

3 E
SECTION

Outpatient dialysis services

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

3E-1 The Congress should maintain current law and update the composite rate by 1.6 percent for 2005.

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

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3E-2 The Congress should establish a quality incentive payment policy for physicians and facilities providing outpatient dialysis services.

COMMISSIONER VOTES: YES 17 • NO 0 • NOT VOTING 0 • ABSENT 0

SECTION 3E

Section 3E: Outpatient dialysis services

In this section:

- Are Medicare payments adequate in 2004?
- How should Medicare payments change in 2005?
- Updating payments for composite rate services in 2005
- Using payment incentives to improve dialysis quality

Current aggregate Medicare payments for outpatient dialysis services appear to be adequate. Our review of the evidence shows beneficiaries are not facing systematic problems in accessing care, the volume of services provided is increasing, providers have sufficient capacity to meet demand, quality is improving for some measures, and providers' access to capital is good. Our estimate of the Medicare margin for composite rate services and injectable drugs is 2.7 percent in 2004. To account for changes in providers' costs in 2005, the Congress should update the composite rate for outpatient dialysis services by 1.6 percent. Updating composite rate payments will maintain beneficiaries' access to care but additional steps need to be taken to ensure beneficiaries receive high-quality health care. Although quality has improved for some measures, current efforts have not uniformly improved care for all beneficiaries. Consequently, Medicare should provide payment incentives to physicians and facilities to improve the quality of dialysis care. By directly rewarding quality, the program would send the strong message that it values the care beneficiaries receive and encourages investments in quality.

End-stage renal disease (ESRD) is a chronic illness characterized by permanent kidney failure. Occurring at the last stage of progressive impairment of kidney function, the illness is caused by a number of conditions including diabetes, hypertension, glomerulonephritis, and cystic kidney disease. Persons with ESRD require either chronic dialysis or a kidney transplant to maintain life. Because of the limited number of organs available for transplantation, the majority of ESRD patients receive chronic dialysis. The 1972 amendments to the Social Security Act extended Medicare benefits to people with ESRD, and about 300,000 patients were enrolled in 2002.¹

Medicare spending for outpatient dialysis services furnished by freestanding dialysis facilities totaled \$5.6 billion in 2001.

- Medicare pays a prospective payment—the composite rate—for each dialysis treatment provided in dialysis facilities (in-center) or in patients' homes.² The average composite rate was about \$130 per dialysis treatment and payments for these services accounted for 59 percent of total Medicare payments to facilities in 2001.
- Facilities receive additional, separate payments for furnishing certain services during dialysis. Payments for injectable drugs represent the second largest component of spending. In 2001, Medicare's payments for injectable drugs averaged about \$80 per dialysis treatment and payments for these services accounted for 41 percent of total Medicare payments to facilities.
- 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 whether it is administered in dialysis facilities or in patients' homes. Facilities receive 95 percent of the average wholesale price (AWP) for separately billable injectable drugs other than erythropoietin administered during in-center dialysis. Spending for other services for which facilities receive separate payments—primarily medical supplies, laboratory services, and blood products—accounted for less than 1 percent of their payments in 2001.

Medicare spending for outpatient dialysis services furnished by freestanding facilities increased by 9 percent per year between 1996 and 2001.³ Two factors that contribute to the growth in Medicare spending are the increasing size of the ESRD population and the diffusion of new technologies.

- Incident rates per million population have been increasing steadily since 1980 (USRDS 2003). For example, the number of new ESRD patients increased by about 6 percent annually between 1990 and 2001. Increasing incident rates have been linked to the aging of the U.S. population, as well as increases in the number of people with diabetes, which is a risk factor for ESRD.
- New technologies—particularly injectable drugs, such as erythropoietin, iron supplements, and vitamin D analogues, which were not available when the outpatient dialysis payment system was implemented in 1983—have also increased Medicare's spending for dialysis services. Between 1996 and 2001, spending increased by 12 percent per year for erythropoietin and 25 percent per year for other injectable drugs.

In response to concerns about how Medicare pays for outpatient dialysis services, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) changes how Medicare pays for injectable drugs and dialysis treatments (see text box at right). Beginning in 2005, the composite rate payment will be augmented by the difference between Medicare's payments and providers' acquisition costs for injectable drugs (i.e., the "spread") and this augmented payment will be adjusted for patient case mix. In addition, facilities will be paid the acquisition cost for dialysis injectable drugs.⁴

These changes partly reflect concerns previously raised by MedPAC that Medicare's policies do not appropriately pay for outpatient dialysis services. We have shown that injectable drug spending has significantly increased since the mid-1990s and that the profitability of these services is offsetting the decreasing payment margins under the composite rate. These findings led the Commission to make a series of recommendations to modernize how Medicare pays for outpatient dialysis services. These recommendations included broadening the payment bundle to include widely used services currently excluded from it and adjusting for factors affecting providers' costs, including patient case mix, the frequency of dialysis, the dose of dialysis, and the dialysis method (MedPAC 2001). MedPAC has also called for efforts to measure and report on dialysis quality to ensure provider accountability. By modernizing the payment system for outpatient dialysis, Medicare can better achieve its objectives of controlling costs and promoting access to quality services.

Changes to the outpatient dialysis payment system by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) makes substantial changes to how Medicare pays for renal dialysis services. The Act calls for the Secretary to: (1) case-mix adjust payments for certain services; (2) report to the Congress on the design and features of a bundled prospective payment for dialysis services; (3) conduct a demonstration study of a bundled payment system; and (4) make other changes, including updating the composite rate by 1.6 percent in 2005 and restoring the exemption to the composite rate for pediatric facilities.

Adjust payments for differences in case mix.

Beginning on January 1, 2005, the Secretary is required to enact a basic case-mix adjusted payment system for dialysis services, but not to create a broader payment bundle. That is, Medicare will still separately pay for injectable drugs that are excluded from the current payment bundle. Providers will be paid:

- a case-mix adjusted payment for composite rate services and the difference between payments for and the acquisition cost of injectable drugs and biologicals, and
- the acquisition cost of existing injectable drugs and biologicals.

Beginning in 2006, the Secretary will increase case-mix adjusted payments by the estimated growth in expenditures for injectable drugs and biologicals. The Act requires the Secretary to include new injectable drugs in the case-mix adjusted payment beginning in January 1, 2007.

The Secretary will obtain information about the acquisition cost of injectable drugs and the rate of growth in expenditures for these items from two studies conducted by the Office of Inspector General. The first study will include existing drugs and biologicals (for which a billing code existed prior to January 1, 2004) and is due to the Congress on April 1, 2004. The second study will include new drugs and biologicals (for which a billing code did not exist prior to January 1, 2004) and is due to the Congress on April 1, 2006.

The Secretary can enact a geographic index for the case-mix adjusted payment, but a new index must be phased in over a multiyear period. Currently, the composite rate is adjusted for differences in labor costs using two dated hospital wage indices. MedPAC recommended that the Secretary develop a wage index based on market wage rates for occupations typically used in furnishing dialysis (MedPAC 2001).

Finally, the MMA requires that the case-mix adjusted payment system result in the same aggregate amount of expenditures for such services as would have been made in 2005, 2006, and 2007 if payments were not case mix adjusted.

Design a bundled payment system. The Secretary is required to submit to the Congress by October 1, 2005 a report on broadening the outpatient dialysis payment system to include injectable drugs, laboratory tests, and other items currently excluded from it. The report will describe:

- the services included in the payment bundle,
- how the system will account for the relative resource use of different types of patients,
- how the system will account for geographic differences in wages,
- the appropriateness of adjusting payments to account for additional costs incurred by rural facilities,
- the methods to be used to establish payment rates, and
- the methods to be used for appropriate updates.

Conduct a demonstration. Beginning on January 1, 2006, the Secretary is required to conduct a three-year demonstration to test a broader payment bundle that includes injectable drugs and clinical laboratory tests that are currently excluded from it. The Secretary is required to ensure that a sufficient number of providers participate in the study, but that the number not exceed 500, and that an adequate number of different types of

(continued next page)

Changes to the outpatient dialysis payment system by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (continued)

providers are included, such as those located in rural and urban areas. While facilities participate in the demonstration, their composite rate will be increased by 1.6 percent.

The MMA also requires the Secretary to establish an advisory panel that will include clinicians, economists, and researchers with expertise in dialysis services; and representatives from MedPAC, the National Institutes of Health, the Network organizations, Medicare's

quality improvement organizations, patient organizations, and provider groups.

Other changes. The MMA increases the composite rate by 1.6 percent beginning in January 1, 2005. It restores exceptions for the composite rate for pediatric facilities retroactive to October 1, 2002. Pediatric facilities are those with at least 50 percent of their patients under 18 years of age. ■

In this chapter, we assess the adequacy of outpatient dialysis payments and make an update recommendation for the composite rate payment in 2005. We then discuss reasons why Medicare should use quality incentives as another mechanism to promote access to quality dialysis care. By rewarding quality, the program would send the strong message that it values the care patients receive and encourages investments in quality.

Are Medicare payments adequate in 2004?

The first question in applying MedPAC's approach to updating payments is whether the current level of Medicare's payments for outpatient dialysis services is adequate. The Commission answers this question by assessing aggregate Medicare payments and costs for both dialysis services and injectable drugs for which facilities receive separate payment. Our assessment includes the payments and costs for injectable drugs because their use has increased substantially throughout the 1990s and their effect on the financial performance of dialysis providers is significant. Including payments and costs for separately billable drugs gives a more accurate picture of the financial performance of dialysis providers.

The findings from our analysis of beneficiary-focused and provider-focused measures suggest that aggregate payments for dialysis services and injectable drugs are adequate. We base this conclusion on the following evidence:

- Beneficiaries do not appear to have systematic problems accessing outpatient dialysis services.

- Providers have sufficient capacity to treat dialysis patients.
- The volume of services—dialysis treatments and separately billable drugs—is growing.
- Providers continue to improve the quality of care furnished to beneficiaries, as assessed by measures of dialysis adequacy and anemia management.
- The dialysis sector appears to have sufficient access to capital, as shown by the continued growth in the number of for-profit freestanding facilities.
- Current payments for composite rate services and injectable drugs cover efficient providers' costs. The aggregate Medicare margin for 2001 is 5.2 percent when the effect of CMS's most recent audit of facilities' cost reports is considered (see text box, p. 178). We estimate that the aggregate Medicare margin will be 2.7 percent in 2004, assuming that the share of revenues for injectable drugs relative to composite rate payments increases between 2001 and 2004 by the 1999–2001 trend in injectable drug spending.

Beneficiaries access to care

A review of the published literature shows no evidence of beneficiaries facing systematic problems in obtaining needed dialysis care in 2002 and 2003. Reports of facility closures tend to be linked to local issues, such as rising real estate prices in certain areas, shortages of technicians and nurses, and states' certificate-of-need regulations.

Access to specific types of dialysis—in-center hemodialysis, peritoneal dialysis, and home hemodialysis—shows little change over time. Between 1998 and 2002, at least 96 percent of all facilities offered in-center hemodialysis, about 40 percent offered continuous cycling peritoneal dialysis, and about 45 percent offered continuous ambulatory peritoneal dialysis.

Our analysis of the pattern of facility closures suggests that beneficiaries should not be having problems accessing care in rural areas, health professional shortage areas (HPSAs), lower-income areas, or areas where a higher proportion of minorities reside. Specifically, facilities that closed were as likely to be located in rural, health professional shortage, and lower income areas as those that remained in business between 1998 and 2002. For example:

- 26 percent of facilities that remained open were located in rural areas compared with 28 percent of facilities that closed;
- 10 percent of facilities that remained open and 10 percent of facilities that closed were located in HPSAs;
- 22 percent of all households were receiving public assistance in areas served by facilities that remained in business and facilities that closed; and
- 15 percent of the population were African American in areas served by facilities that remained in business and facilities that closed.

A disproportionate number of facilities that closed were small, nonprofit, and hospital based.⁵ However, beneficiaries' access to care does not appear to have been adversely affected as a result of these closures because these facilities were not disproportionately located in rural areas, HPSAs, or areas where minorities or lower income populations reside.

Our finding—that facilities that closed were more likely to be small, nonprofit, and hospital based than facilities that remained open—is consistent with the changes in the characteristics of dialysis providers in the 1990s and through 2002 (Table 3E-1). During this time, freestanding facilities increased from 70 percent to 83 percent of all facilities, while for-profit facilities increased from 61 percent to 80 percent of all facilities. Our finding that freestanding and for-profit facilities have steadily increased as a share of the total throughout the 1990s suggests that dialysis facilities are sufficiently profitable to stand on their own and that furnishing dialysis services to ESRD patients is financially attractive to for-profit providers.

In addition, quality of care does not appear to have been adversely affected by the closures of small, nonprofit, and hospital-based facilities. Providers continue to improve the quality of care furnished to beneficiaries, as assessed by measures of dialysis adequacy and anemia management (Table 3E-2, p. 164). Investigators assessing the relationship between facilities' profit status and quality of care report differing results. Recent studies by MedPAC,

**TABLE
3E-1**

Total number of dialysis facilities is growing; for-profit and freestanding are a higher share over time

	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
Total number of dialysis facilities	2,343	2,502	2,732	2,940	3,172	3,394	3,619	3,805	3,961	4,132
Percent of all facilities										
For profit	61	62	65	67	71	75	77	78	79	80
Nonprofit	33	32	30	28	25	22	20	19	18	17
Government	6	6	5	4	4	3	3	3	3	3
Freestanding	70	72	74	75	77	79	81	82	83	83
Hospital-based	30	28	26	25	23	21	19	18	17	17
Urban	77	77	77	76	76	75	75	75	75	75
Rural	23	23	23	24	24	25	25	25	25	25

Source: Data compiled by MedPAC from the 1993–2002 Facility Survey file from CMS.

**TABLE
3E-2**

The quality of dialysis care has improved for some measures

Outcome measure	1998	1999	2000	2001
Percent of in-center hemodialysis patients:				
Receiving inadequate dialysis	20	16	14	11
With low anemia levels	41	32	26	24
Who are malnourished	18	20	20	18
Percent of peritoneal patients:				
Receiving inadequate CAPD	45	32	31	32
Receiving inadequate CCPD	42	35	38	30
With low anemia levels	38	31	27	24
Who are malnourished	41	44	44	39

Note: CAPD (continuous ambulatory peritoneal dialysis). CCPD (continuousycler-assisted peritoneal dialysis). The two predominant types of peritoneal dialysis are CAPD and CCPD. The share of all dialysis patients treated with peritoneal dialysis has declined from 13 to 10 percent between 1998 and 2001; nearly all other dialysis patients were treated with in-center hemodialysis during this time. Comparing the outcomes between hemodialysis and peritoneal dialysis is complicated because the data presented above are not adjusted for differences in the demographic and clinical characteristics of these patient groups. See CMS 2002 for the definitions of dialysis adequacy, anemia status, and nutritional status.

Source: CMS 1999–2002.

CMS, and others have concluded that facilities’ profit status is not associated with patients’ outcomes (Frankenfield et al. 2000, Held et al. 2002, MedPAC 2003b, Port et al. 2001, Wolfe et al. 2002). By contrast, other investigators have found a positive 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).

Some providers contend that they are limiting their exposure to Medicare patients. Using data from CMS’s facility survey, our data show little correlation between the proportion of Medicare patients and facility closings during this time.

Finally, no data yet exist on how satisfied beneficiaries are with the care provided by outpatient dialysis facilities. In March 2000, MedPAC recommended that CMS should collect information on ESRD patients’ satisfaction with the quality of and access to care (MedPAC 2000). Accordingly, CMS and the Agency for Health Care Research and Quality are developing a consumer assessment survey for care delivered in facilities. This survey will be a part of the other surveys assessing

consumer satisfaction, some of which are used by MedPAC to assess access to care in other sectors, including home health.

Changes in the supply of dialysis facilities

The capacity of providers to furnish care has increased steadily between 1993 and 2002 as shown by the similar growth in the number of facilities, in-center hemodialysis stations, and patients:

- dialysis facilities grew 7 percent annually (Table 3E-1),
- in-center hemodialysis stations grew 8 percent annually, and
- in-center hemodialysis patients grew 6 percent annually.

We focus on in-center hemodialysis because most dialysis patients—about 90 percent—are treated with this dialysis method. Providers have kept up with the demand for dialysis by increasing the number of facilities rather than increasing capacity within facilities. We based this finding on our analysis of trends in the following:

- average hemodialysis stations per facility,
- average in-center hemodialysis treatments per facility,
- average in-center hemodialysis treatments per dialysis station, and
- average of in-center hemodialysis shifts per week.

The total number of in-center hemodialysis treatments provided by dialysis facilities has increased by about 9 percent per year between 1998 and 2002, but the average number of hemodialysis stations per facility has remained relatively constant at about 17 per facility. Average total dialysis treatments per facility also have remained relatively constant, ranging from 9,000 to 9,400 per year during this time period. The number of in-center hemodialysis shifts per week increased, from 9.5 per week in 1998 to 11.3 in 2002, but only one-fifth of all facilities offered treatments after 5 p.m. between 2000 and 2002.

Opening new facilities may improve access to care by reducing the time beneficiaries spend in traveling to obtain care. Researchers have noted that transportation to and from the dialysis facility can affect patients’ compliance with their prescribed treatment, with some patients

shortening their dialysis treatments or skipping treatments (Rocco and Burkart 1993, Sehgal et al. 1998, USRDS 1997). However, the sustained growth in the number of dialysis facilities raises questions about the optimal efficiencies of scale and the trade-off between opening new facilities and increasing the capacity of existing facilities.

Finally, the growth in the number of facilities has occurred at the same time that an increasing proportion of dialysis patients are treated with in-center hemodialysis instead of peritoneal dialysis (the predominant method used at home). In 2001, 90 percent of all dialysis patients received in-center hemodialysis, an increase from 81 percent in 1990. By contrast, use of peritoneal dialysis has declined during this time (USRDS 2003). This trend has occurred even though facilities' costs for peritoneal dialysis are lower than their costs for hemodialysis and Medicare pays the same rate for both dialysis methods. Several reasons may explain this trend:

- Certain patients may prefer the social interaction of in-center care, might not be sufficiently independent to perform home dialysis, or may have clinical characteristics that preclude the use of peritoneal dialysis.
- The rapid growth in the number of dialysis facilities throughout the 1990s has created an incentive to direct patients to treatment in-center so that facilities operate at capacity.
- The profitability of separately billable drugs may also provide an incentive for in-center care. Facilities can separately bill for all clinically necessary injectable drugs for in-center patients; by contrast, for home patients, they can only bill for erythropoietin. Beginning in 2006, however, clinically necessary injectable and oral dialysis drugs administered by patients in their homes will be covered under the Medicare Part D, voluntary prescription drug benefit.

Changes in the volume of services

Between 1993 and 2002, 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 8 percent annually; in comparison, the number of dialysis patients increased, on average, by 6 percent during this time period.

The growth in payments for injectable drugs increased more rapidly than the growth in payments for dialysis

treatments in the 1990s.⁶ Between 1996 and 2001, total payments for erythropoietin furnished by freestanding dialysis facilities increased by 12 percent per year, and total payments for other injectable drugs increased by 25 percent per year. In contrast, payments for composite rate services increased by 6 percent per year during this same period.

Consequently, revenue from injectable drugs has become increasingly important relative to revenue for composite rate services during the past five years. For freestanding dialysis providers, revenue from injectable drugs relative to that from composite rate services has increased from about 30 percent of total payments in 1996 to 41 percent of total payments in 2001. Until the outpatient dialysis payment system is modernized and injectable drugs are included in the prospective payment bundle, little incentive will exist to manage the use of these drugs to optimize clinical results while being cost conscious.

The use of injectable drugs has grown for several reasons. First, many of the agents—including erythropoietin, iron supplements, and vitamin D analogues—were only approved by the Food and Drug Administration in the early 1990s. Following their approval, their use has been advocated in clinical guidelines set forth by the National Kidney Foundation (NKF). The use of many of these drugs has enhanced the quality of care furnished to dialysis beneficiaries and their quality of life. For example, the increased use of erythropoietin has reduced the proportion of dialysis patients suffering from anemia, which contributes to morbidity if not treated effectively. Medicare's coverage decisions will also affect use of these drugs. For example, CMS made a national coverage decision to cover injections of levocarnitine for patients with ESRD beginning on January 1, 2003.⁷

However, the profitability of certain injectable drugs has provided incentives in how they are used. For example, 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. CMS data shows that the proportion of hemodialysis patients prescribed erythropoietin subcutaneously declined from 12 percent in 1998 to 10 percent in 2001 (CMS 2002). The predominant use of intravenous erythropoietin persists despite the publication of the NKF's Dialysis Outcome Quality

Initiative Clinical Practice Guideline for the treatment of anemia, which advocated subcutaneous administration.⁸

Data from the U.S. Renal Data System (USRDS) also raise questions about the efficiency of providers in furnishing injectable drugs. Using Medicare claims data, the USRDS found substantial variation in spending across the different providers. Specifically, per patient per month spending varied from \$421 to \$501 for erythropoietin, \$58 to \$86 for injectable iron, and \$95 to \$157 for vitamin D analogues across the four major for-profit chains and hospital-based facilities (USRDS 2003). As noted later in this section, some of this variation may be related to case-mix, as providers' costs vary based on patients' characteristics. Our previous finding—that beneficiaries' outcomes are poorer for facilities with higher than average costs—could suggest that the profitability of injectable drugs may be providing incentives for their overuse, to the extent possible, by certain providers (MedPAC 2003b).

Changes in the quality of care

Clinical performance indicators collected by CMS show continued improvements in the quality of dialysis care, as evidenced by the declining percentage of hemodialysis and peritoneal patients receiving inadequate dialysis and suffering from anemia (Table 3E-2). For example, the proportion of hemodialysis patients receiving inadequate dialysis declined from 20 percent in 1998 to 11 percent in 2001. However, no clinically important changes or improvements were found in the percentage of hemodialysis and peritoneal dialysis patients with adequate or optimal serum albumin levels in 2001 compared with those of previous years. Mean serum albumin levels below certain norms have been shown to be a marker for diminished patient survival. Some providers and researchers contend that increased use of certain types of medical interventions, particularly parenteral nutrition, would improve the outcomes of certain patients. Medicare's coverage policies limit the number of dialysis patients who qualify for these interventions.⁹

A recent report by the General Accounting Office (GAO) raised important issues about the quality of dialysis care in the U.S. (GAO 2003). GAO's analysis focused on quality assurance issues: how well facilities are meeting Medicare's baseline standards of care and conditions of coverage and how well CMS and the state survey agencies (under contract to CMS to perform onsite inspections) are targeting and conducting inspections. GAO concluded that

infrequent, poorly targeted, and inadequate inspections by state survey agencies allow quality problems to go undetected. MedPAC examined many of these issues in June 2000 and made three of the recommendations included by GAO: (1) to increase the frequency of inspections, (2) to implement intermediate sanctions, and (3) to publicly release the results of the survey and certification efforts on CMS's website that provides information about each dialysis facility.

Currently, Medicare uses three levers to maintain and improve dialysis quality:

- quality assurance efforts that aim to ensure that facilities meet minimum standards of care,
- quality improvement efforts that aim to improve the quality of care furnished by facilities, and
- public reporting of facility-specific information in CMS's Dialysis Facility Compare website to promote more active consumer participation in health decisions.

At least two other levers are available to improve quality in fee-for-service Medicare: linking payment to quality and using disease management and other care coordination services. Later in this section we discuss the use of incentives that reward high-quality care. MedPAC has endorsed linking payment to quality (MedPAC 2003b).

MedPAC plans to discuss the use of disease management, which may also offer opportunities to improve quality of care, in forthcoming work. In the case of ESRD, policymakers and clinicians are interested in the potential of disease management to improve quality because such management has the potential to coordinate and improve care for all of a beneficiary's comorbidities. ESRD beneficiaries require care for other chronic, high-cost conditions—in 2001, about 78 percent of dialysis patients had hypertension, 45 percent had diabetes, and 32 percent had congestive heart failure (USRDS 2003). Consequently, ESRD beneficiaries are costly; although representing less than 1 percent of all beneficiaries, they account for about 6 percent of all Medicare spending and their average spending was \$58,000 in 2001. Not surprisingly, a substantial portion of spending—36 percent—is for dialysis and injectable drugs.

Policymakers and clinicians are also interested in the potential of disease management because the current outpatient dialysis payment system fails to promote the optimal provision of coordinated dialysis care. These

deficiencies include the size of the prospective payment bundle—a single dialysis session—and the content of the bundle—which currently excludes commonly furnished services. It is noteworthy that inpatient care accounted for 36 percent of 2001 spending. Finally, disease management also offers opportunities to improve the care furnished to beneficiaries with chronic kidney disease before they develop permanent kidney damage by delaying the progression of the disease and by better preparing patients for dialysis and kidney transplantation.

Dialysis facilities' access to capital

Dialysis facilities need access to capital to improve their equipment and to open new facilities to accommodate growth in the number of patients requiring dialysis. In 2002, 83 percent of all dialysis facilities were freestanding, 80 percent were for profit, and the four largest for-profit chains accounted for about two-thirds of freestanding facilities. The four largest for-profit national chains appear to have adequate access to capital, as demonstrated by growth in the number of clinics, the number of patients they treat, and their earnings. In 2002, these national chains acquired 35 facilities and opened 104 facilities.

Data from industry sources show continued growth in revenues between 1998 and 2002 ranging from 10 to 25 percent for these chains. Information from analysts suggests that these providers have few problems with accessing capital; bond ratings for two of the largest chains, although below investment grade, are neutral going forward. Key operational ratios for 2002 for the four national chains suggests average or above-average performance:

- Return on total capital, a measure of how effectively a company uses capital, ranges from 5 to 30 percent.¹⁰
- Return on equity, a key measure of capital efficiency, ranges from 5 to 63 percent (before tax) and 3 to 31 percent (after tax).

Analysts also note that the sector benefits from stable dialysis treatment revenues (because patients require maintenance dialysis unless they undergo kidney transplantation) and attractive growth prospects fueled by the aging of the population and the increasing rate of diabetes and obesity. However, they also have noted that dialysis providers face potential pressures from private payers and Medicare. Although about three-quarters of the patients of these chains are insured by Medicare as the

primary payer, the proportion of revenues from Medicare ranges from 50 to about 65 percent across the chains.¹¹ Finally, the stocks of these for-profit chains have in large part enjoyed positive ratings by financial analysts in 2003.

Factors other than Medicare's payment rates may also influence access to the capital markets for these four chains because each chain operates other lines of business. All four chains operate clinical laboratories and, as noted later, the revenues derived from furnishing laboratory services for Medicare patients are not yet included in MedPAC's analysis of payments and costs.¹² Two chains also manufacture dialysis equipment and supplies.

Data from industry sources suggest that smaller chains also have adequate access to capital, as demonstrated by their ability to acquire existing facilities. Furthermore, new organizations are entering the dialysis sector, indicating that private investors have a positive outlook on this sector. For example, a newly formed organization was able to raise \$23 million in private equity to develop and acquire outpatient dialysis facilities. Another newly formed organization is focusing on providing care to patients with chronic kidney disease and furnishing home dialysis therapies.

Payments and costs for 2004

The Commission assesses current payments and costs for dialysis services by comparing Medicare's payments for composite rate services and injectable drugs with providers' Medicare-allowable costs. Cost reports provide data on the costs providers incur to furnish dialysis services and injectable drugs. Data from 2001 cost reports were used to estimate Medicare's payments for dialysis services and 2001 claims data were used to estimate Medicare's payments for separately billable injectable drugs. We would have preferred to use 2002 data but CMS's on-line database was lacking cost reports for more than half of all freestanding dialysis facilities. By contrast, the database contained cost reports for 91 percent of all freestanding facilities in 2001.

The lag between data collection and data access is frustrating to users of the data, especially considering that freestanding dialysis facilities are required to submit their cost reports to CMS's contractors—fiscal intermediaries (FIs)—within three months following the close of their cost reporting period and that failure to do so may result in suspension of payments (CMS 2004b). It is unclear whether the lag is due to delays by the fiscal intermediaries or CMS. Under prospective payment, the

information from cost reports is important for assessing payment adequacy, the result of which can affect beneficiaries' access to care.

Consequently, we encourage CMS to make a priority its responsibility for maintaining the timeliness and integrity of the data. We further note that the resources to carry out this responsibility must be provided by the Secretary and the Congress.

The Commission has traditionally expressed the relationship of aggregate payments to costs as a payment-to-cost ratio. For the first time, we provide facilities' payment margin—another way to assess the relationship of payments to costs. A margin is calculated as payments less costs divided by payments—conceptually, the amount of revenue a provider keeps. Finally, similar to last year's analysis, we assess providers' costs in two ways. First, we used the actual costs reported by providers that have not yet been audited by CMS. Second, we adjust the actual costs by the ratio of allowable costs to reported costs from the most recent (1996) complete audit of cost reports (see text box, p. 178).

For 2001, we estimate that the aggregate Medicare margin for composite rate services and injectable drugs is 5.2 percent (which translates into a payment-to-cost ratio of 1.05) when the effect of the audit is considered (Table 3E-3). Aggregate margins vary based on a facility's size, affiliation with a national chain, and profit status. This finding stems from differences in the cost per treatment, which is on average 8 percent lower for facilities that are large, affiliated with a national chain, and for profit compared with facilities that are small, not affiliated with a chain, and nonprofit.

Aggregate margins for composite rate services and injectable drugs declined from 10.5 percent in 1999 to 5.2 percent in 2001 even though the composite rate was increased twice during this period. Factors influencing this decline include the spike in providers' costs between 2000 and 2001 for composite rate services, which is discussed later in this section, and the increase in the acquisition cost of erythropoietin during this time.

We estimated 2004 payments and costs for composite rate services and injectable drugs administered during dialysis treatment using data from the 2001 cost reports and outpatient claims submitted by freestanding dialysis providers. Current law leaves the composite rate payment unchanged between 2002 and 2004. We estimated the increases in composite rate costs over the same period by

**TABLE
3E-3**

Aggregate margins for composite rate services and injectable drugs for freestanding dialysis facilities, 2001

Type of facility	As reported	Adjusted for audit
All facilities	2.4%	5.2%
Small	-6.8	-4.2
Medium	1.6	4.8
Large	5.7	8.2
Nonprofit	-5.7	-4.2
For profit	3.1	6.0
Nonchain	-1.4	-0.1
Chain	3.6	6.4
Urban	2.5	5.4
Rural	1.8	4.3

Note: Small facilities are defined as those reporting dialysis sessions less than or equal to the 25th percentile of all dialysis sessions, medium facilities are defined as those reporting dialysis sessions greater than the 25th percentile but less than the 75th percentile of all dialysis sessions, and large facilities are defined as having greater than or equal to the 75th percentile of all dialysis sessions.

Source: Data compiled by MedPAC from the 1996 and 2001 cost reports and the 2001 institutional outpatient file from CMS.

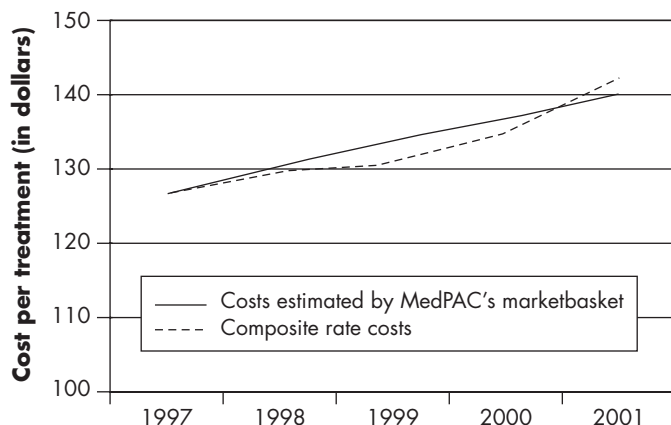
assuming that they will grow at the same rate predicted by MedPAC's dialysis market basket index. Average per unit costs increased at a rate lower than the increase in the dialysis market basket index between 1997 and 2000 but at a higher rate between 1997 and 2001 (Figure 3E-1). Using these assumptions, we estimated the 2004 aggregate margin for the following two scenarios:

- that payments from injectable drugs relative to composite rate payments would increase between 2001 and 2004 based on the past trend of injectable drug spending increasing from 37 to 41 percent of facilities' payments between 1999 and 2001; and
- that payments from injectable drugs relative to composite rate payments would not change between 2001 and 2004.

Under the first scenario (the share of revenues for injectable drugs relative to composite rate payments increases by the 1999–2001 trend in injectable drug spending), the aggregate margin is estimated to be 2.7 percent. Under the second scenario (assuming no change

FIGURE 3E-1

MedPAC's market basket index tracks actual growth in composite rate costs



Note: MedPAC's market basket index are historic values (not corrected for forecast error).

Source: CMS cost reports of dialysis facilities, 1997–2001.

in payments for injectable drugs relative to composite rate payments), the 2004 aggregate margin is estimated to be 2.1 percent.

Although the aggregate margin for composite rate services and injectable drugs is the most comprehensive measure we have to assess the financial performance of dialysis facilities, it does not account for the potential profitability of all services associated with outpatient dialysis.

Certain dialysis-related laboratory tests are paid outside the composite rate bundle. In this case, Medicare pays the clinical laboratory, not the dialysis facility, for these laboratory services. However, each of the national dialysis chains owns clinical laboratories and those entities receive Medicare payments for dialysis-related laboratory tests. These chains reported that dialysis-related laboratory services increased payment by about 4 percent per session. MedPAC recommended that the payment bundle for dialysis services include both injectable drugs and laboratory services that are currently excluded from it (MedPAC 2001, MedPAC 2003a).

Appropriateness of composite rate costs

Providers' costs for composite rate services increased by 5.4 percent between 2000 and 2001. This rate of increase exceeded the 3.6 percent increase predicted by MedPAC's dialysis market basket index (corrected for market basket forecast error) for this same time period. MedPAC's analysis shows that two categories of costs spiked in 2001:

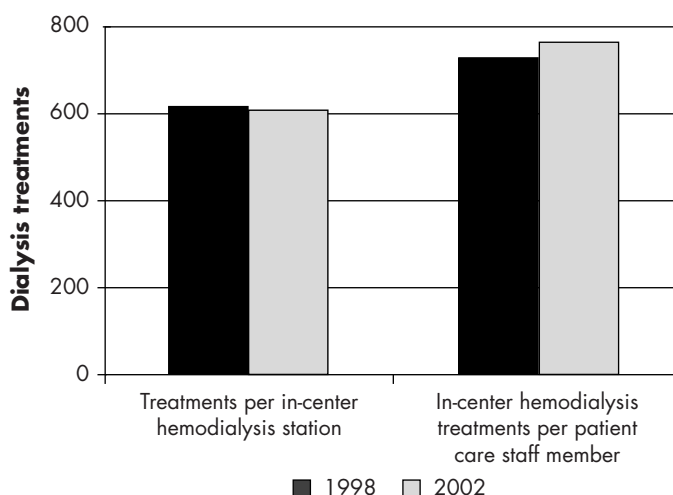
- Labor costs increased by 6 percent, compared with a 3 percent increase between 1997 and 2000; and
- General and administrative costs increased by about 7 percent, compared with a 2 percent increase between 1997 and 2000.

Historically, dialysis providers have adopted efficiencies in service delivery, enabling them to keep their costs at or below the dialysis market basket index. It is too soon to tell whether the growth in providers' labor and administrative costs between 2000 and 2001 is an anomaly. Like other health care providers, dialysis providers contend that their labor costs have increased because they face increased competition for recruiting registered nurses and technicians (driven by possible labor shortages). Unfortunately, the cost report data do not allow for an analysis of the specific components comprising the costs reported as general and administrative, the other category within which costs spiked between 2000 and 2001. Providers contend that since 2000 they have faced significant increases in the cost of utilities, liability, and health insurance. However, indicators from the Bureau of Labor Statistics suggest that the spike in labor costs may have reached its peak in 2002.

MedPAC also evaluates the appropriateness of current costs by examining selected measures to assess changes in the services furnished by facilities. Indicators of staff composition and productivity have improved for some measures (Figure 3E-2). Between 1998 and 2002:

FIGURE 3E-2

Productivity of dialysis facilities, 1998 and 2002



Source: CMS cost reports of dialysis facilities, 1998 and 2002.

- the proportion of technicians to patient care staff increased from 0.51 to 0.54, and
- the ratio of patients to technicians increased from 16.2 to 18.3.

Finally, the average duration of hemodialysis sessions slightly increased from 212 minutes in 1998 to 217 minutes in 2001 (CMS 1999, 2002).

Thus, it is too soon to draw conclusions about the appropriateness of the composite rate cost base. MedPAC will monitor future trends in providers' costs and also changes in the dialysis product, which we discuss in the following section.

Appropriateness of costs for injectable drugs

Based on MedPAC's previous findings, we expect that the costs of separately billable drugs have grown more rapidly than the costs of composite rate services. Costs for separately billable drugs increased by about 12 percent between 2000 and 2001. This change is consistent with the trends between 1998 and 2000. The payment method for separately billable drugs gives providers no incentives to improve efficiency. In contrast, prospective payment methods provide incentives to control costs because payment is based on a predetermined rate unaffected by incurred costs or posted charges.

Substituting new, more costly drugs for older, less expensive drugs may be another reason why providers' costs for injectable drugs per dialysis treatment increased during the 1997–2001 period. For example, the price of a vitamin D analogue (paricalcitol), newly approved in 1998, is twice that of the older agent it has displaced (calcitriol).¹³ Between 2000 and 2001, spending for paricalcitol increased from \$172 million to \$386 million; in contrast, spending for calcitriol decreased from \$127 million to \$67 million.

How should Medicare payments change in 2005?

As noted earlier, MedPAC accounts for expected cost changes in the coming year primarily through the forecast of input price inflation. In the early 1990s, the Commission developed an outpatient dialysis market basket index because none was available from CMS. The Commission's market basket consists of price proxies for hospitals, skilled nursing facilities, and home health

agencies, and uses four cost categories: labor, capital, other direct costs, and general and administrative. Each year, we update the share of each cost category using the most recent cost report available.

In 2003, CMS released its market basket index for dialysis composite rate services, as mandated by the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000. The major difference between the two market baskets is the price indexes used to estimate the rate of price change (text box, p. 171). CMS's and MedPAC's market basket indexes, corrected for market basket forecast error, predicted cost growth of 2.8 percent and 2.9 percent, respectively, between 1997 and 2001. By comparison, average composite rate costs grew by 3.0 percent during this period.

We have two concerns about CMS's dialysis market basket, which we raised in our report on the Secretary's methods to expand the dialysis payment bundle (MedPAC 2003a). First, CMS does not indicate how frequently the base weights will be updated. For the inpatient hospital prospective payment system, for example, CMS updates the base weights every five years. Second, CMS does not specifically address whether it used audited cost report data to develop the weights. The share of total costs that each category represents (capital, labor, other direct, and general and administrative) could change as a result of auditing.

MedPAC's market basket index currently predicts that costs will increase by 2.3 percent between 2004 and 2005, whereas CMS's index predicts that costs will grow by 3.0 percent.

Another factor considered by MedPAC's update framework that may affect dialysis facilities' costs in the next payment year is scientific and technological advances. This factor is designed to include only those new technologies that are quality-enhancing and costly, and that have progressed beyond the initial stage of use but are not yet fully diffused into medical practice. Our review of the literature suggests that the costs of most medical advances will primarily be accounted for through the payments for separately billable drugs. These payments represent increased expenditures and do not need to be factored into the update.

Finally, MedPAC has adopted a policy standard or goal for the productivity growth of efficient providers. To

How MedPAC's and CMS's market baskets for dialysis services differ

The goal and overall structure of MedPAC's and CMS's market baskets are similar. Both market baskets are designed to assess how much it would cost, over time, to purchase the same mix of goods and services that were purchased in a base period. Both market baskets are constructed in three steps. The differences between the two market baskets are highlighted below.

In step one, cost weights are developed using data from the cost reports submitted by freestanding dialysis facilities and represent the proportion of total costs that each cost category represents. For MedPAC's market basket, the four cost categories and their share of total costs are capital (19 percent), labor (44 percent), other direct (15 percent), and general and administrative (22 percent). Each year, MedPAC uses the most current cost report data to update the cost weights. For the 2004 market basket, cost weights are based on 2001 cost report data.

For CMS's market basket, the eight categories and their share of total costs are capital (14 percent); wages and salaries (39 percent); employee benefits (7 percent); pharmaceuticals (1 percent); supplies (18 percent); lab services (0.4 percent); housekeeping and operations (4 percent); and general and administrative (17 percent). CMS does not update the cost weights each year; rather, the cost weights are based on 1997 report data.

In step two, price proxies are selected to estimate the rate of price change for each cost category. The main difference between MedPAC's and CMS's market baskets are the different price proxies used. MedPAC uses price proxies from the hospital prospective payment system (PPS), skilled nursing facility (SNF), and home health market baskets. CMS uses price proxies from the Producer Price Indexes, Consumer Price Indexes, and Employment Cost Indexes (ECI). Although different price proxies are used by each market basket, the price proxies are based on the same cost index. For example, MedPAC uses the labor compensation proxies for hospital PPS, SNF, and home health services to estimate the price change for labor costs. Each of these price proxies is based on the ECI. By contrast, CMS estimates the price change for labor costs using the ECI (wages and salaries) for health care workers (private), the ECI for employee benefits for health service workers (private), and the ECI for compensation of professional and technical workers (private).

In step three, the cost weight for each category is multiplied by the sum of the indexes of the respective price proxy to arrive at a weighted index for each cost category. The sum of the products for all cost categories yields the aggregate index of the market basket in a given year. This step is calculated in a similar fashion by MedPAC and CMS. ■

estimate productivity increases, MedPAC uses the 10-year moving average of multifactor productivity in the economy as a whole, which is 0.9 percent.

Updating payments for composite rate services in 2005

Based on our review of the adequacy of payments for outpatient dialysis services and expected cost changes in the coming year, the Commission recommends the following:

RECOMMENDATION 3E-1

The Congress should maintain current law and update the composite rate by 1.6 percent for 2005.

RATIONALE 3E-1

Medicare's aggregate payments for composite rate services and separately billable services are adequate. Quality of care continues to improve for some measures. Beneficiaries face no systematic problems in accessing care. Capacity and the number of providers continues to increase.

IMPLICATIONS 3E-1

Spending

- This recommendation has no impact relative to current law.

Beneficiary and provider

- This recommendation has no impact relative to current law.

Using payment incentives to improve dialysis quality

Like other providers, Medicare does not financially reward outpatient dialysis providers—physicians and facilities treating dialysis patients—to improve quality. In June 2003, MedPAC expressed an urgent need to improve quality in fee-for-service Medicare and in care furnished by private plans. Linking payment to quality could encourage broader use of best practices by first identifying the best way to treat patients and then rewarding providers that follow the guidelines. A Medicare program that rewarded quality would send the strong message that it values the care beneficiaries receive and encourages investments in improving care.

MedPAC finds that linking payment to the quality of care provided by physicians and facilities treating dialysis patients is needed as another lever to improve dialysis quality. Current efforts, though successful on some dimensions, have not uniformly improved dialysis adequacy and anemia status for all patients. Furthermore, other aspects of care have shown little improvement, raising continued concerns about quality. In its most recent report on dialysis quality, CMS recommended that additional efforts are needed to improve nutritional care and vascular access management. Despite some improvement in dialysis adequacy and anemia status, patients and policymakers remain concerned about the unchanged rates of hospitalization during the past 10 years and the poor long-term survival of dialysis patients:

- Rates of admission for hospitalizations for cardiovascular and infection-related causes, the two leading causes of morbidity among dialysis patients, increased by 16 and 30 percent, respectively, between 1991 and 2001; African American and Asian patients showed the greatest increases.
- Adjusted annual mortality rates have remained relatively constant at 167 and 165 per 1,000 patient-years at risk between 1991 and 2001, respectively. Mortality rates for females and African Americans increased during this time (USRDS 2003).

RECOMMENDATION 3 E - 2

The Congress should establish a quality incentive payment policy for physicians and facilities providing outpatient dialysis services.

The recommendation targets providers who treat dialysis patients—dialysis facilities and physicians who are paid a monthly capitated payment. Implementing a quality incentive payment policy could improve the quality of dialysis care. The outpatient dialysis sector is a ready environment for linking payment to quality. Credible measures are available that are broadly understood and accepted. All dialysis facilities and physicians should be able to improve upon the measures, which could include adequacy of dialysis. Obtaining information to measure quality will not pose an excessive burden on dialysis facilities and physicians. Measures can be adjusted for case mix so that dialysis facilities and physicians are not discouraged from taking riskier or more complex patients.

IMPLICATIONS 3 E - 2

Spending

- This recommendation should not affect Medicare benefit spending.

Beneficiary and provider

- Beneficiaries should see improvements in care.
- Some physicians and facilities could receive higher payments or lower payments. In addition, some physicians and facilities may need to shift resources to improvement efforts.

Medicare should implement quality incentives for both facilities and physicians treating dialysis patients to allow quality improvements to reach as many beneficiaries as possible. Both provider types collaborate to care for dialysis patients and only together can they improve quality in the long term. Medicare pays physicians a monthly capitated payment for furnishing ESRD-related services that include determining the dialysis prescription, providing outpatient evaluation and management, dialysis visits, telephone calls, and patient management during the month. This payment method is unique in the physician fee schedule and Medicare has used it since 1983. Recently, CMS modified the capitated amount by adjusting the monthly payment according to the number of face-to-face visits the physician has with the patient during the month. Before this change, CMS paid the same monthly amount per patient regardless of the number of times the physician saw the patient during the month.

As described later in this section, MedPAC believes that a system linking payments to quality should:

- reward facilities and physicians based on both improving the care they furnish and exceeding thresholds,
- be funded by setting aside a small proportion of total dialysis payments, and
- distribute all payments that are set aside for quality to facilities and physicians achieving the quality criteria.

Linking payment to quality holds providers accountable for the care they furnish. Capitated payments and prospective payment systems give providers an incentive to reduce their costs by minimizing the services they furnish to the extent possible. Measuring quality and financially rewarding providers furnishing quality care will help ensure that providers are not stinting on care. Measuring the quality of care and holding providers financially accountable will take on additional importance if Medicare broadens the dialysis payment bundle and reinforces the incentives of prospective payment. Another advantage in linking payment to quality is that financial rewards would accrue to providers investing in the processes that improve care. The financial rewards will help providers furnishing high-quality care defray the capital and labor costs associated with these improvements.

Medicare's quality assurance efforts alone do not go far enough in improving dialysis quality. Quality assurance and quality improvement represent two different approaches for influencing the quality of care. As noted previously, the goal of quality assurance is to ensure that minimal standards of care—conditions of coverage—are met by facilities. Currently, the dialysis conditions of coverage consist mainly of structural requirements designed to ensure the capacity of facilities to safely furnish quality health care. Medicare can exclude dialysis facilities not meeting its conditions of coverage, although the program has rarely done so. By contrast, quality improvement efforts encourage providers to assess their performance, implement changes, reassess based on outcomes, and strive for continuous improvements. Quality incentives, along with CMS's other quality improvement activities, will together be important tools for driving improvements in quality.

In addition, Medicare's efforts to indirectly reward certain dialysis facilities through its public disclosure of facility-specific outcome measures do not go far enough in improving quality. High-quality providers could benefit financially when demand shifts toward them, thus

increasing their revenue. In the case of public reporting and dialysis, however, no evidence exists that this mechanism has succeeded in shifting demand.

Although acting through different mechanisms, Medicare's quality levers—quality assurance, quality improvement, public reporting of quality data, and quality incentives—all work toward maintaining and improving the quality of care for most patients. However, patients are also an important part of the solution toward improving dialysis outcomes. Outcomes are adversely affected for patients who do not comply with their providers' treatment regimens—including showing up for dialysis treatment, remaining for the prescribed treatment, and adhering to medication and diet regimens. Noncompliance is much more common among U.S. patients than patients from other countries (Bleyer et al. 1999). In addition, certain characteristics, such as age, are associated with noncompliance, highlighting the need to case-mix adjust measures so that providers are not discouraged from taking riskier patients (Leggat et al. 1998).

Finally, CMS is using quality incentives in the agency's new ESRD disease management demonstration (see text box, p. 174). Medicare will pay program participants—dialysis facilities and private health plans—an incentive if they improve quality and if they demonstrate high levels of care compared with the national average. We applaud CMS for linking payment to quality in the demonstration. Quality incentives should not, however, be limited to demonstration efforts, but rather should apply to all fee-for-service dialysis providers so they can improve care for as many patients as possible. A drawback in using quality incentives in a demonstration only is that the bidders may primarily consist of high-quality facilities and not be representative of all facilities. By contrast, incentives that are made a part of the outpatient dialysis payment system will affect both low- and high-quality providers.

Quality incentives are feasible for outpatient dialysis services

The outpatient dialysis sector is a ready environment for tying quality measures to payment:

- Measures are available that are evidence based, developed by third parties, and agreed-upon by the majority of providers.
- CMS can collect provider-specific information without excessive burden on providers.

How CMS's ESRD demonstration will work

This demonstration tests the effectiveness of disease management services to end-stage renal disease (ESRD) beneficiaries and different approaches to paying for their care in traditional Medicare and under capitated arrangements. CMS is reviewing proposals from would-be participants and is anticipating initiating the demonstration in 2004.

- Participating fee-for-service providers and private plans will coordinate patients' care.
- For traditional Medicare, the demonstration will pay for an expanded bundle that includes commonly used drugs and laboratory tests not currently included in the composite rate bundle. The Medicare add-on payment for the expanded bundle is \$71.63 per session (not including vascular access services) and \$86.63 (with vascular access services).
- Capitated providers will be paid using the new risk-adjusted ESRD payment method developed by CMS.
- Traditional Medicare providers will be at partial risk for all services furnished to participating patients. Capitated providers may propose risk sharing arrangements.

CMS is linking payment to quality for both fee-for-service and capitated providers. Five percent of the payment rate will be reserved for incentive payments related to quality improvement activities. CMS is using five indicators—dialysis adequacy, anemia management, nutritional management, bone disease, and vascular access. Providers will be paid an incentive payment if they improve quality of care and/or if they demonstrate high levels of care compared with a national average. By linking payment to both improving care and exceeding national targets, providers at both ends of the quality spectrum will be able to earn incentive payments. Specifically, for each of the five measures, providers will be paid one-half of one percent for:

- improving care within their facility. CMS will set improvement targets using a method that bases the target on improvements in the "quality deficit." The quality deficit would be defined as 100 percent minus the providers' actual rate for assigned beneficiaries in the previous year. Improvement targets will be set at 10 percent over the deficit from 100 percent.
- exceeding a national target for quality. CMS will set national targets at 20 percent above the nationwide percentage deficit from 100 percent. ■

- Measures can be adjusted for case mix so that providers are not discouraged from taking riskier or more complex patients.
- Many providers can still improve upon some of the measures.

Evidence-based measures are available

For dialysis care, measures are available that are evidence based and broadly understood and accepted. Nephrology organizations are continually publishing clinical guidelines about the care of patients with ESRD and chronic kidney disease. From these guidelines, CMS has developed a series of performance measures. Since 1993, CMS has monitored key aspects of the dialysis process, including anemia and nutrition levels, dialysis adequacy, and most recently, vascular access management, in the agency's

annual survey of dialysis patients. CMS Dialysis Facility Compare publishes facility-specific measures about dialysis adequacy, anemia management, and survival.

Collecting data will not be burdensome

CMS already has in place a mechanism to collect dialysis adequacy information from the claims submitted by providers. The recently implemented Standardized Information Management System, a national information infrastructure that electronically links all 18 ESRD network organizations—CMS's contractors for improving dialysis quality and collecting and disseminating data—with the agency, is expected to help the development of consistent quality improvement efforts and the collection and analysis of information on processes and outcomes of care.

Measures can be adjusted for differences in case mix

A major issue in developing financial incentives is to ensure that providers do not “cherry-pick” patients, i.e., refuse to care for patients who are sicker or more complex on average than other patients. MedPAC’s analysis of the association between quality and providers’ costs showed that beneficiaries’ outcomes are poorer for facilities with higher than average costs for composite rate services and injectable drugs, which may suggest that higher-cost facilities may be furnishing care to more medically complex beneficiaries (MedPAC 2003b). In addition, MedPAC’s analysis also showed that certain patient characteristics are associated with poorer outcomes, a finding confirmed by Hirth and others (2003).

What data sources can CMS use to risk adjust quality measures? Providers are required to collect clinical information on all patients when they first enter Medicare’s ESRD program.¹⁴ This rich source of information provides a measure of the total disease burden of ESRD patients and is unmatched for any other patient group in Medicare. Some researchers contend that facilities could improve the validity of the data reported. A recent study suggested that comorbid conditions were significantly underreported, but diagnoses were not falsely attributed to patients (Longenecker et al. 2000). Clearly, facilities will have every incentive to improve reporting when this information is used for payment purposes.

CMS can supplement information from the medical evidence report with the diagnoses reported on patients’ Part A and B claims. CMS’s new risk adjuster for paying for ESRD patients enrolled in private plans uses claims data.

Providers can improve upon these measures

Although dialysis adequacy and anemia status have improved significantly during the past decade, the improvement has not occurred at all facilities. The GAO noted that in 2000: (1) about 15 percent of facilities furnished inadequate dialysis to one-fifth or more of their patients; and (2) nearly half of all facilities did not meet the guideline for anemia management for one-fifth or more of their patients (GAO 2003). Research has shown that variation in patient outcomes is attributable to facility- and patient-specific causes.

New opportunities exist to improve upon other aspects of dialysis quality, particularly nutritional management (as

noted previously), vascular access care, and bone disease management. CMS data show the need for improvements in vascular access care.¹⁵ Recent survey data from the Dialysis Outcomes and Practice Patterns Study also show that additional efforts are needed to educate providers and their staff to improve vascular access care. Only 79 percent of medical directors and 59 percent of nurse managers in the U.S. prefer arteriovenous (AV) fistulas over synthetic grafts. By contrast, all medical directors and nurse managers in Europe and Japan preferred AV fistulas for patients starting hemodialysis in their units.

New opportunities also exist to use quality incentives for vitamin D analogues, which are injectable drugs used to treat bone disease. The National Kidney Foundation recently released a clinical guideline on this topic. Providers furnish injectable vitamin D analogues to help manage patients’ bone metabolism, and Medicare spending for this drug class has increased steadily, from \$126 million in 1996 to \$454 million in 2001. Using incentives will promote the appropriate use of vitamin D analogues. CMS has not yet included bone disease as a clinical performance measure, but, as noted previously, the agency’s ESRD demonstration links payment to quality for this clinical area.

What are the key implementation issues?

Measure sets and data collection tools are credible and broadly used in the outpatient dialysis setting. Nonetheless, designing a system to distribute the incentive payments will be a complex undertaking. The key issues in implementation include:

- How should providers be rewarded?
- Will additional funding be required?
- Which quality measures should be used?

In assessing different ways to design quality incentives for outpatient dialysis services, MedPAC sought alternatives that would:

- improve the quality of dialysis care for as many patients as possible, and
- minimize unintended consequences, such as cherry picking of patients or distorting resource allocation to the measured areas from the unmeasured areas.

How should providers be rewarded?

Should providers be rewarded based on improving the care they furnish, exceeding national averages, or some combination of both?

MedPAC concludes that a fair and balanced approach will reward providers based on some combination of both methods. By using both methods, providers at both ends of the quality spectrum will be able to achieve financial incentives. Reaching a large share of providers will result in improving the quality of dialysis for many patients. CMS's new ESRD demonstration uses a mixed strategy when linking payments to quality. For each measure used, the agency awards one-half of one percent of payments for improving quality and one-half of one percent for exceeding national targets.

Using a mixed strategy minimizes the negative aspects of each reward method. Linking payments to quality based only on improvements could reward providers who achieve significant improvement but remain at a relatively low level of quality. By contrast, establishing a target goal alone could encourage all providers to improve. However, setting goals too high might discourage providers at the low end from trying to improve. And, in the case of certain dialysis measures (adequacy and anemia), setting target goals too low might motivate high-quality providers to relax their efforts to improve outcomes.

Even with accurate risk adjustment, both methods individually run the risk of providers cherry-picking patients. Providers would have an incentive to select patients with lower outcome scores if the payment were linked solely to showing improvement. By contrast, providers would have an incentive to select patients with higher outcome scores if payment were linked solely to exceeding target goals.

Will additional funding be necessary?

Linking quality to payment should not require additional funding by Medicare. Previous MedPAC analysis demonstrated that better dialysis adequacy and anemia management are not related to providers' costs for composite rate services and are worse for providers with higher costs for composite rate services and injectable drugs. As mentioned earlier, data from the USRDS show that per beneficiary spending for injectable drugs varies across different provider types. Thus, it does not appear that additional funding is necessary to pay for better care. Some providers are concerned that the changes by the MMA in paying for composite rate services and injectable

drugs will reduce aggregate dialysis spending. The Congressional Budget Office, however, estimated that these changes are budget neutral.

MedPAC has concluded that all payments that are set aside for quality should be awarded to facilities and physicians who meet the quality criteria. Doing so will result in payments being redistributed based on how facilities and physicians perform but should not result in lower aggregate dialysis payments. This task is administratively feasible for CMS, although it will increase the workload for both the agency and its contractors—carriers, fiscal intermediaries, and ESRD networks. CMS has already faced some of these tasks when designing the ESRD disease management demonstration and implementing a program that pays private plans more for meeting two quality criteria for treating patients with congestive heart failure.

Initially, MedPAC supports setting aside a small proportion of physicians' and facilities' payments as a means to motivate investment in better care. For facilities, a 1-percent set-aside would equal about \$70 million assuming total Medicare payments of \$7 billion for dialysis and injectable drugs in 2001. For physicians, a 1-percent set-aside would equal about \$15 million assuming total Medicare payments of \$1.5 billion for dialysis capitation services in 2001 (USRDS 2003).

Beginning with a small set-aside has several advantages. It minimizes the adverse effect on providers who initially are not able to meet the quality criteria. It also discourages providers from de-emphasizing improvements in areas outside the incentive program, such as infection control programs. As providers become more accustomed to being rewarded for quality, Medicare should consider expanding both the proportion of payments that are set aside and the measures that are used.

Which quality measures should be used?

Clinical areas that both facilities and physicians can improve include dialysis adequacy and management of anemia, vascular access, nutrition, and bone disease. CMS is linking payment to these five measures in its new demonstration project (text box, p. 174). When assessing issues with implementing quality incentives, we considered: (1) past trends in improving care; and (2) whether other factors, such as Medicare's coverage and payment policies, inhibit facilities and physicians from improving quality.

Dialysis adequacy and anemia management are two clinical areas for which quality has substantially improved in the past decade, although not uniformly across all providers. Payment can be easily linked to quality since CMS has already developed clinical performance measures. The past improvements show that facilities and physicians can improve care.

Vascular access is a clinical area in which substantial improvements in quality are needed.¹⁶ Medicare could link payment to quality for one aspect of vascular access care—monitoring for stenosis. Both dialysis facilities and physicians treating dialysis patients are responsible for regularly checking the access for the presence of stenosis. CMS developed clinical performance measures to assess vascular access care in 2000.

Medicare may face challenges in linking payment to quality for another aspect of vascular access management—increasing the use of AV fistulas—because:

- Other providers, particularly vascular surgeons who perform the access procedure, play an important role in the type of vascular access that is selected.
- Medicare’s payment policies may encourage the use of grafts instead of AV fistulas.¹⁷
- Medicare coverage starts the fourth month after the onset of ESRD for patients eligible for Medicare solely because they have ESRD (i.e. they are not age-entitled). During the first three months following ESRD onset, providers may choose the least costly alternative for patients with no health insurance or insured by Medicaid.
- The care patients receive before they need dialysis may affect the type of access selected. AV fistulas require more time for placement and maturity than the other types of vascular access. Consequently, renal care must be initiated at least three to six months prior to the start of dialysis for successful placement of an AV fistula. Researchers have shown that a substantial proportion of patients with chronic kidney disease do not see a nephrologist in the one year prior to starting dialysis. For example, Kinchen and colleagues (2002) reported that only 48 percent of dialysis patients were treated by a nephrologist in the one-year period before initiation of dialysis.

CMS has recently initiated a quality improvement effort to increase the use of AV fistulas. This effort should increase AV fistula use.

Nutritional management is another clinical area in need of substantial quality improvement. CMS has measured one aspect of nutritional management—serum albumin levels—since 1993. However, linking payment to improvements in patients’ nutritional status faces an important obstacle. Medicare’s coverage policies limit the number of dialysis patients who qualify for certain nutritional interventions administered during the dialysis session. Moreover, the Health Insurance Portability and Accountability Act of 1996 does not permit providers to furnish items or services for free or for a cost other than fair market value.

Despite these policies, both facilities and physicians can conduct outreach efforts to educate patients about the importance of complying with their diet regimen. For example, hemodialysis patients need to watch how much they drink because fluid can build up between dialysis treatments, causing swelling and affecting patients’ blood pressure and risk for adverse cardiovascular events.

Finally, bone disease management is another clinical area for which Medicare could link payment to quality. Drug therapies used to manage bone disease include injectable drugs (vitamin D therapies) and oral agents (phosphate binders). Medicare already pays for injectable drugs and, with the passage of the MMA, oral drugs will be a covered benefit. Although CMS has not yet developed performance measures for this clinical area, the agency is linking payment to this aspect of care in the demonstration project, so measures should be available soon.

What other issues exist?

Other issues that Medicare should consider when linking payment to quality include:

- continuing other quality improvement efforts,
- collaborating with provider and patient groups,
- keeping the measures current with medical knowledge,
- verifying the data, and
- excluding pediatric patients.

Implementing quality incentives should not displace other quality improvement efforts conducted by CMS. Rather, they should complement current efforts to monitor, report on, and improve the quality of dialysis care. Continuing other quality improvement efforts will be important to ensure that providers do not de-emphasize the quality in areas not measured in the incentive program.

To successfully implement quality incentives, CMS will first need to collaborate with patient and provider groups. The agency has a good track record for doing so. Most recently, CMS created an expert panel for patient and provider groups to collaborate on the agency's research effort to expand the dialysis payment bundle. During 1999–2000, CMS worked with patient and provider groups when implementing its Dialysis Facility Compare website.

The measures used to link payment to quality must be kept current as medical knowledge grows and new clinical guidelines are released. In 2000, the agency updated its effort by including measures of vascular access care. We strongly urge the agency to include bone disease measures in its performance measure data set. As mentioned previously, the NKF recently released a clinical guideline on this topic. It will also be important for CMS to develop uniform methods for providers to measure indicators. For

example, the timing of the blood urea nitrogen sample collection can affect the measurement of dialysis adequacy. Finally, whichever measures are used, it may be necessary to use different targets for each dialysis method.

CMS will need to verify the data linking payment to quality for at least a sample of providers. The agency already has developed a sampling methodology of dialysis facilities for its clinical performance measurement project.

Finally, when implementing financial incentives, Medicare might want to consider excluding pediatric patients. The population of pediatric patients is quite small; in 2000, there were only about 675 pediatric dialysis patients. In addition, pediatric cases are generally more complex to treat than older patients. The physician fee schedule pays more for treating younger patients. Furthermore, nephrology groups have developed different clinical performance guidelines for pediatric cases. ■

Using audited cost data to determine Medicare-allowable costs

MedPAC's analysis of current costs uses only Medicare-allowable costs. CMS's contractors—fiscal intermediaries (FIs)—audit cost reports submitted by certain institutional providers to ensure that the costs reported by providers are Medicare allowable. The Balanced Budget Act of 1997 required the Secretary to audit cost reports of each dialysis provider at least once every three years beginning in 1996. The most recent year for which the FIs audited a majority (62 percent) of cost reports from freestanding facilities was 1996. By comparison, 1 percent of 2001 cost reports have been audited.

MedPAC compared the audited cost report data for 1996 with the 1996 data as submitted.¹⁸ Our analysis showed that the allowable cost per treatment for composite rate services and injectable drugs for freestanding facilities was about 96 percent of the reported cost of treatment. All types of facilities were affected by the audit (MedPAC 2003c). For example, allowable costs as a percentage of reported costs were 96 percent for medium-sized facilities and 97 percent for small and large facilities. But variation did exist depending on the facilities' audit status. Allowable costs of facilities whose cost reports were reopened were 81 percent of their reported costs. By contrast, for all other facilities, allowable costs ranged from 97 to 100 percent of their reported costs. The audit resulted

in the greatest proportional decline in general and administrative costs compared with labor, capital, and other direct costs. Our finding that allowable costs are less than reported costs is consistent with an audit performed by CMS in 1988, which determined that the allowable cost per treatment for freestanding facilities was 88 percent of the reported cost per treatment (Prospective Payment Assessment Commission 1993).

If history is any guide, a portion of the reported costs for services furnished between 1997 and 2001 will most likely be found nonallowable when these reports are audited by CMS. Considering the effect of the difference between reported and allowable costs is important in assessing the relationship between current payments and costs. Consequently, we assessed providers' costs for services furnished between 1997 and 2001 in two ways. First, we used the actual costs reported by providers that have not yet been audited by CMS. Second, we adjusted the actual costs reported by providers by the ratio of allowable costs to reported costs derived from the analysis of the 1996 cost reports. We calculated the ratio of allowable costs to reported costs in 1996 by each type of facility and applied this adjustment to the 1997 to 2001 costs of the corresponding facility type. Our approach assumes that the ratio of allowable costs to reported costs for 1997 to 2001 will be the same as in 1996. ■

Endnotes

- 1 To qualify for the end-stage renal disease program, individuals must be insured under the Social Security or Railroad Retirement program, entitled to monthly benefits under the Social Security or Railroad Retirement programs, or the spouse or dependent child of an eligible beneficiary.
- 2 The composite rate was designed in 1983 to include all nursing services, supplies, equipment, clinical laboratory services, and drugs associated with a single dialysis session.
- 3 Medicare spending includes program outlays and beneficiary cost sharing.
- 4 Dialysis injectable drugs were excluded from the average wholesale price reforms included in the MMA.
- 5 The size of the facility is defined in each year based on the 25th and 75th percentile of dialysis sessions. Small facilities are defined as those reporting dialysis sessions less than or equal to the 25th percentile of all dialysis sessions, medium facilities are defined as those reporting dialysis sessions greater than the 25th percentile but less than the 75th percentile of all dialysis sessions, and large facilities are defined as having greater than or equal to the 75th percentile of all dialysis sessions.
- 6 Medicare pays for many different injectable drugs furnished by freestanding dialysis providers. Each injectable drug has its own unit of measurement. Because of the difficulty in aggregating different units of measurement, we express volume in terms of total Medicare payments.
- 7 Levocarnitine supplements the loss of carnitine, a naturally occurring body substance that helps transport long-chain fatty acids for energy production by the body. Patients on hemodialysis can suffer carnitine deficiencies from dialytic loss, reduced renal synthesis, and reduced dietary intake. Patients must show improvement from the levocarnitine treatment within six months of initiation of treatment for Medicare to continue to pay for the treatment.
- 8 Some providers contend that erythropoietin is predominately furnished intravenously because patients experience less discomfort than when it is furnished subcutaneously.
- 9 Daily parenteral nutrition is limited to patients “with severe pathology of the alimentary tract which does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the patient’s general condition” (CMS 2004a).
- 10 Return on invested capital is calculated by dividing earnings before interest and taxes for 2002 by the sum of long-term debt and shareholders’ equity at the end of 2001. Return on equity (before tax) is calculated by dividing earnings before income taxes for 2002 by shareholders’ equity at the end of 2001. Return on equity (after tax) is calculated by dividing net income for 2002 by shareholders’ equity at the end of 2001.
- 11 The extension of Medicare secondary payment provisions from 18 to 30 months by the Balanced Budget Act of 1997 increased the number of dialysis patients with a private payer as their primary source of insurance.
- 12 We have not yet included laboratory payments in our analysis of current payments because of the difficulty in distinguishing dialysis-related tests from those tests ordered for other comorbidities.
- 13 The National Kidney Foundation’s clinical guideline recommends use of vitamin D therapy—calcitriol, alfacalcidol, paricalcitol, or doxercalciferol—to reduce the parathyroid hormone levels in hemodialysis and peritoneal dialysis patients meeting specific clinical criteria. The clinical guideline also recommends trials to compare the effectiveness of each of these agents among dialysis patients.
- 14 The medical evidence report (Form 2728) used for this purpose collects information on patients’ weight, ability to ambulate and transfer, current smoking status, and the prevalence of 17 conditions including hypertension, diabetes, peripheral vascular disease, HIV positive status, chronic obstructive pulmonary disease, and congestive heart failure.
- 15 The three types of vascular access are arteriovenous (AV) fistula, an AV graft, and a venous catheter. The AV fistula is considered the best long-term vascular access for hemodialysis because it provides adequate blood flow for dialysis, lasts a long time, and has a complication rate lower than the other access types.
- 16 Services related to vascular access care include: (1) surgically placing the vascular access, the site on a patient’s body where blood is removed and returned during hemodialysis; (2) ongoing monitoring of the site to minimize the risk of complications, such as stenosis (narrowing of graft and blood vessel) and infection; and (3) treating and managing complications.
- 17 The Medicare allowable payment rate for surgically placing AV fistulas is less than the payment rate for grafts. Payment for catheters are similar to those for creating AV fistulas.
- 18 The audit status of freestanding dialysis cost reports is classified into one of four categories: as submitted, settled, settled with an audit, or reopened.

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