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**United States**
**General Accounting Office**
**Washington, D.C. 20548**

**Health, Education and Human Services Division**

B-277455

July 11, 1997

The Honorable Pete Stark
Ranking Minority Member
Subcommittee on Health
Committee on Ways and Means
House of Representatives

Dear Mr. Stark:

Subject: Medicare: Data Limitations Impede Measuring Quality of Care in Medicare ESRD Program

Several research studies indicate that care furnished to Medicare beneficiaries with end-stage renal disease (ESRD) does not meet established standards. Patients undergoing dialysis, the most common form of therapy, are often anemic, undernourished, experience complications, or die prematurely. At least one of these studies concluded that differences in patient mortality among dialysis providers is related to differences in the characteristics of dialysis facilities rather than those of patients.[1] Some providers and renal disease experts are also concerned about the influence of various provider ownership and financial arrangements on the quality of care furnished to ESRD patients. For example, in 1991 the Institute of Medicine (IOM), an advisory body that examines issues related to public health, expressed concern that the federal government was not monitoring the health care quality implications of the growth in for-profit dialysis facilities and those owned by large chains.[2] More recently, some dialysis providers have alleged that ESRD patients belonging to health maintenance organizations (HMO) receive poorer care than patients belonging to the standard Medicare ESRD program. These latter concerns have

[1]William McClellan and J. Michael Soucie, "Facility Mortality Rates for New End-Stage Renal Disease Patients, American Journal of Kidney Diseases, Vol 24, No. 2 (Aug. 1994), pp. 280-89.

[2]IOM, Kidney Failure and the Federal Government, Richard Rettig and Norman Levinsky, eds. (Washington, D.C.: National Academy Press, 1991), pp. 159-63.



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become more immediate because the Congress is considering legislation to lift the current restriction against ESRD patients joining Medicare HMOs with risk contracts.[3]

Because of your concerns about the quality of care furnished to Medicare ESRD patients, you asked us to (1) identify accepted performance standards for measuring quality of care provided ESRD patients; and (2) using these performance standards, compare the quality of care furnished to ESRD patients between providers such as chain-affiliated and unaffiliated dialysis facilities, and between HMOs and providers paid through the standard Medicare ESRD program.

To attempt to answer these questions, we interviewed ESRD experts and reviewed relevant literature about measuring the quality of care furnished to ESRD patients. We also investigated several data sources that potentially could be used to analyze the differences between various provider types. These sources included the ESRD Core Indicators Project results for 1993, 1994, and 1995 conducted by the Health Care Financing Administration (HCFA), which administers the Medicare program, and special studies conducted by the United States Renal Data System (USRDS) Coordinating Center, which maintains extensive data on patient characteristics and treatment for all ESRD patients.[4] For this study, we elected to use the Core Indicators Project data because they included the most recent available data (1995) containing indicators that measure clinical factors that most experts considered to be related to outcomes for ESRD patients. We also obtained data from HCFA files identifying all ESRD beneficiaries enrolled in Medicare risk HMOs. We did our work between May 1996 and June 1997 in accordance with generally accepted government auditing standards.

In summary, we found that most experts we interviewed and applicable literature we reviewed agree that clinical indicators measuring dialysis

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[3]HMOs with Medicare risk contracts are paid an amount fixed in advance by Medicare for each beneficiary to provide all Medicare-covered services. Thus, the HMO assumes the financial risk of providing all necessary care in return for the fixed payment amount.

[4]The USRDS was created and is maintained by the Coordinating Center under a contract with National Institute of Diabetes and Digestive and Kidney Diseases. This contract is presently held by the University of Michigan Kidney Epidemiology and Cost Center, which also conducts specific ESRD-related research studies for other sponsors.

effectiveness, anemia, and nutritional status–urea reduction ratio, hematocrit levels, and serum albumin levels, respectively–are valid performance indicators for measuring the quality of care ESRD patients receive.[5] These indicators are currently used by HCFA to evaluate the care furnished to Medicare beneficiaries with ESRD. Almost all experts we interviewed and applicable literature we reviewed also agreed that these indicators were correlated with morbidity and mortality, the ultimate outcome measures.

We were unable, however, to evaluate the differences between the quality of ESRD care furnished in chain-affiliated and unaffiliated dialysis facilities or the care provided by HMOs and providers in the standard Medicare ESRD program because of limitations with data availability. Existing HCFA data about chain affiliation of dialysis facilities is unreliable. When we matched ESRD beneficiaries in HCFA's Core Indicators files with HCFA data on ESRD beneficiaries who belong to HMOs, we found too few beneficiaries belonging to HMOs in each annual sample to give us confidence in the results. Even after we combined the three annual files, the sample size was too small to permit us to make reliable inferences about differences in quality of care between the HMO and non-HMO ESRD populations when comparing beneficiaries with similar characteristics such as age, gender, race, socioeconomic status, and health conditions. If HCFA maintained up-to-date information about the chain affiliations of dialysis facilities and included a larger sample of HMO enrollees in its Core Indicators Project, a comparison could be made of different types of providers and delivery systems that would give us greater confidence in the results. HCFA program officials agreed and said they would consider collecting data to perform these analyses.

## BACKGROUND

ESRD is chronic failure of kidney function. Persons with this degree of kidney disease will die within a short time without long-term kidney dialysis or a kidney transplant. Treatment for chronic kidney failure is very costly. In 1994, Medicare paid a total of about $8.2 billion to treat approximately 242,000 ESRD beneficiaries who received covered services–almost $34,000 per patient. In

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[5]The urea reduction ratio is the ratio of the reduction of the level of blood urea nitrogen, a metabolic toxin, resulting from the dialysis treatment. Hematocrit is a measure of the percentage of total blood volume, which consists of oxygen carrying mature red blood cells. Serum albumin is a measure of the amount of albumin, a simple protein, found in the blood.

contrast, in 1994, the average Medicare expenditure was $4,637 per enrollee without ESRD.

In 1972, 7 years after Medicare was enacted to cover many of the health care expenses incurred by persons 65 years old and older, the Congress enacted legislation that extended Medicare eligibility to persons under age 65 with ESRD.[6] This categorical eligibility was enacted because many persons who could have benefited from dialysis or a transplant died because they could not afford to pay for their care and payments from other sources were inadequate. Under the 1972 provision, most U.S. residents not yet entitled to Medicare who develop ESRD become Medicare eligible 3 months after beginning kidney dialysis.[7] Medicare's ESRD program has grown rapidly since its early years. Between 1978 and 1995, the number of ESRD patients covered by Medicare grew from 45,000 to an estimated 248,000–an average annual increase of more than 10 percent per year. However, very few of these patients are enrolled in Medicare HMOs.

Under current law, a beneficiary diagnosed with ESRD is prohibited from enrolling in a Medicare HMO. However, persons already enrolled in such an HMO when diagnosed with ESRD may remain enrolled in it.[8] By the end of 1995, only about 6,400–2.6 percent of ESRD beneficiaries–were enrolled in Medicare risk HMOs. This percentage is only one-fourth of the percentage of all Medicare beneficiaries enrolled in risk HMOs–10.1 percent at the end of 1995. However, the administration has proposed legislation to end the prohibition. While it does not appear that this proposal will be enacted in 1997, the pending House reconciliation bill includes a requirement for the Department of Health and Human Services to conduct a study and make recommendations. If the administration's proposal is enacted in the future, we

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[6]P.L. 92-603, Social Security Amendments of 1972.

[7]Medicare eligibility can begin sooner if the patient receives a kidney transplant or enters into a course of training for home dialysis.

[8]ESRD beneficiaries, like other Medicare beneficiaries, may elect to disenroll from a Medicare HMO effective the beginning of the next month. However, they then become liable for Medicare coinsurance and copayments, which are substantial for these patients. This can be a significant burden for beneficiaries without some form of secondary health insurance. We do not have estimates of the number of ESRD patients who disenroll from Medicare risk HMOs once diagnosed with ESRD.

believe that the numbers of ESRD patients in HMOs could grow rapidly because the beneficiaries would incur fewer out-of-pocket costs.

Kidney dialysis is the most common form of treatment for chronic kidney failure. The most frequent form of dialysis is hemodialysis, a process that involves passing the patient's blood through a device that removes metabolic poisons and excess fluids. In 1993, 59 percent of ESRD patients received hemodialysis, usually provided in a hemodialysis facility three times per week.[9]

Several studies evaluating the quality of dialysis care for ESRD patients are currently under way. The HCFA Core Indicators Project is a multiyear study intended to improve dialysis care in the United States. For each year since 1993, project staff have selected a random sample of patients from each of HCFA's 18 ESRD network geographic areas.[10] The sample is designed so that the results will support conclusions applicable to each network area and to the nation. For each randomly selected patient, clinical data necessary to measure certain quality indicators are obtained from medical records. These data are analyzed by HCFA and the networks and then given to dialysis centers to be used as a benchmark against which improvements in care can be measured. Data from 1993 through 1995 are now available, and during 1997, the project is collecting data from 1996. Results from this project showed that in 1993–before the adoption of a formal standard–only 43 percent of a nationally representative sample of adult hemodialysis patients received adequate dialysis.[11] Results for 1995, although considerably better, were still poor–only 59 percent of a similar sample of patients received adequate dialysis.

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[9]The other therapies include kidney transplantation (27.3 percent of ESRD patients), peritoneal dialysis (11.3 percent), and home hemodialysis (0.2 percent). Peritoneal dialysis is usually performed by patients in their homes and involves introducing dialysis fluids directly into the patient's abdominal cavity.

[10]The 18 network areas, designated by the Secretary of HHS, cover the nation. In each network area, a network organization under contract to HCFA conducts oversight activities for the appropriateness of services and patient safety for ESRD patients. Two of the 18 networks did not participate in the first year of the project. All networks have participated since then.

[11]Adequate dialysis is defined as a urea reduction ratio of less than or equal to 0.65. This standard was recommended in November 1993 by a consensus conference convened by the National Institutes of Health.

Other studies of ESRD care are also being conducted. The USRDS Coordinating Center is collecting data over time on a large sample of dialysis patients. One of its goals is to characterize the total renal patient population and another is to develop and analyze data on the effects of various treatment modalities by disease and patient group categories. Significant amounts of information have been produced through this effort, some of which corroborates that ESRD patients generally receive poor care. Another national study, also being conducted by the Coordinating Center and funded by Amgen Corporation, is determining the impact of hemodialysis practice patterns on patient outcomes.[12] Data from this study are not yet available.

## HCFA'S CORE INDICATOR PROJECT USES THREE GENERALLY ACCEPTED ESRD QUALITY INDICATORS

Morbidity and mortality are among the often used indicators for outcomes associated with quality care. As a result, when evaluating the quality of care for ESRD patients, many experts rely on indicators that studies have shown to be closely associated with morbidity and premature mortality among dialysis patients. We found that commonly agreed upon indicators of quality are measures of dialysis effectiveness, level of anemia, and nutritional status (urea reduction ratio, hematocrit level, and serum albumin level, respectively).[13] Since 1994, as part of its ESRD Core Indicators Project, HCFA has collected data annually on these indicators to provide a basis for improving care furnished to Medicare ESRD dialysis patients.[14]

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[12]Amgen Corporation is a manufacturer of genetically engineered drugs, including recombinant human erythropoietin (EPO), which is used to treat anemia in dialysis patients.

[13]An alternative, and according to many experts, superior, measure of dialysis effectiveness to the urea reduction ratio is Kt/V. Kt/V, however, requires additional information and must be estimated using a complex formula. A HCFA official told us that in an effort to keep the data collection instrument short, the Core Indicators Project had decided not to collect all the necessary information to calculate this measure. In its comments on this correspondence, however, HCFA said that it will collect all information needed to calculate Kt/V for the 1997 data collection effort.

[14]A work group composed of renal community representatives established to provide guidance to HCFA identified a total of four indicators at the start of the Core Indicators Project. HCFA has dropped the fourth–blood pressure–as a measure of quality because no clinical standard exists for blood pressure

DATA TO EVALUATE QUALITY OF CARE AMONG DIFFERENT PROVIDERS ARE UNAVAILABLE

Because HCFA reimburses dialysis facilities at a fixed rate per dialysis session for patients in the standard Medicare ESRD program, facilities have a strong incentive to control costs.[15] The rate is not increased for inflation and, in fact, has declined in absolute dollars since the current reimbursement method was implemented in 1983. This cost-control incentive may be especially strong in for-profit facilities, which constitute over 60 percent of the total, because they need to pay a return on equity to investors as well as other expenses associated with operating a dialysis facility. Many for-profit dialysis facilities belong to multifacility chains. HMOs have a similar incentive to control costs because they are fully capitated for all care provided to an ESRD beneficiary.

In its 1991 report on the Medicare ESRD program, the IOM pointed out that the proportion of for-profit and chain-affiliated dialysis facilities compared with nonprofit facilities was increasing. The IOM report expressed concern that no one was monitoring the implications of this change for quality of care to patients.[16] In addition, some providers and consumer advocates we interviewed alleged that they had observed that care provided to patients belonging to some HMOs was of lesser quality than that provided to beneficiaries in the standard Medicare ESRD program. Therefore, we had planned, using HCFA data, to determine whether statistically significant quality differences existed (1) between the care furnished to beneficiaries served by chain-affiliated dialysis facilities and unaffiliated facilities and (2) between the care furnished to beneficiaries enrolled in HMOs and those receiving care paid for through the standard Medicare program.

We were unable to analyze differences in the quality of care furnished by chain-affiliated dialysis centers and those without such an affiliation because HCFA's data on chain affiliation are unreliable. A HCFA official told us that these data have not been consistently updated to reflect the rapid changes in the industry. For example, chain A's purchase of a dialysis facility from chain B might not

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levels in patients with ESRD. Experts we interviewed agreed that blood pressure is not a good quality indicator for dialysis patients.

[15]This so-called "composite rate" covers all services normally associated with a dialysis treatment. Other services, such as some diagnostic tests and administration of some drugs, notably EPO, are compensated separately.

[16]Kidney Failure and the Federal Government, pp. 162-63.

have been noted in HCFA databases. Or a new dialysis chain may have been formed as a result of a merger of several unaffiliated centers, but these changes may not have been recorded. When we found we were unable to use HCFA data, we attempted to obtain information on chain affiliation of dialysis facilities directly from the larger chains we could identify. However, not all those we contacted provided the data.

We also could not determine whether differences existed between the quality of care furnished to Medicare beneficiaries with ESRD in HMOs and those covered by the standard Medicare program. The number of ESRD patients in the Core Indicators Project samples found to be enrolled in HMOs was very small. The number of HMO cases in any one of the 3 years that data were available ranged from 80 to 150. Even after we combined the date for the 3 years, the maximum number of HMO cases available for analysis was 335, with available cases for some analyses falling below that number because of missing data elements.[17] We were particularly concerned that the small number of cases limited our ability to compare beneficiaries with similar characteristics such as age, gender, socioeconomic condition, and race.

Because of the differing financial incentives inherent in different care delivery systems, we believe it is as important to monitor the quality of care furnished to patients by different provider types as it is to monitor the quality of care furnished to all patients regardless of provider. In discussing our work with HCFA officials, we suggested that the Administrator of HCFA (1) maintain current information about members of chain-affiliated dialysis facilities, and (2) modify the ESRD Core Indicators Project to collect sufficient data on ESRD patients enrolled in risk HMOs to permit a valid comparison of the quality of care of hemodialysis patients in HMOs with those in the standard Medicare ESRD program. The HCFA officials we talked with agreed with our suggestions and said they would keep us informed of what they did in this regard.

## AGENCY COMMENTS

HCFA chose not to comment formally on this letter, although it did provide technical comments, which we incorporated where appropriate. In these technical comments, HCFA stated that it will collect the core indicators data from the last quarter of 1996 on all ESRD patients enrolled in Medicare

[17]In contrast, the maximum number of non-HMO cases available for analysis was just over 18,000.

managed care plans. The core indicators data from ESRD patients in these plans will be compared with the core indicators data from the patients in the standard Medicare ESRD program. These data will be collected during the summer of 1997, and HCFA anticipates that the comparative analysis will be available by the end of 1997.

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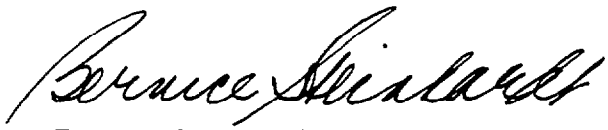
We will make copies of this correspondence available to interested parties on request.

If you have any questions about this correspondence, please call me at (202) 512-6543 or Assistant Director Sandra K. Isaacson at (202) 512-7174. Other major contributors to this study included Peter Schmidt and George Lorenzen.

Sincerely yours,



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