availability issues. In the future, it may be fruitful to assess the relationship between these processes and outcomes of dialysis care and providers' costs. ■

10 In 1978, the Congress established the ESRD networks to provide regional oversight for Medicare-certified dialysis facilities. The networks' goals include ensuring that ESRD beneficiaries have immediate access to renal treatment and are furnished quality care through medical standards developed by the scientific community. There are currently 18 networks funded by withholding 50 cents per treatment from the composite rate paid to facilities.

11 Vascular access is the site on a patient's body where blood is removed and returned during hemodialysis. The provision of adequate hemodialysis is dependent on repeated and reliable access to the patient's blood stream. Three types of vascular access are predominantly used: arteriovenous fistulas, arteriovenous grafts, and catheters. The most common complications of these types of vascular access are stenosis (narrowing of graft and blood vessel), infection, and thrombosis (clotting). Arteriovenous fistulas are associated with fewer complications than arteriovenous grafts and catheters.

12 Based on the clinical guidelines developed by the National Kidney Foundation, CMS's Clinical Performance Measure Project calls for having: (1) arteriovenous fistulas as the access for at least 50 percent of incident hemodialysis patients; (2) less than 10 percent of prevalent hemodialysis patients maintained on catheters as their permanent dialysis access; and (3) routine monitoring of patients' arteriovenous grafts for stenosis.

13 As noted in Chapter 7, CMS does not yet release information about individual physicians. Several issues have complicated efforts to implement nonfinancial and financial incentives for individual physicians, including the availability of sufficient sample size to ensure data validity.

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