

C H A P T E R

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**Improving the quality of
care for beneficiaries with
end-stage renal disease**

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

8A The Secretary should determine clinical criteria for dialysis patients to receive increased frequency or duration of dialysis. The Secretary should then examine the feasibility of a multitiered composite rate that would allow different payments based on the frequency and duration of dialysis prescribed, as well as other factors related to adequacy of dialysis.

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8B MedPAC reiterates the recommendation made in its March 1998 and March 1999 reports calling for an increase in the composite rate.

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8D In fulfilling the requirements of the BBA regarding improving the quality of dialysis care, the Secretary should take into consideration the quality assessment and assurance efforts of renal organizations.

Improving the quality of care for beneficiaries with end-stage renal disease

Medicare's payment for dialysis, which has not increased since 1991, affects the quality of care for dialysis patients. Payment policies for treating anemia and malnutrition—complications of end-stage renal disease—also may affect the quality of care. The Medicare Payment Advisory Commission recommends that the Secretary of Health and Human Services improve the quality of dialysis care by modifying payments for dialysis, covering nutritional therapy for malnourished end-stage renal disease patients as a renal benefit, and considering the quality assessment and assurance efforts of renal organizations. Certain clinical outcomes and patient survival over the past five years have improved, but policy changes to permit higher doses of dialysis and appropriate clinical use of nutritional supplements could foster further improvement.

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 - Quality of dialysis care
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The Medicare end-stage renal disease (ESRD) program, established in 1973, provides entitlement to Medicare benefits for persons who require dialysis or a kidney transplant to maintain life. Beneficiaries must be fully insured or entitled to monthly benefits under Social Security or Railroad Retirement programs or the spouse or dependent child of an eligible beneficiary. This entitlement is nearly universal, covering 93 percent of all dialysis patients in the United States.

Many renal organizations claim that Medicare's policies have affected the quality of care provided to dialysis patients. Indeed, the Balanced Budget Act of 1997 (BBA) mandates the Secretary of Health and Human Services to develop "methods to measure and report on quality of renal dialysis services provided under Medicare (BBA 1997)." This is not the first time Congress has shown an interest in the quality of ESRD care. The Omnibus Budget Reconciliation Act of 1987 requested the Institute of Medicine (IOM) study aspects of the Medicare ESRD program, including the effect of reimbursement on quality of care (IOM 1991).

The Department of Health and Human Services oversees quality assessment and assurance in the ESRD program through both the Health Care Financing Administration (HCFA) and the Public Health Service. Traditionally, rates of mortality and hospital admission were used to measure quality of care. In the past decade, additional clinical indicators have emerged, including the adequacy of dialysis and patients' anemia and nutritional status.

This chapter presents recent evidence on the quality of renal dialysis in the United States and offers recommendations to improve the quality of dialysis care. Specifically, the Medicare Payment Advisory Commission (MedPAC) recommends that the Secretary of Health and Human Services:

- study alternative approaches to paying for dialysis to increase the dose of dialysis.

- cover nutritional supplements for malnourished ESRD patients as a renal benefit.
- consider the quality assessment and assurance efforts of renal organizations.

Patient population and treatment

During the first quarter-century of the Medicare ESRD program, the number of beneficiaries with ESRD increased nearly 30-fold, from approximately 10,000 people in 1973 to nearly 290,000 at the end of 1996. Until the early 1970s, patients receiving continuous renal replacement therapy usually were restricted to the relatively young without systemic illnesses. As clinical experience accumulated and treatment techniques improved, older patients and those with coexisting illnesses also were treated. Consequently, the demographic and clinical characteristics of the ESRD patient population have changed significantly over time.

For example, in 1996, patients age 65 and older constituted nearly half of all new ESRD patients, compared with one-quarter of all patients in 1978. Diabetes, a contraindication to treatment 30 years ago, is now the leading cause of ESRD and accounts for nearly 40 percent of new patients, compared to one-fifth of new patients in 1978.

At current rates of annual growth, HCFA estimates the ESRD population will nearly double every 10 years (HCFA 1998a). This prediction is not surprising, given the aging U.S. population, the increase in the incidence of diabetes with age, and the overall increase in the incidence of type II diabetes in the United States in the latter half of the 20th century.

The incidence of treated ESRD has increased worldwide since 1986. The United States had the highest incidence of treated ESRD, 276 patients per million population, in 1996. Japan (226 patients

per million) and Germany (153 patients per million) follow (USRDS 1998). Canada, France, Sweden, and Austria have treatment rates about one-half that of the United States. These varying rates reflect differences in the known proportion of patients accepted for treatment in each country. For example, the median age for treatment in the United States is very high relative to those of other countries. Studies also suggest the ESRD population in the United States has more comorbid conditions and that beyond the United States, larger proportions of women, elderly, and racial minorities die untreated (Friedman 1996). Prevalence of ESRD also varies among the United States and other countries. Japan had the highest prevalence of ESRD (1,397 per million), followed by the United States (1,131 per million) in 1996.

Before 1960, no treatment other than dietary modification was available. Since then, types of treatment options for patients with ESRD have grown to include hemodialysis, peritoneal dialysis, and transplantation. Despite payment policies that encourage home dialysis, in-center hemodialysis has been the most common treatment method in the United States for the past decade, with 61 percent of ESRD patients undergoing this procedure. Less than 1 percent of patients undergo home hemodialysis. About 10 percent undergo peritoneal dialysis, which includes continuous ambulatory and continuous cycling peritoneal dialysis. Finally, 27 percent of patients have a functioning kidney transplant (USRDS 1998).

During therapy for renal failure, patients may move from one treatment to another. Many factors influence the choice of treatment, including distance to a dialysis center; personal preference; and patients' education, socioeconomic status, comorbid conditions, and age. Nearly half of all children undergo peritoneal dialysis (mostly continuous cycling peritoneal dialysis), while hemodialysis use increases with age. Younger patients are more likely than older patients to receive kidney transplants.

Quality of dialysis care

The years since inception of the ESRD program have been distinguished by remarkable clinical achievements that have prolonged and improved the quality of life of affected patients.

Notwithstanding these achievements, renal researchers and organizations are concerned about the effect of Medicare's payment and coverage policies on quality of dialysis care. One issue is the contribution of the composite rate, which has not increased since 1991, to the inadequate dialysis researchers report. Medicare's coverage policies for interventions to treat anemia and malnutrition also may affect quality of care.

Because dialysis payments have not increased since 1991, MedPAC is concerned about the quality of dialysis care. In this section, we examine recent evidence of the quality of dialysis care, as measured by the following quality indicators:

- clinical outcomes, including the adequacy of dialysis and patients' anemia levels and nutritional status;
- morbidity, measured by rates of hospital admission; and
- mortality.

Quality measures for dialysis care

A prominent concept for measuring quality includes evaluating structure, processes, and outcomes of care (Donabedian 1966). Structures of care refer to the basic provisions of medical care, including the characteristics of providers, patients, and the health care system. Processes of care include both technical and behavioral aspects of medical care, such as the diagnosis, prescription, and delivery of treatment to patients, as well as the personal interactions between patients and clinicians. Outcomes of care include

mortality, rates of hospital admission, clinical outcomes, and patients' functional status, well-being, satisfaction, and quality of life.

Considerable uncertainty surrounds the measurement of quality of care—in any given clinical setting—as well as how best to convey information about quality to providers, payers, and patients. For dialysis patients, quality measurement traditionally has emphasized mortality and morbidity, as measured by rates of hospital admission. More recently, several biochemical markers related to morbidity and mortality have emerged as outcome measures; they measure adequacy of dialysis, anemia levels, and the nutritional status of patients.

Adequacy of dialysis

Adequate dialysis is defined as the amount of dialysis required to treat ESRD so that patients receive the full benefit of dialysis therapy. Adequacy is influenced by a number of patient-related factors (such as comorbidities, compliance with the prescribed dialysis regimen, adherence to salt and water intake limitations, and weight) and technical factors (such as duration and frequency of dialysis, vascular access, choice of dialyzer membrane, and blood and dialysate flow rate).

Inadequate dialysis shortens survival and leads to malnutrition, functional impairment, and decreased quality of life (Ifudu et al. 1998). A recent study also reported that increasing the level of dialysis in patients receiving inadequate dialysis improves their anemia status (Ifudu et al. 1996). Many renal organizations, as well as the IOM in its 1991 seminal report on the quality of ESRD care, have questioned whether Medicare's reimbursement system, in general, and the structure of the composite rate, in particular, have contributed to the delivery of inadequate dialysis. Prompted by an annual mortality rate approaching 25 percent among dialysis patients, a Consensus Development Conference Panel of the National Institutes of Health (NIH)

concluded that “the dose of hemodialysis and peritoneal dialysis has been suboptimal for many patients in the United States,” and it called for an increase in the dialysis dose (Consensus Development Conference Panel 1995).

Two measures of adequacy of dialysis are the urea reduction ratio and Kt/V. The urea reduction ratio is the percentage reduction in blood urea nitrogen concentration during a single dialysis session and is usually measured once per month. Kt/V is a dimensionless index based on the dialyzer clearance rate (K), the time spent on dialysis (t), and the volume of fluid completely cleared of urea in a single treatment (V). The National Kidney Foundation (NKF), NIH, Renal Physicians Association (RPA), and HCFA have advocated a urea reduction ratio of 65 percent or more or a Kt/V of 1.2 or more as a threshold for adequate dialysis. Lower levels are associated with increased mortality, although the dose of dialysis beyond which further reductions in mortality do not occur is not well established.

Average values of the urea reduction ratio and Kt/V have steadily improved during this decade, according to clinical outcomes data HCFA has collected. For example, among hemodialysis patients, the average urea reduction ratio increased from 63 percent in 1993 to 68 percent in 1997 (HCFA 1994, HCFA 1998b). Despite these improvements, however, inadequate dialysis persists in over 30 percent of hemodialysis patients, suggesting the need for continued improvement in the delivered dose of dialysis. Specifically, 18 percent of patients had a urea reduction ratio of 60 to 64 percent, and 15 percent had a urea reduction ratio less than 60 percent (HCFA 1997).

The following discussion focuses on hemodialysis (because nearly 85 percent of all dialysis patients undergo this procedure) and examines potential changes to the composite rate that might increase dialysis dose.

Adjusting the composite rate based on the duration and frequency of dialysis treatment

As stated previously, duration of dialysis is an important element affecting adequacy (Held et al. 1991, Laird et al. 1983). Several studies have shown that mortality in patients treated with hemodialysis is partly influenced by the length of hemodialysis sessions. For example, results from a retrospective analysis suggest an increase in mortality among patients whose thrice-weekly hemodialysis treatments were shorter than 3.5 hours each (Held et al. 1991). Lowrie and Lew analyzed data on a sample of more than 12,000 patients and found that shorter treatment times were associated with higher mortality (Lowrie et al. 1990). Improved outcomes also have been reported in hemodialysis patients receiving extremely long (such as eight hours three times a week) or more frequent treatments (five to seven times per week) (Charra et al. 1996, Kjellstrand et al. 1998a, Kjellstrand et al. 1998b).

The length of hemodialysis treatment ranges from 3 to 4 hours per session. Overall, in the past 20 years, the length of dialysis sessions in the United States has decreased because of a number of factors, including the development of such new technologies as high-efficiency polymer membranes, which permit more rapid dialysis treatments; patient compliance; and the reduction in real dialysis payments (Held et al. 1990, Pastan et al. 1998). On the other hand, based on the evidence that shorter dialysis sessions may result in greater mortality, the length of dialysis treatments appears to be slowly increasing, from an average of 3.3 hours per session in 1993 to 3.5 hours per session in 1996 (HCFA 1994, HCFA 1999a).

Under Medicare, dialysis facilities are paid a composite rate, a prospective fixed amount for each dialysis treatment they provide. This rate does not vary

according to patient characteristics or the content of the service provided, including the length of dialysis. In general, providers may bill Medicare for no more than three dialysis sessions per week. As set forth in 42 CFR 413.182 through 413.192, HCFA may approve exceptions to a facility's dialysis payment rate using the following criteria: atypical service intensity (patient mix), isolated essential facilities, extraordinary circumstances (such as earthquakes, floods or other natural disasters), self-dialysis training costs, or frequency of dialysis (for fewer than three treatments per week). No extra payment is made for longer or more frequent dialysis treatments that might be required in certain patients.

This reimbursement policy differs from the methods used to pay for physician and inpatient hospital care. For example, payment for physician evaluation and management services is based on seven components designed to account for a number of factors, including the length of the visit, the complexity of medical decisionmaking required, the risk of complications, and the number of diagnoses or management options. In the inpatient hospital prospective payment system, reimbursement is based on diagnosis related groups, which account for how the presence of substantial complications or comorbidities affects the consumption of hospital resources and the presence or absence of many surgical procedures.

RECOMMENDATION 8A

The Secretary should determine clinical criteria for dialysis patients to receive increased frequency or duration of dialysis. The Secretary should then examine the feasibility of a multitiered composite rate that would allow different payments based on the frequency and duration of dialysis prescribed, as well as other factors related to adequacy of dialysis.

A multitiered composite rate would pay dialysis facilities more for providing longer or more frequent dialysis sessions. An important advantage of this system is that increases in dialysis payments would be specifically allocated to extend dialysis treatment times. Clearly, a multitiered composite rate would be more complex to implement than the existing single rate. Medicare would need to develop clinical criteria for determining which patients would qualify for additional payment for longer or more frequent dialysis sessions. Medicare already collects one measure of dialysis adequacy, the urea reduction ratio, and the program would need to determine what other types of clinical information would need to be collected. These clinical criteria should be developed in collaboration with renal organizations.

Several studies have concluded that higher payments may be needed to increase the length of dialysis sessions. Hirth and colleagues concluded that for the average facility, increasing treatment duration by 10 percent would increase costs by 2.7 percent and that longer dialysis treatments may be the most economical method of increasing the adequacy of dialysis (Hirth et al. 1999). In an earlier study, Held and colleagues examined the effect of the 1983 composite rate reduction on hemodialysis treatment times (Held et al. 1990)¹. After the payment reductions in 1983, average treatment times decreased by 6 percent, to 4.7 hours from 5.0 hours, in freestanding facilities and decreased by 8 percent, to 4.7 hours from 5.1 hours, in hospital units.

Increasing the composite rate

Would dialysis adequacy change by simply increasing the composite rate? In a recent survey, researchers at the Johns Hopkins University posed a series of hypothetical reimbursement scenarios to a nationally representative

1 Payment for outpatient dialysis was capped at a uniform flat rate of \$138 per treatment from 1973 to 1983. In 1983, Medicare enacted a series of policy changes, including reducing the composite rate to an average of \$129. This policy change resulted in reductions of approximately 9 percent in the approved charge per dialysis treatment for freestanding facilities and 11 percent in the approved charge for hospital units.

RECOMMENDATION 8B

MedPAC reiterates its recommendation made in its March 1998 and March 1999 reports calling for an increase in the composite rate.

The Commission believes that any increase in the composite rate should be used to improve the quality of care for patients with ESRD.

Anemia

Among ESRD patients, anemia primarily results from a relative or absolute deficiency of erythropoietin production by the kidneys, develops early in the course of renal failure, becomes prominent as the disease progresses, and contributes to morbidity. Before the availability of recombinant human erythropoietin (rHuEPO or Epoetin alfa), which stimulates the production of red blood cells and treats anemia associated with ESRD, the mainstays of anemia therapy in ESRD were blood transfusions and androgen injections. A recombinant version of the human protein, rHuEPO has improved quality of life and various physiological functions, including cognitive function and exercise tolerance. Since its introduction, rHuEPO has diffused relatively quickly among dialysis patients—84 percent of patients incident to hemodialysis received rHuEPO in 1996 (USRDS 1998).

As part of its Dialysis Outcomes Quality Initiative (DOQI), the National Kidney Foundation (NKF) developed clinical guidelines for managing and monitoring anemia in dialysis patients. The guidelines include information about a number of management issues, including when an anemia work-up should be conducted, administration of rHuEPO, and administration of supplemental iron. The NKF also recommends a target hematocrit range of 33 percent to 36 percent and notes that a hematocrit greater than 30 percent has been associated with increased survival and improved quality of life (NKF 1997).²

sample of facility administrators (Thamer 1999). Asked how they would respond if the composite rate increased by 20 percent, respondents indicated they most likely would: 1) increase patient education, 2) increase capital investment, and 3) increase staffing. “Changing dosing of dialysis,” one of the available answers permitted in this survey, was not among the most frequently reported responses. Significantly, however, this survey did not include nephrologists, who direct dialysis-related care, including prescribing the dialysis dose.

Patient education, staffing, and capital investments are clearly linked to the adequacy of dialysis. Patient education programs increase patients’ understanding of ESRD, their acceptance of the nature of their disease, and their ability to make choices about treatment—including their compliance with the prescribed dialysis regimen. Dialysis patients have reported that education is vital to them at all stages of their treatment by giving them the tools they need to take active and effective roles in their treatments (IOM 1991). Patients ranked information about the details of daily care, nutrition and diet, different treatment modalities, finances and insurance, and family issues as very important.

Researchers have reported a relationship between reduced dialysis payments and facility staffing, including the substitution of technicians for registered nurses and the decreased availability of social workers and dieticians (Held et al. 1990, IOM 1991). Registered nurses, social workers, and dieticians each play a valuable role in the management of dialysis patients. In one study, for example, dialysis patients indicated that the availability of and the information provided by these providers were very important aspects of their care (Rubin et al. 1997). Changes in the number and composition of dialysis staffs do not by themselves indicate that patient outcomes

have been adversely affected. Additional research is needed to understand the effect of these staffing changes on quality of care.

Compliance is a critical issue in managing the care of dialysis patients. The time required for adequate dialysis disrupts the day-to-day activities of patients. Younger patients and patients new to dialysis are more likely to skip sessions or terminate treatments early, resulting in inadequate dialysis. In an international evaluation of hemodialysis patient compliance, United States patients were more likely not to comply than patients in Japan and Sweden. In four facilities, U.S. patients missed 2.3 percent of prescribed treatments (Bleyer et al. 1999). Even an occasionally missed dialysis treatment places patients at a much higher risk for serious renal complications, including volume overload and hyperkalemia. Ultimately, additional patient education and more staffing may increase compliance with the prescribed treatment regimen, thereby improving the adequacy of dialysis.

Capital investment also is linked to the adequacy of dialysis. The Commission’s review of new and emerging technologies suggests continuing improvements in numerous technologies important in the dialysis process, including synthetic and modified cellulose membranes and urea monitoring, kinetic modeling, and water purification systems (MedPAC 1999). Upgrading to these quality-enhancing technologies is expensive, however, which may affect their rate of diffusion. For example, use of synthetic and modified cellulose dialysis membranes is associated with a reduced risk of death, compared to cellulose membranes, but they are also more expensive (Hakim et al. 1996). These newer membranes have diffused gradually, from 33 percent in 1990 to 55 percent in 1993 and 79 percent in 1996–1997 among incident hemodialysis patients (USRDS 1999). Use of these membranes also widely varies by geographic region.

2 Hematocrit is the fraction of total blood volume made up of red blood cells.

Average hematocrit levels of dialysis patients have increased in this decade, from 30.5 percent in 1993 to 33.2 percent in 1997 (HCFA 1998). However, despite the wide diffusion of rHuEPO and the dissemination of the DOQI guidelines on anemia management and monitoring to providers, nearly 30 percent of hemodialysis patients had hematocrit levels lower than 30 percent in 1997 (HCFA 1998). Other factors contributing to anemia include inadequate dialysis dose, iron deficiency, infection and inflammation, occult gastrointestinal blood loss, hyperparathyroidism, vitamin deficiency, hemolysis, and bone marrow disease (Ifudu et al. 1996).

Medicare's policies also have influenced the management of anemia in dialysis patients. From 1989 to 1991, Medicare's fixed payment policy resulted in lower prescribed doses of rHuEPO than suggested by the labeling approved by the Food and Drug Administration, which recommends a starting dose of 3,400 to 6,800 units per treatment (assuming an average patient weight of 68 kilograms). By contrast, in 1990, the average dose ranged from 2,500 to 2,800 units per treatment (Collins et al. 1998).

Consequently, Congress changed payment from a flat rate per dose to a unit-dependent rate of \$11 per 1,000 units in 1991. For patients initiating use of rHuEPO, HCFA reimbursed its use only for patients with hematocrit levels up to 30 percent (unless medical justification showed the need for rHuEPO, despite levels greater than 30 percent). For patients already using rHuEPO, HCFA reimbursed its use for patients with hematocrit levels no higher than 36 percent. Medical providers could submit statements of medical justification for rHuEPO use exceeding these standards. These policy changes increased rHuEPO dosage levels, from 2,700 units in 1990 to 3,800–4,000 units in 1993 for patients with hematocrit levels less than 30 percent (Collins et al. 1998). In 1993, based on a

recommendation from the Office of Inspector General, the rHuEPO payment rate was reduced to \$10 per 1,000 units. This change did not result in a noticeable change in rHuEPO dosing patterns.

In July 1997, HCFA implemented the Hematocrit Measurement Audit policy, directed at increasing the stability of hematocrit levels. Under this policy, the agency did not allow payment for rHuEPO for patients with hematocrit levels exceeding 36.5 percent, based on a three-month rolling average. This policy specifically required intermediaries to identify patients with hematocrit levels (reported on rHuEPO claims) exceeding 36 percent and calculate their average levels in the prior 90 days. If this average level exceeded 36.5 percent, the fiscal intermediary denied payment for rHuEPO. The new policy also eliminated medical justification for patients with hematocrits greater than 36 percent.

Many experts in the renal community believe this policy led to a reduction in average hematocrit levels (Collins et al. 1998, Nissenson et al. 1999). In July 1998, HCFA revised this policy by increasing the threshold hematocrit level to 37.5 percent, conducting post-payment review, and reinstating the policy of appeals based on medical justification. Further follow-up will be needed to determine the impact of this policy change on reimbursement for rHuEPO and patient outcomes.

Nutrition

Malnutrition is a frequent complication of ESRD and is a significant cause of morbidity and mortality in dialysis patients. It factors into a decreased response to dialysis therapy, more frequent hospitalization, less successful recovery from surgery, trauma, infection, and an increased risk of mortality. Surveys of the nutritional status of maintenance dialysis patients indicate that from 18 percent to 56 percent of patients suffer from protein-energy malnutrition,

with about 33 percent of patients having clinically recognizable mild-to-moderate malnutrition and 6 percent having severe malnutrition.

Serum albumin level is a clinical marker frequently used to assess the nutritional status of patients. Albumin levels lower than 3.5 gm/dL (based on the bromocresol green laboratory method) are associated with increased mortality compared with higher levels of serum albumin. According to HCFA, about 20 percent of hemodialysis patients had serum albumin levels less than 3.5 gm/dL in 1997. Unlike the improvements HCFA reported from 1993 to 1997 in dialysis patients' adequacy and anemia status, serum albumin levels have shown no clinically important changes in this same time period (HCFA 1998b).

Available medical interventions to prevent or treat malnutrition in dialysis patients include:

- intradialytic parenteral nutrition (IDPN) for hemodialysis patients,³
- intermittent parenteral nutrition (IPN) for peritoneal dialysis patients,
- oral nutritional supplements,
- enteral tube nutrition, and
- total parenteral nutrition.

Medicare's coverage policy severely limits the number of ESRD patients who qualify for these treatments, for the reasons below (Knerr et al 1991, McCann 1994). Because of the prevalence of malnutrition in ESRD patients, Medicare should cover nutrition therapy for patients with ESRD.

RECOMMENDATION 8C

The Secretary should determine clinical criteria for ESRD patients to be eligible for oral, enteral, or parenteral nutritional supplements. Coverage for these supplements should then be provided to eligible ESRD patients as a renal benefit apart from the composite rate.

3 Intradialytic parenteral and intermittent parenteral nutrition treats malnutrition during dialysis by adding amino acids to the hemodialysate or peritoneal dialysate, respectively, providing an intermittent source of protein.

Many renal providers believe that IDPN and IPN have distinct clinical advantages for managing malnutrition compared with the alternative nutritional interventions.⁴ Several observational studies suggest improved outcomes associated with IDPN use (Capelli et al. 1994, Chertow et al. 1994, Foulks 1994), but Medicare's policy limits the number of dialysis patients who qualify for these interventions because IDPN and IPN are classified as prosthetic devices, with coverage limited to patients with a nonfunctioning gastrointestinal tract.⁵ In dialysis patients, in contrast, the primary barrier to adequate nutrition is inadequate intake of protein and calories (Kopple 1999).

Medicare's coverage policies also limit the use of enteral tube feeding. As with IDPN and IPN, enteral tube feeding is classified as a prosthetic device and therefore restricted to patients with a nonfunctioning gastrointestinal tract.⁶ A statutory change will be necessary for coverage of enteral tube and parenteral nutrition because the Social Security Act specifically defines prosthetic devices as devices that replace all or part of an internal body organ. Because Medicare does not pay for oral nutritional supplements at all, a statutory change also would be required to provide coverage.

Inpatient hospitalization

Hospitalization rates may reflect the quality of dialysis care because patient morbidity significantly affects the frequency and duration of hospital care. Medicare coverage and payment policy also may affect rates of hospital admission. The relevant questions are:

- Whether the level of payment influences the level of resources available for dialysis.
- Whether less adequate treatment leads to increased morbidity, as indicated by higher rates of hospitalization and longer stays.

The IOM's 1991 report compared two prevalent patient groups for 1982 and 1984 and suggests a relationship between changes in the rate of dialysis payment and hospitalization and mortality (see mortality results in the next section).⁷ Using a price-level model, researchers estimated that a decrease of \$10 in the standardized price of dialysis leads to a 2 percent to 4 percent increase in hospitalization. However, a first-difference model does not detect a correlation between price change and hospital use (IOM 1991).

Overall, the mean number of hospital admissions for dialysis patients remained stable from 1993 through 1996, ranging from 1.45 to 1.49 per calendar year per dialysis patient (USRDS 1998). Mean hospital days have fallen about 11 percent over the same period. In 1996, about 25 percent of dialysis patients were hospitalized once, and 35 percent were hospitalized more than once.

In addition to chronic renal failure, the leading reasons for hospital admission are in Table 8-1. Patients frequently are hospitalized for complications of dialysis such as electrolyte disorders, vascular access problems, and anemia, and for underlying causes or comorbid conditions associated with ESRD, such as diabetes, congestive heart failure, and hypertension (Thamer et al. 1996).

As expected, renal failure patients are more likely to be hospitalized for

complications of dialysis compared with patients with other chronic, progressive diseases. For example, these patients are at five to nine times the risk of being hospitalized for anemia and electrolyte disorders, compared to patients with ischemic heart disease or diabetes. Despite the impressive technical advances in dialysis, such as improvements in dialysis machines, water purification systems, and the composition of dialysate, inpatient hospitalization remains high among dialysis patients.

Mortality

Despite an aging population that includes a greater proportion of persons with diabetes, survival of dialysis patients has improved steadily in the 1990s. The adjusted annual death rate for dialysis patients fell to 22 deaths per 100 patient-years in 1996 from 26 deaths per 100 patient-years in 1989. The adjusted five-year rate for survival patients has improved to 29 percent in 1991 from 24 percent in 1981 (USRDS 1998).

Cardiovascular disease accounts for about 50 percent of all deaths in dialysis patients, while infections account for 15 percent of deaths. Nearly one in five patients withdraws from treatment before death, with many more older patients withdrawing than younger patients (USRDS 1998).

Many clinical factors contribute to mortality in kidney failure patients, including inadequate dialysis, suboptimal quality control in dialysis delivery, inadequate nutrition, and the presence of selected comorbidities. For example, patients with diabetes have significantly poorer survival than patients with hypertension, glomerulonephritis, and polycystic kidney disease (Byrne et al. 1994).

4 Reported clinical advantages of these treatments include: (1) a central venous line (used in total parenteral nutrition) is not needed, (2) the removal of excess water and mineral intake during dialysis, and (3) a high protein-to-calorie ratio corrects a disproportionate deficit in the intake of dietary protein.

5 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" (HCFA 1999b).

6 Enteral tube nutrition is limited to patients with a "functioning gastrointestinal tract who, due to pathology to or nonfunction of the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition" (HCFA 1999b).

7 The IOM developed two models. The price-level model analyzes whether hospitalization and mortality rates associate with variations in price levels among facilities at a given time. This model analyzes whether rates are higher at facilities receiving lower standardized payments during a specific year. The first-difference model uses each facility as its own control by comparing rates in each facility at two different times. This model analyzes whether the rate at a facility changed when the payment it received changed.

**TABLE
8-1**

Reasons for hospitalization of patients with renal failure, 1991

Reason for hospitalization	Rate of hospitalization (per year per 10,000 patients with renal failure)	Relative risk of hospitalization compared to patients with ischemic heart disease	Relative risk of hospitalization compared to patients with diabetes
Vascular access problems	1055.6	81.6*	28.7*
Congestive heart failure	943.2	8.9*	6.7*
Diabetes	348.9	10.6*	1.0
Pneumonia and influenza	331.6	4.8*	2.9
Electrolyte disorders	286.9	10.6*	5.1*
Myocardial infarction	276.9	1.1	2.5
Ischemic heart disease	269.5	0.5	1.5
Cerebrovascular disease	179.9	3.2*	1.6
Pulmonary edema and respiratory failure	173.8	12.4*	6.2*
Sepsis and septicemia	173.3	13.1*	3.9*
Gastrointestinal hemorrhage	162.4	15.8*	10.5*
Hypertension	154.6	5.1*	2.7
Conductive disorders	132.8	2.0	2.2
Urinary tract infection	102.6	9.0*	2.6
Anemia	92.2	8.9*	5.0*

Note: These rates are based on the first-listed diagnosis on hospital discharge forms for patients in the third (chronic renal failure) and fourth (ESRD) stages of chronic renal disease. They are adjusted for age by the indirect method to reflect the distribution of the US population in 1991.

*Statistically significant at $p < 0.05$.

Source: Thamer M, Ray NF, Fehrenbach SN, et al. Relative risk and economic consequences of inpatient care among patients with renal failure, *Journal of the American Society of Nephrology*. May 1996, Vol. 7, No. 5, p. 751-762.

result from differences in the consistency of data reporting and the types of information systems for maintaining the collected data. During the past two decades, the United States has developed extensive databases of information on ESRD patients' demographic and clinical characteristics, courses of care, and outcomes. Conversely, researchers have noted a consistent underreporting of deaths from renal failure in many European countries (Friedman 1996).

Although population characteristics and different protocols for treating patients explain some of the observed differences in ESRD mortality rates, several studies controlling for treatment modality and important demographic covariates have concluded that mortality rates still appear to be higher in the United States than in other countries (Hornberger et al. 1997, Marcelli et al. 1996). Other studies also suggest that the hemodialysis dose prescribed and delivered in the United States is lower than recommended and lower than those in other countries (Delmez et al. 1992, Gotch et al. 1990, Held et al. 1994, Sargent 1990).

A large, current observational study, the Dialysis Outcomes and Practice Patterns Study, examines differences in dialysis practice patterns and outcomes in the United States, five European countries (France, Germany, Italy, Spain, and the United Kingdom), and Japan and may explain these observed mortality differences. This study also will examine how specific clinical practice patterns affect other outcomes, including rates of hospital admission, vascular access, and quality of life. Researchers are collecting data for 4,800 patients in the United States, 3,000 patients in Europe, and 1,800 patients in Japan.

Quality assurance and assessment projects

During the past two decades, public and private organizations have conducted numerous projects to monitor and analyze the quality of ESRD care. In 1978, Congress established the ESRD networks to provide regional oversight for

The IOM's 1991 report compared two prevalent patient groups for 1982 and 1984 and found a suggestive relationship between changes in the dialysis payment rate and mortality (IOM 1991). Using a price-level model, researchers found that higher standardized dialysis payments related to lower mortality rates. However, using a first-difference model, they did not detect a correlation between price change and mortality rates.

Many studies indicate that mortality rates among ESRD patients in the United States are 20 percent to 50 percent higher than in other countries (Friedman 1996). In general, it is difficult to determine whether this difference is a statistical artifact or whether it reflects real differences in the quality of patient care. Several factors may explain cross-

national differences including: differences in population characteristics, access to care, medical practice patterns, data reporting, and information systems. The United States has the highest rate of treated ESRD patients per million population, and it treats patients who are older and sicker and have more coexisting conditions than patients in other countries. Practice patterns—including treatment modality, dose of dialysis, use of reprocessed dialyzers, and types of dialyzer membrane used—also differ between the United States and other countries. The kidney transplantation rate is higher in the United States than other countries, such as Japan, where relatively young, healthy patients do not receive transplants and instead remain on dialysis. Finally, cross-national differences in mortality rates

Medicare-approved dialysis and transplantation facilities. The 18 current networks are funded by withholding 50 cents per treatment from the payment to dialysis facilities. The National Forum of ESRD Networks facilitates the exchange of information among the 18 regional networks, the renal providers, and HCFA, and promotes improved quality of care through education and the collection, analysis, and dissemination of data.

HCFA sponsors many efforts, described in Table 8-2, to monitor and assess the quality of ESRD care.

In response to the BBA requirement to develop a method to measure and report the quality of renal dialysis services under Medicare, HCFA has developed clinical performance measures based on the NKF DOQI guidelines. They include five hemodialysis adequacy measures, three peritoneal dialysis measures, four vascular access measures, and four anemia management measures. HCFA uses these clinical performance measures for population-based quality improvement rather than as tools to evaluate the care of specific patients or as standards for quality assurance. The agency is collecting data to measure clinical performance for a nationally representative sample of adult dialysis patients and is considering the feasibility of disseminating facility-specific data for several of these clinical performance measures.

MedPAC supports the past and current efforts by HCFA and the USRDS to measure and monitor the quality of dialysis care. Their continued collection, analysis, and dissemination of quality indicators help the renal community to closely monitor patient care and outcomes. Collecting clinical performance measures should assist in future efforts to analyze the quality of dialysis care.

Private efforts by several renal organizations also have enhanced the quality of ESRD care. The nephrology community has developed several clinical practice guidelines to assist clinicians who care for ESRD patients. RPA published the

TABLE 8-2

Current renal quality initiatives sponsored by HCFA

Quality initiative	Goal of program
End-Stage Renal Disease Health Care Quality Improvement Program	To improve the health of Medicare beneficiaries. Since 1994, HCFA has monitored quality in its ESRD Core Indicators Project, which collects clinical information annually on four key indicators (adequacy of dialysis, hematocrit value, nutritional status, and blood pressure control) on a national sample of adult in-center hemodialysis and peritoneal dialysis patients.
Clinical performance measures project	To develop clinical performance measures, which essentially will replace the quality indicators used in HCFA's ESRD Core Indicators Project. The project also will measure and report on the quality of Medicare's renal dialysis services, as the BBA required.
Demonstration project on ESRD capitated care	Required by the Omnibus Budget Reconciliation Act of 1993 to determine if high-quality ESRD care can be delivered in a globally capitated payment system. Demonstration sites include Southern California (Kaiser Permanente), Nashville (Phoenix Healthcare), and Southern Florida (Health Options).
Standard Information Management System Project	To permit electronic transfer of standardized information from dialysis facilities to the ESRD networks and HCFA.
United States Renal Data System	Operated by the National Institute of Diabetes and Digestive and Kidney Diseases with HCFA. The system collects, analyzes, and distributes information on the incidence and prevalence of treated ESRD, modality of treatment, causes of death, patient survival, and hospitalization in its annual reports and special studies.

Source: Data compiled by MedPAC, 1999.

first guideline on adequacy of hemodialysis in 1993 (RPA 1996). The NKF DOQI then developed four practice guidelines on adequacy of hemodialysis, adequacy of peritoneal dialysis, vascular access management, and anemia treatment, and is developing a fifth guideline on nutrition, expected to be published later this year. Numerous renal organizations, including the NKF, RPA, and the American Association of Kidney Patients, educate patients and providers about ESRD.

RECOMMENDATION 8D

In fulfilling the requirements of the BBA regarding improving the quality of dialysis care, the Secretary should take into consideration the quality assessment and assurance efforts of renal organizations.

MedPAC's research workplan

As required under its mandate, the Commission will continue to address ESRD payment and quality issues in the coming year.

How Medicare's payment policies affect quality of care

MedPAC will continue its research efforts to explore the relationship between payment methods and levels and quality of care. In 1998, HCFA began requiring providers of hemodialysis to report the urea reduction ratio monthly for every patient. These data may permit retrospective analyses of the association between dialysis adequacy and the use of health care services, including the risk,

rates, and causes of hospital admission. Another important issue relates to the effect of Medicare's policies on the diffusion of certain dialysis modalities. For example, patients on daily home hemodialysis have improved their quality of life. Medicare's reimbursement policy poses a barrier to its diffusion, however, because it caps payment for most patients at an amount equal to the cost of providing three hemodialysis sessions per week.

How Medicare payment policies affect innovation

Little is known about the effect of Medicare payment policies on innovation and technological change. Numerous innovations in membranes, dialysate, and other dialysis-related technologies occurred from the mid-1960s to the early 1980s, partly sponsored by the NIH Artificial Kidney and Chronic Uremia program. In its 1991 report on quality of renal care, the IOM suggested that unchanged dialysis payments, which

initially encouraged providers to adopt cost-reducing and more efficient technologies, appear to restrict further technical improvements (IOM 1991). Previous Commission analyses suggest that the substantial innovation in hemodialysis and peritoneal dialysis care in the 1980s and first half of the 1990s, such as the development of high flux dialyzers and synthetic hemodialysis membranes, has slowed in the late 1990s (MedPAC 1999). More research should study the effect of payment on innovation and technological improvement. ■

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