MEDICARE END-STAGE RENAL DISEASE (KIDNEY FAILURE) PROGRAM

HEARING

BEFORE THE

Subcommittee on Health

OF THE

COMMITTEE ON WAYS AND MEANS
HOUSE OF REPRESENTATIVES

ONE HUNDRED FOURTH CONGRESS

FIRST SESSION

APRIL 3, 1995

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MEDICARE END-STAGE RENAL DISEASE (KIDNEY FAILURE) PROGRAM

MONDAY, APRIL 3, 1995

HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The Subcommittee met, pursuant to call, at 10 a.m., in room 1100, Longworth House Office Building, Hon. Bill Thomas (Chairman of the Subcommittee) presiding.

[The advisory announcing the hearing follows:]

ADVISORY

FROM THE COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON HEALTH

FOR IMMEDIATE RELEASE
March 27, 1995
No. HL-8

CONTACT: (202) 225-3943

THOMAS ANNOUNCES HEARING ON THE MEDICARE END-STAGE RENAL DISEASE (KIDNEY FAILURE) PROGRAM

Congressman Bill Thomas (R-CA), Chairman of the Subcommittee on Health of the Committee on Ways and Means, today announced that the subcommittee will hold a hearing on the Medicare end stage renal (kidney failure) disease program. **The hearing will take place on Monday, April 3, 1995, in the main committee hearing room, 1100 of the Longworth House Office Building, beginning at 10:00 a.m.**

Oral testimony at this hearing will be heard from invited witnesses only. However, any individual or organization not scheduled for an oral appearance may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing.

BACKGROUND:

Medicare covers individuals who suffer from end stage renal disease (ESRD) if they are insured under the Social Security program or are the spouse or dependent of a person insured under Social Security.

ESRD is fatal without treatment, which is either transplantation or dialysis. Successful transplants more than doubled between 1980 and 1992 in the general population due to the introduction of cyclosporine, an effective immunosuppressive drug. In 1991, there were over 4,600 transplants performed on Medicare ESRD patients. Nonetheless, dialysis remains the primary treatment due to a shortage of kidneys available for transplantation and medical factors which make transplantation unsuitable for certain patients.

In 1995, there are approximately 200,000 Medicare beneficiaries with ESRD, up from 97,200 in 1985. Medicare spending for ESRD patients will total $8 billion, or $38,900 per beneficiary. In 1985, Medicare spent $2.8 billion on ESRD beneficiaries, or $29,000 per beneficiary.

In announcing the hearing, Chairman Thomas stated: "The Medicare program has saved thousands of lives for persons suffering from end stage renal disease and will continue to do so in the future. I believe the subcommittee has a responsibility to make sure the program continues to meet its objectives in a cost-effective manner. I am anxious to hear from the Administration and the experts about the quality of care provided to patients, and the applicability of capitation and managed care to this portion of the Medicare program."

FOCUS OF THE HEARING:

The hearing will focus on oversight of the Medicare ESRD program, examining trends in costs, beneficiaries, and the number and organization of providers, as well as changes in medical practice patterns and the quality of care provided to beneficiaries. In addition, the hearing will examine current and alternative payment policies and how the ESRD program may fit into a broader reform of the Medicare program.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Any person or organization wishing to submit a written statement for the printed record of the hearing should submit at least six (6) copies of their statement, with their address and date of hearing noted, by the close of business, Monday, April 17, 1995, to Phillip D. Moseley, Chief of Staff, Committee on Ways and Means, U.S. House of Representatives, 1102 Longworth House Office Building, Washington, D.C. 20515. If those filing written statements wish to have their statements distributed to the press and interested public at the hearing, they may deliver 200 additional copies for this purpose to the Subcommittee on Health office, room 1136 Longworth House Office Building, at least one hour before the hearing begins.

FORMATTING REQUIREMENTS:

Each statement presented for printing to the Committee by a witness, any written statement or exhibit submitted for the printed record or any written comments in response to a request for written comments must conform to the guidelines listed below. Any statement or exhibit not in compliance with these guidelines will not be printed, but will be maintained in the Committee files for review and use by the Committee.

1. All statements and any accompanying exhibits for printing must be typed in single space on legal-size paper and may not exceed a total of 10 pages including attachments.

2. Copies of whole documents submitted as exhibit material will not be accepted for printing. Instead, exhibit material should be referenced and quoted or paraphrased. All exhibit material not meeting these specifications will be maintained in the Committee files for review and use by the Committee.

3. A witness appearing at a public hearing, or submitting a statement for the record of a public hearing, or submitting written comments in response to a published request for comments by the Committee, must include on his statement or submission a list of all clients, persons, or organizations on whose behalf the witness appears.

4. A supplemental sheet must accompany each statement listing the name, full address, a telephone number where the witness or the designated representative may be reached and a topical outline or summary of the comments and recommendations in the full statement. This supplemental sheet will not be included in the printed record.

The above restrictions and limitations apply only to material being submitted for printing. Statements and exhibits or supplementary material submitted solely for distribution to the Members, the press and the public during the course of a public hearing may be submitted in other forms.

Note: All Committee advisories and news releases are now available over the Internet at GOPHER.HOUSE.GOV, under 'HOUSE COMMITTEE INFORMATION'.

Chairman THOMAS. The Subcommittee will come to order.

Welcome to the Health Subcommittee hearing on the Medicare ESRD, End-Stage Renal Disease, Program. ESRD is unique within Medicare. It is the only disease which triggers Medicare coverage at any age. There is no disputing this program's dramatic and positive results in the lives of ESRD patients.

Medicare coverage of dialysis and other treatments has spared hundreds of thousands of Americans from premature death. We must not lose sight of that profound accomplishment.

Because the ESRD Program is unique within Medicare, I think we have a tendency to overlook it, but we shouldn't because it is a very significant and important program. In 1995 Medicare is expected to spend nearly $8 billion, or over 4 percent of all total spending on over 200,000 ESRD patients. That is about $40,000 per beneficiary.

Today's hearing is intended to meet several objectives. First, the Subcommittee needs an overview of the program and how well it is meeting its objectives. What are the treatments for ESRD patients and how has treatment changed over time, if in fact it has? What are the trends in terms of costs and numbers of beneficiaries? What is the quality of care provided to patients? What are the current payment policies for dialysis and other treatments, and are there alternatives that should be explored?

Second, this Subcommittee is going to examine opening up the Medicare Program to more coverage choices for the beneficiaries, much like employers in the private sector have done to enhance competition, improve quality, and reduce costs. We need to explore how the ESRD Program may or may not fit into such an approach.

I look forward to hearing from our witnesses, but prior to that, I would recognize my colleague from California, Mr. Stark.

[The prepared statement follows:]

STATEMENT OF CHAIRMAN THOMAS
HEARING ON THE MEDICARE END-STAGE RENAL DISEASE
(KIDNEY FAILURE) PROGRAM
APRIL 3, 1995

Welcome to the Health Subcommittee hearing on the Medicare End-Stage Renal Disease, or ESRD, program.

ESRD is unique within Medicare. It is the only disease which triggers Medicare coverage at any age.

There is no disputing this program's dramatic and positive results on the lives of ESRD patients. Medicare coverage of dialysis and other treatments has spared hundreds of thousands of Americans from premature death. We must not lose sight of that profound accomplishment.

Because the ESRD program is unique within Medicare, I think we have a tendency to overlook it. But we shouldn't, because it is a very significant and important program. In 1995, Medicare is expected to spend nearly $8 billion, or over 4% of all total spending, on over 200,000 ESRD patients. That's about $40,000 per beneficiary.

Today's hearing is intended to meet a couple of objectives.

First, the Subcommittee needs an overview of the program and how well it is meeting its objectives. What are the treatments for ESRD patients, and how has treatment changed over time? What are the trends in terms of costs and numbers of beneficiaries? What is the quality of care provided to patients? What are the current payment policies for dialysis and other treatments, and are there alternatives that should be explored?

Second, this Subcommittee is going to examine opening up the Medicare program to more coverage choices for the beneficiaries, much like employers in the private sector have done to enhance competition, improve quality, and reduce costs. We need to explore how the ESRD program may or may not fit into such an approach.

I look forward to hearing from our witnesses.

Mr. STARK. Thank you, Mr. Chairman.

I want to congratulate you for holding this hearing. The ESRD Program has been a success and literally saved, I suppose, millions of lives, but the program is fraying around the edges. I think that a comprehensive approach to the treatment of this disease could easily improve the quality of care and save money. We ought to reform the payment system, perhaps through a capitation method, and that ought to make the dialysis centers a little more anxious to ensure that hospitalization isn't necessary, and that where appropriate, we should see that patients receive transplants or are treated at home, with a caveat that treatment at home, I think, ought to be done in only the most extreme conditions.

While reform holds great promise, I think we have to be very careful. This is a vulnerable population, literally and figuratively, and underservice can quickly lead to death.

In March the Health and Human Services Inspector General issued a report that two-thirds of the ESRD and disabled persons in HMOs wanted to leave the HMO—but they felt they couldn't. They really felt trapped in them. They are twice as likely as senior enrollees in HMOs to say that the HMOs have hurt their health. They are twice as likely to complain, but those are the figures we are getting.

To date, capitated plans have not managed the ESRD patients well. HCFA, the Health Care Financing Administration, is about to begin a demonstration project to test whether some form of capitation might work, and more importantly, what quality measures we need to ensure we don't kill the patients. We can't cut corners in reforming this program, and I think we should wait to see what the demonstration shows us.

I have introduced two bills and I would like to ask the witnesses today to comment on them. One sets up a demonstration to see if we can save money and help patients by delaying the onset of kidney failure, and, at least in layman's terms, generally the onset of kidney failure is discovered early, and I think dietary changes can prevent a lot of failure if people will follow their instructions. I don't know whether a demonstration would show that we could encourage that, but I think it is worth a look.

Second, the second bill says we should not pay dialysis centers if they don't achieve a specific measurable level of cleaning the blood for most of their patients. I think that is—it is a measurable standard. It is an empirical standard, and if witnesses don't support the standards set in the bill I have introduced, what standards should we use?

I mean, it seems to me we can't move to a managed care system if we can't have a specific standard by which we manage the treatments that we are purchasing with Federal dollars. I hope that we can hear from the witnesses today about those issues, and I commend you for having the hearings.

Thank you very much.

[The prepared statement follows:]

STATEMENT OF CONGRESSMAN PETE STARK
WAYS AND MEANS SUBCOMMITTEE ON HEALTH
APRIL 3, 1995

OVERSIGHT OF THE END-STAGE RENAL DISEASE PROGRAM

Mr. Chairman:

Congratulations for holding this hearing. I wish we had made the time to do this in the last Congress.

The ESRD program has been a success and literally a life-saver, but it is fraying around the edges:

> --some providers are gaming the payment system, charging extra for questionable tests and services;
>
> --hospitalization rates are much higher than they should be;
>
> --we are spending more and more on drugs with less and less to show for it;
>
> --some centers provide poor quality and are almost death traps for their patients; and
>
> --we talk about assuring quality in the program, but after more than twenty years, can't seem to agree on a specific standard for dialysis.

I think a comprehensive approach to the treatment of this terrible disease could easily improve quality of care and save money. Reforming the payment system--perhaps through a capitation system--could make dialysis centers zealous to ensure that hospitalization is not necessary, and that where appropriate, patients receive transplants or are treated at home.

But while reform holds great promise, we must be very, very careful. This is a very vulnerable population, and underservice can quickly lead to death. In March, the HHS Inspector General issued a report that 66% of ESRD and disabled persons in HMOs wanted to leave their HMOs but felt they couldn't. They are twice as likely as senior HMO enrollees to say that HMOs have hurt their health. To date, capitated plans have not managed ESRD patients well.

HCFA is about to begin a demonstration project to test whether some form of capitation might work--and what quality measures we need to ensure we don't kill patients.

We shouldn't cut corners in reforming this program--we should wait to see what the demonstration shows us.

In the interim, I've introduced two bills that I'd like today's witnesses to comment on:

> One would set up a demonstration to see if we can save money and help patients by delaying the on-set of total kidney failure and thus postpone the day that dialysis is needed.
>
> The second says we shouldn't pay dialysis centers if they don't achieve a certain specific, measurable level of cleaning the blood of most of their patients--as expressed in the formula Kt/V equal to or greater than 1.2. If witnesses don't support the standard set in this bill, what standard would they propose--and how can they support moving to a managed care system if they can't accept a measurable, specific life-saving standard?

Chairman THOMAS. I thank you very much.

Any other colleagues can put a written statement in the record.

Dr. Smits, the Deputy Administrator of the Health Care Financing Administration, your written testimony will be made a part of the record and you can begin to inform, enlighten, and educate us in any way you see fit in the time that you have.

STATEMENT OF HELEN L. SMITS, M.D., DEPUTY ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION

Dr. SMITS. Thank you, Mr. Chairman. I won't read my prepared testimony, but I will go through all of the topics since one of the aims of the hearing is to review in general the status of the program.

This is a serious matter and this is serious testimony, but I can't resist beginning by saying I am very sorry that Nancy Johnson isn't here. I used to run a hospital in her district and I am sure she will share with me the feeling that this is a very good day for Connecticut women.

Moving on to ESRD, when I was a resident, an intern starting in 1967, renal failure was a relatively common cause of death in hospitals. It was tragic, painful to watch, and I think all of us in the field greeted with great enthusiasm the passage in 1973 of Medicare coverage for this illness.

The cost of the ESRD Program is often held up as an example of how you can't control costs in government programs, but I think in fact as you dissect the program, you see that this is in many ways a very successful program in which per capita costs have dropped markedly and which we have also offered the treatment to very large numbers of people, much greater than were originally predicted.

As you know, all of those who are eligible for Medicare or spouses or children of those eligible for Medicare become eligible under the ESRD provisions 3 months after the onset of renal failure.

The original estimate was that 10,000 beneficiaries would be covered annually. We are now covering about 200,000 and the numbers continue to rise. I will talk a little more as we go along about why that is happening.

Treatment for complete kidney failure is dialysis, which can be mechanical with an extracorporeal machine or can use the body's own ability to dialyze through peritoneal dialysis where fluids are put into the stomach. Mechanical dialysis is done either in centers or at home. Peritoneal dialysis is always done at home. Facilities do receive facility rates for patients that they oversee who are either receiving mechanical or peritoneal dialysis at home.

Kidney transplantation is also a very satisfactory solution to this illness and is the cause for a number of beneficiaries leaving the ESRD status on Medicare, but there aren't enough kidneys to go around, and in addition, many of the successful kidney transplants remain on disability status even following transplantation.

The first chart which you see here shows you why the numbers have grown so dramatically since the early seventies. At the time that the program first started—this chart starts in 1978, 5 years after the program began—what we really expected is that the great

majority of patients would be those with glomerulonephritis or other attacks on the kidney itself, such as massive blood loss where the patient totally recovers but the kidneys were killed in the process.

We did not expect that very many hypertensive or diabetic patients would come into the program because these patients didn't do well on dialysis at the time. As you can see, the greatest rise has been in the diabetic patient who has many other ailments at the time they come to dialysis, while the hypertensive patient, after some early increased glomerulonephritis, has stayed fairly stable. We have seen some increase in hypertensive patients as well.

Beneficiaries are also older than we had originally anticipated. We are bringing into dialysis many people who are already Medicare qualified because of age.

In terms of cost, there are a number of ways to look at it, but this chart shows you one of the clearest ways and that is, if you look at the total cost of the ESRD Program per person compared to the cost of the rest of Medicare per person, you will see that we started out with the ESRD patients being about 30 times more expensive than everyone else in Medicare, and they are now in the vicinity of 10 times more expensive than everyone else in Medicare.

Also, you can see that the dramatic drop in cost took place at the beginning of the inclusion of ESRD patients, and up until about the middle eighties. Now the ESRD Program is inflating roughly as fast as the rest of Medicare.

The next chart gives you an idea of how the costs for the ESRD Program break out. Remember, this is two dramatically different groups of patients: transplant patients and dialysis patients.

Inpatient costs are still about 44 percent of the total cost. That does include the very high cost of transplantation in the year of the transplantation; outpatient costs, about 33 percent; and physician and suppliers costs, about 21 percent. As I am sure you know, the outpatient facilities are paid on essentially a capitated blended rate, and doctors are also paid on a capitated blended rate.

The capitated rate for facilities was set in 1983 when other prospective payment was established and hasn't been changed since then. Physician payment is now rolled into the general physician payment and I believe 1995 is the first time there has been an increase. In the future, it will be treated equally with other physician payments in its category.

One area that has been of great concern because of its impact on the total cost to Medicare is the Medicare secondary payer provision. Under OBRA 1993, anyone who has group health insurance is expected to treat Medicare as the secondary payer for 18 months. That provision is to expire. The President has asked you to extend this provision, and it has been marked up and reported out of this Committee as an extension.

I am very clear that the quality of the services received by Medicare beneficiaries is of great concern to all of you. The method by which HCFA influences quality in the ESRD is twofold. One is the regulatory process, the conditions of coverage by which we survey and inspect facilities; and the other is through the networks, private organizations with membership that includes all of the provid-

ers in a given region that collect and analyze data and are very active in the benchmarking process.

The conditions of coverage that we now use are like many of our conditions, rather old and very process oriented. We are in the first stages of moving them toward more outcome-oriented conditions.

I am also pleased to say that we are looking at a process by which we would inform patients about the quality of care. We would encourage patients to learn about the quality of their own dialysis to track their own rate of adequacy of dialysis. We believe this is a situation where the individual consumer can have a great deal of effect on quality.

Through the networks and working jointly with providers, we are also in a benchmarking quality improvement mode looking at four key factors which include: the adequacy of dialysis; the level of hematocrit because anemia is a consistent problem for these patients; adequacy of control of blood pressure; and the adequacy of nutrition as measured by a fairly simple blood test of protein in the blood.

That process is a collaborative one, and is intended to improve continually over time. As you probably know, the new definition of adequate dialysis was quite recently set by the profession at Kt/V of 1.2. Only about 40 percent of the patients were receiving that level at a point in time when the new rate hadn't been set. We do expect to see those numbers increasing over time.

I know that one of the primary goals of this hearing is to talk about whether ESRD patients should be more generously included in managed care. At present, you can be in managed care with ESRD only by acquiring the disease while you are already in a managed care plan.

The problem that we face—could I have the last chart again? The problem that we face in changing that law is severalfold. First of all, we need to have a reasonable rate to pay managed care. As you can see, since we are paying facilities and doctors on capitation, the part of the expenditures that are most amenable to control would be hospitalizations.

Right now we have a single rate for ESRD patients in managed care which mixes the costs of the posttransplant patient with the costs of the dialysis patient. Since posttransplantation is less expensive, that means the rate underpays for dialysis at least on average, overpays posttransplantation and leaves the facility—the HMO itself at something of a risk in terms of underpayment for the expensive short period in time during the transplantation.

We would like to have a better payment rate that distinguishes among those three groups of patients and doesn't put the HMO in the position of having to overcontrol costs in the area of dialysis for those patients who appropriately remain on dialysis for a long period.

We have had the RAND Corp. devise a payment method for us. We are in the process of soliciting sites for a managed care demonstration, and we estimate that service delivery will begin in about 1 year.

Our position at this time is that rapid movement into managed care before the demonstration is completed or at least before early data are available from the demonstration would be unwise.

Thank you very much. That concludes the formal part of my testimony. I would be glad to answer questions.

[The prepared statement and attachments follow:]

STATEMENT OF HELEN L. SMITS, M.D.
HEALTH CARE FINANCING ADMINISTRATION

Mr. Chairman, and members of the subcommittee, I am pleased to be here this morning to discuss Medicare's program for people with end stage renal disease (ESRD). I'd like to begin with a basic explanation what ESRD is and how it is treated. Following this, I'll discuss how it became a condition for Medicare eligibility, present a profile of ESRD beneficiaries and the current program, review new developments in quality improvement, and address issues relating to ESRD and managed care.

ESRD AND ITS TREATMENT

ESRD is a kidney impairment that is irreversible, cannot be controlled by conservative management alone, and requires dialysis or transplantation to maintain life.

Kidneys filter the blood and regulate concentrations of essential fluids and body minerals, such as magnesium, sodium, and potassium. When kidneys fail to perform adequately, toxins accumulate in the blood, which results in a complex condition called uremia. Left untreated, uremia is uniformly fatal. Even with aggressive use of the therapies currently available, mortality in the ESRD population is significant. About one-half of persons under age 35 will survive ten years on dialysis; one-half of those between the ages of 35 and 64 can be expected to survive for four years; and less than one-half of those over age 65 will survive two years after dialysis is initiated.

Treatment for poorly functioning kidneys is limited to dialysis or transplantation, with dialysis being the most frequent. Dialysis is a process of removing dissolved substances from the patient's body to maintain the chemical balance of the blood when the kidneys have failed. There are two types of dialysis: hemodialysis, in which the blood is pumped through a machine that "cleans" it and then returns it, and peritoneal dialysis, in which a solution is put into the peritoneal cavity and removed taking with it the accumulated toxins. Each hemodialysis treatment requires a minimum of several hours, often three to four times a week. Approximately 82 percent of Medicare ESRD beneficiaries use hemodialysis, which is primarily given in outpatient facilities. About 18 percent use peritoneal dialysis, which is given in the home.

Transplants--or grafts--are becoming increasingly common, but are still relatively rare due to a shortage of available organs. The operation is expensive, and patients are required to take immunosuppressive drugs for the rest of their lives to prevent organ rejection. Transplant recipients who are under 65 and are not otherwise disabled lose Medicare entitlement 36 months after a successful transplant. However, only 50 percent of successful transplant recipients actually leave Medicare after 36 months; the 50 percent who remain retain entitlement on the basis of age or disability.

PROGRAM HISTORY

Treatment of ESRD requires expensive advanced medical technology. In 1972, Congress enacted legislation[1] that extended Medicare eligibility to ESRD patients. Thus, the ESRD program is the only portion of Medicare in which eligibility is based on the presence of a medical condition.

In terms of saving lives, the program has been enormously successful. Currently over 200,000 Americans are either on dialysis or have a functioning kidney transplant. Without Medicare-financed coverage, it is unclear how the vast majority of these people would have been able to afford this life-saving treatment.

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[1]Social Security Amendments of 1972 (P.L. 92-603, section 299(I))

ESRD beneficiaries account for approximately one-half of one percent of the total Medicare population (183,000 in CY 1991) and four percent of total Medicare expenditures ($6.1 billion in CY 1991).

ELIGIBILITY REQUIREMENTS

To qualify for Medicare under the renal disease provision, a person must be diagnosed with ESRD and be either (a) entitled to a monthly Social Security benefit, (b) fully or currently insured under Social Security, or (c) the spouse or dependent child of a person who meets at least one of these requirements. There is no minimum age for eligibility under the renal disease provision. For beneficiaries who are not otherwise entitled to Medicare, entitlement for the ESRD program ends 36 months after a successful transplant or 12 months following the last dialysis treatment (unless the beneficiary receives a transplant or begins a new course of dialysis during these periods).

About 93 percent of all ESRD patients meet requirements for Medicare entitlement. The remaining seven percent are covered through other sources, such as Medicaid, the Department of Veterans Affairs or private insurance.

ESRD BENEFICIARY PROFILE

Although the typical ESRD beneficiary is middle-aged, the largest and fastest growing age group of the ESRD population is persons age 65 and older, and census projections show that the "graying" of the ESRD population will likely continue into the foreseeable future. Slightly more men than women are diagnosed with ESRD: In 1991, 54 percent of new ESRD cases were men and 46 percent were women.

The ESRD population displays a great deal of diversity and important age-race-disease interactions. For example, although most patients are white, black persons and Native Americans are over-represented in the ESRD population as compared to the overall US population. Black persons have more than three and a half times the risk of renal failure than white persons; they are also more likely than white persons to experience renal failure as a result of hypertension or non-insulin dependent diabetes. Native Americans, Asian Americans and some Hispanic Americans also have markedly higher risks of renal failure than white Americans.

The number of beneficiaries with ESRD has grown rapidly since the beginning of the program. Original estimates were that 10,000 persons would begin treatment each year out of a potential pool of 20,000. Yet, in 1993, approximately 60,000 persons began treatment, which reflects an increase averaging nearly 10 percent a year since 1978. From 1978 to 1991, the total number of persons enrolled in the program grew more than 400 percent, from nearly 45,000 to approximately 183,000. This unanticipated growth has primarily been caused by a change in medical practice that resulted in extending dialysis to persons whose primary disease is not renal, but who experience renal failure as a result of other diseases (primarily diabetes and heart disease). For example, before enactment of the ESRD program, diabetes was a medical contraindication to dialysis treatment; now, however, diabetes is the most common co-morbidity within the ESRD population. Other factors that contribute to the growth in the ESRD population include the general aging of the population, longer life expectancy, and improved survival rates among the sick.

CHART A shows new ESRD enrollees over time and the cause of their renal failure. Overall, the three most common causes of ESRD are diabetes, hypertension and a type of kidney disease called glomerulonephritis.

From 1978 to 1992, the proportion of ESRD beneficiaries with a functioning transplant doubled from 11 percent to 22 percent. Recent improvements in technology and immunosuppressive drugs, which are used to prevent organ rejection, have increased the survival of transplant patients. In general, transplants

are desirable because beneficiaries have a better quality of life and because associated expenditures for health maintenance are much lower than those for dialysis. Unfortunately, kidneys available for transplant are in short supply. In 1993, more than 23,000 persons were on the transplant waiting list; of this number, fewer than half (10,000) received kidney transplants.

Due to additional health complications in the aged, elderly patients tend not to be good candidates for transplantation. As a result, transplants are generally performed in the younger population. In 1987, 45 percent of the ESRD population under age 35 had a functioning graft, compared to 25 percent of those aged 35 to 64, and only two percent of persons over age 65.

EXPENDITURES AND PAYMENT METHODS

In 1991, total expenditures in the ESRD program were just over $6 billion. This total includes all Medicare payments for inpatient hospital care, outpatient services (mostly dialysis), physician services, skilled nursing care, and home health care. Program outlays have been increasing annually at an average of more than 14 percent. This is primarily attributable to increases in the ESRD population.

Although ESRD is expensive to treat, HCFA has successfully contained per capita costs. In the mid-1970s, the average cost per ESRD beneficiary was 30 times as much as the average for all Medicare beneficiaries; by 1991, the difference in average per capita costs had shrunk to nine times (CHART B).[2] Thus, while inflation has greatly increased the costs of the Medicare program generally, the combination of increased transplantation and cost controls on both dialysis and physician care have tempered per capita increases.

Chart C shows the breakdown of ESRD expenditures by category. Several payment methods are used in the ESRD program. Renal facilities are paid a prospective composite rate for outpatient and home dialysis treatments. The average payment per treatment is $126 for independent facilities and $130 for hospital-based facilities. Renal facilities that meet certain regulatory exception criteria (e.g., atypical patient population, isolated essential facility) can receive a higher composite rate. Because these treatments are covered under Part B of Medicare, Medicare pays 80 percent of the composite rate and the beneficiary pays the remaining 20 percent, either out-of-pocket or through a supplemental insurance policy.

Except for two statutory changes that resulted in a net decrease of $1 per treatment, payment rates have remained constant since August 1983. The number of independent renal facilities, however, has continued to increase to meet patient demands: from 1983 to 1994, the number of these facilities has nearly tripled (from 627 to 1,795). Moreover, independent facilities, which account for 71 percent of all renal facilities, continue to have positive margins, on average, on their Medicare business.

Patients who dialyze at home are able to select from two payment methods: Method I, in which supplies are obtained from a provider, and the provider bills Medicare as if the dialysis were received in a facility; or Method II, in which the beneficiary purchases the supplies directly from a supplier and is reimbursed the provider rate from HCFA. In 1991, approximately 25,000 beneficiaries dialyzed at home; about 16,000 selected Method I and 9,000 chose Method II. Expenditures for outpatient services, which are primarily dialysis related, totaled more than $2 billion and accounted for 33 percent of the total ESRD program costs in 1991.

As a result of a regulation in 1994, physicians providing dialysis-related services are now paid under Medicare's physician fee schedule. The capitated monthly payment is now approximately $190. Total expenditures for physicians and

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[2]In 1974, the average annual per capita expenditures for a Medicare beneficiary and an ESRD beneficiary were $530 and $16,200, respectively; by 1991, they were $3,250 and $32,700.

suppliers in 1991 were $1.3 billion, or 21 percent of total ESRD costs. In addition to office visits, surgeon fees and other physician-related services, supplies for home dialysis patients who elect Method II for payment are included in this amount.

As with the rest of the Medicare program, payments for hospital care are based on the hospital prospective payment system and are predetermined, depending on the diagnosis and/or procedure associated with the hospital stay. At 44 percent of total ESRD costs, inpatient expenditures totaled almost $2.7 billion in 1991.

Approximately 90 percent of ESRD dialysis beneficiaries use a drug called erythropoietin (EPO) to combat anemia. Payment for EPO is made on a per unit basis, set by law at $10 per 1,000 cc's. The average dose is now just more than 4,700 cc's. In 1994, Medicare expenditures for EPO were $736 million, which translates into an annual amount of $5,600 per patient (based on average use).

Medicare Secondary Payer (MSP)

Under OBRA 93, Medicare is the secondary payer to specified group health plans for the first 18 months in which a beneficiary is entitled to Medicare on the basis of ESRD. This provision is scheduled to expire at the end of FY 1998. The President's budget proposed making it permanent; as you know, this provision was recently marked-up and reported out by this Committee. This estimated savings from this proposal are $50 million in FY 1999 and $70 million in FY 2000.

ESRD NETWORKS

HCFA contracts with 18 private ESRD Network Organizations that cover the US, the District of Columbia, Puerto Rico, the Virgin Islands and the Pacific Trust Territory, Guam and American Samoa. The Networks are organized groups of Medicare-approved ESRD providers in a designated area that collectively furnish the necessary care for ESRD patients in the area. Networks were established to ensure that Medicare beneficiaries receive high quality ESRD-related care. They monitor the quality of care provided to Medicare patients by reviewing items and services furnished in dialysis and transplant facilities. In particular, the Networks are responsible for:

- encouraging the use of treatment settings that are most compatible with the successful rehabilitation of the patient;
- encouraging patients, providers of services, and ESRD facilities to participate in vocational rehabilitation programs;
- developing Network goals for the placement of patients in self-care settings and undergoing or preparing for transplantation;
- developing criteria and standards related to the quality and appropriateness of patient care;
- evaluating the procedures used by Network facilities and providers to assess the appropriateness of patients for the proposed treatment modalities;
- implementing procedures evaluating and resolving patient grievances;
- using standards of care established by the Network to conduct on-site reviews of facilities and providers as necessary;
- collecting, validating and analyzing data for the preparation of reports on the ESRD program;

- providing data on the ESRD population to the US Renal Data System for analysis by Department of Health and Human Services; and

- identifying facilities that do not meet Network goals, assisting those facilities in developing corrective plans, and reporting to the Secretary those who are not providing appropriate medical care.

HCFA and the Networks have worked well together in a public-private partnership and we feel that the Networks are fulfilling their statutory mission.

QUALITY IN THE ESRD PROGRAM

Survey and certification of facilities

A facility becomes "certified" (and therefore eligible for payment) in the ESRD program through an initial survey to determine if the facility meets health and safety standards. Periodic follow-up surveys are conducted to monitor compliance with regulations. If a complaint about poor health and safety practices is received about an ESRD facility, a focused complaint survey is conducted. The surveys are conducted by State health departments, under contract to HCFA.

Conditions for Coverage

Providers and facilities must meet the requirements for institutional dialysis services and supplies established by the Secretary of Health and Human Services in order to be covered by Medicare. These participation requirements are called "Conditions for Coverage." The current regulations are primarily process-oriented and do not adequately support the outcome-oriented approaches to quality management that HCFA is initiating. Last year, HCFA determined that a thorough revision of these conditions was necessary.

In March 1994, we met with representatives from the ESRD industry to begin discussing these changes. We envision that the new standards will reflect current standards of practice and support a comprehensive outcomes-oriented approach to quality management. It will emphasize the total patient experience and actual organizational performance. Specifically, the proposed revised regulations will include standards for evaluating the adequacy of dialysis. Last November, a first draft of the proposed revised regulations was informally distributed to industry representatives for comment; we hope to have the Notice of Proposed Rulemaking published for public comment by the end of the year.

ESRD Health Care Quality Improvement Program (HCQIP)

HCFA is focusing on outcomes-oriented research to respond to the need to improve the care of Medicare ESRD patients. This approach has been named the ESRD Health Care Quality Improvement Program (HCQIP). HCQIP is based on the principle that HCFA can help improve the quality and cost-effectiveness of care by helping the facility bring typical care in line with best practices. The project's goal is to improve care provided to ESRD patients by establishing benchmarks for care and documenting improvements.

As part of the program, we have identified four core indicators for dialysis care that will be tracked over time. The indicators chosen for the project were adequacy of dialysis, anemia, blood pressure control, and nutritional status. The adequacy of dialysis measures are based on the Renal Physicians Association's guidelines and on the findings of an NIH consensus conference. The first measurements of these indicators was completed in October 1994 and focused on outpatient hemodialysis care. Measurements will be repeated in 1995 and 1996 and expanded to include peritoneal dialysis.

A second part of the HCQIP concentrates on improving the management of anemia for in-center hemodialysis patients by educating facilities about clinical data analysis and by providing information on trends of national, regional and facility-specific hematocrit levels and EPO usage.

We are very excited about our HCQIP and believe it has the potential to continue to improve the care provided to ESRD beneficiaries. As in other parts of the Medicare program, the HCQIP is a cooperative effort between renal providers and HCFA. We appreciate the support that the renal community has provided in this effort and look forward to their continued active participation.

ESRD AND MANAGED CARE

Attention has focused lately on the potential for managed care to provide savings in the Medicare program. However, as we look to expand managed care options for Medicare beneficiaries, we are clearly faced with challenges in figuring out how to care effectively for Medicare beneficiaries in systems that were originally designed to care for relatively healthy people.

In the current Medicare program, beneficiaries who already have ESRD may not enroll in Medicare managed care plans. This legislative exclusion resulted from apprehension about the ability of managed care plans to effectively treat ESRD patients and from concerns about financing and liability. However, Medicare beneficiaries who are already enrolled in managed care plans may not be involuntarily removed from the plan if they develop ESRD. As a result, approximately 6,300 ESRD beneficiaries are currently enrolled in managed care plans.

Quality

Generally, managed care plans that have ESRD beneficiaries have found it easier to contract out for dialysis and other services rather than incorporate these services into their existing health systems. Consequently, the managed care industry has only limited experience in caring for this special population. Moreover, although managed care programs and their participating facilities must meet quality certification requirements that are similar to those in the fee-for-service market, the unique needs of ESRD beneficiaries raise concerns about access issues in a restricted provider network.

In March 1995 the Inspector General of the Department of Health and Human Services found that beneficiaries with disabilities or ESRD who disenrolled from managed care reported more access problems in several crucial areas of their care than did aged beneficiaries who disenrolled. This group also was the most likely to believe that cost-containment was more important to the providers than providing the best medical care possible and most likely to seek out-of-plan care while still enrolled in the HMO. In addition, and perhaps more telling, 66 percent of beneficiaries who are disabled or have ESRD and are enrolled in managed care report wanting to leave their HMOs. We find these concerns distressing and plan further examination of the situation.

Payment

We also need to address the adequacy of our payments to managed care plans. In health care discussions, there is a tendency to equate high cost with uninsurability. However, while dialysis costs are high, they are actually fairly predictable. The real issue here is the calculation of an actuarily fair payment rate

The adjusted average per capita cost (AAPCC), which is used to determine the payment amount to managed care plans that contract with Medicare, does not currently account for the difference in expenses associated with the different treatment options. Maintenance costs for dialysis patients are about $44,000 per year, compared to $7,400 per year for beneficiaries with a functioning transplant.

Thus, the average of the two results in a rate that underpays plans for dialysis patients and overpays them for transplant patients.

Upcoming demonstration

We are hopeful that an upcoming demonstration will lead relatively quickly to improvements in the payment methodology. In an effort to further explore issues related to ESRD and managed care, we commissioned the RAND Corporation to study concerns relating to the incorporation of ESRD patients in a managed care program. The study dealt with payment amounts, reinsurance provisions, barriers and incentives. We have used this information to design a demonstration that will test a new payment methodology for capitated systems. We expect to solicit proposals for sites within the next four months and estimate that service delivery could begin in the second half of 1996.

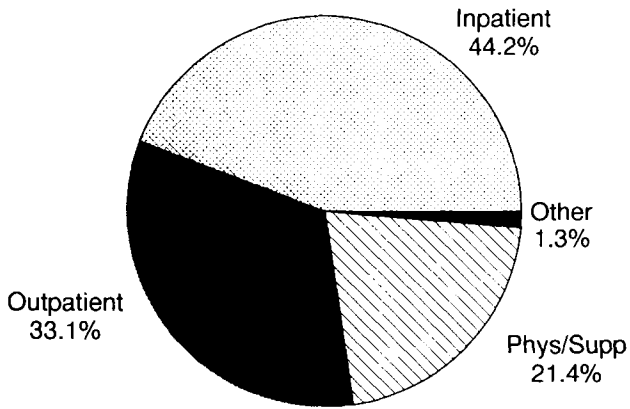
CONCLUSION

Medicare's ESRD program provides life-saving coverage to many who would otherwise be unable to afford necessary treatment. With more than 90 percent of persons with ESRD on Medicare, Medicare is by far the largest payer of ESRD-related services and supplies. We have a strong interest in the quality of care provided to our beneficiaries and close working relationships with our partners in the provider and advocacy communities. HCFA will continue to seek ways to increase the efficiency of the program without compromising patient care or access.

I hope this has been informative. I am happy to answer any questions you might have about the ESRD program.

Medicare Program Expenditures

for ESRD, by Type of Service: 1991



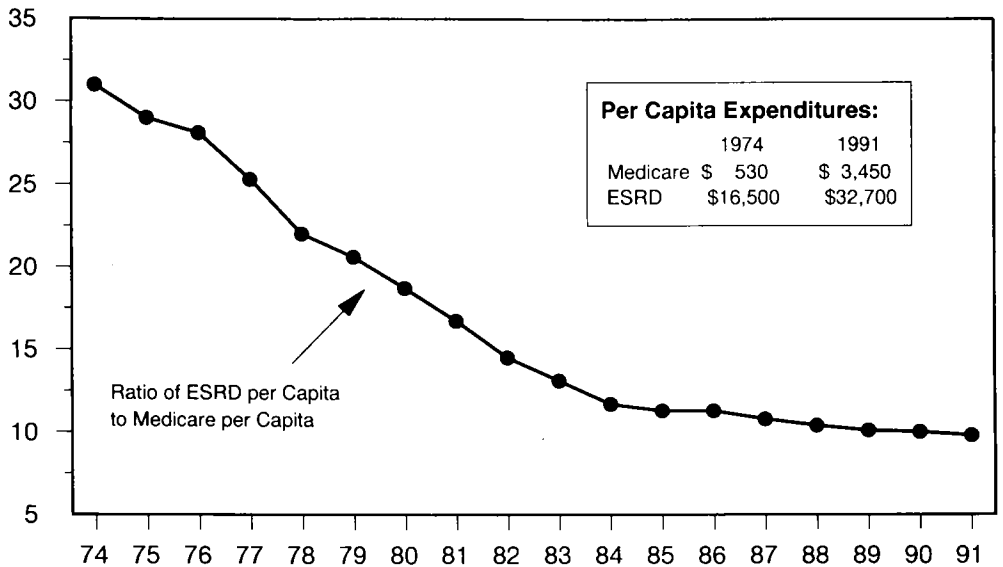
1991 - $6.1 Billion

- Inpatient = Hospitalizations
- Outpatient = Dialysis
- Phys/Supp = Physician Services and Home Dialysis Supplies
- Other = Home Health/ Skilled Nursing

P78 AS330A

Source: HCFA, ESRD, PMMIS

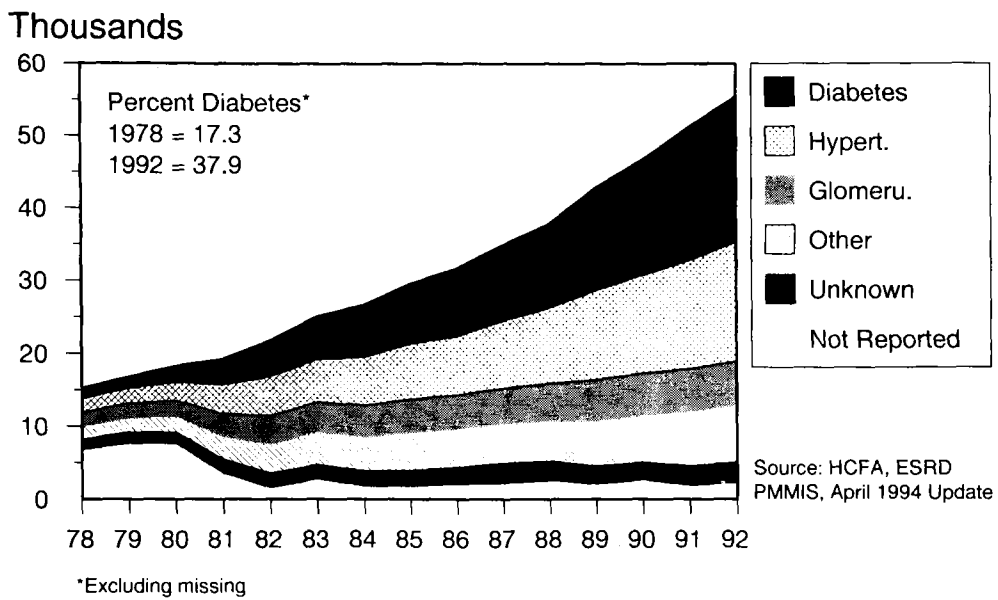
Medicare Expenditures per Person (74-91)
Ratio of ESRD to Total Medicare



Source: HCFA, BDMS, PMMIS, April 1992 Update

P78 AS330C

New Medicare ESRD Enrollees by Cause of Renal Failure: 1978 to 1992



P78 AS330B

Chairman THOMAS. Thank you very much, Dr. Smits.

Before I recognize my colleague from Nebraska, since we had several charts up there and you made some statements, some folks may want an answer to some of the statements that were made.

For example, in terms of the distribution of the types of patients on ESRD, you indicated, I believe, that there was some surprise that the diabetes and hypertension group was larger than anticipated. Why?

Dr. SMITS. We got better at dialyzing them. Again, you have to remember, when I was in training, there were a few dialysis slots available. We tended to give them to the youngest and healthiest. There actually—we had successful transplantation at about the same time, so in some cases you were dialyzing only those people you had hope of taking to transplantation.

Once you began to get broader experience, in the first years of the program, those people came on, people with end-stage renal disease and no other medical problems, but we then began to recognize that patients with controlled diabetes, for example, shouldn't be denied dialysis simply because, in the past, we hadn't had enough to go around and we had kept them out.

Young diabetics, especially, have done quite well on dialysis and to a certain extent with transplant, which is something we didn't anticipate. The severe hypertensives often do very well on dialysis, so frankly, we are much, much better at providing the service than we were in 1973.

Chairman THOMAS. You indicated on a line chart that initially the program was about 30 times more expensive. Now it is down to 10 times. Is that through significant changes in this program, more high technology being applied to a broader Medicare universe, or a combination of both?

Dr. SMITS. Actually, you see the same thing if you look at per capita costs and correct it for inflation. Part of it is efficiencies from doing it on a large scale, better understanding of how to do it well. The large facilities now have great economies in the purchase of equipment, building facilities, in the way they purchase and handle the supplies that go into it, better handling of staff, some shortening of dialysis time over the ones I knew in the very early seventies. Although it has stayed pretty stable for well over 10 years, a whole series of factors contribute to simply doing it better because it is being done on a planned, large scale.

Chairman THOMAS. So efficiencies—economy of scale as well?

Dr. SMITS. Yes.

Chairman THOMAS. On the pie chart, which was a 1991 representation of inpatient versus outpatient, 44 percent inpatient, 33 percent outpatient, with a 21 physician support, 21 percent physician support piece of pie. Ten or twelve years ago, what would that pie chart have looked like, inpatient versus outpatient?

Dr. SMITS. I am sorry, Mr. Chairman. Ten or twelve years ago I was running a hospital in Nancy Johnson's district and I don't know. I would be glad to submit it for the record.

Chairman THOMAS. I understand, the huskies had never been heard of. I was just going to try to get people who might be looking at that to get a feel for the changes between inpatient versus outpatient, but if we don't have it, that is fine.

Dr. SMITS. I think, yes, you will definitely see a ratio change with the outpatient becoming smaller and the inpatient larger, but we would be very glad to submit that for the record.

[The following was subsequently received:]

The distribution of Medicare payments from the past twenty years is shpwn below:

	1974	1984	1991
Reimbursements in Millions	$264	$2,341	$6,070
Percent Distribution:			
Total	100%	100%	100%
Inpatient	38.0	43.3	44.2
Outpatient	51.4	38.6	33.1
Physician/Supplier	10.5	17.7	21.4
Other	0.2	0.5	1.3

The shift in payments has occurred for a number of reasons. The major shift is due to the fixed payment rates for dialysis, which accounts for almost all of the outpatient category. The second factor has been the gradual shift of the patient population off of dialysis and on to a functioning kidney graft status.

In 1978, 11 percent of the ESRD population had a functioning kidney transplant. By 1991 this had increased to 22 percent. This shift of patients not only decreases the share of ESRD Medicare program going to dialysis, it also helps to restrain the overall increase in ESRD per capita costs.

Chairman THOMAS. I just wanted to try to indicate that I believe that was the case, and therefore, that portion of the expense has grown significantly. That was my guess, but if we don't have it, that is OK. I was just trying to bring some context to the charts that you had presented.

Thank you very much.

The gentleman from Nebraska.

Mr. CHRISTENSEN. Thank you, Mr. Chairman. Ms. Smits, what percentage of ESRD beneficiaries are already eligible for Medicare because they are disabled or aged?

Dr. SMITS. Over one-half are already aged and the other one-half become eligible through the process of ESRD. I would estimate that the number who qualify for disability first and then for ESRD is quite small.

Mr. CHRISTENSEN. Would it be possible to get an accurate number on that?

Dr. SMITS. Oh, yes.

[The following was subsequently received:]

In the four year period 1990 through 1993, there were 206,000 persons who experienced renal failure and entered Medicare's ESRD program. The distribution of these patients by initial entitlement status is shown below:

- Old Age: 38.1 %
- Disability: 20.2 %
- Renal Only: 41.7 %

Mr. CHRISTENSEN. The second question I have is: Would a more preventive approach to care in the Medicare Fee-for-Service Program help reduce the numbers of people who develop ESRD, more of a preventative approach to this problem?

Dr. SMITS. That is a very interesting medical question. My sense is that the prevention ought to be as early as possible and that with respect both to diabetes and hypertension, the period of really effective prevention may have been before they aged into Medicare. These are long-term chronic effects on the kidneys. So, again, I would have to bow to the very sophisticated renal physicians who are following me.

But, yes, everyone believes you could have less ESRD with better prevention, but whether you could do it starting at 65 is an interesting question.

Mr. CHRISTENSEN. I have an additional question. I was talking with a constituent this week in Omaha about the drug EPO, Epogen. Are you familiar with whether HCFA bundles the payments to local providers on this drug?

Dr. SMITS. Yes. We don't bundle. We pay—we make a payment for the drug, yes.

Mr. CHRISTENSEN. In the past, I am told that out of nearly two-thirds of all developed countries in the world, we reimburse at a significantly lower rate for Epogen than most of all western developed countries; is that correct?

Dr. SMITS. I don't know the international comparisons. We are buying it in very large—in much larger volumes than anyone else, so the ordinary pressures of the market would suggest we probably ought to be paying less for it, but, I again, would be glad to get you the international figures for the record.

[The following was subsequently received:]

Current information on international prices is hard to find. Anecdotal reports show that the United States pays less than Western Europe. A JAMA article published on July 10, 1991 by Sisk, et al included a table of EPO prices from 18 countries as of December 1989 which use currency rates from June 1990.

At that time, the United States was listed as paying $41 per 4,000 unit vial. Other countries ranged from a high of $130 in Greece to a low of $36.13 in Finland. According to these listings, the United States is in the lower third of these countries.

In early 1992, an informal study of dialysis facility nurse administrators in the United States suggests that EPO prices has dropped. The list price was $10 per 1,000 units but many units got "volume" discounts that dropped the price to $9.25 to $9.50 per 1,000 units or $37 to 38 per 4,000 unit vial. We have heard rumors that the price has dropped further since 1992.

Mr. CHRISTENSEN. Is there any evidence to show whether bundling, instead of paying as you go on Epogen, would cost the taxpayer more money rather than the other alternative method? Is there any evidence to show that we could do it at a cheaper rate, providing better health care coverage, providing better treatment of illnesses?

Dr. SMITS. That is a very difficult question. Epogen, as I am sure you know, is a biologic that is currently—it is not technically patented but it is currently under exclusive licensing. That exclusivity will expire next year. I think when you have essentially one very large buyer and one seller, you have a very odd market. I certainly think it is appropriate, as other manufacturers come into the business, to look into different ways of paying for Epogen.

Mr. CHRISTENSEN. OK, thank you, Doctor.

Chairman THOMAS. The gentleman from California will inquire.

Mr. STARK. Just to follow up, we pay about $10 for a thousand cc's for EPO now, is that about right?

Dr. SMITS. I have all these figures.

Mr. STARK. Somebody behind you is nodding on your staff. And if they use 4,700 cc's 3 times a week, it is good money. When we figure it probably costs 50 cents to manufacture 1,000 cc's, so that your idea of some other manufacturers coming in could lower our costs even more, could they not? It would be a great savings, I think.

Would you say that much of the inflation in the ESRD Program has come from items that we don't cover in the composite rate?

Dr. SMITS. Well, as you can see, it is not inflating as fast as the rest of Medicare. The items that we don't cover in the composite rate, the big one is hospitalization, where we do control the rates paid for the hospitalization. It is hard to talk about this as a program suffering badly from inflation. Whether you could contain the costs still further if you had a composite rate for everything, including hospitalization, is certainly an important question.

Mr. STARK. We are going to hear testimony from somebody, I suppose that has an interest in an HMO, that the ESRD Program

is probably the most extreme example of immense human and economic waste caused by Medicare fee-for-service. I think they are suggesting that we should put everybody in an HMO.

But if you have looked at the charts in the testimony on HMO versus non-HMO patients, it occurs to me that they are not really comparable. My guess would be that there is a difference in the composite of the HMO patients from others. Can you enlighten me there as to whether I am——

Dr. SMITS. I have looked at the charts but I haven't seen the tables behind them. It doesn't seem very likely that the small number of patients in HMOs are particularly similar to the average in Medicare as a whole.

Mr. STARK. Younger?

Dr. SMITS. Probably younger, yes. Probably healthier, and this is, I think—some of your questions about prevention are ones we ought to be asking the HMO industry because this is a setting where, over time, the care should, in fact, reduce the total rate of the onset, at least in certain categories.

Mr. STARK. What kind of penalties—you mentioned this 1.2 on a Kt/V and I don't know what that is except I guess you divide V into Kt, and if you get more than—if you get less than 1.2, we are not doing it right.

How do you punish or how do you encourage or what do you do to get these dialysis centers to hit the goal?

Dr. SMITS. Well, Kt/V is really a mechanical function, it is a measure of how effectively the clearance took place. The standard used to be 1. The profession itself upped that standard very recently to 1.2. When the standard was 1, more than 70 percent of all patients were meeting it. As soon as the standard became 1.2, that same measurement showed that only 40 percent of the patients were meeting it.

I think the challenge here is first to look very carefully at what that really means. I respect the professional standard. It is a useful one, but we need to look at what kind of benefits, does this really make a dramatic difference in quality of life or survival, which would mean we ought to——

Mr. STARK. Do you think there could be a minimum standard, that we ought to say, hey, if you don't hit this standard, you are out of the game or we don't pay you?

Dr. SMITS. I think there could be a minimum standard. I wouldn't want to have it the benchmark standard that everybody is working toward, but I certainly think there should be a minimum standard.

Mr. STARK. There isn't one now?

Dr. SMITS. No, we don't have one now, but we are looking very carefully at focusing the regulations much more on outcomes and that is one of the areas we——

Mr. STARK. Some kind of interim punishment or penalty or—if they don't hit it, I would gather.

The renal administrators and physicians want a repeal on the ban for referral to hospital facilities, and it is my understanding that physicians get about $15 a treatment in a dialysis center and closer to $180 per visit when they visit a patient in the hospital; is that correct?

Dr. SMITS. I believe so.

Mr. STARK. Which would give some incentive, would it not, or would it not appear to treat somebody in the hospital setting rather than the dialysis setting?

Dr. SMITS. Yes. In fairness, some hospital dialyses are much more complicated. Some are done when the patient is often sick with other problems and the rate would also apply to a patient who is newly in renal failure who is often quite difficult to dialyze at the beginning.

Mr. STARK. But it would also apply to routine dialysis in the hospital?

Dr. SMITS. Yes.

Mr. STARK. Thank you.

Chairman THOMAS. Before I ask the gentleman from New York to inquire, why is there such a significant discrepancy on reimbursement between inpatient and outpatient, $15 to $180?

Dr. SMITS. The physician on the outpatient side is——

Chairman THOMAS. If they were driven by money, you wouldn't have a more significant inpatient versus outpatient ratio here.

Dr. SMITS. You mean that if the doctors were all trying to get the patients into the hospital in order to get the higher fee?

Chairman THOMAS. Yes.

Dr. SMITS. I think the incentives are much more complicated than that. They are paid on a flat rate in the facility per month. They don't have to see the patient every dialysis. Many of them see the patients once or twice a month, sometimes in big facilities.

The group as a group will round on every patient every time. It really varies considerably. I think the settings where the doctor really does try to overcome Medicare's pressures not to admit and pick the patient out of the dialysis facility and put them in the hospital in order to get the extra money is unlikely.

Chairman THOMAS. Thank you.

The gentleman from New York, Mr. Houghton, will inquire.

Mr. HOUGHTON. Thank you very much, Mr. Chairman.

Dr. Smits, I have a specific question and then a more general one. The specific question is, How about the administration's support increasing the number of months during which Medicare would be secondary to ESRD beneficiaries' employer-based coverage?

What do you feel about that?

Dr. SMITS. I think that——

Mr. HOUGHTON. It would save quite a bit of money.

Dr. SMITS. Yes, it certainly would. I think there is some anxiety that in the absence of comprehensive health reform, you might see perverse effects, particularly the elimination of dialysis as a benefit from private plans.

Mr. HOUGHTON. Yes, but is the administration thinking about this?

Dr. SMITS. We have considered it in great depth and the President made the recommendation that he has made and that you have supported, which is to preserve the current timeframe.

Mr. HOUGHTON. The more general question I guess keys from the issue that Mr. Stark brought up about prevention, and you have talked about in some of your comments.

Now, we all talk about wellness programs, but when you take a look at something like dialysis and the cost, it is something like 5 percent of all Medicare costs. I mean, it is just extraordinary. Do you have anything that you can do in terms of not just the dietary issue, but other things which can eliminate some of these huge costs later on?

Maybe you have some charts and maybe you have some ideas on this thing, but when we are talking about saving money and helping people have a longer life, it doesn't seem to me there is almost any area which sponges up funds and real tragedy more than this one.

Dr. SMITS. Again, that is a very interesting question. I am not entirely sure, if you looked at it carefully, that you would save money. You can prevent renal failure, or at least delay it significantly in diabetics, if they are under very tight control. That is expensive. That means—there have been some recent trials looking at very frequent doctor or nurse visits, very frequent blood testing, very tight monitoring to hold blood sugars to something similar to the blood sugars that the rest of us manage normally.

That costs over years in order to prevent the end-stage renal disease. It is better. It is better for the patient, but whether it is less expensive than dialysis I think is an interesting question. Similarly with hypertension.

Mr. HOUGHTON. But have there been any tests on this? There must have been some examples where people have tried this type of process to try to find a way of cutting costs.

Dr. SMITS. You have to go disease by disease. Some of the recent work in diabetes certainly suggests it is manageable there. We do know that if hypertension is detected early and controlled rigorously, it is also manageable there. Again, although I would be glad to submit comments for the record, I think probably the best people to discuss this with are the renal physicians who follow me.

[The following was subsequently received:]

To the best of our knowledge, there have been only a few clinical trials to test mechanisms to slow or retard the progression of chronic renal disease into end stage renal disease. Nothing has been shown to work.

The largest study was the Modification of Diet in Renal Disease (MDRD). It failed to show that progression could be altered by diet. More recently there was a trial on the control of diabetes. The basic aim was to prevent blindness in diabetic patients, but it did give some weak evidence of beneficial renal effects as well. However, at this time there is no evidence that renal failure can either be prevented or even slowed. Needless to say, if no one knows how to prevent ESRD, it is difficult tc project what types of prevention efforts would be be cost effective.

Mr. HOUGHTON. Thank you very much.

Chairman THOMAS. The gentleman from Georgia, Mr. Collins, who is not a Member of the Subcommittee, but I believe has an interest in this area, might like to inquire.

Mr. COLLINS. Thank you, Mr. Chairman, yes, and I do appreciate your allowing me to participate in this hearing this morning. I wanted to respond to a constituent who had a daughter who was being treated by a center in Georgia and she died in January 1993, and I would like to submit for the record, Mr. Chairman, a statement by me and also a statement from that particular person.

[The prepared statement follows. The letter from the constituent was not available at the time of printing.]

SUBCOMMITTEE ON HEALTH, COMMITTEE ON WAYS AND MEANS
END-STAGE RENAL DISEASE PROGRAM
MAC COLLINS
APRIL 3, 1995

Mr. Chairman, I appreciate the opportunity to participate in this morning's hearing of the Subcommittee on Health to discuss issues surrounding the Medicare End-Stage Renal Disease Program.

I have many concerns about this program. Last year I introduced the Elizabeth A. Greeson Dialysis Coverage Act that provided additional protections for patients who receive treatment through dialysis clinics that receive funds from the Medicare program. Mrs. Greeson was an end-stage renal disease patient receiving treatment through a dialysis clinic in Atlanta. Tragically, Elizabeth Greeson lost her battle with the disease in January of 1993. She was a patient at a clinic that was cited for several health and procedural violations. Additionally, the Georgia Department of Human Resources recommended to the Health Care Financing Administration that the facility be terminated from the Medicare program within 90 days. To this date, the facility remains open, operating business as usual.

As legislators, I believe that it is our responsibility to review the standards of these programs to ensure that we are providing the necessary protections that will prevent needless losses such as these.

Currently, American taxpayers pay $8 billion per year through Medicare to ensure that care is provided for some 200,000 end-stage renal disease patients. These funds go to private dialysis treatment clinics, entrusted with the responsibility of providing good care and treatment.

My legislation requires that private medical facilities, offering medicare-financed end-stage renal dialysis kidney treatment, make necessary arrangements to ensure these services are available on a 24 hour basis.

Currently, federal regulations require renal dialysis centers and facilities have an affiliation agreement or arrangement in writing for the provision of inpatient care and other hospital services. My legislation would essentially codify this regulation by requiring renal dialysis centers, as a condition of receiving Medicare funds for these procedures, either provide dialysis treatment on a 24 hour, "on-call" basis, or make an arrangement with a local facility that has the capacity to provide these services during periods when the facility is not open. Additionally, patients that receive care at the private clinics should be notified of this arrangement so that they are fully aware that emergency services are available at an alternate local facility.

The primary purpose of this bill is to stress to privately-owned facilities that their responsibility includes the well-being of the patient, and not merely monetary profit. These facilities provide fundamental treatments for patients who cannot live without them. Consequently, these private facilities should be accountable for treatment when it is needed for the preservation of life -- 24 hours a day; not merely during business hours.

I believe it is necessary to codify this condition and clarify in law that private renal dialysis clinics, receiving tax payer funds, provide for this type of arrangement.

I appreciate the opportunity today to participate and hear testimony about the program and its effectiveness; as well an opportunity to pose questions to officials about the legislation I am working on again this Congress.

For Elizabeth Greeson who battled kidney disease, legislative improvements come too late. But by legislatively strengthening the program, we will improve how we provide end-stage renal disease treatment and enable other families to avoid tragic loss due to failures of the health care system.

Thank you Mr. Chairman.

Mac Collins

Mr. COLLINS. But my question is about reports by the Georgia Department of Human Resources who conduct investigations and certifications of dialysis facilities. Once those reports are made, and if the recommendation is made to HCFA for termination of such facility as far as delivery of service, what is the normal procedure after such a determination is made and recommendation is made by HCFA?

Dr. SMITS. We then proceed to—if we agree that the conditions in the facilities jeopardize the life and health of patients, we can and do terminate.

Mr. COLLINS. Well, I want to refer to this particular center, which seems to be twice in 1 year that the Department of Human Resources actually recommended termination, but, however, this facility is still in operation. Is that kind of normal procedure or is——

Dr. SMITS. How many times—first of all, I can't comment on that facility——

Mr. COLLINS. I am using that facility as an example. Would that be normal procedure, if you had two such recommendations in 1 year, they could still continue to provide the service?

Dr. SMITS. I don't think that is particularly common. We have terminated a number of facilities. How many times we have received recommendations and not acted on them, I don't know.

Is the facility in a remote area?

Mr. COLLINS. No. Atlanta.

Dr. SMITS. So it is not a question of access.

Mr. COLLINS. No. Do you have a record of termination? How many facilities—do you have off the top of your head how many facilities may have been terminated in, say, a 12-month period using calendar year 1993?

Dr. SMITS. They gave it to me in my book and I am afraid I can't remember it. Can I submit it for the record?

Mr. COLLINS. I would love to see those numbers.

[The following was subsequently received:]

In Calendar Year 1993, 28 facilities were terminated (1 involuntarily). In 1994, 32 facilities were terminated (5 involuntarily). In 1995, 2 facilities were terminated (none involuntarily).

In addition I would like to discuss the specific center you have referred to as an example. There were three complaints made to the Georgia Office of Licensure and Regulation against Peachtree Dialysis Center in Atlanta, Georgia in 1993. One complaint was made by the father of a young woman, who was a dialysis patient at the facility and had died. Also, in November 1993, two other patients at this ESRD facility filed complaints against the facility. One of these complainants made 16 allegations against the facility.

An on-site investigation was completed on November 30, 1993, by the Georgia Department of Human Resources, Office of Regulatory Services. The investigation revealed that one Condition for Coverage was not met and substantiated some, but not all, of the allegations. The facility developed acceptable plans of correction for all of the deficiencies and compliance was confirmed on a follow-up visit on January 26, 1994. Since the facility met all of the conditions of coverage and met additional criteria it was not terminated from the Medicare program.

In addition, the ESRD Network serving the area received a complaint about the ESRD facility from the father of the patient who died. The network reviewed the medical record of the patient in question and referred the case to the Georgia Professional Review Organization (PRO), which also conducted a review of the case. Neither the Network nor the PRO found that care was inappropriately rendered. They completed their investigation on June 9, 1994.

A review of this facility's compliance history reveals that a January 29, 1992 complaint investigation found that the facility was not in compliance with the Condition for Coverage relating to staffing requirements. The facility corrected this problem as well. Also, the facility was found out of compliance with the Patient's Rights Condition for Coverage on the August 1991 survey, but subsequently corrected its deficiency.

In conclusion, Peachtree Dialysis Facility has been found to be out of compliance with some basic conditions on at least three occasions since 1991. Patient complaints have been brought against the facility, and some of the complaints have been substantiated. However, in each case, the facility developed a Plan of Correction and corrected its deficiencies. Consequently, the facility remains Medicare certified.

At this time, there are no outstanding issues between the State Survey Agency or the ESRD Network and the Peachtree Dialysis Facility. However, I would be happy to discuss this case further if there are any additional questions you may have.

Mr. COLLLINS. Any restrictions in the Medicare rules or regulations pertaining to profit centers by physicians who may be treating a patient and have profits or investment within a center?

Dr. SMITS. The recent self-referral law, which would apply to some aspects of renal disease, and those regulations are not yet written, but in the past, no, there was no prohibition on a physician referring for dialysis to a center in which he or she also had a financial interest.

Mr. COLLINS. But you are in the process, if I understood right, of new regulations being written to address that situation?

Dr. SMITS. Yes.

Mr. COLLINS. OK, good.

The particular area where we have some legislation that we are introducing pertains to emergency care, such as weekend care for dialysis where a center would be required to have an affiliate agreement with a hospital or someone else to take care of a patient and to notify the patient that such agreement is in place.

Do you have any comment on such as that so that we can assure, even in a place like the city of Atlanta, that a patient who depends on a dialysis center would be covered on a weekend?

Dr. SMITS. I would certainly expect that the physician who is being paid a capitation rate for that patient should always either be available or have an arrangement, have a call arrangement, that it isn't just having a hospital available. It is having someone available who has access to your personal records and knows you. I have not heard of that previously as a problem. That is certainly something we will be glad to look at.

Mr. COLLINS. Could I request that you have a member of your staff contact my office where we can further discuss this particular case and this particular center and try to come to some kind of resolution on it?

Dr. SMITS. Yes, sir.

Mr. COLLINS. See if there have been any updates or changes made that will help the people in this area?

Dr. SMITS. Yes, we would be very happy to.

Mr. COLLINS. Thank you.

Thank you, Mr. Chairman.

Chairman THOMAS. You mentioned earlier the method of payment between dialysis, transplant, postoperative, and followup may cause some problems for HMOs. You mentioned that we should examine the way we pay, but we really, I don't think, discussed in any meaningful way, the relative costs, for example, of a successful kidney transplant. We hope all the transplants will be successful.

I have a friend who died of kidney failure who had several kidney transplants. They were all temporarily successful, none of them permanently successful, so I am acquainted with the problems when the transplants are not successful.

I am interested in the cost of the transplant, postoperative costs, how long that might be, the long-term costs of maintaining someone who has had a successful kidney transplant versus a path of dialysis and continued dialysis for that same period.

Dr. SMITS. Successful transplantation is much more cost effective.

[The following was subsequently received:]

In fact, an analysis can be found in the May 1992 publication of Seminars in Nephrology (Volume 12, No. 3). The article is "Comparison of Treatment Costs Between Dialysis and Transplantation" by Paul Eggers who works for the Office of Research and Development at the Health Care Financing Administration. I would be happy to send a copy of this article to this Committee. To summarize briefly, the article shows that the high initial costs of transplantation are recovered in avoided dialysis costs in about 4.5 years. The net savings per transplant over a ten-year timeframe was estimated to be about $41,000. This "payback" period is shorter for living related donor (LRD) transplants than for cadaver transplants due to the higher rates of graft survival among LRD transplants. Similarly, aggregate ten-year savings are greater for LRD transplants than for cadaver transplants.

The analysis was conducted based on 1989 reimbursement patterns.

At that time EPO was just beginning to be used to treat anemia in dialysis patients. Since 1989, dialysis patient care has become more expensive because of EPO (there is very little off-setting savings). In addition, transplant success rates continue to improve. Consequently, a recent analysis of pediatric transplant recipients (not yet published) suggests that the payback period is now closer to three years and the ten-year cumulative savings is closer to $100,00 per transplant. Although not yet analyzed separately, the payback period is likely to be somewhat longer for adult transplant recipients and the cumulative savings somewhat less.

Dr. SMITS. The limiting factor there to a great extent is the availability of kidneys. The technology—or success rate in this country with transplantation is really very good. But kidneys become available in the situation of tragedy, and we certainly don't want to be in the position of encouraging more automobile accidents in order to have more kidneys.

Chairman THOMAS. I think you would get agreement from the Subcommittee on that. Is it a problem of matching up as much as it used to be, or are we able to maintain a functioning kidney now easier than we used to?

Dr. SMITS. We are much better at the match. We understand the immunology a great deal better than we did 15, 10, or 5 years ago.

Chairman THOMAS. Do we provide a successful rate roughly in terms of all transplants?

Dr. SMITS. The current success rate?

Chairman THOMAS. Yes, ballpark. Is it 60, 80?

Dr. SMITS. It is over 90, isn't it?

Chairman THOMAS. Over 90 percent?

Dr. SMITS. I am told 80 percent for cadaver—over 80 percent for cadaver, over 90 percent for living related donors.

Chairman THOMAS. So it is the condition of the donor as well.

Mr. CRANE. Mr. Chairman, would you yield?

Chairman THOMAS. Certainly.

Mr. CRANE. After a transplant, what is the annual cost, roughly, of the immunosuppressive drugs?

Dr. SMITS. I am sorry. I don't remember that specific figure individually. I will be glad to give you that for the record. It is probably one of the highest elements of cost posttransplant.

[The following was subsequently received:]

The Batelle Corporation conducted a study for HCFA on immunosuppressive protocols for kidney transplantation in 1989. The results of that study showed that yearly immunosuppressive costs, after the initial period following a transplant, were between $3,200 and $4,000 per patient. Although we have not had an update to this study, we assume that annual costs are about $4,500 per patient.

In 1994, Medicare spent $55 million on immunosuppressive therapy. The Omnibus Reconciliation Acts of 1993 extended the coverage period for immunosuppressive therapy from 12 months to 18 months. Although costs will increase significantly for immunosuppressive therapy but still be less than dialysis. We estimate that we will spend $80 million for immunosuppressives in 1995.

Secondly, as I mentioned earlier, the use of immunosuppressives after transplantation is certainly more cost-effective than dialysis in the long-term treatment of the ESRD patient. In fact, the May 1992 edition of Seminars in Nephrology, Volume 12, Number 3 contained an analysis entitled "Comparison of Treatment Costs Between Dialysis and Transplantation." This analysis has definitely proven the cost effectiveness of immunosuppressive therapy.

In short, our estimates show that in 1995 Medicare will spend approximately a total of $42,000 per patient annually on dialysis, while after transplantation, Medicare will spend $4,500 per patient annually for immunosuppressive therapy. Clearly immunosuppressive therapy is cost effective in the treatment of ESRD.

Mr. CRANE. Thank you.

Chairman THOMAS. Obviously, quality of life would be significantly improved as well. We have been looking not only at dollars and cents, but obviously, the ultimate goal is to provide——

Dr. SMITS. The fact is that one-half of the people after transplant leave the program because they are able to go back to work.

Chairman THOMAS. Very good.

Dr. SMITS. Let me just mention again that because we have this demonstration coming, the RAND Corp. has worked out detailed rates for us for potential HMO payment. I think we should put those in the record so you can inspect them in detail.

[The following was subsequently received:]

The exact payment rates will be determined based (1) partially on analyses conducted by Brandeis University of ESRD expenditure data and (2) through negotiations with potential bidders on the demonstration. However, it is very likely that there will be two basic payment rates, one for dialysis patients and one for patients with a functioning kidney transplant.

In 1991, the yearly cost to Medicare for a dialysis patient was about $44,000; for a functioning graft patient, was $7,400. A monthly equivalent of these amounts would be a rough approximation of what would be paid. In addition, both of these amounts are likely to be adjusted for patient case-mix, such as age and the presence of diabetes. Finally, it is expected that a special one-time payment will be needed to pay for the cost of the transplant.

This question was asked of a different panel and th information given was incorrect. This is the correct answer:

o **When does Amgen's exclusivity to market erythropoeitin expire?**

A: Amgen's exclusivity to market EPO is protected by the Orphan Drug rules under the FDA. The Orphan Drug Act gives Amgen exclusive rights to market EPO for the treatment of anemia associated with ESRD for seven years. During this time, the FDA will not consider applications from other companies for the same basic product. The FDA granted this protection to Amgen specifically for this medical condition. This protection ends on December 31, 1996. Amgen also has Orphan Product protection for the marketing of EPO for the treatment of anemia associated with HIV. This was granted on December 31, 1990 and expires on December 31, 1997.

These protections under the Orphan Drug Act are distinct from the patent Amgen holds on the organism that produces EPO. The patent is distinct from FDA approval. It expires on October 27, 2004.

Chairman THOMAS. Very good. Thank you.

The gentleman from California.

Mr. STARK. Two issues that are just very difficult to deal with. At one point a year or two ago, I had suggested that we do something like a congressional commendation, a medal or something like that for people who would donate organs—wouldn't cost much and it would be a symbolic gesture to encourage it. We tended to run into lots of problems with postage stamps and other things we have.

Is there anything that might be considered, or perhaps the Secretary might have a secretarial commendation, on the theory that sometimes it is just an omission of someone who has died, and people are in shock and really need a little encouragement to perhaps make the donation? That is one thing I would like you to consider.

Second, the question that certainly none of us like to discuss and ought not to be the subject of legislation, but whether you have thought about it, there is some indication, and I think Dr. Rettig is going to testify later, that we are dialyzing folks who, for other reasons, are so ill that whether or not the dialysis is successful, they are going to die from something else.

We certainly don't want to be setting standards to say, no, let Uncle Joe die, but on the other hand, could we educate—is there something we could do to educate either the patients or those who would hold the proxy for the patient in cases of extreme illness where there are other complications that might serve the patients and their families better?

I don't know. It is an area which I have always hesitated to think about legislating, but encourage the people who disseminate information to allow families to make a better informed choice. I don't know whether you have a program like that or whether you are any more interested in doing it than I would be as a legislator.

Dr. SMITS. Let me answer both questions with personal experience. First, I have been there in the room asking families to donate organs. That is a very tough job, and any support there is, any publicity, any general knowledge that the families come to that meeting with is helpful to us.

We try continuously to remind people about the benefits, and it is possible that some kind of public acknowledgment, particularly to the families who agree to cadaver donation, would be very welcome. A living related donor is a much more personal decision and does not usually face the same problems.

In the question of who we dialyze in this country, I have worked in nursing homes and I have seen patients—I have cared for patients on dialysis where it made me very uncomfortable that dialysis had been started and that it was being continued. At the same time, I would not like to see the government try to make that decision or to hold facilities to some sort of standard.

The private sector has developed essentially advanced directives for dialysis, a way of looking at that decision. What happens sometimes is you begin dialyzing in the hope that the other elements of the illness will improve and they don't, and then it is very hard to stop. There is an advanced directive that helps the doctor and the families go through what is, by rights, their joint collective decision, and once that had been developed, we did distribute it to all dialysis facilities in the country and encouraged them to use it.

We would certainly be very pleased to work in any other collaborative way with providers if we can help with this but, again, there are times when families absolutely want dialysis, no matter what you and I believe about the quality of life.

Chairman THOMAS. I think if we will work toward simplification, computerization, and continued collection of data for outcomes, that we can begin to develop some profile analysis in which we can either encourage or discourage based upon very solid evidence which allows us to lead people to the proper decision with some data that might be helpful, even in a difficult family time.

Dr. SMITS. When you raise the question in most settings of shouldn't we stop for this patient, what you have is a whole lot of people who say, Oh, no, no, we can't, there is absolutely no way to; we have started, we must keep on. And I think simply distributing the advanced directive and helping people think through the process will at least send some message that it isn't necessarily terrible to stop if it is appropriate for that patient's circumstances.

Chairman THOMAS. Now I think it is appropriate to turn it over to the gentlewoman from Connecticut whose women yesterday were not very gentle but very, very good.

Mrs. JOHNSON. Top notch. Just to welcome you, Dr. Smits, and say that I regret that I wasn't able to hear all your testimony, but I do appreciate the good work you have done for us in Connecticut, and I particularly appreciate your opening your testimony by recognizing the accomplishments of our women's basketball team in their come-from-behind victory. It is really important for women's success to be recognized, and particularly when they demonstrate the discipline, courage, and concentration that coming from behind takes. Nice to have you.

[Discussion off the record.]

Chairman THOMAS. The next panel is Dr. Rettig, Dr. Powe, and Dr. Blagg, please. Thank you, doctors.

Any written testimony that you have will be made a part of the record and you can inform us, educate in any way you see fit, in the 5 minutes you have. We will start with Dr. Rettig and then move across the panel.

STATEMENT OF RICHARD A. RETTIG, PH.D., SENIOR SOCIAL SCIENTIST, RAND CORP.

Mr. RETTIG. Thank you, Mr. Chairman. My name is Richard Rettig. I am a senior social scientist at the RAND Corp. where I have been since February of this year. Previously, I worked there from 1975 to 1981. I was not part of the ZAND group that did the recent capitation study. From 1987 until early this year, I was at IOM, the Institute of Medicine of the National Academy of Sciences. In that capacity, I was study director for the study of the institute called forth in OBRA, the Omnibus Budget Reconciliation Act of 1987.

My remarks today do not necessarily represent the views of either the Institute of Medicine or the RAND Corp.

I have submitted a longer statement for the record, as well as a number of background materials, and two papers that deal with the legislative history of this program and how it came to pass in 1972, which may interest the Members.

OBRA 1987 asked the IOM to study the program. I served as director of that study. My remarks pertain mainly to that 1991 report, a copy of which you have, including a summary which is available for all Members, and to an initiative that the IOM took in 1993 and 1994 as a followup.

I should echo the comments of several Members that the program has been very successful in saving lives that would have ended abruptly or prematurely. It has also been successful in holding down the per treatment cost of dialysis. The aggregate cost is high because treatment is expensive and the patients are growing rapidly in number.

I have five points to make today, Mr. Chairman, and Members. First is epidemiology. You saw Dr. Smits's charts. The program has been growing very rapidly in the elderly patient population. Those 65 to 74 and 75 years of age and above constitute 44 percent of all new enrollees in 1992. Diabetes and hypertension provide a major source of new patients, and it may be that as we treat these dis-

eases better, we increase the pool of individuals who then experience kidney failure.

The population also includes a large portion of minority patients. Twenty-nine percent of all new patients in 1992 were African Americans: they have a failure rate four times that of the white population.

During the IOM study in 1991, we asked Dr. Eggers of the HCFA to project the ESRD patient population to the year 2000. He did so and made three estimates: a slow growth resulted in 210,000 patients, moderate growth reached 240,000 patients, and 270,000 patients was the rapid growth estimate.

It is clear from HCFA data that the actual numbers in the year 2000 will exceed the high, rapid growth estimate made in 1989. My point is that there is no escape from the epidemiology of this program as the fundamental driver of the costs. That ought to be very clear in everybody's minds as the Subcommittee searches for cost reductions. It is that underlying epidemiology that drives costs.

Reimbursement is my second point. This is important because total program costs are very high and the beneficiaries are few in number relative to the total Medicare population.

At the level of outpatient dialysis per treatment reimbursement, the ESRD Program has been a great success. Historically, the rate was unchanged for 10 years, was reduced in 1983, was modestly reduced again in 1986, and has had no adjustment for inflation during the entire 20-plus years of this program. Congress added $1 to the composite rate in 1990.

In our study, the IOM analyzed the real dollar decrease in per treatment payment from 1974 through 1989. The result of the analysis was that the 1989 payment rate was approximately 40 cents on the 1974 dollar. A recent update of that analysis showed that payment today is closer to 30 cents on the 1974 dollar.

Reimbursement and quality are my third point. The IOM found in its study that reductions in quality, as measured by the outcomes of hospitalization and mortality, could not be correlated with reimbursement reductions. Staffing changes could be, but these changes couldn't be correlated with outcomes. That is as much a problem of measurement as it is of the phenomenon which we have heard from the others.

In perspective, two trends are occurring. Epidemiology continues to add to the patient population; second, there is a continued reimbursement decline on the outpatient treatment side. These two trends can't go on forever. Either quality will decline or reimbursement must be increased. Fourth, what is needed is a system of quality assessment. The community has been concerned with mortality and adequacy. In addition, at a conference in 1993 and a workshop in 1994, the IOM strongly urged the adoption of functional status, health status, and health-related quality of life measures of quality.

Mr. RETTIG. There are good instruments to obtain such data. They can be derived from patients. They ought to be derived from patients. Only as we get such data, in my judgment, will we really begin to put in place a system in which the quality implications of cost reduction are firmly understood.

Fifth, let me end by saying the 1972 legislation called for a medical review board to screen "the appropriateness of patients for the proposed treatment procedures." The meaning of that term has not been defined. The IOM report had a chapter on ethics that specifically asked whether too many patients were accepted for treatment.

The existence of an entitlement has often been interpreted by clinicians as an obligation to treat, regardless of other complicating medical conditions and the prognosis for patient benefits. The willingness of some clinicians to accept for treatment, for example, elderly demented patients, a persistent vegetative state patient, or a blind diabetic amputee is widely recognized and discussed, if not well documented.

The Subcommittee recommended that guidelines for patient acceptance be developed involving patients and professionals. Thus, we raised an issue, but did not resolve it. My personal conclusion today is the slow pace of guidelines development reflects the great difficulty physicians and others have in dealing with this issue. Although we concluded that this issue was not one on which legislation was appropriate, I conclude it is not an issue on which the Congress should continue to remain silent.

The time has come for Congress to ask the patient and provider communities to address the issue of appropriateness of patients for treatment with respect to developing guidelines for patient acceptance criteria. Congress need not and should not consider legislation. It can and should clearly indicate to the public and all interested parties the importance it attaches to discussing and addressing this hard issue.

Thank you.

[The prepared statement and attachment follow:]

TESTIMONY OF RICHARD A. RETTIG, PH.D.
RAND CORPORATION

Mr. Chairman, Members of the Committee. My name is Richard Rettig. I am a Senior Social Scientist at the RAND Corporation, where I have been since mid-February of this year; I previously worked at RAND from 1975-81. From 1987 until early this year I was a Senior Staff Officer at the Institute of Medicine of the National Academy of Sciences. In both organizations I have done work related to the Medicare End-Stage Renal Disease program. Most recently, at the Institute of Medicine, I was the responsible staff officer for a major study, a conference, and a workshop related to the ESRD program.

I am pleased to testify today before this committee, which has been involved in all legislative aspects of this program.

Some time ago, I wrote a legislative history of how Section 2991 (the kidney disease entitlement amendment to the Social Security Amendments of 1972) was adopted. That amendment authorized treatment for permanent kidney failure, by both dialysis and kidney transplantation, as a near-universal entitlement covering an estimated 92-93 percent of the United States population. More recently, I wrote a related paper, with the help of the Congressional staff who were involved in the 1972 legislation. Both papers have been supplied to the committee staff and Members may find them useful analyses of the political background to this program.

I should say at the outset that the Medicare ESRD program has been very successful, especially for those individuals for whom it was originally intended. Thousands and thousands of individuals whose lives would otherwise have ended prematurely and abruptly due to kidney failure have had those lives extended and have pursued productive activities of benefit to themselves, their families, and the society. The program has also been very successful in holding down the per treatment costs of dialysis. However, the aggregate cost of the program, estimated to be $8 billion in this year, is a function of the patient population, which continues to grow, and the per patient per year treatment cost, which is very high.

The Omnibus Budget Reconciliation Act of 1987 called for an Institute of Medicine (IOM) study of certain aspects of the ESRD program. That study, conducted by an expert committee for which I served as study director, was published in 1991 by the National Academy Press as Kidney Failure and the Federal Government. A single copy of that very thick report has been provided to the Committee. In addition, twenty-five copies of the report summary have also been provided, as have multiple copies of a 1991 paper in the New England Journal of Medicine by Dr. Norman G. Levinsky, the IOM committee chairman, and myself, that also summarizes the study.

My remarks today pertain mainly to the 1991 IOM report and to a follow-up initiative that the Institute took in 1993 and 1994. In addition, I will share with you some of my personal views about the program for your consideration. I should emphasize that my remarks do not necessarily represent the views of either the Institute of Medicine or the RAND Corporation.

In OBRA 87, the Congress asked the IOM to consider the following five issues:

- The epidemiology of the ESRD patient population
- Access to treatment, especially for those not covered by Medicare
- The effects of reimbursement on quality
- The measurement of quality
- Data

DATA

In my remarks today, I will comment only in passing that the data for the ESRD program are probably the best there are in the Medicare data system. This is due to the dedication and competence of several key professionals at the Health Care Financing Administration (HCFA) and to the work of the United States Renal Data System, now housed at the University of Michigan and supported by contract by the National Institute of Diabetes and Digestive and Kidney Diseases (of the National Institutes of Health) and HCFA. There are some opportunities for making more creative use of these data, in my judgment, about which I will comment below.

EPIDEMIOLOGY

The growth of the ESRD patient population has been the single most important cost driver. For some time, the patient population has been growing increasingly older. For example, in 1992, of nearly 56,000 new patients enrolling in the program, 20% were in the 55-64 years-of-age group, 26% were 65-74 years old, and 18% were over 75. Nearly two-thirds (64%) of the new patients were over 55 years of age and 44% were over 65 years old. Moreover, in the 1987-92 period, the *average annual growth* of new patients over 65 years was 11.6% and those 75 years and older grew at a rate of 15.7%.

Patients are also presenting in large numbers with primary diagnoses of kidney failure of diabetes and high blood pressure. In 1992, 36% of all new patients had a diagnosis of diabetes as the primary cause of kidney failure; and for 29 percent of new patients, hypertension was identified as the primary cause of kidney failure.

The patient population is also includes a large proportion of minority patients. For example, 29% of new patients in 1992 were African-American; for whom the rate of kidney failure is nearly four times that of the white population.

The IOM, in conducting its study, asked Dr. Paul Eggers of HCFA to project the ESRD patient population to the year 2000. Using actual data through 1988, and using three different assumptions of slow, moderate, and rapid growth, the estimates were 210,000 patients (slow growth), 240,000 (moderate growth), and 275,000 (rapid growth) by the end of the decade. Total program enrollment in 1992 had already reached 200,000 patients, indicating the difficulty of estimating the growth of the patient population and that year 2000 actual numbers are likely to exceed the earlier high estimate.

I dwell on these numbers for one simple reason. Whatever the Members of this Committee think about this part of Medicare, there is no escape from the fact that the growth of the patient population is the primary factor driving cost increases. I will return to this later.

ACCESS

The kidney failure treatment entitlement is as close as we come in the United States to universal coverage of any condition. Individuals are eligible for entitlement if they are currently or fully insured under Social Security, have been diagnosed as having permanent kidney failure, and have applied for benefits, or are the spouse or dependent child of such an individuals. Thus, over 90% of the U.S. population are covered by Medicare for permanent kidney failure.

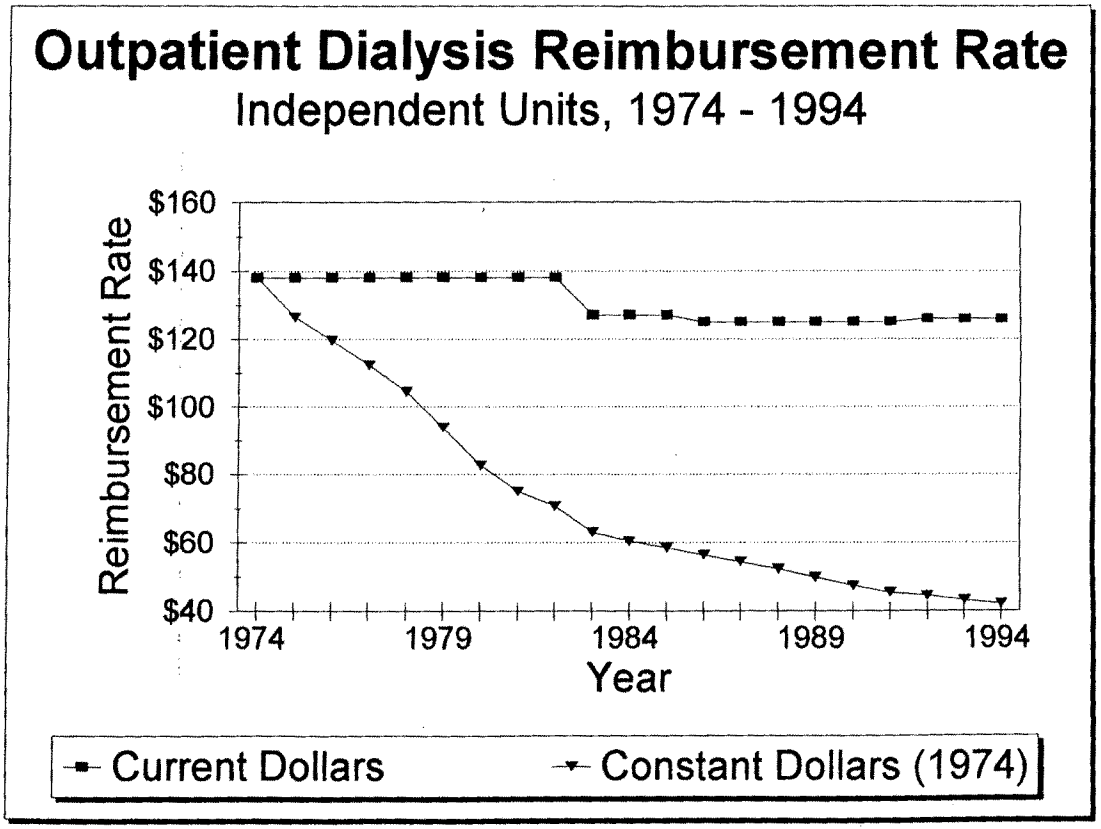
The IOM committee made basically two recommendations regarding access. First, it recommended that there be universal coverage of all American citizens and resident aliens. If the nation is prepared to insure more than 90 percent of the population, the committee r easoned, it ought to complete the task and insure the entire population. It is safe to say that the Congress greeted this recommendation with studied indifference.

Second, with respect to kidney transplantation, the IOM committee recommended that coverage for immunosuppressive drugs be made coterminous with the duration of coverage for the transplant patient. The 1972 legislation had limited coverage for the procedure to 12 months, which Congress extended to 36 months in 1978. The rationale for the recommendation about immunosuppressive coverage was that the most cost-effective treatment and the one with the highest quality of life on average should not be jeopardized by a failure of Medicare to pay for the necessary drugs. As a result of the Omnibus Budget Resolution Act of 1993, coverage of immunosuppressive drugs has been extended from 12 months to 18 months effective January 1 of this year; it will increase to 24 months in 1996, to 30 months in 1997, and to 36 months on January 1, 1998 and thereafter.

REIMBURSEMENT

Reimbursement for ESRD treatment is important for a simple reason: total progam costs are very high and the beneficiaries are few in number relative to the total Medicare population, perhaps one-fourth of one percent.

At the level-of-per-treatment reimbursement, the ESRD program has been a great success. The IOM committee analyzed the real dollar decrease in per treatment payment from 1974 dollar through 1989. A combination of an unchanged reimbursement rate for 10 years, followed by a downward revision in 1983, a more modest downward revision in 1986, and NO ADJUSTMENT FOR INFLATION at any time during the program's history, resulted in a 1989 payment rate that was approximately 40 cents on the 1974 dollar. A recent update through 1994 puts the figure closer to 30 cents on the 1974


Outpatient Dialysis Reimbursement Rate
Independent Units, 1974 - 1994
Reimbursement Rate
$160
$140
$120
$100
$80
$60
$40
1974
1979
1984
1989
1994
Year
Current Dollars
Constant Dollars (1974)

dollar. (The 1989 adjuster used was the GNP implicit price deflator; the more recent figures uses the Consumer Price Increase--Urban deflator (CPI-U).)

In 1991, the IOM committee recommended no further explicit reimbursement reductions and also that the payment rate be updated annually, consistent with the rest of Medicare. Congress did add $1 to the composite rate in 1990.

REIMBURSEMENT AND QUALITY

The OBRA 1987 charge directed the IOM to examine the effects of reimbursement on quality of care. We did so, using mortality and hospitalization as outcome measures and treatment unit staffing as a measure of input use. The findings were as follows: (1) the relation of reimbursement reductions to increases in patient mortality were suggestive but not conclusive; (2) the relation of reimbursement reductions to hospitalizations were also suggestive but not conclusive; and (3) the relation of reimbursement reductions to reduced staffing were -- not surprisingly -- clear, but these effects could not be related clearly to changed patient outcomes.

To be sure, every clinician (physicians, nurses, social workers), administrator, and patient representative to whom we spoke believed that quality had suffered in response to reimbursement reductions. The IOM committee saw no reason to doubt them. But the problem of measuring the relation of aggregate data on reimbursement to quality of care, especially outcomes, is very difficult and, in my judgment, there is no inconsistency between what practitioners see and what aggregate data fail to capture.

Regarding patient outcomes of care, mortality is the measure that has preoccupied the U.S. nephrology community. This concern for mortality is appropriate but it is not enough. It is noteworthy that the United States Renal Data System has reported improved survival among all groups of patients and for all modalities of treatment in recent years, during which there has been no improvement on reimbursement.

In the past five years or so, the "adequacy" of dialysis has become the primary clinical measure of quality of care for the dialysis patient population. Adequacy is a complex clinical measure of the appropriate "dose" of dialysis for a given patient. A good deal of progress has been made in recent years with respect both to the measurement of adequacy and the delivery of adequate dialysis care. Measuring adequacy is very important, but, in my view, not enough.

It is worth noting, both with respect to mortality and adequacy, that large administrative data bases are increasingly being used to generate data on local treatment unit performance, then these date are fed back to these units, allowing them to compare their performance to other units in their region and to all units in the nation. This emerging system, or set of systems, of data acquisition, analysis, generation of information on national and regional performance, and feedback to local treatment units is very promising.

QUALITY ASSESSMENT

The 1991 IOM report had a rather general, conceptual chapter on the measurement of quality, appropriate for the time but limited in many ways. As a follow up, the IOM held a conference in September 1993 on "Measuring, Managing, and Improving Quality in the End-Stage Renal Disease Treatment Setting." The proceedings of that meeting were later published in the August 1994 issue of the American Journal of Kidney Diseases. A copy of that proceedings issue has been made available to the staff.

The conference concurred in the importance attached to mortality and adequacy of dialysis as measures of quality, but also •lent strong encouragement to going beyond these measures to include measures of functional outcomes, health status, and health-related quality of life. The organizing committee believed that systematic measurement of how well patients were doing, not just the measurement of laboratory and clinical values, was very important in a chronic disease patient population.

In a December 1994, the IOM held a related workshop to answer the question of how to measure functional outcome, health status, and health-related quality of life. Four well-validated measurement instruments were examined: the Duke Health Profile, the Dartmouth COOP charts, the Medical Outcome Study 36-Item Short Form, and the RAND Kidney Disease Quality of Life instrument. The results of that workshop are being prepared for publication.

Dr. Robert Brook testified before this Subcommittee several weeks ago, saying that measurement of quality was possible. Indeed it is and it is certainly possible in the data-rich ESRD program. But neither the Health Care Financing Administration nor the nephrology community have been very quick to exercise leadership regarding the measurement of quality. There are two areas in particular that the Committee might consider asking for more vigorous action.

The first of these is in relating cost data to outcomes of treatment at the facility level. Although there has been a marked improvement in attitude,orientation, and competence of personnel in the Health Standards and Quality Bureau in recent years regarding the assessment of quality in the ESRD program, there appears to me to be little or no discernible interest in the Bureau of Policy Development (which is responsible for reimbursement) in relating cost data to information about quality. The IOM committee, in 1991, recommended that this issue be taken up and systematically addressed. It is long past the time that a good faith start on this matter be undertaken.

To do so requires that HCFA link several existing data bases that have yet been linked. It is currently possible with existing data bases to identify high reimbursement and low reimbursement treatment units (both ends of the spectrum) and to examine high and low mortality rates (both ends of another continuum) and to initiate the systematic examination of the relation between resource inputs and outcomes of care. This endeavor should be done. This Committee should provide clear guidance to HCFA and the nephrology community on this point. Absent the systematic analysis of the relation

of cost to quality, we will continue to be subjected to a series of anecdotes that serve the purposes of the user but do not help policy makers. It is also the case that the USRDS was barred by the National Institutes of Health in its first five year contract from considering reimbursement and clinical issues together, even though the data permitted such examination. It appears that that problem has been remedied in the second five-year contract. But this Committee should make clear to NIH and to HCFA that the public interest is not served by the failure to examine cost and clinical data together.

The second area in which HCFA and the nephrology community might be asked by this Committee to be more forthcoming is in the development of a system for the acquisition of data on the functional status, health status, and health-related quality of life of the ESRD patients. In a chronic disease patient population, it is entirely reasonable to ask about patients' physical functioning and limitations, their social functioning, bodily pain, general mental health, vitality, and general health perceptions. Well-validated instruments exist for acquiring such data. Several of these are deliberately short, to ease the costs of data collection and analysis and to facilitate their use in busy clinic settings.

Resistance to the use of functional and health status and quality-of-life measures stems, in my view, from several sources: (1) these instruments have been developed by health services researchers and are unfamiliar to many clinicians; (2) the utility of these instruments has yet to be demonstrated for patient monitoring and patient management; (3) functional and health status data have yet to be correlated with clinical outcome data; (4) measuring these factors adds to the cost of treatment; (5) systematically-acquired patient data may challenge physician authority; and (6) these data may provide the basis for limiting what HCFA can do with respect to reimbursement reduction (direct or indirect).

Some of these reasons for resistance have merit, others do not. If improving the outcomes of patient care is an objective shared by the Congress, HCFA, the provider community, the general public, and -- above all -- by patients, this Committee should encourage greater progress in this area than we have seen to date.

EPIDEMIOLOGY, COST, AND ETHICS

Mr. Chairman, Members of the Committee. Let me return to the epidemiology of the ESRD program. It should be clear that the growth of the patient population drives cost growth of the ESRD program. It should also be clear that cost containment has been extraordinarily successful on a per treatment basis, largely through the absence of adjustment for inflation. But the two trends of the increasing treatment requirements of an increasingly older and medically complicated patient population and a relentless reduction of reimbursement cannot persist indefinitely without either quality suffering or expenditures increasing. Obviously, it is impossible to calibrate the appropriate relationship between epidemiology and cost without the systematic acquisition of data about quality of care. This is one implication of the epidemiology of the ESRD patient population.

A second implication is the need to examine the major clinical contributors to kidney failure of diabetes and hypertension. As the nation improves its treatment of these diseases, it may simultaneously be increasing the pool of prospective patients destined for kidney failure. Consideration should be given to the progress of medical research, to the implications for behavioral change by individuals, especially related to diet, and to the probable costs of a health care system that fails to provide adequate primary care to many low income citizens early in their lives only to reap the costs of providing very expensive treatment for the failure of a major organ system later in life.

Finally, I should note that the IOM committee in its 1991 report included a chapter on ethics that was specifically concerned with whether too many patients were accepted to treatment. The existence of an entitlement has often been interpreted by clinicians as an obligation to treat kidney failure, regardless of other complicating medical conditions and the prognosis of patient benefit. The willingness of some clinicians to accept for treatment, for example, an elderly demented patient, a persistent vegetative state patient, or a blind diabetic amputee is widely recognized and discussed, if not well-documented.

The IOM committee recommended that "patients, professionals in adult and pediatric nephrology, and bioethicists develop guidelines for evaluation of patients for whom the burdens of renal replacement therapy may substantially outweight the benefits." We thus raised, but did not resolve, a very hard question, and encouraged a discussion that continues to the present.

Although the IOM committee concluded that this issue was not one on which legislation was appropriate, my personal conclusion today is that the slow pace at which guidelines development has progressed reflects the great difficulty that physicians and others have in confronting this issue. I have also concluded that this is not an issue on which the Congress should continue to remain silent.

The 1972 legislation that authorized this entitlement included the following paragraph:

- "The Secretary is authorized to limit reimbursement under Medicare for kidney transplant and dialysis to kidney disease treatment centers which meet such requirements as he may by regulation prescribe: *Provided*, That such requirements must include at least requirements for a minimum utilization rate for covered procedures and for a medical review board to screen the appropriateness of patients for the proposed treatment procedures [emphasis added]."

I believe the time has come for the Congress to ask the patient and provider communities to address the issue of the "appropriateness of patients" for treatment with respect to developing guidelines for patient acceptance criteria. It need not and should not consider legislation. It can and should indicate to the public and to all interested parties the importance that the issue be responsibly addresssed.

Mrs. JOHNSON [presiding]. Dr. Powe.

STATEMENT OF NEIL R. POWE, M.D., M.P.H., M.B.A., ASSOCIATE PROFESSOR, JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE

Dr. POWE. Thank you, Members of the Subcommittee. I am an associate professor of Medicine at Johns Hopkins University. I am currently directing an End-Stage Renal Disease Patient Outcomes Research Team or PORT funded by the U.S. Agency for Health Care Policy and Research. The work focuses on defining the effectiveness and cost of treatment for individuals with end-stage renal disease.

I previously led a national study for HCFA of the effectiveness of erythropoietin, a relatively new and expensive treatment for anemia of ESRD. This study included an evaluation of the impact of different payment methods on access, outcomes, and cost.

In my testimony today I will address the issue of how payment methods to reimburse providers will affect cost, access to care, and quality of care.

The first issue is cost. The medical care of ESRD patients is expensive. Persons with ESRD consume 8 to 10 times more medical resources on an annual basis than the average Medicare beneficiary. Total Medicare expenditures for ESRD are likely to grow due in large part to the continuing increase in the population of older adults who are experiencing ESRD. The large costs suggest that there is an opportunity to develop and implement clinical, organizational, and payment innovations that will help reduce the cost of ESRD care.

Both renal physicians and facilities are paid a fixed payment for treatment for medical services related strictly to dialysis. This partial capitation method of payment has been viewed as an effective means of controlling program costs. Evidence for this is that expenditures for nondialysis, noncapitated care, have grown at a faster rate than expenditures for dialysis care. The extension of provider responsibility to manage the total care of the ESRD patient using capitation methods that encompass all services is therefore very attractive as a means of continuing cost containment. Capitation has the potential to impose discipline on medical spending through more predictable outlays. Furthermore, capitation methods reward efficient providers and have the potential to promote better coordination of care because a provider is made fully accountable and encouraged to provide more comprehensive care.

Capitation payments are often constructed with the assumption that all patients are average. However, patients with ESRD are heterogenous; heterogenous with regard to other medical conditions and the resources necessary to provide their care. For example, persons with ESRD and diabetes or age greater than 65 years have higher expenditures than persons without these attributes.

Other conditions such as heart disease, bone disease, and bleeding disorders are frequently present. If Medicare were to pay an average fee to providers who take care of less severely ill patients, the program might pay more than necessary. On the other hand, if a provider were to care for patients who are more severely ill and consume more necessary medical resources, it might lose money

and become economically inviable under a system which pays only an average capitation rate. Thus, it is essential that a program of full managed care and capitation incorporate risk-adjusted payments for comorbid disease. Risk-adjusted payment rates account for the fact that all patients are not average.

The second issue is access to care. Medicare payment for ESRD since 1972 has allowed and maintained access to care for over a half a million individuals. Because the number of providers of ESRD care now exceeds 2,000, most individuals have a choice of providers from which to receive care.

In a move to comprehensive managed care of ESRD, an organization choosing to participate must be able to provide the full range of services that these patients require; outpatient dialysis care, outpatient nondialysis care, inpatient care, and transplantation services which offer persons with ESRD the possibility of resuming a near normal life. Some organizations may not have these capabilities. Thus, in some areas of the country under a mandatory full capitation program, choice of providers could be restricted. Furthermore, a new payment system must permit choice and access to likely cost-effective ESRD technologies such as peritoneal dialysis, transplantation, and medications.

My last issue and equally important issue is quality of care. Payment for capitation must recognize that while there is a financial incentive to use resources more wisely, there is also the potential that providers might cut back on necessary and expensive medical care that is beneficial to patient well-being. Therefore, it is prudent that a reformed system of fully managed and capitation care implement more careful oversight. This includes monitoring and enforcement of quality standards.

Unfortunately, much work needs to be done to develop appropriate quality standards such as clinical practice guidelines for the care of the ESRD patient. Our patient outcomes research project will help in this regard.

Thank you.

[The prepared statement follows:]

TESTIMONY OF NEIL R. POWE, M.D.
JOHNS HOPKINS UNIVERSITY

Thank you Mr. Chairman and members of the Committee. My name is Neil R. Powe, M.D., M.P.H., M.B.A. I am an Associate Professor of Medicine at the Johns Hopkins University. I am currently directing an End-Stage Renal Disease Patient Outcomes Research Team (PORT) funded by the U.S. Agency for Health Care Policy and Research. My work focuses on defining the effectiveness and cost of treatment for individuals with End-stage Renal Disease who now number over 150,000. I previously led a national study for the Health Care Financing Administration of the effectiveness of recombinant human erythropoietin therapy, a relatively new, effective and expensive treatment for anemia of End-Stage Renal Disease. This study included an evaluation of the impact of different payment methods on access, outcomes and costs.

In my testimony today, I will address the issue of how payment methods to reimburse providers who care for individuals with ESRD will affect costs, access to care and quality of care.

The first issue is cost. The medical care of individuals with ESRD is expensive. Persons with ESRD consume eight to ten more medical resources on annual basis than the average aged Medicare beneficiaries. While ESRD beneficiaries account for only 6 tenths of a percent of the Medicare population they disproportionately account for over 4 percent of Medicare expenditures. Epidemiologic studies suggest that total Medicare expenditures for ESRD are likely to grow due in large part to the continuing increase in the population of older adults who are experiencing ESRD. The large per patient costs and rising total Medicare costs suggest that their is opportunity to develop and implement clinical, organizational and payment innovations that will help reduce the cost of ESRD care.

Since 1983 providers of dialysis care, both physicians and facilities, have been paid by HCFA under the composite rate methodology, which pays a fixed payment per treatment for medical services related strictly to dialysis. This method of payment has been viewed as an effective means of controlling program costs. Evidence for this is that expenditures for non-dialysis, non-capitated care for dialysis patients have grown at a faster rate than expenditures for dialysis care. These non dialysis, noncapitated services include care for other health conditions and hospitalizations. The extension of provider responsibility to manage the total care of the ESRD patient using capitation methods that encompass all services is therefore very attractive as a means of continuing cost-containment. Capitation has the potential to impose discipline on federal medical spending for ESRD patients through more predictable outlays. Furthermore, capitation methods reward efficient providers and have the potential to promote better coordination of care because a provider is made fully accountable for comprehensive care.

The second issue is access to care. Medicare payment for ESRD care since 1972 has allowed and maintained access to care for over a half a million individuals. In addition, because the number of providers of ESRD care has doubled over the past 15 years and now exceeds 2000, most individuals with ESRD have a choice of providers from which to receive care. Private-sector for-profit and non-profit organizations versus government-run facilities comprise most of the centers that provide care. In a move to comprehensive managed care of ESRD, an organization choosing to participate in care for ESRD persons must be able to provide the full range of health care services that these persons require. This includes outpatient dialysis care, outpatient non-dialysis care and inpatient care. In addition, transplantation services which offer persons with ESRD the possibility of resuming a more normal life must also be available. Some organizations may not have these capabilities. Thus, in some areas of this country under a mandatory full capitation program, choice of providers for individuals with ESRD could be restricted if not enough providers are capable of organizing the complete care of these patients. Furthermore, a new payment system must permit choice and access to likely cost-effective ESRD technologies such as peritoneal dialysis, transplantation and medications (such as recombinant human erythropoietin and cyclosporine) that enhance the quality of life of the ESRD patient.

Capitation payments are often constructed with the assumption that all patients are average. However, persons with ESRD are heterogenous; heterogenous with regard to other medical conditions and the resources necessary to provide their care. For example persons with ESRD and diabetes or over the age of 64 years have higher expenditures than persons with

ESRD without these attributes. Other comorbid conditions such heart disease, bone disease and bleeding disorders are frequently present. A system of full capitation for individuals with ESRD must recognize the differences in disease severity and resource use between patients. If the Medicare program were to pay an average fee to providers who take care of less severely ill patients, the program might pay more than necessary. On the other hand, if a provider were to care for persons with ESRD who are more severely ill and consume more necessary medical resources, it might lose money and become economically inviable under a system which pays only an average capitation rate. Thus, it is essential that a program of full managed care and capitation incorporate risk-adjusted payments for comorbid disease. Risk-adjusted payment rates account for the fact that not all patients are average.

The last and an equally important issue is quality of care. Payment for capitation must recognize that while there is a financial incentive to use resources more wisely, there is also the potential that providers might cut back on necessary and expensive medical care that is beneficial to the well-being of individuals with ESRD. Most health indicators in the ESRD population are already below that of the general population. For example, on average, approximately one out of five ESRD patients dies each year in the United States. There is the risk that if payment levels to providers are not adequate, providers might reduce care to the point of negatively impacting patient outcomes. Therefore, it is prudent that a reformed system of fully managed and capitated care implement more careful oversight. This includes monitoring and enforcement of quality standards. Much work needs to be done to develop appropriate quality standards such as clinical practice guidelines for the care of the ESRD patient. Our PORT project will help in this regard.

In summary, innovative payment approaches should be explored for the care of persons with ESRD. However, the methods should be carefully selected to control costs, maintain access to care, allow choice of providers and enhance the quality of care.

Thank you.

Chairman THOMAS [presiding]. Thank you.

STATEMENT OF CHRISTOPHER R. BLAGG, M.D., EXECUTIVE DIRECTOR, NORTHWEST KIDNEY CENTERS

Dr. BLAGG. Thank you. I am Christopher Blagg. I am executive director of the Northwest Kidney Centers in Seattle, which is a large community-based, nonprofit corporation, the oldest freestanding dialysis unit in the world. I have been asked to talk about the capitation study because I was one of the consultants to the study that was completed by the RAND Corp.

My written testimony contains an outline of the issues, and I don't propose to go through them except to say that I think it was a successful study. It identified payment methodology based upon a rate for dialysis, a rate for the patient with a functioning transplant, specific lump sum payments for a kidney transplant, or for a kidney transplant failure, both of which are expensive events, and as Dr. Powe mentioned also, risk adjustment for sick patients who may be outliers, and so forth.

I included some of the cost data from the study in my written testimony. The problem is how to contain costs for patients with a disease that requires very expensive treatments and for whom the costs can vary widely, depending upon patient characteristics, complications, and the treatment the patient receives.

I would reverse the order of the things Dr. Powe has just said and say the most important thing, I believe, is quality of care. It is most important if we are going to go to capitation that we ensure we have good measures of quality of care first.

Several years ago we became concerned because the mortality rates in U.S. hemodialysis patients were significantly higher than for patients in Europe, Australia, and other Western countries. It is only as we have collected more data and started to do some things looking at quality that this has begun to change.

I believe that at this point in time we are not going to be able to get much economy by cutting the costs of dialysis. This is because as we are trying to provide better dialysis, we are going to use more expensive dialyzers, and are probably going to increase the length of time we dialyze patients. Where we can contain costs is in terms of hospitalization, physician services, access surgery services, and so forth. Those are the areas where capitation would give the opportunity to reduce costs. So, if we are going to go to capitation, first we must ensure we have good quality control; that any capitation program deals with the problem of selection so we don't get selection bias and skimming off of the better patients to capitation.

Second, we must make sure that whatever the system is, it does not skew patients' choices. Patients need to have access to transplantation and to various forms of home dialysis. It is possible to skew things, depending how you set up the system. I think you need to find ways of encouraging patients to enroll in managed care if this is what we are going to do, because right now I believe it is true to say that Medicare continues to have problems in getting patients generally to enroll in managed care.

I think you also have to take into account geographic variations in costs in different parts of the country. You certainly must also

take into account the occasional patients for whom costs can be extremely high.

You also have to take into account the fact that the population is changing. As you have heard, the number of patients is increasing, increasing faster than was anticipated. Not only that, the population that is increasing is changing and becoming sicker, so you have more complex patients who, again, are going to cost more money.

Managed care would have the advantage of providing better coordination of care, but I would emphasize that at a time like this when we are just beginning to get a handle on quality in the ESRD Program, it is not the time to go to capitation. We need to do the demonstration studies that HCFA is proposing and learn from these, because here we are dealing with a disease in which all the patients are sick. This is a different situation to the general HMO situation where you have the whole population to select from, and a lot of people who are not sick. Here you have a sick population with a chronic condition that is very expensive to treat, and we need more experience with capitation before we go to this generally.

One final comment. Mr. Stark at the beginning of the hearing made a comment about home dialysis only being useful in exceptional circumstances. I disagree with that. We in health are particularly enthusiastic with the idea that home hemodialysis eventually may come back into wider use. There is data from the U.S. Renal Data System which is not yet published, but was mentioned at a meeting 2 weeks ago. This showed that not only is the quality of life better with home hemodialysis, but the survival of patients, when adjusted for all the factors that may affect survival, is significantly better than survival for patients who are on in-center hemodialysis. That is my little plug from Seattle.

In summary, I think capitation could well prove a fruitful approach to containing costs in the ESRD Program, but I do not believe this is the moment to look at it generally. Let's do a demonstration project first.

Thank you very much.

[The prepared statement follows:]

STATEMENT OF CHRISTOPHER R. BLAGG, M.D.
EXECUTIVE DIRECTOR
NORTHWEST KIDNEY CENTERS

Testimony to House Ways and Means Health Subcommittee, Monday, April 3, 1995:

My name is Christopher Blagg, I am a nephrologist from Seattle, and Executive Director of the Northwest Kidney Centers and Professor of Medicine at the University of Washington.

Northwest Kidney Centers (NKC) is a non-profit, community-based organization that provides dialysis services throughout Seattle and most of King County, Washington, as well as serving as the Organ Procurement Agency for Western Washington and the states of Alaska and Montana. NKC has six dialysis facilities that provide outpatient hemodialysis for 600 patients. A further 124 patients are treated by home hemodialysis, and 93 by CAPD and other forms of peritoneal dialysis at home. Currently, 59.2% of all NKC patients either have a functioning kidney transplant or are treated by home hemodialysis or peritoneal dialysis. NKC serves a medical staff of 37 nephrologists from private practice, the University of Washington, and Group Health Cooperative, a large HMO.

I have been involved with dialysis for more than 30 years, and with the NKC for 23 years. During that time I have also been involved in various ways with legislative activities, consulting with the Health Care Financing Administration (HCFA), with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), with planning of end-stage renal disease (ESRD) services at the state level, and with various professional organizations.

I have had an interest in the concept of capitated reimbursement for ESRD treatment for a number of years, and served as a member of the advisory committee to the Rand Study "Designing a Capitation Payment Plan for Medicare End Stage Renal Disease Services". I also met with congressional staff in the past to support inclusion of a demonstration project on capitation for ESRD in HCFA's Social HMO demonstrations. At this time, I am waiting for publication of the Request for Proposal from HCFA for this demonstration project. NKC will then consider whether or not to respond with a proposal to participate in this.

THE RAND CAPITATION STUDY:
This research project, funded by HCFA, evaluated the options for a capitation payment system for patients with ESRD that would combine payments for hospital and outpatient services, including physician services. Medicare claims data from 1990 for all part A and part B services for ESRD patients were analyzed and used to estimate total payments, including Medicare and copayments and deductibles. Monthly payment amounts were standardized to national averages. The study used 1990 data from 136,047 patients who used dialysis services only during the year, 27,740 patients who only had a functioning kidney transplant, 6,185 patients who received a transplant, and 1,773 patients whose transplant failed during the year.

Capitation Program Principles:

- Control cost by an appropriate mix of services and their efficient delivery;

- Promote quality of care in terms of appropriate care and outcomes and patient satisfaction;

- Promote equity for patients, including free choice of both treatment modality and health plan;

- Provide equity for health plans by payment methods that take into account differences in patient resource needs and ability of plans to compete for patients.

Components of a Capitation Plan

1. **Benefits package** that includes all part A and part B services. This could also include additional benefits or reduction in copayments as incentives for enrollment.

2. **Marketing and enrollment** that allows any Medicare ESRD beneficiary with part A and part B entitlement to enroll at any time. Enrollment and disenrollment must be monitored to detect bias in patient selection.

3. **Delivery systems** comprised of health plans contracting with HCFA and with dialysis providers, hospitals, laboratories and physicians. Contracts between health plans and providers should be flexible in such matters as risk-sharing and profit-sharing agreements.

4. **Payment methods** based on monthly capitation amounts for patients on dialysis or with a functioning kidney transplant. Payment must take into account patient characteristics, including age and a diagnosis of diabetes, as well as extra costs in preparation for a kidney transplant and following transplant failure.

5. **Quality assurance** provisions.

6. **Monitoring and oversight** of the quality of health care services and the financial viability of health plans on behalf of the government in order to protect the interests of Medicare ESRD beneficiaries.

Payment Methodology Recommendations

- Monthly capitation payments for patients on dialysis, risk-adjusted for differences in costs related to patient characteristics;

- Monthly capitation payments for patients with functioning transplants;

- A fixed lump sum payment for each kidney transplant and for each transplant failure to cover the incremental costs of these infrequent and expensive events;

- Separate payments for Medicare part A and part B benefits;

- Use of multiple linear regression models to risk-adjust for additive payment adjustments. While they explain only about 3% of total variation in average monthly payments, there are a few extremely expensive dialysis patients. Separate sets of risk adjustments for part A and part B payments are recommended to take into account age, sex, diabetes as cause of ESRD, and previous graft failure. An important adjustment for part A payments is a one-time payment for patients in their first month of treatment if Medicare is already primary payor. Other risk factors also should be evaluated.

- A fixed loss outlier payment policy as one means to mitigate health plan risk from unusually expensive patients. Outlier payments would be paid for cases with medical expenses during the calendar year exceeding the capitation payment plus $50,000;

- Care must be taken to avoid incentives for health plans which would discourage the use of transplantation or home dialysis as options;

- There are clear rural and urban differences to be taken into account.

AVERAGE 1990 MONTHLY STANDARDIZED PAYMENTS

	Part A	Part B	Total	Annual
Dialysis	$ 1,334	$2,049	$ 3,393	$40,716
Transplanted	$ 472	436	908	10,896
One-Time Payment For Transplant	$33,971	$3,948	$37,919	
One-Time Payment	$ 8,958	$3,167	$12,125	

Table 1 illustrates some of the data from the Rand study. It is important to note that these estimates are based on 5 year old data from 1990. Any demonstration will require careful updating of the financial estimates used to set reimbursement rates.

COMMENTS

Patients with ESRD are expensive to treat, and the 1995 estimate of $8 billion for Medicare is only part of the cost. The total cost of ESRD treatment to Medicare and other sources in 1995 will be some $11.2 billion, based on a methodology used to estimate cost in the United States Renal Data System 1994 Annual Data Report. The problem is how to contain costs for patients with a disease requiring very expensive treatments and for whom costs can vary widely, depending on patient characteristics, complications, and the treatment, while at the same time maintaining or improving the quality of care.

Quality of care is particularly important, as some years ago it became clear that dialysis patients in this country had a significantly higher average mortality risk than patients in other western countries. At that time, U.S. patients were receiving some 20% less dialysis than those elsewhere. To improve the adequacy of dialysis requires use of either larger more expensive dialyzers or of a longer dialysis time which is also more expensive. Thus, it seems unlikely the cost of dialysis treatment itself can be reduced much, if at all. Any costs

saving in the Medicare ESRD Program must come from other economies involving hospitalizations, access surgery, physician services, and other items. Capitation is certainly worth exploring as a potential means of controlling these costs.

Nevertheless, the Rand study does not go into detail about how the implementation of capitation for ESRD should be carried out. This is a significant problem because, on the one hand, dialysis providers and nephrologists in general are not yet experienced with a capitation approach and, on the other hand, existing health plans have relatively limited experience with ESRD patients. Thus, it is most important that the next step towards capitation for ESRD be a demonstration project or projects to gain experience with this for a very expensive chronic disease with widely varying costs for some patients. Another reason for such a study is that by the time it is concluded and the results assessed, physicians and providers will have had much more exposure to managed care generally, and so will be more open to innovative changes in reimbursement.

Several concerns are important in devising a capitated health care system for the ESRD program. First, and most important, measures of quality control are essential in any such scheme in order to avoid risk to patients. In addition, methods must be developed to deal with several other issues:

- means to prevent selection bias so as to deal with the problem of health plans enrolling an overlarge proportion of less expensive patients;

- means to address the influence of health plan and provider financial incentives on the choice of treatment modality. The Rand study shows how payment subsidies can be created by the choice of time cutoffs. Subsidies could be used as incentives, for example, to encourage transplantation and possibly home hemodialysis - the treatments with the best survival and quality of life. In any case, it is important that patients are educated fully about, and have access to, all modalities of treatment;

- means to encourage beneficiaries to choose to enroll in a managed care plan. Slow enrollment continues to be a nagging problem with Medicare managed care options generally.

- payments must also take into account geographic variation. For example, hospital days and hospital costs vary widely by region, by urban or rural location, and are higher in teaching hospitals and disproportionate share hospitals. Thus, geographic differences in reimbursement are common now, and can only be adjusted over time;

- means to deal with health plan risk that might occur as a result of inclusion of an unexpectedly high proportion of patients with extremely high costs. This problem could be minimized by adjustment of payments if appropriate, or by use of outlier payments;

- means to adjust the capitation rate to match the changing ESRD population. The number of patients continues to increase, with an ever larger proportion of complex

cases that require more services and have only a limited ability to improve their health status.

The cost containment potential with capitation relates particularly to the opportunity to manage the individual patient much more closely. Dialysis costs and the costs of a kidney transplant are relatively fixed, but better and more coordinated care using a case management approach could improve care, reduce the frequency of hospitalization and access surgery problems, and consequently reduce costs. More coordinated management would also allow opportunity to reexamine the frequency of physician visits and the frequency and number of laboratory studies, both of which help to drive costs in the fee-for-service setting. This becomes important as the incidence rate for new ESRD patients continues to grow by some 8% annually, while the number of practicing nephrologists is expected to decrease in the near future.

In summary, a capitated approach to the ESRD program has potential merits in terms of cost containment and improving adequacy of dialysis and quality of care. The Rand study dealt in detail with financial issues but not with the details of implementing such a program. The next step should be the demonstration project under development by HCFA which will give the opportunity to learn the issues and problems in implementing capitation. A time when the quality of dialysis treatment in the U.S. is only beginning to improve as a result of monitoring of facilities and physician and patient education, is not the moment to radically change reimbursement without further experience with capitation. Nevertheless, I believe this approach will prove fruitful and will be the next major innovation in funding of the Medicare ESRD program.

Thank you for considering these comments.

Chairman THOMAS. I thank the panel very much. The gentlewoman from Connecticut will inquire.

Mrs. JOHNSON. Dr. Powe, do you agree with Dr. Blagg that if we go to capitated rates they need to be adjusted for severity, that their needs to be more than one rate?

Dr. POWE. I thoroughly support that. I am concerned that, as I said, Medicare might pay more if a provider were to select rather healthy ESRD patients and vice versa, that if providers took care of the very sick, they may not be viable as organizations.

Mrs. JOHNSON. We appreciate the danger of that. In the past have there been problems with oversight of quality?

Mr. RETTIG. I think what has happened in the past 10 years is great attention to mortality as an outcome measure; next, a great attention to adequacy of dialysis, accompanied by hematocrit, blood pressure, and nutrition.

The argument that emerged from the IOM conference held in 1993 is that there is a marvelous opportunity in this chronic disease patient population of 200,000, who present three times a week, to get data on how well the patients are doing. There are instruments for doing that. They are called questionnaires and they are filled out by patients.

Sometimes patients find it easier to respond to a questionnaire than they do to talk to their physician. I think it is long past the time when this program should have been collecting data on physical function, bodily pain, social and role function, general health perception, and general mental health. A complete quality assurance system, whether capitated or not, needs all those elements—mortality, adequacy, functional and health status.

Mrs. JOHNSON. I think that is an excellent comment. Has there been any problem in the past with quality? Because if we are going to build quality in, and some of you have suggested that one of the dangers is that we tend to build that in through regulatory systems that also affect costs and not necessarily in a way that improves quality. I want to know whether there are any past problems with quality and that is not to say that the kind of questionnaire that you recommend would be costly, but wouldn't be very useful.

I am not sure from Dr. Blagg's comments that he isn't envisioning a proper controlling form of government oversight of quality. Have there been problems in the past?

Mr. RETTIG. I think there have been, but they are documented extensively on mortality and about the same on hospitalization. There are very good data systems that have begun to generate data on adequacy of dialysis. But you don't have a complete picture. You have anecdotes. That is part of the problem in responding to the question.

I am arguing the need for putting a systematic mechanism in place to acquire such data.

Dr. BLAGG. I agree. I am not suggesting that the government should be applying strict sanctions in this area. Rather, the information should be available to both patients and to physicians and also to the public in general so that by peer pressure we can improve quality. I agree there was a problem. It is now beginning to get better, and that is why I say now is not the time to change the reimbursement system.

Mr. RETTIG. Let me extend that if I may. There are very good data systems. They can generate data on a facility-specific basis on some outcomes and then those data can be compared to regional and national data. They can be fed back to the facility and potentially they can be made available to patients. I think they should be made available to the patients, and that would be much more powerful than any system of sanctions.

Dr. POWE. I agree that there have possibly been isolated problems with quality in different areas of the country. I think on a broad scale, the care of ESRD patients is excellent. I think that we need to understand more how to measure quality of care. It can be measured in a variety of ways and we need to get better at doing that, and then setting some standards by which we all can work to achieve.

Mrs. JOHNSON. Thank you.

Chairman THOMAS. The gentleman from California.

Mr. STARK. I am sure that Mr. Collins is going to be recognized again, and he has a case of quality that doesn't seem to have much to do with medical training to me. It is just providing the service and it could be in fashion to Members. I will let him go on about it.

Dr. Blagg, in the very round figures when you talk about capitating ESRD dialysis, for most people it is three times a week, $47. The dialysis itself is about $20,000 give or take $1,000, regardless of who the patient is, isn't that——

Dr. BLAGG. I agree.

Mr. STARK. Capitating that we are not going to change a thing. It is the other stuff, and here is where the cheese binds, that many of these people on whom we are spending $20,000 a year for dialysis which may vary in its quality, for hospital—we are spending an equal amount for hospital admissions 15 days a year hither and yon because they get an infection from a poorly run facility, because they are not checked at the facility to see whether or not they need a better dietary control, so that the cost that we are trying to control isn't the dialysis center as much as problems that might have been prevented if the dialysis center was more holistic in its approach to caring for people. Am I on the right track?

Dr. BLAGG. I agree, except it involves the physician as well as the dialysis center.

Mr. STARK. Dialysis, we are not going to save money one way or the other. We could go about that by having tougher standards, really enforcing inspection and getting rid of the bad operators——

Dr. BLAGG. I am not sure that would make that much difference to costs. In my testimony, I said that as far as dialysis is concerned, it would be a mistake to try to cut costs there.

Mr. STARK. I am not saying cut the cost. I am saying we are doing about everything we can do there——

Dr. BLAGG. Things are changing, going the right way there. What may be the way we can save money is by better coordination of patient care and making patients have fewer hospitalizations perhaps, by——

Mr. STARK. You can't make them do that, but there might be some incentives, it seems to me, to get extra fees for peripheral services—that is an accusation, so I don't know that. But the big

cost variance, it seems to me, is this 1 to 15 days in the hospital to fix something or because somebody gets much sicker than just the routine dialysis.

Dr. BLAGG. A significant part of that relates to blood access surgery. That accounts for one-quarter of all hospitalizations.

Mr. STARK. Shouldn't we do these test programs first before we jump into that? I don't know that all HMOs are qualified to jump into this—a very small number of our population have it and I am inclined to agree. We pretty much have a capitated rate for dialysis.

The question is how do we take care of these peripheral things and I think all three of you—I wish I could talk more with you about the programs, but it does seem to me that we are not talking about dialysis, but other treatments that people receiving dialysis get.

Dr. BLAGG. I agree. I feel strongly. Do the demonstrations, and see whether capitation works, see what the problems with it are before making any radical changes in the reimbursement system.

Mr. STARK. Thank you.

Chairman THOMAS. The gentleman from Nebraska.

The gentleman from New York.

Mr. HOUGHTON. I would like to ask a couple of questions. Maybe, Dr. Blagg, you could sort of break this down a bit—you are for capitation, yet you are not for it on a short-term base. That always can be so, that there have been innumerable tests on this and I don't know why we can't move forward on it with full confidence.

Dr. BLAGG. I am concerned that at this point we are only learning the ways to really manage quality control in this program, and that to disturb the whole system by going to full-scale capitation now would cause more problems than it would solve.

I would like to see us really in control of quality first and seeing that we have a capitation system that will do the things I mentioned like ensuring that patients have appropriate access to different treatments, ensuring that patients have access to choose capitation in a way that prevents, if you will, skewing of the patient population, and so forth.

The RAND study gave good information on the financial implications of capitation as of 1990. What it did not do was spell out in detail how to do the mechanics of the process.

Mr. HOUGHTON. I understand that, but I want to push you a little bit on this because you will have one study, develop studies. You will have something you feel is reasonably satisfactory. You will have a policy and move into it and then something else will come along. It is inevitable. It is not an end result. It is a process of constantly understanding what the quality is. Why isn't the quality sufficient now?

Dr. BLAGG. I think there are a number of reasons why there are problems with quality, but it is a lot better than it was 5 years ago. At that time, American nephrology in general was concerned about shortening the time that patients were on dialysis, and Americans don't like to sit around longer in the dialysis unit than they need to. This helped in terms of costs. It helped to cut the costs so there were more profits, more margin if you are a nonprofit organization.

At that point, we didn't know enough about what were the right measures to judge quality. We now have some handle on this and things are improving. But I would be very concerned to make a big change to capitation at this time.

Mr. HOUGHTON. I would respect that. Let me get into another area with some of the big economic forces involved, because you have the balancing of care and cost. It is going to be a constant issue. But our job now is to try to make sure we are doing the right thing for the next 20 years rather than just sticking with a system which has been pasted together and is certainly not very efficient and enormously costly.

What are those things which we can impact here? There is capitation, competition, early detection in terms of wellness programs, and basic knowledge about families and lifestyles. If there were one or two big economic thrusts that we could make assuming that the care was going to be there, what would you focus on? Maybe the other gentlemen would like to comment also.

Dr. POWE. I think the issue of prevention of this problem is an area that has been neglected. Although we know that diabetes and high blood pressure cause kidney failure, we don't have a clue as to why some individuals with diabetes or hypertension go on to develop kidney failure. We need to understand that better so that we can develop interventions that will have an impact on that.

Mr. RETTIG. I demur slightly from that. I don't think there are major opportunities for prevention. That issue has been on the table for 30 years and is dependent on medical science making a big bite into hypertension and diabetes.

At the present time, the way we are controlling those diseases we may be increasing the pool of individuals who live with those problems and who then have extended lives during which their kidneys fail. I don't think there is a big economic bang for the prevention buck to be had until medical research gives us far more knowledge.

Mr. HOUGHTON. If we had a system, which we don't have and probably will never have, that required everybody to take a medical examination every year, and we understood not only the obvious results of that, but also delved in a little bit about eating, lifestyles, drinking, smoking, and elements of the family background which might be conducive to certain things, that wouldn't help? That wouldn't help in the prevention?

Mr. RETTIG. If it were massive and controlling.

Mr. HOUGHTON. But I mean——

Mr. RETTIG. Sure it would help, but at the margins. You are talking about behaviors that have to have changed 20 years before somebody manifests kidney failure. What do you do——

Mr. HOUGHTON. Or basic family knowledge.

Mr. RETTIG [continuing]. When you reason with your young daughter about the cost of smoking, if you haven't been through that, I can tell you I have, about the long-term cost of smoking. When somebody figures that one out, how to be persuasive, then come back to diabetes 20 years before the presentation of kidney failure.

Mr. HOUGHTON. It just seems to me that there are an awful lot of innocent people out there who try to live a decent life and ulti-

mately pick up the check for people who could have been helped earlier if some detection and wellness program had been out there for them.

Mr. RETTIG. The intersection with the low-income population of this country suggests to me primary care and universal coverage in that area would cut deeply into manifestation of problems that need expensive treatment down the line. That is my personal view and I can't document it, but I think we have to begin to think along those lines.

Dr. BLAGG. I am in agreement with Dr. Rettig. I believe that if we were to give better care before these patients come to dialysis, we might make marginal savings. The patients might not be as sick when they start dialysis, might not need as much hospitalization at that time. But even if we can slow the onset of dialysis by diet and the other efforts we make, patients are still going to end up getting kidney failure. So, you slow the process but the end result is the same.

Chairman THOMAS. It is always tough wrestling with mere mortals. We are talking about an organ that is kind of like a fuel filter and eventually it simply fails. It is not like smoking-lung cancer. You don't have that kind of a connection.

I agree with you, the value expended certainly would create quality of life in a number of other areas, but it wouldn't necessarily change the fact that at the end they would wind up with kidney failure.

Dr. BLAGG. If we all live to be 150 we will all get kidney failure.

Chairman THOMAS. Eventually that part is going to wear out.

The gentleman from Texas.

The gentleman from Illinois.

The gentleman from Georgia.

Mr. COLLINS. I am not going to take but just a moment, Mr. Chairman. My concern is in the area of quality of care. You probably heard when I was questioning Mrs. Smits about the particular situation of a center in Georgia. The Rand study was based on Medicare recipients; did I understand that right?

Dr. BLAGG. That is correct. They took the financial data on all Medicare recipients for the year 1990.

Mr. COLLINS. Are all kidney dialysis patients under Medicare?

Dr. BLAGG. Dialysis and transplant patients for 1990. They excluded a very small number of patients for lack of information or other reasons, but it was something on the order of 190,000 patients as I recollect it.

Mr. COLLINS. But are all patients with this problem under Medicare or are they private pay?

Dr. BLAGG. The estimates they made included the private pay portion, too. They calculated that.

Mr. COLLINS. You did include private pay?

Dr. BLAGG. Yes.

Mr. COLLINS. Are there any variances in the private pay versus Medicare?

Dr. BLAGG. I can't tell you the extent of this. There would be differences, because dialysis facilities may charge private payers more than they charge Medicare.

Mr. COLLINS. That is—what about in the area of service? Quality of service; would you say there is a difference in private pay versus Medicare in quality of service?

Dr. BLAGG. I don't think so because the same facility may be billing primarily private payers for some patients and billing Medicare for other patients. I don't think there is any difference there.

Mr. RETTIG. If I could interject, 92 or 93 percent of the American public are covered for kidney failure under Medicare under the Social Security statute. The remaining less than 10 percent are those with no work history. They are not fully or currently insured under Social Security.

Private pay, in effect the Medicare secondary payer is a cost-shifting mechanism. One rationale is to take the cost of the ESRD Program off the Federal budget and put it on private pay in the expectation that the private payment rate is higher. But it is the same set of facilities doing it and it is a time-limited thing on private pay. One comes back to the issues of measuring quality in precisely the same way that one began.

Mr. COLLINS. Ninety-two percent you say are under Medicare. That is an interesting——

Mr. RETTIG. Fully or currently insured.

Mr. COLLINS. That is an interesting shift from private insurance to government so-called insurance.

Mr. RETTIG. The ESRD entitlement is the nearest thing we have to universal health insurance in this country—fully or currently insured under Social Security, diagnosis of chronic renal failure, and you apply for benefits.

Dr. BLAGG. In 1973 when the legislation was passed, many patients either didn't have insurance or their insurance didn't cover renal disease, and Americans were dying from a disease that was potentially treatable. That is why Congress, in its wisdom, decided to fund this program not realizing what a Pandora's box they were opening.

Mr. COLLINS. Yes, it did open quite a Pandora's box, because if you take that $40,000 annual figure that is per patient under Medicare and you extend that by an average annual earnings of around $50,000, at 3 percent you are talking about 5.2 million working people earning $50,000 a year to cover the cost of those 200,000. An interesting figure.

Thank you, Mr. Chairman.

Chairman THOMAS. Thank you. I have questions that have been presented in other testimony. Dr. Blagg, you indicated that you thought there should be more hemodialysis at home. Has there been a change in technique, equipment, or knowledge that would lead you to believe that?

Dr. BLAGG. There is a potential for new equipment that I think will become available for testing within the next couple of years. This will enable patients to do hemodialysis at home without an assistant. We continue to do a lot of home hemodialysis in Seattle because we actually use our surplus funds to pay for assistance for patients to do hemodialysis at home. We think this is the best treatment. I think that 5 years from now we will see a significant increase in the use of home hemodialysis with new technology.

Chairman THOMAS. On the first page of your statement you indicated you are waiting for publication of the request for proposal from HCFA for this demonstration project before you decide whether or not you are going to respond to try to participate in it. What are you looking for in the proposal?

Dr. BLAGG. I want to see what HCFA is going to require. I don't know what they are going to propose. I have to look at a study from the point of view of a large dialysis program working with a lot of physicians. We have a large HMO, Group Health in Seattle. I have to look at the whole picture before deciding that I want to recommend to our board of trustees that we take part in this study. It is very interesting, but I don't want to do anything that would jeopardize our program in any way.

Chairman THOMAS. I understand HCFA is responding to a 1993 requirement for the demonstration project. Are we late in this? Should we have done this 4 or 5 years ago or is the timing pretty good because of changes that have been made? How good is this timing?

Dr. BLAGG. I think the timing has been reasonable. It has taken HCFA some time to actually put together its request for proposal. But perhaps time is important so they can do this properly.

Chairman THOMAS. My problem with demonstration projects is that once you start them you have to wait until they are concluded, then you have to examine the evidence and make some timid decisions. I was shocked, yesterday I was turning the channel and came on CNN in which there was an interesting news piece on patients suffering from ALS and that apparently there has been a secondary benefit from perhaps a drug given to hemophiliacs, but a drug that was not necessarily prescribed directly for ALS and they had been communicating with each other over the Internet and had begun some self-experimentation on dosages not run directly through doctors.

One of my worries is, I was listening to the discussion about demonstration projects and producing information and moving in an old-fashioned way in a slightly different world, that we may lose control if we do not move more rapidly. What I heard several times was we ought not to go into attempting to finance in different ways the clear need for a different financing structure until the demonstration project has concluded.

I guess my answer is, why not, if we have some minimum evidence that we can make a shift, we can make that shift and can then change later. I am not naive in thinking that we can't just go in and out of a structure, but it seems to me we are going to have a clear indication of the direction we need to move and we ought to begin moving in that direction. Perhaps we should begin moving and utilize the demonstration project as a finalizer in terms of the ultimate relationship between the new funding mechanism. Any reaction?

Dr. BLAGG. The Medicare ESRD Program to this point has probably been the most cost effective of all Federal programs as shown by the data that Dr. Smits presented and ratio of the cost of the end-stage renal disease population to the general Medicare population. I am sure there aren't any other programs that have been as effectively, so I don't see the urgency that you do capitation. If

you start the demonstration project, say, in 1996, maybe by the end of 1997 or 1998, you are going to at least know where it is going and what the problems are.

Chairman THOMAS. I don't feel a sense of urgency in terms of need to move, but this seems to be one of those in which it ought to lend itself more to a managed care structure and it doesn't in part because of the financing. If we could make some adjustments there, we might, in fact, get better quality for the same dollar.

Dr. BLAGG. I think that is correct. The more managed coordination of care is what will improve this, but capitation is an innovation to most of the ESRD population and their physicians, and we need time to get used to it.

Dr. POWE. I think we need to learn from this demonstration and learn to do this right, and I think the demonstration is going to be very useful in regard to how to construct a fully capitated program from an organizational perspective across this country. I am concerned it may not work in some areas of this country and things could be bad.

Chairman THOMAS. Dr. Powe, if you will comment briefly on the question of drugs versus mechanical intervention. Has it limited the ability to move more toward drugs because of the cost? Or, is it the treatment question? What is the cost effectiveness in terms of use of drugs versus dialysis?

Are dollars and cents because of the cost of drugs affecting that at all, or is it that it is very limited range treatment capability?

Dr. POWE. I should make this clear; the drugs that we are referring to are not used to dialyze the blood so they are not a substitute for dialysis. These are drugs——

Chairman THOMAS. There could be a maintenance aspect to it.

Dr. POWE [continuing]. These are drugs to maintain other conditions which occur in association with kidney disease.

Mr. RETTIG. Mr. Chairman, I have two comments in response to your question. I am not a big fan of demonstrations. I wrote a paper that demonstrations are anecdotes for action quite often and your concern for not wishing to wait seems to me quite appropriate. However, it is possible to conceive of the ESRD Program with this chronic population as a marvelous test bed for doing lots of things conceptually, doing a probe in the managed care environment here and doing something else there. That takes a certain amount of organizational skill and some efforts, but you can theoretically approach that.

Practically, I yield to others on how feasible it is to use the program in this way. I will say, regardless of the financing mechanism, you need a quality assessment, quality assurance system in place. I was here 2 weeks ago when Dr. Brook testified before this Subcommittee on quality and said quality can be measured, quality can be measured.

The arguments that I have made this morning are, I believe, the direction I think the quality system has to evolve regardless of whether it is financed by capitation or an extension of the current program.

Chairman THOMAS. Last, because some people may not fully appreciate the difference between the heart and a kidney, one is a pump and the other is a filter and we have been much more suc-

cessful in artificial hearts than we have in artificial kidneys. In fact, we have those, except the machines are so large they aren't very portable.

Are there any opportunities from your folks' perspective in the next 5 to 10 years to have breakthroughs, technology or combination of drugs and technology to get people away from a triweekly need to tie themselves to a machine? Are we looking at where we are going to be for perhaps the next decade or so? What is the cutting edge on kidneys?

Dr. BLAGG. I think there are several things. New equipment will make home hemodialysis more practical, which will be very beneficial to some patients. I suppose it is feasible that within the next 5 to 10 years we may have a wearable artificial kidney. It isn't necessarily a bad thing to dialyze longer or more frequently. There is a study in Canada going on in which patients are dialyzing themselves every night with wonderful results. A very small number of patients are doing this at home.

Of course, when you get down to it, the real answer is to have more kidneys donated and do more transplants. We are also waiting for this xenotransplantation—taking kidneys from other species, probably pigs, and using these for transplants. It may take 5 or 10 years before this becomes practical. But when it does, the whole situation changes.

Dr. POWE. Peritoneal dialysis is a form of dialysis that doesn't require the patient to go to the facility three times a week. Currently, only about 17 percent of patients in this country receive peritoneal dialysis. We don't understand the reasons for that. Some are medically unsuitable for peritoneal dialysis, but this is a modality that should be explored in greater detail.

Chairman THOMAS. Any other questions? I thank the panel very much.

The next panel would come forward, Dr. Latos, Mr. Sims, Ms. Wish, Mr. Bowden, and Dr. Ludin, I believe.

Any written statement you have will be made a part of the record. We will start with Dr. Latos and move across.

STATEMENT OF DERRICK L. LATOS, M.D., PRESIDENT, RENAL PHYSICIANS ASSOCIATION

Dr. LATOS. Thank you. Good morning, Mr. Chairman and Members of the Subcommittee. I am Derrick Latos. I have been a practicing nephrologist in Wheeling, West Virginia, for 18 years and currently serve as president of the RPA, Renal Physicians Association.

I would like to thank you for the opportunity to testify, and I welcome the Subcommittee's interest in reviewing the ESRD Program. I would like to offer the RPA's resources in assisting you in drafting policy designed to improve an already excellent program.

I had prepared something more specific for my oral testimony, but much of what I had prepared has already been discussed in detail. What I think I would like to do is to highlight some issues and leave what time is available to address some comments and questions from the panel.

One interesting feature of the Medicare ESRD Program that is unique among all other programs for Medicare is that this program

provides comprehensive care, which includes specialized dietician and social work services for both patients and their families.

One of the concerns that the Renal Physicians Association has as well as others is that in privatizing the Medicare system, we are very concerned that various health plans may consider some of these services as extras and not really germane to the specific medical therapy. There is considerable data already in existence in the published literature that shows the valuable input of appropriate and timely nutritional intervention.

In response to some of Dr. Rettig's comments, we would agree that the quality assurance programs in the Medicare ESRD Program are very unique, and it is our feeling that they have not been and probably cannot be replicated by private industry.

A big concern that we have heard discussed many times today is how do we save money yet assure the quality of care that we are trying to deliver today. It is clearly realized that much of the growth in ESRD expenditure is due simply to the increase in the number of people receiving this lifesaving therapy, which is both dialysis and transplantation, but at the same time it is incumbent upon the provider community, as well as Congress, to maximize efficiencies while continuing to improve the quality of the program.

We have heard ample testimony this morning attesting to the very high cost of hospitalization for this generally sick, older, and complex population of individuals. There is no question that many hospitalizations for dialysis and transplant patients may be preventable, and many cannot. One of the major reasons for hospitalization has to do with vascular access complications.

People undergoing chronic dialysis need to have a way of circulating their blood into the artificial kidney. I would point out for the record that several months ago the Renal Physicians Association met with staff from HCFA and presented data that suggested that considerable savings could be realized if the use of a therapy to dissolve clots in some of these vascular grafts, if that were made available and then reimbursed as an outpatient service, then many hospitalizations could be shortened and sometimes prevented.

We don't have data to show what has happened yet, but we certainly appreciate the position HCFA took that changed the reimbursement policy. We think that will clearly improve the outcomes for patients in the sense of decreasing their hospital time. We also believe that there will be data to show that costs have been substantially decreased with that.

Another critical issue, we believe, is that there must be strengthened efforts to educate renal physicians and other providers regarding issues that assure the delivery of cost-effective dialysis and transplant care. The use of practice guidelines such as those recently developed by the Renal Physicians Association, which deals with the adequacy of hemodialysis, will in fact have a measurable beneficial effect on patient outcomes.

Other guidelines already in development will help to assist practitioners in selecting patients for renal replacement therapy which is very much needed, as well as in the appropriate use of expensive, but necessary technological advancements.

We are aware of the growing interest in utilizing managed care programs for Medicare beneficiaries, including those with end-stage

renal disease. The nephrology community has had 20 years experience in dealing with a capitated approach to health care and the RPA is conducting an extensive analysis of the effects of current and proposed capitation systems for nephrologic care, including dialysis and transplantation. We will be developing additional innovative approaches and look forward to sharing our views with the Members of this Subcommittee and others.

We feel there are other areas for important potential cost savings for the ESRD Program and that some of these need to be examined in much more detail. We have not heard a lot yet, but we need to identify and enhance the identification of basic mechanisms of diseases that cause kidney failure.

There needs to be improvement in the detection and management of renal disease in its early phases, and I would be remiss if I did not comment on the role of the nephrologist and the other members of the renal health care team in early intervention and involvement.

The issues of managed care that sometimes tend to keep the specialist, including nephrologists, away from the patients until an advanced stage when clearly dialysis is the only option, needs to be examined, and we have in fact published some information on this and would look forward to further testimony.

Finally, the development of more effective strategies in the treatment of ESRD needs to be examined. There are already studies doing that, but we think there needs to be more.

Last, I offer a suggestion that programmatic improvements must also provide stronger rehabilitation initiatives since excellent dialysis care and successful renal transplantation are only the bare essentials for restoration of an individual with ESRD to a healthy productive life, and that is the kind of life envisioned by Congress 20 years ago when they put this program together.

That concludes my oral comments. I would be happy to answer questions.

[The prepared statement follows:]

STATEMENT OF DERRICK L. LATOS, M.D.
PRESIDENT
RENAL PHYSICIANS ASSOCIATION

April 3, 1995

INTRODUCTION

Good morning, Mr. Chairman, members of the Subcommittee. My name is Derrick L. Latos, MD. I am a practicing nephrologist from Wheeling West Virginia and I am the President of the Renal Physicians Association (RPA). RPA is a professional organization of nephrologists whose goals are: to insure the optimal care under the highest standards of medical practice of patients with renal disease and related disorders; to act as a national representative for physicians engaged in the study and management of patients with renal disease and related disorders; and to serve as a major resource for the development of the national health policy concerning renal disease. The RPA would like to thank the Ways and Means Subcommittee on Health for this opportunity to provide written and oral testimony. RPA's written statement will focus on many of the issues that are currently affecting the renal community, especially in light of the increasing expenditures and numbers of patients in the ESRD program. We are very aware of the critical budget constraints that our country as a whole is facing. We also recognize Congress' function in examining the federal role in caring for ESRD patients as well as Congress' desire to promote competition among medical providers in order to cut costs and improve delivery of medical care. Because of this concern, we welcome this chance to provide the Subcommittee with our views on all facets of the ESRD program.

OVERVIEW

In 1991, more than 230,000 people were treated for end stage renal disease (ESRD), the vast majority under the Medicare program. Between 1984 and 1991, the number of ESRD patients doubled–to one patient per 1,387 U.S. residents–and the number of ESRD patients is expected to double again in the next seven years, according to an estimate from the United States Renal Data System (USRDS). The incidence of ESRD continues to rise at a rate of over 8% each year. The number of new program enrollees exceeds the number of deaths by an increasing amount: from +10,000 in 1982 to +17,000 in 1991. The prevalence of ESRD in elderly individuals has increased at a greater rate than in the population as a whole: Currently, more than 30% of all dialysis patients are over the age of 65. Minorities are four times as likely as non-minorities to develop chronic renal failure, and, on average, they are younger at the onset of disease than are non-minorities.

In 1991, the total direct cost of ESRD was $8.6 billion. Of this amount, the federal government paid $6.15 billion, or 72%. Medicare payments for ESRD are growing approximately 5% annually in constant dollars, with virtually all of the increase attributed to the increased patient population. Reimbursement rates paid to providers per dialysis treatment have actually declined when adjusted for inflation. The RPA believes that the greatest potential for reducing the high costs of chronic renal disease will be found by identifying basic mechanisms responsible for the disease and devising better, and more cost-effective strategies for treatment.

PRIVATIZATION OF THE ESRD PROGRAM

It is RPA's understanding that several Members of Congress, health policy analysts, economists, and even some members of the renal community, believe that the ESRD program should be "privatized". By privatization, we understand this to mean that the federal government could be charged with providing vouchers for patients with ESRD who would then be able to choose a health plan to take care of their renal-related needs. Under this scenario, the continued existence of the ESRD program would be in doubt.

Presently, the RPA has not take a position on this issue. However, we would like to point out some of the inherent difficulties this approach would face.

Although some managed care companies have stated that they would be interested in covering the health needs of the ESRD patient, we believe that at closer inspection, many insurance companies are likely to balk at the very high prices of covering the ESRD population. As a 1991 Institute of Medicine Report noted, according to 1987 data, the average annual expenditure for a

typical ESRD patient was $32,000. Estimates of the cost for caring for an ESRD patient today are more than $50,000. Assuming that health care companies still decide they would like to cover ESRD patients, it is reasonable to conclude that premium increases will have to be spread to other policy holders. These increases would differ by geographic area, thus penalizing some policy holders and not others. This would provide employers with a disincentive against hiring individuals with ESRD because of the extra cost of insuring the ESRD patient and the extra costs of insuring their remaining employees.

RPA fears that insurance companies competing for dialysis business would attempt to find the lowest common financial denominator, paying at rates below what Medicare pays today. Cost of care will become the predominant concern of the insurance company. Unlike the current ESRD format, where patients have the ability to choose their nephrologist, health plans would instead contract with nephrologists on a lowest cost-of-care basis. Thus, many patients would have to terminate existing physician relationships. Also, because health plans would contract with a limited number of physicians to provide dialysis, there would be a corresponding decrease in the number of dialysis facilities available to the patient for his or her dialysis treatments. Easy access to these facilities is critical to the successful treatment of the ESRD patient, who is often too sick to travel great distances. It seems doubtful that large health plans would take this geographic factor into account when enrolling physicians in their dialysis panels. ESRD patients are inherently different from other health plan enrollees. Individuals with renal failure are older and sicker than the general population and without access to dialysis treatment, they simply will die. Because of the life-threatening nature of their disease, ESRD patients can not be treated in the same manner as other health plan enrollees who are healthier and not in constant need of a physician's care.

RPA is also concerned that insurance companies could be tempted to develop treatment guidelines which would exclude coverage for ESRD patients with unusually complex comorbid conditions such as cancer or diabetes. This could lead to a situation similar to the period before the ESRD program began, when patients often were chosen for dialysis on the basis of their age, emotional stability, and chances of continued production to society. Before 1972, minorities, women, and low-income individuals were underrepresented in the dialysis recipient community.

Currently, Medicare is the only program offering comprehensive care for ESRD patients, including, in addition to, dialysis, nutritional counseling, psychological counseling, assistance in finding support groups, and other services. RPA is concerned that health plans, on the other hand, could place limits on the amount of dialysis treatments allowed, or place a monetary cap on the cost of care, similar to the way mental health benefits are treated. Such limits or caps would threaten medically necessary care for ESRD patients.

Also, under the ESRD program, the ESRD Network Organization and the United States Renal Data System (USRDS) exist to oversee the quality of care provided to ESRD patients and these groups work to improve health care outcomes. Under a system fueled mainly by private insurers, it would be very difficult to continue with such an effective oversight program. As is becoming increasingly clear, quality assurance systems are critical to the proper delivery of dialysis care. Insurance companies do not have the capabilities to provide the intensive quality agenda already being pursued by the ESRD program.

Current managed care practice encourages primary care physicians to "gatekeep" and may even have financial disincentives not to refer patients to specialists. Direct access to a nephrologist is essential to ensure quality care for patients with chronic renal disease, and patients with acute renal disease.

RPA also believes it is important to view "privatization" in the political sense. The ESRD population is one of the most vulnerable segments of the country. They are chronically ill, older, and in many cases, minorities. Very likely, a two-tiered system of care could result, with poorer patients enrolling in cheaper, and correspondingly lower quality health plans, while wealthy patients would be able to access fee-for-service plans. The ESRD program, on the other hand, has been very successful in keeping patients with ESRD alive, and has kept ESRD expenditures to a minimum. RPA anticipates that creating a nation-wide voucher system affecting this sick patient population would undermine the program's success and could have serious health ramifications in the future.

PATIENT POPULATION

The number of patients in the ESRD program has grown substantially over time, increasing from approximately 10,000 beneficiaries in 1973 to nearly 250,000 today. The ESRD population is diverse in age, sex, race, and has changed over the time span of the program. Increasingly

ESRD has become a disease of racial minorities and the poor in America. While African-Americans make up only 13 percent of the country's population, this group accounts for 35 percent of the dialysis population. An additional 5 percent of the patients are Latino or Native American. Further, many patients with ESRD are people who are financially disadvantaged even before they develop ESRD. Twelve percent of the dialysis population under age 65 has no insurance coverage at the time of ESRD, and 20 percent of the ESRD population depends on Medicaid for insurance coverage. Several investigators have shown a statistically significant correlation between renal failure and finances, such that increasing poverty is associated with an increased prevalence of ESRD. Complicating these trends is the limited access to medical care in rural areas. Five of the six ESRD Networks that report the greatest incidence of ESRD are composed of rural states, where geographic access to care may be problematic. These demographic trends are not simply persisting, but in fact worsening.

The ESRD patient population is becoming increasingly older. Before the creation of the Medicare ESRD program in 1972, candidates for dialysis and transplantation were selected for treatment based on subjective criteria. Due to limited resources and the financial barriers to dialysis and transplant care, candidates for ESRD treatment were generally under age 65. This is reflected in the fact that those over 65 accounted for only 5 percent of total enrollment in the program in 1974. However, this quickly increased to 11 percent in 1975, climbed to 18 percent in 1978, and by 1988, those over 65 made up 38 percent of the total ESRD population. Thus the incidence of treating renal failure is much higher among the elderly than the general population. The proportion of elderly patients among those being treated for ESRD continues to increase, perhaps in part because medical technology keeps patients alive longer than in the past. It should be noted that the growth among the very old ESRD population is also striking. Among those 85 and older, new ESRD patients increased by 18 percent annually between 1978 and 1988.

Elderly ESRD patients are also sicker than their younger counterparts. Diabetes and hypertension account for an increasing proportion of cases. In 1978, among new elderly ESRD patients with a specified diagnosis leading to renal failure, 16 percent were diabetic and 38 percent were hypertensive. By 1988, these proportions had increased to 29 and 42 percent respectively. Elderly patients generally arrive at permanent kidney failure with more comorbidity than younger patients, including unstable hemodynamics, vascular disease, and impaired function. In particular, elderly diabetics exhibit the comorbidities typical of that disease, including visual problems, neuropathy, and amputations.

In sum, the ESRD patient population has become increasingly older and sicker, and these trends are expected to continue throughout the 90's. The needs of these patients therefore are greater than ever before and provide nephrologists and their staffs with great medical challenges.

ROLE OF THE NEPHROLOGIST

Because of the increased penetration of managed care in the health system, defining the role of the nephrologist has become increasingly important. Primary care physicians have shown hesitancy to assume responsibility for the overall medical management of end-stage renal disease patients. They have, as a rule, relinquished this responsibility to the nephrologist who is specifically trained to address the unique technology related to dialysis and the unique medications related to renal transplantation.

Some managed care providers have tried to reduce the role of the nephrologist in the care of the end-stage renal disease patient. Most primary care physicians, however, are not trained to treat the complex multi-system medical problems usually seen in end-stage renal disease patients, are unfamiliar with the particular medications and technology prescribed for such patients. They would also prefer that the nephrologist provide general medical care, as the nephrologist is most likely to see the patient frequently on dialysis or in transplant follow-up, and address the patient's problems as a part of those interactions.

Furthermore, as a rule, the pre-dialysis patient requires interventions that are unfamiliar to primary care physicians. The role of the nephrologist for a pre-dialysis patient involves an initial consultation for diagnostic purposes related to the etiology and natural history of the patient's renal disease and global recommendations for management. The nephrologist is then re-consulted as the patient approaches end-stage renal disease so the patient can be "plugged into" the system for dialysis or renal transplantation. If care of the pre-dialysis patient is provided exclusively by the primary care physician, the nephrologist may not have an opportunity to evaluate the patient until the patient is near end-stage or, in extremis, thus requiring the urgent initiation of renal replacement therapy. When the opportunity to evaluate options for the treatment of end-stage renal disease is made available earlier, the patient can weigh alternatives while in a

healthy and stable condition, and perhaps with the intervention of the nephrologist, avoid or delay the eventual development of ESRD.

Early nephrology referral is consistent with increased emphasis on preventive care to improve outcome and to decrease costs. An early provision of nephrology care for the patient with chronic progressive renal insufficiency would yield great dividends in terms of quality of care, improved outcome, and cost containment.

Scope of Practice

The nephrology subspecialty may be defined as a hybrid discipline. Under certain circumstances, nephrologists function as primary care physicians, while in other circumstances they serve as uniquely skilled subspecialists, which includes active participation on pediatric or adult critical care units.

There are three categories of patients with renal disease for whom nephrologists serve as primary care physicians:

- children or adults who have mild or moderate chronic renal failure and are treated in an ambulatory setting prior to their entry into the ESRD Program; that is, for treatment by dialysis and/or transplantation. These patients with chronic renal failure may have renal disease from immune origin, as in many forms of glomerulonephritis; from infectious disease, as in chronic pyelonephritis; from heredity disease, most notably polycystic kidney disease; from hypertension or diabetes; and from other causes. The need for nephrologists' active involvement in patient care early in the course of renal disease is emphasized by a recent publication dealing with complications at the time of initiation of dialysis therapy. Those patients seen and followed by nephrologists early in the course of their renal disease had much better blood pressure control, were less anemic, and enjoyed better nutritional status than those referred late. All those referred late were in pulmonary edema, required emergency creation of vascular access, and the need for and length of hospitalization at the time of initiation of dialysis was two and six times greater, respectively, than for those referred earlier to nephrologists. This study underscores the critical need for a greater number of properly trained nephrologists to serve as primary care physicians or to provide care in collaboration with the referring physician to this expanding patient population.

- patients who have kidney or kidney-pancreas transplants are given long-term care by the nephrologist, particularly the transplant physician. There is very powerful evidence that, when these patients receive treatment from transplant physicians instead of non-experts, both patient and graft survival are positively affected.

- individuals receiving chronic dialysis, either hemodialysis or peritoneal dialysis.

The outpatient activities of nephrologists account for well over 90% of the billings of most nephrologists. However, in tertiary or referral medical centers, ambulatory nephrology practice may account for a smaller percentage of nephrology billings. Thus, the main portion of the nephrology practice is providing for the ongoing medical needs of patients with renal disease.

Nephrologists also serve as **subspecialty consultants**. The principal groups of patients for whom nephrologists serve as subspecialty consultants include:

- Patients who develop acute renal failure, often due to acute tubular necrosis, in an in-hospital setting.

- Hospitalized patients who develop electrolyte abnormalities.

- Hospitalized patients who develop hemodynamic imbalances either because of cariogenic factors, renal factors, or, in certain instances, iatrogenic factors resulting in a low urine output and reversible renal failure.

- Pregnant women who are at high risk -- most notably, those with pregnancies complicated either by urinary tract infection, hypertension or pre-eclampsia; patients who have chronic renal failure or who have received transplantation, who become pregnant; and diabetic patients, particularly those with Type I diabetes mellitus, who become pregnant.

- Patients who develop severe metabolic bone diseases as a complication of their renal disease or other factors.

- Renal stone disease

- Evaluation and treatment of edematous states
- Complicated hypertension, resistant to standard treatment
- Evaluation of hematuria and proteinuria

In all these instances, nephrologists provide either direct care or consultative care to patients with significant, and often life-threatening, illnesses. These patients are provided nephrologic care in various settings, including outpatient offices, acute care medical and surgical hospital beds, and critical care units.

Therefore, a nephrologist is a hybrid physician, who serves as a primary care physician in certain instances, and as a subspecialist in others. RPA believes that nephrologists should remain the primary care physicians for ESRD patients who are treated with dialysis or transplantation. Such an arrangement will provide for optimal patient care, better outcomes and likely less expense.

ERYTHROPOIETIN

RPA does not agree with the concept that reimbursement for Erythropoietin (EPO) should be bundled into the Medicare ESRD composite rate. It is RPA's belief that there is no clinical or quality-assurance reason to bundle EPO payments into the composite rate

EPO is a hormone produced by the kidney which is necessary for the body's production of red blood cells. Patients with kidney failure produce an inadequate level of EPO which results in anemia. Epotin, a bioengineered form of EPO, is administered to these patients in order to maintain the proper level of red blood cells. The EPO drug is currently reimbursed by Medicare at a rate of $10 per 1,000 units. This reimbursement policy is the most rational method available and the safest for the patient because it allows the nephrologist to prescribe EPO solely on the basis of the patient's need.

We believe that a primary motivation behind the proposal to bundle EPO into the composite rate is financial. Large volume providers of the drug can purchase EPO from the manufacturer at a discount. If EPO is bundled into the composite rate, large volume providers will be able to increase their financial return because of their buying power, thereby creating a disparity in financial returns between large and small distributors.

It is also our understanding that there is an interest in bundling EPO reimbursement into the composite rate in order to provide an economic disincentive against over-prescribing the drug. The perception that EPO is being over-prescribed is based on HCFA data which demonstrates that EPO dosing has continuously increased per patient while the average hemocrit (a marker of the degree of anemia) has remained flat. If this is the case, then the question of why patients are becoming resistant to the effects of EPO should be addressed by quality assessment and quality improvement methodologies, not economic disincentives.

Similarly, RPA is aware that anecdotal evidence exists regarding overdosing of EPO. However, a policy decision on bundling EPO into the composite rate should not be based on such assertions, rather, should be made after data has been collected and a scientifically accurate solution developed. The RPA is currently exploring different statistical models and other data driven studies regarding bundling and capitation of dialysis services, including EPO dosing, in order for the renal community and policy makers to come to such a solution. Additionally, the Health Services Quality Bureau and the renal Networks are planning a study on the quality and cost effectiveness of EPO. Therefore, RPA believes that a decision to bundle EPO into the composite rate would be pre-mature at best until proper data has been collated and analyzed. Once this has occurred, a scientifically accurate policy decision can be made.

PHYSICIAN OWNERSHIP/SELF-REFERRAL

As the Subcommittee is well aware, the Omnibus Reconciliation Act of 1993 (OBRA 93) contained language expanding the original self-referral prohibition to certain other designated health services. Among these designated health services was the listing "inpatient and outpatient hospital services". This language would prohibit situations where a nephrologist contracts with a hospital to provide its inpatient or outpatient dialysis services if the nephrologist (or group of nephrologists) had a financial interest in the dialysis service. This prohibition effectively hampers the continuum of care that nephrologists provide to their dialysis patients and it may have an adverse affect on a patient's access to inpatient dialysis. We ask that you work to fix this problem to ensure that dialysis care is not impeded.

The principal concerns underlying the self-referral prohibition language of OBRA 93, inflated charges and unnecessary utilization of services, do not apply to inpatient dialysis services. Most inpatient dialysis services are furnished to End Stage Renal Disease (ESRD) patients who are Medicare beneficiaries and are therefore covered by Medicare through the Prospective Payment System (PPS). Under this system, the hospital receives a fixed amount of reimbursement to cover all services furnished to an inpatient. Thus, opportunities for increased costs to governmental payors as a result of inpatient dialysis contracts involving nephrologists are virtually non-existent.

Similarly, over-utilization is not an issue. Again, most patients requiring inpatient dialysis have ESRD. Dialysis is a treatment that is prescribed for those with irreversible kidney failure who must receive regular dialysis to live. Dialysis is not an elective procedure for ESRD patients and its medical necessity cannot be questioned. Once diagnosed, most ESRD patients require dialysis several times a week, for two to four hours per session, for the remainder of their lives. Dialysis is always therapeutic and never diagnostic.

In addition, unlike situations where, for example, a referring physician has an ownership interest in an MRI facility, nephrologists are directly involved in the supervision and care to their patients receiving inpatient dialysis. Indeed, this provision of dialysis services is simply an extension of the nephrologist's practice.

Prohibiting large numbers of inpatient dialysis contracts involving nephrologists will have untoward, adverse patient care consequences: Given the fact that inpatient dialysis contracts are very common in the industry, the question will become: who will assume the responsibility of providing these services? Many hospitals do not provide inpatient dialysis and often lack the expertise and desire to do so. Non-nephrologist entities could assume a greater responsibility for providing this service. However, it is questionable whether these entities could assimilate all, or even a significant part of, the potential new arrangements. More importantly, it is undesirable from a patient perspective to bifurcate the responsibility of professional inpatient nephrological care and the technical components of inpatient dialysis, placing the latter in the hands of non-physician controlled entities.

Finally, it should be recognized that the training and support for the conduct of home dialysis is often integrated with inpatient services. Therefore, prohibitions on inpatient dialysis contracts are likely to have a broader negative impact extending to patients' access to dialysis in the home.

Congress agreed with RPA's views on this issue and drafted legislative language exempting nephrologists when they refer patients for any dialysis related services. This language was included in all the major health care reform bills originating in the House, including the Ways and Means bill, the Gephardt bill, and the Rowland-Bilirakis Bi-partisan bill. RPA, as well as many other medical societies would like to work with Congress in order to clarity and improve the OBRA 93 self-referral law. We look forward to this effort.

QUALITY ISSUES/NETWORKS

The RPA and all the members of the Renal Coalition are dedicated to quality delivery of dialysis care. The ESRD program has one of the finest and most comprehensive quality programs in medicine. The spearhead of this quality assurance process is the ESRD Networks.

The End-Stage Renal Disease Networks provide a cost effective mechanism to ensure the most efficient use of Medicare dollars for dialysis treatment and kidney transplantation through monitoring quality of care indicators and maintaining timely, complete data on the ESRD program. These functions are administered at the regional level, providing direct and immediate access from the provider to the Health Care Financing Administration through the ESRD Network.

The 18 Networks are in immediate contact with 2,642 dialysis providers and 241 transplant centers, serving approximately 245,996 patients in 1994. The ESRD Network budget is funded through dialysis payments to facilities.

History. For the first few years of the ESRD program, dialysis services were limited and dialysis programs were run autonomously with no coordination within the national Medicare system. In 1978, The ESRD Network program was designed to provide an oversight system to unite dialysis providers with the common goals of providing immediate access to treatment, treating patients with the quality care through medical standards developed by the scientific community, and helping the patient maintain a quality life which enables each individual to live as a functioning member of society.

Today, the United States is divided into 18 Network regions. Each Network is administered by a governing body made up of representatives of the local dialysis providers. A Medical Review Board, representing the providers, acts as the advisory group on clinical issues. In this way, the Networks benefit from the expertise and leadership of renal professionals, representing outstanding health care and academic institutions throughout the country.

Quality Improvement. RPA believes the effective way to impact care is through continuing examination and evaluation of practice. The Networks impact care by three methods: encouraging quality improvement for all providers, identifying providers in need of assistance in maintaining quality standards: and by conducting intensive special studies of practice areas, using the results to develop practice recommendations.

Continuous Quality Improvement. The 18 ESRD Networks have been involved since 1991 in implementing continuous quality improvement (CQI) concepts into the dialysis setting. These concepts encourage each provider to look at its own program and define areas for improvement, then design action plans to meet these goals. Networks are instrumental in the process by providing in-service training to dialysis staff members, including physicians, administrators, nurses, dieticians and social workers, on what CQI is, how it has worked successfully in industry and in other health care settings. Further, the Networks provide continuing resources and information for the facilities as they design their own CQI programs; and, provide comparative data profiles to allow each facility to assess its performance relative to other providers within the region, state, and nation, and identify areas for improved service. Rather than only seeking the outliers, CQI is employed for all providers regardless of the size of the patient base or quality of care being provided.

When problems are detected with a dialysis provider, the Network begins one-to-one evaluation of the center and its program to help pinpoint causes. The provider is mandated to develop its own plan of action to correct problems. The Networks serve a vital role as a catalyst for improvement by identifying the problem and assisting with solutions. The Networks have had a direct impact in improving these facilities, or in closing them when the providers were unable or unwilling to change.

Data Collection. The Network ESRD data base constitutes the most comprehensive disease specific registry in the world. Networks process and validate all patient data for the Medicare ESRD program. Beside Medicare beneficiaries, this data base includes non-Medicare patients, Medicare secondary and Veterans Affairs patients.

Patient Satisfaction. Patients are the ultimate benefactor of the ESRD Network Program. Working with dialysis providers to ensure quality care means healthier patients, with fewer hospitalizations. But the Networks also work directly with patients in many ways, serving as a clearinghouse of information, and encouraging patients to interact with the renal community.

Grievance Resolution. All Networks maintain a grievance process, enabling the patient to voice concerns about a dialysis provider directly to an objective third party. Monitoring grievances is one way the Network can tract facility performance or be made aware of problems which require further intervention.

Many grievances result from a miscommunication between a facility and a patient. With the Networks acting as an objective third party, most grievances can be resolved quickly.

Many complaints are resolved before they end in a formal grievance. Of an estimated 1,200 patient contacts during 1994, only 106 complaints resulted in formal grievances. This mark of success shows the Networks have developed an expertise in resolving these concerns at an early stage, avoiding major conflicts, and often litigation.

RPA Involvement in quality issues. RPA has been heavily involved in the quality improvement arena. Recently, RPA published clinical practice guidelines on the adequacy of hemodialysis. The RPA noted that in the 1980's, credible data documented a decrease in survival rates of patients undergoing maintenance hemodialysis for treatment of ESRD. This occurred despite advances in dialysis technology. The trend of unfavorable U.S. dialysis survival, documentation of extreme variability in the quantity of dialysis prescribed and delivered, and controversy concerning what constitutes an adequate quantity of dialysis were the stimuli which prompted the RPA to develop these practice guidelines on the adequacy of hemodialysis. The membership of the Practice Guidelines Committee was made up of experts from the entire renal community. The goals of the guidelines were to define parameters of hemodialysis having significant positive and negative effects on patient survival and defining the recommended quantity of hemodialysis delivered which is required for adequate treatment of ESRD so patients receive the full benefit of

hemodialysis therapy. These guidelines will hopefully serve to improve the survival rates of patients on hemodialysis and serve as an example of the renal community's mission to improve the quality of life of the ESRD patient.

MEDICARE SECONDARY PAYOR PROVISION FOR ESRD

The Renal Physicians Association would oppose legislative initiatives designed to extend the Medicare Secondary Payor provision for ESRD services beyond twenty-four months. Currently, Medicare is the secondary payor for ESRD services for eighteen months.

RPA believes that extensions beyond the already envisioned 24 months would have a detrimental effect on dialysis patients. Such an extension could lead to higher insurance costs to ESRD patients as insurance companies try to offset the price affects of the extension. Large price increases could lead to patients dropping their coverage altogether. Some health plans could drop their ESRD coverage completely. RPA is also concerned that such an extension would cause health plans to continue to lower the ESRD reimbursement rates. In addition, an extension beyond twenty-four months could provide employers with a disincentive for hiring ESRD patients or even those predisposed to ESRD, such as individuals with hypertension or diabetes.

BIOMATERIALS AVAILABILITY

As the Subcommittee may know, there is an impending threat to the availability of the raw biomaterials used in the manufacture of implantable medical devices. Because of massive class action suits over bodily injuries alleged to have been incurred from silicone breast implants, the providers of raw biomaterials to device manufacturers may withdraw entirely from the medical market. Possible medical and legal settlement costs reportedly cost in the billions while revenues to the suppliers often compare at less than $1 million.

The problem lies with U.S. tort law that allows an individual who has suffered bodily injury from a product to sue all participants involved in the manufacture of the product. In medicine, this applies to the suppliers of biomaterials for device manufacture.

Because of this liability situation, in 1992 suppliers of raw biomaterials informed medical device manufacturers that they were withdrawing from the medical device market for all implantable devices and some temporary devices. They would continue to supply these materials for up to 36 months to allow time for the manufacturers to develop alternative sources. The 36 month deadline ends on December 31, 1995. Disruption of this biomaterial source would prove disastrous for dialysis patients. Because of the suppliers withdrawal, teflon will no longer available for use in vascular access grafts. Without the use of these grafts, dialysis, quite simply, becomes almost impossible.

As a result of this situation, Senator Joseph Lieberman introduced the Biomaterials Access Assurance Act of 1995 which would eliminate raw materials liability when the raw materials supplied to the medical device manufacturer either meets the specifications as advertised by the raw materials manufacturers, or meets the specifications established by the medical device manufacturer. Without this liability relief critical biomaterials, like teflon, will be taken off the market leading to critical shortages of vascular access grafts as well as other implantable devices. We strongly urge the Subcommittee to work with Senator Lieberman and other members of Congress to ensure that patients continue to have access to needed medical devices critical to their care.

CONCLUSION

The RPA fully supports Medicare's ESRD program. The program is responsible for the lives of nearly 250,000 people. Despite the increasing age and sickness of the ESRD patient, the renal community has worked hard to make dialysis care both high quality and cost-effective. As a result, expenditures for the program have been kept to a minimum. However, RPA is concerned that further cuts could lead to quality problems. Nephrologists and other providers in the renal community are dedicated to serving the needs of our patients and to continually improving the delivery and outcomes of dialysis care. RPA welcomes the Subcommittee's oversight of the ESRD program and we offer our fullest assistance in helping members of Congress draft policy to improve an already superlative program.

STATEMENT OF TERRAN WARREN SIMS, B.S.N., R.N., C.N.N., IMMEDIATE PAST PRESIDENT, AMERICAN NEPHROLOGY NURSES' ASSOCIATION

Ms. SIMS. Good morning, Mr. Chairman and Members of the Subcommittee. My name is Terran Warren Sims. I am a registered nurse and I am the immediate past president of the ANNA, American Nephrology Nurses Association. Our association represents over 10,000 nurses who specialize in the care of patients with ESRD.

We have provided information on the ESRD Program to legislators and policymakers since the inception of the program in 1972. We applaud the Congress for establishing the ESRD Program and we support its continuation. It has demonstrated an ability to provide cost-effective care to an increasing number of older, sicker patients in light of a fixed reimbursement that has decreased in real dollars over time.

We believe this program is one of the most striking examples of a publicly funded, privately operated health care program that provides lifesaving medical care for a highly vulnerable, very sick population. At the same time, we are sensitive to the need to decrease the Federal deficit and reduce excessive health care spending, and we respect the mammoth task before the Congress. In keeping with your charge, ANNA comes before you to address issues in the ESRD Program that we ask you to consider.

First, we urge Congress to make the Medicare secondary payer provision permanent and to extend the provision to 24 months. In our written testimony, we address some concerns about extending the provision beyond that time period. Most of the concerns involve the response of the employer group health plans and employers themselves to significant cost shifting from Medicare. We urge you to take these concerns under advisement as you proceed with any extension of this provision.

Second, we support that epoetin continue to be reimbursed separately from the composite rate paid for dialysis services. We provide our rationale fully in our written comments, but our major concern is the incentive to underdose the drug that is inherent in such a fold in. The association has concerns about the impact such behavior would have on the health and rehabilitative potential of the dialysis population and the cost to the Medicare Program of such a scenario.

With regard to managed care, the association continues to support a nursing case management model of care delivery to this chronically ill population. We believe that such a model has the potential to assure the provision of high quality care and to control ESRD Program expenditures for several reasons, which we elaborate on more fully in our written testimony. We worked closely with this Subcommittee in the past to legislate an ESRD capitation study as part of the social health maintenance organization expansion in OBRA 1992.

We urge Congress to continue to support the social HMO project and the ESRD capitation demonstration so the nursing case management model can be more fully evaluated and so the appropriate risk adjusters can be determined for this highly specialized patient population.

In terms of transplantation, given the significant improvements in graft and patient survival in recent years, the number of patients on the waiting list continues to grow, as does the waiting time for a kidney. The gap between the supply and the need for donor organs is greater than ever.

ANNA and other members of the transplant community would be happy to work with the Congress to evaluate legislative measures that would increase the supply of donor organs in this country. We also support continued funding for research in this area, including the use of xenografts.

Finally, ANNA supports the continued partnership between HCFA and the renal community to evaluate and improve the quality of care delivered to the ESRD beneficiaries. We appreciate the Subcommittee's review of the ESRD Program. We have seen firsthand the benefits that this program has had on the beneficiaries and we are grateful for its continuation. We appreciate this opportunity to share our thoughts and observations and would be happy to answer questions when appropriate.

Thank you.

[The prepared statement follows:]

ANNA

American Nephrology Nurses' Association

TESTIMONY OF THE AMERICAN NEPHROLOGY NURSE S' ASSOCIATION PRESENTED TO THE SUBCOMMITTEE ON HEALTH HOUSE COMMITTEE ON WAYS AND MEANS

APRIL 3, 1995

The American Nephrology Nurses' Association (ANNA) is the professional organization representing registered nurses specializing in the care of patients with end-stage renal disease. In our 25th year as a professional society, and representing over 10,000 members, ANNA has repeatedly provided information on the ESRD program to legislators and policy makers since the inception of the program in 1972.

The end stage renal disease program has remained a success over the past 23 years, in part due to the commitment of the Congress to assure quality care to the beneficiaries. As this Congress considers both measures that improve health care delivery to the citizens of this country and methods to reduce overall spending in the Medicare program, we believe there is much to be learned from the successes and limitations of the ESRD program. Medicare entitlement has provided access to care for many patients who were previously denied treatment.

The initial reimbursement rates for outpatient dialysis were set arbitrarily; they were not based on costs. Established in 1973, they remained unchanged until 1983. They were lowered in 1983 and again in 1986, and no adjustments for inflation were allowed.

The estimated Medicare per capita payments for end-stage renal disease during 1991 averaged $38,400. When adjusted for inflation, the per capita costs are increasing minimally, or possibly decreasing. But, in fact, aggregate costs are increasing at over eight percent per year even with adjustment for inflation. This rise is almost totally driven by the increase in the number of patients, as the number of treated patients with kidney failure is increasing at over 9 percent per year.

ANNA is sensitive to the need to decrease the federal deficit and reduce excessive health care spending and we respect the mammoth charge before this Congress. However, we urge the Congress to maintain the ESRD program, one of the most striking examples in this country today of a publicly funded, privately operated health care program that provides lifesaving medical care for a highly vulnerable, very sick population.

EXTENDING SECONDARY PAYER PROVISION

Under current law, Medicare is the secondary payer for individuals with end stage renal disease who have coverage through employer group health plans (EGHPs). Medicare makes payments secondary to such EGHPs for the first 18 months of entitlement, after which Medicare becomes the primary payer.

ANNA supports that this provision be made permanent and that consideration be given to extending the secondary payer provision to 24 months. We have concerns about extensions beyond that time that we hope the Congress will consider.

- Such an extension could provide a disincentive for employers to hire ESRD patients, and ultimately individuals who are predisposed to ESRD, such as diabetics, hypertensives, and minorities.

- Such an extension could provide an incentive for EGHPs to eliminate coverage for ESRD in their plans altogether.

- Such an extension could provide an incentive for insurers to continue to lower their reimbursement for ESRD.

- Such an extension could serve to drive the cost of private insurance even higher, leading individuals to drop their coverage.

The GAO study, *Impact of OBRA-90's Dialysis Provisions on Providers and Beneficiaries*, reported in April 1994 that "as employer-sponsored plans react to increasing costs, they will have greater incentive to search for ways to reduce their expenditures."

If extensions to the secondary payer provision beyond the 24 month period are enacted, ANNA suggests that a provision to evaluate the effects of such a change be crafted into the legislation.

EPOETIN REIMBURSEMENT

ANNA has issued a position statement supporting that epoetin continue to be reimbursed separately from the composite rate paid for dialysis treatment for the following reasons:

1. There is no clinical, economic, or quality of care reason to change the current method for epoetin reimbursement.

2. The current methodology, paying a fixed rate per specified dose of the drug, is based on the number of units of epoetin per dose. This is the most rational method for reimbursement, and the safest for the patient because it permits physicians to prescribe the medication solely on the basis of the patient's need.

3. There are some concerns that folding epoetin reimbursement into the composite rate paid for dialysis services could provide a strong incentive to underdose the drug. The Association has concerns about the impact such behavior would have on the health and rehabilitative potential of the dialysis population and the costs to the Medicare ESRD program in such a scenario.

   The Office of the Inspector General of the Department of Health and Human Services issued a report in 1990 saying it found that lower than predicted average doses of epoetin were being administered, resulting in "a windfall profit of 44 percent to the facilities," when epoetin was reimbursed at a flat rate of $40 per treatment. (OIG Report, 1990, p. 4.)

   Further, an Office of Technology Assessment study reported in the Journal of the American Medical Association in July 1991 concluded that "paying a fixed rate per treatment...gave dialysis facilities a financial incentive to use low doses..."

4. There are no data presently available that suggest epoetin is being overprescribed based on the current reimbursement methodology.

MANAGED CARE

The Association worked with this committee to legislate an ESRD capitation study as part of the Social Health Maintenance Organization (SHMO) expansion in OBRA '92. We also worked with RAND in their short-term evaluation of a capitated payment methodology for this demonstration.

The SHMO project began in 1985 based on a mandate in the 1984 Deficit Reduction Act. The design of this project was to consolidate the acute and chronic care delivery systems and manage care across a full range of services, including acute care, post-acute care, and expanded community care. Initially developed as an integrated care system for the aged, OBRA-'90 amended the original authority to include four new sites and allowed for some important modifications in the demonstration.

One site that was considered was a specialty provider SHMO that would be created to serve a population suffering from a specific high-risk disease, such as end-stage renal disease. ANNA was successful in its efforts to have such a site included as an appropriate one for an ESRD capitation study which would integrate acute and chronic care management for patients with end-stage renal disease through a nursing case management model.

In a nursing case management model, the case manager serves as the principal coordinator of care for the ESRD patient across health care settings, and works with other health professionals involved in the patient's care. In addition, the case manager provides direct care within the legal scope of practice for advanced practice nurses. Such a model has the potential to assure the provision of high quality care and control ESRD program expenditures for several reasons. First, advanced practice nurses with experience in nephrology have the requisite knowledge and skills to monitor and intervene to prevent occurrence of some of the most common causes of hospitalization for the ESRD population. Specifically, aggressive, proactive care is likely to prevent many of the complications associated with vascular access and fluid and electrolyte imbalances. Additionally, nurses have strong preparation in health promotion and their focus on the individual within the context of the family enhances their potential to build on the patient's strengths and capabilities and to maximize the family role in care.

The nurse case manager is a health care provider who can serve as a substitute for physician providers in providing primary care to ESRD patients. In 1990 the National Kidney and Urologic Disease Advisory Board raised concern about the future supply of adult nephrologists, suggesting that current medical school and nephrology enrollment trends portend a future shortage. If this scenario develops, use of advanced practice nephrology nurses in case management roles will free up nephrologists from providing care that can be capably provided by these nurses and enable the nephrologist to focus on care that only they are prepared and qualified to give. Additionally, the case manager role is a mechanism to address one of the concerns raised by the Institute of Medicine study committee, that of lack of continuity of care among the various physician providers for individual renal patients (Rettig & Levinsky, 1991). The emphasis that the case management model places on care coordination and inter-professional collaboration is one means to address this concern.

Dianne Feeney, RN, MS, assistant vice president for care management of Health Services for Children with Special Needs, Inc., in Washington, DC, presented a specific example in a recent issue of the *Nursing Spectrum*:

> "Case managers with organ transplant expertise fill an important niche in managed care organizations. Mr. S, a 44-year-old recently diagnosed with

end-stage renal disease, enrolled in an HMO. Following his first acute care admission as a member, his case manager contacted him and his primary physician to discuss the treatment plan and orient them to plan providers. The case manager arranged a transplant workup with one of these participating providers and initiated discussions with the facility's transplant coordinator. The case manager reviewed benefits, including donor coverage, with all parties. Two months after enrollment Mr. S had a new kidney. The case manager monitored his progress throughout the hospitalization while arranging home infusion therapy as part of discharge planning. Follow-up continued after discharge including coordination of post-transplant medical care and helping Mr. S to obtain anti-rejection medicine, as well as arranging counseling services to enable him and his family to deal with the ongoing issues of chronic illness. The case manager also referred them to a transplant recipient support group."

We urge Congress to continue to support the Social Health Maintenance Organization project and the ESRD capitation demonstration so the nursing case management model can be more fully evaluated and so appropriate risk adjusters can be determined for this highly specialized patient population.

NEED FOR MORE DONOR ORGANS

According to the United States Renal Data System 1994 Annual Data Report, the number of cadaver and living related donor transplants have shown very little increase over the years. However, the kidney transplant waiting list continues to grow so that the gap between the supply and the need for donor organs is even greater than in previous years.

At the end of 1993, there were nearly 25,000 patients on the kidney transplant waiting list; in that same year slightly more than 8,100 cadaver transplants were performed. One year later the number of patients waiting for a kidney had increased to just under 27,500 patients and the number of cadaveric transplants performed was just over 8,300.

In 1992 the median days waiting time on the list for kidney transplantation was 621 days. This is the most recent data available However, in 1991 the median waiting time was 518 days. We can assume from this, and from the increased number of patients waiting, that the current waiting time is even longer than the 1992 figure.

According to one HCFA source, in terms of annualized costs, a dialysis patient dialyzing for one year has TOTAL costs to Medicare of $44,000. In the year he receives a transplant, that patient represents annualized TOTAL costs to Medicare of $88,000. However, in subsequent years as a "functioning graft" patient, TOTAL costs to Medicare average $7,400. (A certain percentage of the successful kidney transplant recipients loses Medicare entitlement at the end of three years following transplantation. Therefore, their costs are shifted from Medicare to other payers, whereas the alternative dialysis costs would have to be borne by Medicare.)

In a May 1992 article in *Seminars in Nephrology*, Paul Eggars notes that one of the basic questions facing any cost comparison of dialysis and transplantation is whether graft survival rates are sufficiently high so that subsequent dialysis cost savings offset the initial transplant costs. In a study conducted by Dr. Eggars on Medicare reimbursement data from 1979, he estimated that the high initial costs of transplantation were recovered in about 4 years for cadaveric transplants and in about 3 years for living donor transplants. Graft and patient survival estimates at that time

showed one-year graft survival rates of 51 percent for cadaver grafts and 75 percent for living donor grafts. This reflects the state of the art in the late 1970s.

Transplant graft survival rates have improved markedly since the estimates used in studies before the advent of cyclosporine as an immunosuppressive agent. In the 1994 United Network for Organ Sharing (UNOS) Center Specific Report, one-year kidney graft survival for a cohort of patients from 10/1/87 to 12/31/91 was 81.6 percent. One-year patient survival rates for the same cohort was 93.8 percent. Given these increases in graft survival, it can be assumed that the initial costs of transplantation are recovered in less than 4 years for cadaveric graft recipients today.

On the basis of this information, ANNA believes that it is in the patients' and the payers' best interest to promote transplantation as a cost effective modality of care for end-stage renal disease. The missing element, however, is an adequate supply of donor organs for the nearly 30,000 patients waiting.

ANNA and other members of the transplant community would be happy to work with the Congress to evaluate legislative measures that would increase the supply of donor organs in this country. We also support continued funding for research in this area, including the use of xenografts. Transplantation not only improves the quality of life of the recipient, but it is also the most cost effective modality of care for this patient population.

QUALITY OF CARE ISSUES

The ANNA applauds Mr. Stark's efforts to promote quality assessment and continuous quality improvement within dialysis facilities and to ensure the adoption, endorsement, and application of industry-wide standards for the benefit of the patients who are the beneficiaries of the ESRD program. We feel that mandating such standards in statute is inappropriate, however, for a number of reasons.

There are eighteen ESRD Network Organizations throughout the country that are currently under contract to HCFA to perform oversight activities to assure the appropriateness of services and protection for ESRD program beneficiaries.

HCFA, with input from ANNA and other members of the renal community, has reshaped the Network program's approach to quality assurance and improvement in order to respond to the need to improve the care to Medicare ESRD patients. This new approach has been named the ESRD Health Care Quality Improvement Program (HCQIP).

The Networks began implementing the HCQIP in July 1994 with the ESRD Core Indicators Project as one of its major projects. ANNA was part of a workgroup from the renal community that was established to provide guidance to HCFA in the development of the ESRD Core Indicators Project.

The purpose of the Project is to: assist ESRD care givers in assessing and improving the care provided to ESRD patients; to describe the prevalence of important clinical characteristics of adult, in-center hemodialysis patients; to identify opportunities to improve care for these patients; and to establish a consistent clinical database for these patients.

The quality or "core" indicators that were selected to describe several conditions of care for adult, in-center hemodialysis patients in the 1994 phase of the project were: adequacy of dialysis, anemia, blood pressure control, and nutritional status.

The most striking opportunity for improving care to in-center hemodialysis patients concerns the adequacy of dialysis. In the last quarter of 1993 only 43 percent of such patients received dialysis which resulted in a urea reduction ratio (URR) of greater than 0.65, the threshold for adequate dialysis recommended by the Renal Physicians Association and a NIH Consensus Development Conference Panel.

Previous studies by the United States Renal Data System have estimated that in 1986 and 1990 the percentage of patients with a prescribed Kt/V of 1.2 (equivalent to a URR of 0.65) was 20 percent and 30 percent, respectively. The 43 percent finding in 1993 suggests that progress is already occurring.

Publication of an educational brochure for patients concerning the adequacy of dialysis is currently under development by HCFA, with the assistance of ANNA and with publication scheduled for this spring. Other activities planned include the distribution of the 1994 Core Indicators Project Report to all dialysis facilities. The Networks will also develop intervention activities to assist dialysis care givers to understand the data report and how to use the information to identify opportunities for improving patient care. The next Core Indicators data collection effort will begin early this summer, looking at adult peritoneal dialysis patients.

In addition to participating in the HCQIP, ANNA has worked in the recent past with HCFA to revise the Chronic Disease Medical Evidence Report to enable HCFA to evaluate the appropriateness of ESRD therapy. We have worked with them on their revision of both the facility survey process and tool and we are actively working with the staff at this time in their review and revision of the conditions of participation.

While there is still much progress to be made, ANNA believes that the combined efforts of the renal community and the HCFA have led to improvements in the quality of care delivered to ESRD patients such that H.R. 1067 is not necessary at this time.

The American Nephrology Nurses' Association appreciates the committee's review of the Medicare End Stage Renal Disease program. We have seen firsthand the benefits this program has had on the beneficiaries and we are grateful for its continuation. We appreciate this opportunity to share our thoughts and observations with the committee and will be happy to meet with staff to discuss them further.

Chairman THOMAS. Thank you very much, Ms. Sims.
Ms. Wish.

STATEMENT OF DIANE WISH, EXECUTIVE DIRECTOR, COMMUNITY DIALYSIS CENTER, CLEVELAND, OHIO, ON BEHALF OF NATIONAL RENAL ADMINISTRATORS ASSOCIATION

Ms. WISH. Good morning, Mr. Chairman, and Members of the Health Subcommittee. My name is Diane Wish and I am the executive director of three freestanding, not-for-profit dialysis facilities in Cleveland, Ohio. I am appearing on behalf of the NRAA, National Renal Administrators Association, and am the current president of that association.

We are delighted to have the opportunity to participate in this important hearing on the Medicare ESRD Program. Our testimony will focus on a number of issues. We would like to begin by emphasizing that the Medicare ESRD Program has been highly successful in providing access to life-sustaining quality care to over 90 percent of individuals with end-stage renal disease in this country.

Thirty years ago, individuals who received a diagnosis of end-stage renal disease faced near certain death. This program has also been extremely cost effective as explained in the latest USRDS 1994 Renal Data Report.

According to this report, while real Medicare payments per year for ESRD continue to rise in response to a growing ESRD population, average payments per patient per year showed little or no growth in the last 5 years. The real level of reimbursement per dialysis treatment, determined through the composite rate schedule, has been declining for almost two decades. The USRDS also noted that the trend of little or no growth in real per capita Medicare payment for all ESRD patients is particularly surprising since Medicare coverage was expanded in 1989 to include EPO, which now is used in over 80 percent of patients.

For these reasons, we would strongly urge the Subcommittee to maintain the ESRD Program as it is currently structured because it has successfully met the objectives of the program in a cost-effective manner.

For the very same reasons and for quality assurance purposes, we also adamantly oppose privatizing the ESRD Program. Such a move would result in serious access to care problems for ESRD beneficiaries, significantly reduced patient choice, and would compromise the quality assurance programs currently in place. If the ESRD Program were privatized, the ability to obtain accurate, validated cost, and quality data would be seriously jeopardized.

HCFA's continuous quality initiatives, which are just beginning to make a significant impact, might be lost forever. We strongly recommend that no further action be taken to privatize the ESRD Program until the results from the ESRD capitation demonstration project are evaluated.

The NRAA can support the concept of managed care for ESRD patients; however, we would want assurances that patients have the option to sign up for a managed care plan or remain in the current ESRD system, and that there be multiple managed care plan choices.

Kidney patients themselves have expressed serious concerns with managed care plans according to an Office of Inspector General's report entitled, "Beneficiary Perspectives of Medicare Risk HMOs," released in March 1995. Until there is better data on quality of care in HMOs for ESRD beneficiaries, the NRAA supports the continuation of Medicare's rule that prohibits new ESRD patients from joining an HMO unless they are in HMOs when their kidney failure begins. Waiting for the findings of HCFA's ESRD capitation demonstration would make the most sense.

We strongly recommend that this Subcommittee seriously consider writing into law the same type of inflation adjustment for dialysis facilities like that provided to hospitals and other Medicare providers. This was an IOM recommendation. We must vie for labor and supplies with those who do receive updates in their payments.

For this year, we earnestly request the Subcommittee increase payments to dialysis facilities by 3.7 percent for fiscal year 1996 to reflect the projected price increases facilities will experience in the coming year and pay for quality improvements. The NRAA is greatly concerned that dialysis facilities will not be able to continue to provide quality care without an increase in payments.

We support HCFA's continuous quality improvement initiatives, including the national anemia study and the core indicator study which supports a 1.2 Kt/V adequacy standard. Those studies have provided benchmark data for dialysis facilities to improve their quality of care.

There is also special concern for low-volume rural facilities and inner city dialysis facilities that treat a kidney patient population which requires extra social services.

Our concern is, based on the fact that we have been doing everything we can to be cost effective during the past 20 years, the list of cost containment possibilities has been exhausted. The new Kt/V standard will only increase our costs. The only things left to cut will impact quality. Our membership strongly believes we are very close to that point.

We also recommend that the ESRD secondary payer provision should be expanded to 24 or 30 months, as it will save Medicare money and help fund the 3.7-percent increase. EPO should not be bundled into the dialysis payment as it will create incentives to underdose patients which would result in higher, rather than lower costs to Medicare, as these patients would require more medical care; in particular, more hospitalizations. The physician self-referral provisions which apply to physician-owned dialysis facilities, concerning the administration of prescription drugs in their facilities and contracting with hospitals for inpatient acute care, should be eliminated as they create unnecessary barriers to needed medical care.

Again, I would like to thank Chairman Thomas for allowing the NRAA to express its views on a wide range of issues before the Subcommittee. The task before you is enormous and the need to control costs is great. We hope you will remember that the ESRD Program is a true model of cost-effective care. Please do not hesitate to call on us for information and data concerning renal care and dialysis facilities as you formulate your recommendations for fiscal year 1996.

Thank you.

[The prepared statement and attachments follow:]

STATEMENT OF DIANE WISH, EXECUTIVE DIRECTOR
COMMUNITY DIALYSIS CENTER

Good morning Mr. Chairman and Members of the Health Subcommittee. My name is Diane Wish, and I am the Executive Director of Community Dialysis Center, which operates three free-standing not-for-profit dialysis facilities in Cleveland, Ohio. I am currently the President of the National Renal Administrators Association (NRAA).

The NRAA is a voluntary organization representing professional managers of dialysis facilities and centers throughout the United States. We represent free-standing and hospital-based facilities, which are for-profit and non-profit providers located in urban and rural areas. Our members manage approximately two-thirds of the dialysis units in this country which provide dialysis services to a majority of Medicare End-Stage Renal Disease patients. The association was founded to provide information and education to our members and to work with the Congress, the Administration, and other oversight organizations on the Medicare ESRD program. Our organization is dedicated to providing quality of care in the most cost effective manner.

We are delighted to have the opportunity to participate in this important hearing on the Medicare ESRD program. Our testimony will focus on: (1) the reasons to maintain the current ESRD program, (2) our concerns with managed care, (3) the need to establish an annual inflation update factor, (4) our recommendation for a 3.7% update for fiscal year 1996 to pay for quality improvements, (5) support for a 24 to 30 month ESRD secondary payer provision, (6) opposition to EPO being folded into the composite rate paid to dialysis facilities and, (7) recommendations for modifying the physician self referral bans as they apply to physician owned dialysis facilities.

MEDICARE ESRD PROGRAM IS SUCCESSFUL AND COST EFFECTIVE

The Medicare ESRD program has been highly successful in providing access to life sustaining quality care to over 90 percent of individuals with end-stage renal disease in this country. Thirty years ago, individuals who received a diagnosis of ESRD faced near-certain death. Dialysis and kidney transplantation were just then emerging as experimental procedures and were available in only a handful of medical centers. More importantly, these treatments were beyond the financial reach of most Americans. The Medicare ESRD program introduced hope where there was none, saving several hundred thousand Americans from premature death by making life-saving treatments financially possible. In fact, the Institute of Medicine, in its landmark study entitled, **Kidney Failure and Medicare Program**, concluded that, "It has been remarkably successful in fulfilling its intended objectives."

This program has also been extremely cost effective as explained in the latest United States Renal Data System (USRDS), **1994 Annual Data Report.** According to this report, "While real Medicare payments per year for ESRD continue to rise in response to a growing ESRD population, average payments per patient per year show little or no growth in the last five years. The real level of reimbursement per dialysis treatment, determined through the composite rate schedule, has been declining for almost two decades." The USRDS also noted that, "This trend of little or no growth in "real" per capita Medicare payment for all ESRD patients is particularly surprising since Medicare coverage was recently expanded to include EPO (9/89), which now is used in over 80 percent of center hemodialysis patients...."

The report further notes that, "With adjustment for the overall change in consumer prices, per capita Medicare expenditures for ESRD increased 1.3 percent per year from 1990-1991 and by an annual average of 0.3 percent from 1987-1991. When adjusting for medical care inflation, real Medicare ESRD expenditure per patient per year actually declined by 3.2 percent from 1990-1991 and 2.9 percent per year from 1987-91. Alternatively, the change in real per capita Medicare expenditures for non-ESRD beneficiaries adjusted for overall inflation, increased an average of 3.5 percent per year between 1987 and 1991."

These facts have led Stuart Altman, chairman of ProPAC to conclude that without the ESRD program Medicare would have paid far more for ESRD patients than it currently does.

For these reasons we would strongly urge the Subcommittee to maintain the ESRD program as it is currently structured because it has successfully met the objectives of the program and in a most cost effective manner.

OPPOSE PRIVATIZING THE ESRD PROGRAM

For the very same reasons and for quality assurance purposes we also adamantly oppose privatizing the ESRD program. We do not believe that sufficient numbers of insurers could be induced into accepting Medicare vouchers for ESRD beneficiaries. Given the costly nature of their care, amounting to over $38,000 per year, we find it extremely hard to believe that Medicare would risk adjust the vouchers high enough to attract significant numbers of insurers to accept these Medicare beneficiaries in their plans. We know ESRD beneficiaries already experience difficulty in purchasing Medigap policies because of pre-existing condition clauses and prohibitively high premiums due to their disease.

Privatizing the program could also result in eliminating the beneficiary safeguards built into the Medicare ESRD program. For example, patients currently have the choice of modalities and the location of where they dialyze. Privatizing the program would result in an unregulated environment in which access to care and patient choice could be negatively impacted. Some physicians could be disenfranchised in the process. Also, there could be a significant negative outcome for academic/hospital-based programs.

We strongly recommend that no further action be taken to privatize the ESRD program until the results from the ESRD capitation demonstration project can be evaluated.

If the ESRD program were privatized the ability to obtain accurate, validated cost and quality data would be seriously jeopardized. HCFA's continuous quality initiatives, which are just beginning to make a significant impact, might be lost forever.

CONCERNS ABOUT MANAGED CARE

The NRAA can support the concept of managed care for ESRD patients. However, we would want assurances: (1) that patients have the option to sign up for a managed care plan or remain in the current ESRD system, (2) that there be multiple managed care plan choices, (3) that access to nephrologist care before kidney failure be assured, and (4) that good consumer protections, including appropriate claims processing and appeal rights be required.

Kidney patients themselves have expressed serious concerns with managed care plans, according to an Office of Inspector General's Report entitled, **Beneficiary Perspectives of Medicare Risk HMOs,** released in March 1995. (See Table A which is a summary of ESRD/Disabled Beneficiary Perspective by enrollee and disenrollee.) For example, the study found that disenrolled ESRD beneficiaries were 41 times more likely than ESRD enrollees to say that medical care received through an HMO caused their health to worsen. The ESRD disenrollees were the most likely to report that their primary HMO doctors restricted access to needed Medicare covered services, did not refer them to specialists when necessary, and did not take their health complaints seriously. They were also the most likely to seek out-of-plan care while still enrolled in the HMO and to believe that holding down the cost of care was more important to primary HMO doctors and the HMOs than providing the best medical care.

NRAA members have also found that their patients are concerned about HMOs. ESRD patients have expressed concerns about having to change physicians, dialyze at a facility that is inconvenient and would require long travel times, or be unable to change dialysis facilities and physicians if not satisfied with the quality of care in the HMO.

NRAA member data, contained in Tables B through E, demonstrate that quality of care in HMOs is no better and by some measure worse. Our data, from 3 dialysis facilities with a total of 411 patients located in the Midwest, indicates that gross mortality rates are better for regular ESRD Medicare beneficiaries than those enrolled in Medicare Risk HMOs and standard mortality rates (i.e. adjusted for age, sex, race and diagnosis) are about the same for both. Comparing hospitalizations and days in the hospital, 3 dialysis facilities with 1047 patients in Ohio, found that the HMO patients had no fewer hospitalizations nor days in the hospital for 1994, than the regular ESRD

patients.

In light of the IG's study and our own data and experiences, to protect ESRD beneficiaries, the NRAA would urge the Subcommittee and Congress to spend more time studying the issue of ESRD beneficiaries and managed care. There is a real need to proceed with caution before creating incentives for these beneficiaries to join Medicare Risk HMOs. Until there is better data on quality of care in HMOs for ESRD beneficiaries, the NRAA supports the continuation of Medicare's rule that prohibits new ESRD patients from joining an HMO unless they are in an HMO when their kidney failure begins. Waiting for the findings of HCFA's ESRD capitation demonstration would make the most sense.

NEED TO INCLUDE A DIALYSIS INFLATION UPDATE IN THE LAW

Medicare's payment structure for dialysis facilities is unique in the Medicare system. Dialysis facilities are paid a prospective payment to cover the cost of providing all dialysis related services, including the cost of a dietitian and social worker. This prospective payment system has been called the first DRG. However, unlike hospital DRG payments, which are annually updated, there is no statutory automatic inflation update to this payment, as there for are hospitals, hospices, nursing facilities and other providers. Instead, payment to dialysis facilities can only be increased by the Congress or the Administration.

Without an inflation adjustment written into the statute, we know only too well that the Congress, in these tight budgetary times, will find it very difficult to increase payments to dialysis facilities, even when they are meritorious.

Because other Medicare providers have inflation adjustments included in their payment formulas, Congress can reduce the update factor, saving Medicare money, and still grant some inflation increase to these providers.

We cannot understand why the composite rate payment does not include a medical inflation adjustment when dialysis facilities must vie with hospitals and physicians, who do receive annual updates, for the same pool of labor and must pay similar amounts for medical supplies, health insurance and other overhead costs.

The Institute of Medicine (IOM), in its two year study of the ESRD program, also concluded that Medicare should provide annual updates for dialysis facilities. Concerned about quality of care, the IOM stated that annual updates were necessary in order to ensure that patients received all of the care they required.

We strongly recommend that this Subcommittee seriously consider writing into the law the same type of annual inflation adjustment formula for dialysis facilities like that provided to hospitals, hospices and other Medicare providers. Then each year the Congress can determine an appropriate update factor as it does for all other Medicare providers.

RECOMMEND A 3.7% UPDATE IN DIALYSIS FACILITY PAYMENTS FOR FY 1996

We strongly request the Subcommittee **increase payments to hospital-based and free-standing dialysis facilities by 3.7%, for fiscal year 1996, to reflect the projected price increases facilities will experience in the coming year and pay for quality improvements.**

ProPAC's Analysis of Increased Costs - ProPAC in its 1993 Report to Congress recommended a 2.5% increase in payments to hospital-based and free-standing dialysis facilities for FY 1994. We never received this update. In ProPAC's 1995 Report to Congress, the Commission's analysis indicated that the prices of inputs used in a dialysis treatment will rise by about 3.7% between fiscal years 1995 and 1996. At a minimum, dialysis facilities should be given an increase to reflect real cost increases. Instead, ProPAC decided to recommend no increase because they believe that free-standing facilities are still reimbursed more by Medicare than their costs. However, if ProPAC had not applied, what we believe was an erroneous 12 percent audit adjustment in calculating the costs of providing dialysis services for FY 1995-1996, they would have concluded that payments were less than 1 percent above costs for free-standing dialysis facilities. Based on our own membership data we actually believe that at least a 10 percent update is appropriate for FY 1996. The NRAA would be happy to share with the Subcommittee the data we provided ProPAC this year, which includes a detailed analysis of the true costs of providing dialysis services in free-standing dialysis facilities.

Medicare Payments Have Been Essentially Frozen - The prospective payment system established for dialysis facilities in 1983 was reduced $2 a payment in 1986 and only increased by $1 a treatment in 1990 for FY 1991. In other words, dialysis facilities did not receive any inflation updates, like other Medicare providers, throughout the 1980s and instead had their payments frozen for most of the decade. Following the dollar increase in 1991, payments have been frozen. No other Medicare provider has had to live without inflation updates for this long. With about 90% of revenues coming from Medicare, dialysis facilities have very little ability to cost shift, and therefore must depend upon adequate Medicare reimbursement.

Costs Continue to Rise - ProPAC projects a 3.7% increase in costs for dialysis facilities between 1995 and 1996. The costs of complying with CLIA, OSHA, and other regulations on water quality and dialyzer reuse, increased labor costs and other overhead costs are making it very difficult for too many dialysis facilities to provide all of the care older and sicker patients now require. Staff to patient ratios cannot be further lowered nor can the ratio of registered nurses to non-registered nurse staff be reduced. ProPAC's analysis confirmed our findings and discovered that staffing ratios and mix have remained flat for the past three years.

Cost of New Quality Standard - Further, the National Institutes of Health (NIH), and the Renal Physicians Association have recommended an increase from 1.0 to 1.2 adequacy of dialysis care standard, known as Kt/V. It is our understanding that this new quality standard will be included in HCFA's proposed changes to the ESRD Conditions of Coverage rules. As an association we strongly support this new standard and believe that dialysis facilities have been moving to meet it since November of 1993. In order to comply with this new standard, many dialysis facilities will have to incur additional costs for labor to dialyze patients longer and or purchase new equipment. ProPAC has concurred in our assessment and stated in its 1995 Report to Congress that, the Commission believes that payments must recognize the additional costs of meeting the new adequacy standards.

Quality May Be Compromised - The NRAA is greatly concerned that dialysis facilities will not be able to continue to provide quality care without an increase in payments. We support HCFA's Continuous Quality Improvement (CQI) initiatives, including the National Anemia study and the [illegible] adequacy standard. These studies have provided benchmark data for dialysis facilities to improve their quality of care. There is also special concern for low volume rural facilities and inner city dialysis facilities that treat a kidney patient population which requires extra social services.

Our concern is based on the fact that we have done everything we can to be cost effective during the past twenty years. The list of cost containment possibilities has been exhausted. The new Kt/V standard will only increase our costs. There comes a point when the only thing left to cut may impact quality. Our membership strongly believes that we are very close to that point.

EXTEND THE ESRD MEDICARE SECONDARY PAYER PROVISION

We urge the Subcommittee to permanently extend the ESRD Secondary Payer provision from 18 months to 24 or 30 months beginning January 1, 1996. Currently, unless the Congress approves President Clinton's FY 1996 budget proposal to permanently extend the 18 month ESRD MSP provision it will sunset in 1998 and then reverts back to a 12 month secondary payer requirement. Extending to 24 or 30 months saves $839 million over 5 years, according to a CBO estimate obtained in 1993 with a 1994 effective date.

Patients Are Not Negatively Impacted - A December 1992 GAO study entitled, **Medicare Millions in End-Stage Renal Disease Expenditures Shifted to Employer Health Plans**, concluded that very few dialysis patients were negatively impacted by the 18 month

secondary payer provision and that Medicare saved millions of dollars. A follow up study by GAO in April 1994 entitled, **Impact of OBRA-90's Dialysis Provisions on Providers and Beneficiaries** stated that, "Our review of payment rules indicates that only rarely will it matter to the beneficiary whether Medicare or the employer plan pays first. The extension should not affect most ESRD patients' out-of-pocket expenses, because specific payment provisions insulate ESRD patients with dual coverage from being singled out for increased out-of-pocket expenditures."

Medicare Will Save Money - The **Impact of OBRA-90's Dialysis Provisions on Providers and Beneficiaries** study also concluded that Medicare would annually save $87 million from the 18 month ESRD secondary payer provision.

The NRAA does not believe extending this provision by 6 or 12 more months will have any appreciable affect on ESRD beneficiary access to employment or health insurance. But it will save Medicare millions of dollars.

We would, however, oppose an open ended ESRD secondary payer provision as we believe this would create access to employment and health insurance problems for ESRD beneficiaries.

OPPOSE EPO BEING INCLUDED IN THE COMPOSITE RATE

It has been suggested by one or two organizations in the renal community that the payment method for EPO be changed to "bundle" the payment for EPO into the composite payment for dialysis. Under this proposal, facilities would be paid an additional amount whether or not EPO was furnished and regardless of the number of units administered.

The NRAA joins with the Renal Physicians Association and the American Nephrology Nurses' Association in urging the Subcommittee and the Congress to reject this approach because of the real potential for abuse. When Medicare initially set the reimbursement at a flat rate of $40 per treatment for most patients, regardless of the amount administered, the Office of Technology Assessment (OTA) and the Office of Inspector General (OIG) issued reports that found that lower than predicted average doses were being administered. Largely on the basis of the OIG report, Congress in OBRA 1990 changed the reimbursement methodology to $11 per thousand units administered. In OBRA 1993, the payment amount was reduced to $10 per thousand units.

There are now additional reasons to reject a flat rate or bundled payment. OTA in an article published in the **Journal of the American Medical Association,** in July 1991, concluded that "paying a fixed rate per treatment with the biologic agent gave dialysis facilities a financial incentive to use low doses ... and fewer than 45 percent of patients who had been treated for 6 months or more had ever attained the target hematocrit." In other words, a bundled payment would create strong financial incentives for some providers to withhold EPO or reduce doses which would result in the return of anemia and a sharp reduction in the health status and the quality of life of many dialysis patients.

Further, folding EPO payments into the composite rate would not result in reduced Medicare expenditures for ESRD patients. This is because dialysis patients receiving EPO have been found to develop fewer comorbid conditions that require inpatient hospital treatment. A recent study conducted by Johns Hopkins School of Medicine and HCFA found that patients on EPO are less likely to have heart failure, angina, myocardial infarction, depression, and strokes than patients not receiving the drug. The study also concluded that use of EPO may be associated with fewer overall hospital admissions and fewer days spent in the hospital.

If financial incentives to withhold EPO led to increased use of transfusions, Medicare would incur the additional costs of treating blood-borne infections and patients would risk development of antibodies, increasing their chances that a kidney transplant would be rejected. These additional costs would most likely wipe out any potential savings associated with bundling EPO payments into the composite rate.

The NRAA would also like to be on record in opposition to lowering reimbursement for EPO. The U.S. price of EPO is already the lowest in the world. The list price according to Amgen is on average 34.4 percent lower than the European price and 68 percent lower than the price in Japan.

EXEMPT PHYSICIAN OWNED DIALYSIS FACILITIES FROM THE INPATIENT HOSPITAL SERVICE AND OUTPATIENT PRESCRIPTION DRUG BAN INCLUDED IN THE 1993 SELF-REFERRAL LAW

As a result of the self-referral ban on "inpatient hospital services" included in OBRA 1993, as of January 1, 1995, physician owned dialysis facilities, group practices and solo practitioners can no longer provide hospitals with the staff and dialysis machines required to dialyze their inpatients, if they refer their own patients to the hospitals.

The NRAA strongly recommends that the Subcommittee explicitly exempt physicians who have ownership or arrangement agreements with hospitals to provide inpatient dialysis services from the ban for the following reasons.

The purpose of the exemption is to assure that hospitals will be able to provide acute dialysis services to their patients. Many hospitals cannot afford to provide 24 hour a day acute inpatient dialysis services and have therefore contracted with local dialysis facilities (solo practitioners, group practices and physician owned) to provide the staff and dialysis machines to dialyze patients with renal failure. Such arrangements result in continuity of care and better quality of care because the same staff is providing the patients with dialysis care in both the inpatient and outpatient setting. The patients also benefit greatly by having their treatments performed by highly qualified staff. If these hospitals had no other option but to hire their own staff, it is likely that the staff would not be as qualified. This would be due to the lack of experience and expertise especially when the volume of treatments they performed was low.

Smaller community hospitals and hospitals in isolated areas rely upon acute care contracts with physician owned dialysis facilities in the community to meet patient care needs that cannot be met in any other way. Without this proposal some hospitals that cannot afford to staff an inpatient dialysis unit may have to transfer their critically ill patients with renal failure to other hospitals. This could negatively impact and compromise these patients' health. It might also jeopardize the continuity of physician care, create additional hardships for the patients and their families and increase the patients' emotional stress.

Further, we do not believe these arrangements should be included in the self-referral ban because the dialysis services are actually an extension of the physician's practice. Also, hospitals already have oversight responsibility for utilization and admission reviews to ensure that patients are not dialyzed inappropriately.

In summary, our proposed correction would: (1) avoid reducing access to inpatient dialysis care; (2) help maintain continuity of patient care and; (3) allow hospitals to enjoy the most cost-effective means of providing inpatient dialysis services.

The NRAA would also urge you to eliminate the OBRA 1993 ban on outpatient prescriptions drugs being dispensed in physician owned dialysis facilities. Nephrologist owned dialysis facilities, like all other dialysis facilities, order a number of prescription drugs to be given to patients while on dialysis. These medications are covered under Medicare's Conditions of Coverage and are reimbursed by Medicare. Peritoneal dialysis, which is performed by a patient outside of the dialysis facility, is also categorized as a prescription drug for Medicare reimbursement. Prohibiting physician owned facilities from prescribing peritoneal dialysis would mean that patients of these physician owned facilities would be precluded from this form of dialysis. We do not believe even the authors of the self referral provision intended to ban the provision of prescription drugs when delivered within the physician owned dialysis facility. Such a ban would effectively deny patients of these facilities from receiving proper care and could endanger these patients' lives.

CONCLUSION

RECOMMENDATIONS

1. We strongly recommend that the Medicare ESRD program be maintained in its current form for now. We would urge that you not consider restructuring this program by *either* privatizing it or mandating managed care for the ESRD population until validated information is available from the ESRD capitation demonstration project.
2. We earnestly recommend that you establish in law an annual inflation update factor as exists for all other Medicare providers.
3. For fiscal year 1996, we urge a 3.7% inflation update, based on ProPAC's analysis of projected increased costs for 1995-1996 and which is now needed to pay for a higher standard of dialysis care.
4. The ESRD Secondary Payer provision should be expanded to 24 or 30 months as it will save Medicare money, not negatively impact ESRD patients, and help fund the 3.7% increase.
5. EPO should not be bundled into the dialysis payment as it will create incentives to under dose patients which could result in higher rather than lower costs to Medicare as these patients could require more medical care and in particular more hospitalizations.
6. We support the continuation of the prohibition on new ESRD enrollees in Medicare Risk HMOs *unless* they are already enrolled when their kidneys fail.
7. The physician self referral ban on physician owned dialysis facilities from administering prescriptions drugs in their facilities and the prohibition on contracting with hospitals for inpatient acute care should be eliminated, as they create unnecessary barriers to needed medical care.

Again, I would like to thank Chairman Thomas for allowing the NRAA to express its views on a wide range of ESRD issues before the subcommittee. The task before you is enormous and the need to control costs is great. We hope that you will remember that the ESRD program is a true model of cost effective care. Please do not hesitate to call on us for information and data concerning renal care in dialysis facilities as you formulate your recommendations for fiscal year 1996.

Table A: Beneficiary Perspectives by Medicare Categories of Aged or Disabled/ESRD				
	Disenrollees		Enrollees	
	Aged	Disabled/ ESRD	Aged	Disabled/ ESRD
Medical care received through the HMO caused beneficiary's health to get worse.	20% (4,094)	41% (358)	2% (17,294)	1% (231)
For a scheduled appointment with their primary HMO doctors, usually waited:				
▸ 1 to 4 days	49% (10,246)	78% (1,630)	51% (468,557)	68% (15,749)
▸ 5 to 8 days	24% (5,011)	15% (314)	26% (237,936)	11% (2,549)
▸ more than 8 days	27% (5,654)	8% (158)	23% (204,855)	21% (4,771)
For a scheduled appointment with specialists, usually waited:				
▸ 1 to 4 days	40% (5,976)	69% (1,218)	35% (258,235)	12% (3,353)
▸ 5 to 8 days	25% (3,797)	13% (222)	29% (213,086)	42% (12,008)
▸ more than 8 days	36% (5,370)	19% (332)	36% (265,888)	46% (13,061)
Primary HMO doctor failed to provide Medicare covered services that were needed.	20% (4,366)	39% (823)	3% (30,648)	4% (1,285)
Primary HMO doctor failed to refer to a specialist when needed.	21% (4,431)	50% (1,054)	5% (42,743)	6% (1,725)
Sought out-of-plan care while a member of the HMO.	20% (4,160)	49% (1,027)	7% (63,392)	7% (2,237)
Primary HMO doctor didn't take their health complaints seriously.	38% (7,892)	48% (976)	11% (104,185)	20% (4,671)
Holding down the cost of care was most important to:				
▸ primary HMO doctor	26% (5,471)	48% (989)	10% (94,109)	2% (586)
▸ the HMO	34% (7,042)	50% (1,030)	11% (105,041)	11% (3,324)

Source: Office of Inspector General's report entitled, "Beneficiary Perspectives of Medicare Risk HMO's," issued March, 1995.

TABLE B

Gross Mortality for:

ALL INSURANCE			
FACILITY	TOTAL PATIENTS	EXPIRED PATIENTS	GROSS MORTALITY PERCENTAGE
A	211	21	9.05%
B	94	7	6.93%
C	106	11	9.40%
ALL	411	39	9.5%

MEDICARE			
FACILITY	TOTAL PATIENTS	EXPIRED PATIENTS	GROSS MORTALITY PERCENTAGE
A	106	10	8.62%
B	41	4	8.89%
C	71	3	4.05%
ALL	218	17	7.8%

HMO			
FACILITY	TOTAL PATIENTS	EXPIRED PATIENTS	GROSS MORTALITY PERCENTAGE
A	71	8	10.13%
B	37	0	0.00%
C	18	4	18.18%
ALL	126	12	9.5%

COMMERCIAL			
FACILITY	TOTAL PATIENTS	EXPIRED PATIENTS	GROSS MORTALITY
A	11	1	8.33%
B	6	1	14.29%
C	8	2	20.00%
ALL	25	4	16%

TABLE C

8 MONTH INTERIM STANDARD MORTALITY RATIOS FOR THREE MIDWEST DIALYSIS FACILITIES

I. FOR ALL INSURANCE CATAGORIES

FACILITY	PATIENTS	SMR
A	79	.50
B	158	.54
C	70	.30
ALL	307	.47

II. HMO INSURANCE

FACILITY	PATIENTS	SMR
A	15	.93
B	61	.54
C	29	0.00
ALL	105	.43

III. MEDICARE INSURANCE

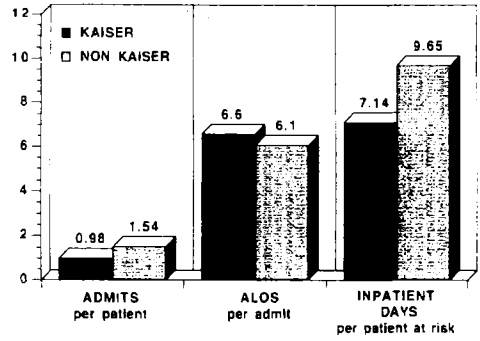
FACILITY	PATIENTS	SMR
A	56	.22
B	90	.51
C	36	.46
ALL	182	.42

IV. COMMERCIAL INSURANCE

FACILITY	PATIENTS	SMR
A	8	2.18
B	7	.98
C	5	.99
ALL	20	1.38

TABLE D

Kaiser Patients Had No Fewer Hospitalizations nor Days in Hospital for 1994



Differences are not significant

TABLE E

No actuarial difference in hospitalizations nor days in hospital for 1994

	KAISER	NON KAISER	SIGNIFICANT DIFFERENCE?
PATIENTS	75	972	n/a
PATIENT DAYS	19477	253653	n/a
HOSPITAL DAYS	536	9382	n/a
% ADMITTED	50.6	62.6	NO
HOSP ADM per 1000 PAT DAYS	3.7	5.9	NO (t-test)
HOSP DAYS per 100 PAT DAYS	2.8	3.7	NO (t-test)

Chairman THOMAS. Thank you very much, Ms. Wish.
Mr. Bowden.

STATEMENT OF A. BRUCE BOWDEN, CHAIRMAN, NATIONAL KIDNEY FOUNDATION

Mr. BOWDEN. Thank you, Mr. Chairman, Members of the Subcommittee. I am chairman of the NKF, National Kidney Foundation, which at age 45, is the oldest and largest of the nonprofit organizations in the United States, representing the interests not only of kidney patients, but of the professional care team that takes care of them.

We appreciate the opportunity to be here this morning to talk about what we view as a tremendously successful 22-year-old program. A number of the benefits of the program have been talked about this morning. One of the most dramatic that hasn't been mentioned is the fact that when this program came in, it ended the existence of committees in hospitals which had to make, on a daily basis, decisions of who would live on dialysis and who would not.

During the life of the ESRD Program, a lot of changes have taken place. The ability to care for a broader range of patients, much more difficult cases, has caused the population to be older, to be sicker, to be poorer, and to be more heavily made up of minorities.

We have submitted written recommendations and I believe they generally fall into four categories. The first one that has been discussed earlier this morning is quality. There is a clear need for quality standards. The most recent USRDS data on mortality, on the high rate of complications and hospitalization, point clearly to the need for quality tools. We believe that government and the renal community should work together on the development of quality tools, not only to measure quality, but also to assure it, that these tools should deal not just with dosage, with Kt/V, but with nutrition, with staffing patterns, and with quality of life issues.

Second, access has been discussed, an equally important area. We believe access means something a little broader than what has been discussed. We believe access means informed access by all patients to all modalities of treatment to include transplantation, home hemodialysis, and peritoneal dialysis. It is not just an issue of geographic access.

Obviously, there are problems with organ donation. Some of those have been discussed. There is a problem with the organ supply. We would again remind the Congress that there is the opportunity to allow a pilot program on the use of financial incentives for cadaveric organ donation, and to allow for the removal of financial disincentives for living related donation. We also believe that Congress has an opportunity not only to allow transplants but to keep healthy transplants by extending Medicare coverage for immunosuppressant drugs for the life of the graft.

The third area that we believe is important is the area of prevention or delay in the progression of kidney disease. Obviously, diabetes and high blood pressure—hypertension—are tremendous causes of end-stage renal disease. We commend Mr. Stark on H.R. 1068 which suggests a demonstration project on the benefits of attempting to delay the onset of ESRD. The NKF is working in a similar

direction. It has had a task force now for almost 3 years on investigating early intervention and prevention. Really, this is a tremendously important area.

The final area that is covered by our recommendations is the area of rehabilitation. We think, as I said earlier, that informed patient choice among all modalities of treatment is tremendously important, which form of treatment best suits their style of life and can support their quality of life. We believe that there should be incentives for units, to emphasize home hemodialysis, which is probably the most effective treatment technique that has yet been shown, also to create night shifts at hemodialysis centers to accommodate working patients.

We also believe that there should be guidelines on staffing patterns, recognizing that these have to be flexible depending on patient makeup, but these staffing guidelines should talk about all the disciplines, nutrition, social work, nurses and technicians, as well as physicians, and should deal not only with the numbers of staff, but also with their qualifications.

In summary, we think this has been a tremendously successful program, but certainly one which, hopefully if some of these modifications would be considered, could be made even more successful.

Thank you.

[The prepared statement follows:]

TESTIMONY OF A. BRUCE BOWDEN, ESQ.
NATIONAL KIDNEY FOUNDATION

Mr. Chairman, Members of the subcommittee, I am A. Bruce Bowden, a practicing attorney from Pittsburgh, Pennsylvania and current Chairman of the National Kidney Foundation (NKF). The NKF is the oldest and largest voluntary health organization representing the concerns of kidney patients and the health care professionals who serve their needs. The Foundation is pleased to have the opportunity to appear before the Committee this morning to discuss the Medicare End Stage Renal Disease (ESRD) Program.

We welcome Congressional oversight on the status of this program. However, we would like to emphasize that the Foundation in its own right has played the role of watch dog continuously since the program's inception in 1973. Our efforts have been focused most recently around a project which we call "Controversies in the Quality of Dialysis Care." That initiative underscored the concern that some aspects of the ESRD program, including its payment system, can be improved. We would like to state at the outset, however, that we do not claim to be experts in reimbursement methodology or on managed care. We would suggest specifically with regard to the role managed care could play in the delivery of ESRD services, that the issue needs careful study and perhaps it would be prudent for the Congress to commission the Institute of Medicine (IOM) or other group to evaluate the implications of such an alternative payment system for this unique patient population.

As patient advocates we would like to make several observations that deserve particular attention as the Committee continues its oversight. We do so in the interest of improving access to and quality of care for Americans who have End Stage Renal Disease.

(1) The Medicare ESRD entitlement has been an overwhelmingly successful program, making life sustaining renal replacement therapy available to hundreds of thousands of people, irrespective of their economic status, their age, gender, race, religion or country of origin.

(2) At the same time we must take into account the changing nature of the patient population being served, which reflects an aging America, improved success in treating ESRD patients with serious comorbidities and an increasing incidence and prevalence of kidney failure among minority groups, which far exceeds their representation in the overall population.

(3) In order to make sure that the program continues to meet its objectives in a cost-effective manner, Congress, the Health Care Financing Administration (HCFA) and the renal community must address the following issues: providing adequate reimbursement for dialysis treatment; establishing a quality assessment methodology and quality assurance system that serves patient and clinical goals; authorizing sensible policies to support transplantation, the most cost-effective ESRD treatment modality; and helping patients, their families, clinicians, and the public come to grips with appropriate criteria for providing long term chronic care to patients of advanced age with multiple comorbid conditions.

HISTORY OF THE ESRD PROGRAM[1]

I want to provide the subcommittee with a brief analysis of the history and results of the Medicare End Stage Renal Disease Program and its relationship and importance to the current discussions about health care and Medicare reform. The program is truly impressive: as Chairman Thomas stated in announcing this hearing, it has saved thousands of lives since it was founded twenty-two years ago. Moreover, it has accomplished this remarkable success while its per-patient costs remained under tight control. Those facts are a source of great pride for the program and provide valuable lessons that may have future usefulness.

The experience with the ESRD Program, however, also teaches that any health delivery system must be more than simply a payment mechanism. We've learned that when the federal government is virtually the only payer for a medical service, cost control can become a dominant consideration in delivering the service. Cost control in isolation can lead to many problems. For instance, it could be argued that reduced dialysis reimbursement may have contributed to the high dialysis mortality rate in the United States, which is the highest of any industrialized nation.

We have learned that quality assurance measures and systems must be included in any payment program from its inception. Any truly successful health care system must be

[1]See Appendix.

concerned with quality, access, translation of scientific advancements and outcomes of patient care, as well as the relationship of these factors to cost.

A landmark in the evolution of the ESRD program was the creation of the United States Renal Data System (USRDS) in 1986. The USRDS is arguably the finest registry of its kind in the world and the epidemiologic data which it collects in conjunction with the 18 ESRD Networks provide direction for the kind of quality improvement initiatives which we advocate.

Epidemiology

There were 11,000 ESRD patients eligible for Medicare at the inception of the program on July 1, 1973.[2] By December 31, 1990, the prevalence of reported ESRD therapy at that point counted 165,353 patients.[3] Today there are over 220,000 Americans currently receiving dialysis treatment. The growth in expenditures under the Medicare ESRD Program can be largely explained by the remarkable expansion in the number of patients served, together with changes in the composition of the ESRD population. Three areas should be highlighted: the shift in age distribution of patients on dialysis or transplantation, alterations in the profile of patients accepted for ESRD treatment (relating to the underlying cause of kidney failure) and increases in the prevalence of patients with serious comorbid conditions. This can be attributed to enhanced ability to provide renal replacement therapy for older and sicker patients.

With respect to the aging of the ESRD population, there were 3,552 Medicare ESRD patients between 70 and 74 years old on December 31, 1980. A decade later there were 14,093 patients in that age group. The growth in the number of ESRD patients over 75 is even more striking -- from 2,578 at the end of 1980 to 16,124 on December 31, 1990. Stated in another way, patients between 70 and 74 comprised 8.5% of the ESRD population in 1990 as opposed to 6.75% in 1980. Comparable percentages for the over-75 age group are 9.75% (1990) and 4.9% (1980).[4]

Per capita Medicare program expenditures for dialysis patients increase with each adult age category. For instance, for 1990, the following annual costs were reported by HCFA:[5]

Age Group	Expenditures Per Dialysis Patient
15-24	$33,220
25-34	$34,495
35-44	$34,795
45-54	$35,960
55-64	$38,256
65-74	$45,405
75 +	$47,926

Another major demographic change has been the growth in the number of ESRD patients with a primary diagnosis of diabetes. On December 31, 1980 there were 4,358 Medicare enrollees in that category, accounting for 8.27% of the ESRD population. This should be compared with the 40,514 Medicare ESRD patients with diabetic nephropathy at the end of 1990, constituting 24.5% of the ESRD population. Indeed, diabetic kidney disease has become the leading cause of irreversible kidney failure in the United States. Moreover, kidney failure is only one consequence of diabetes. Diabetics may become blind and may suffer from neuropathy and peripheral vascular disease which may lead to loss of limbs. Not surprisingly, annualized mean expenditures for dialysis patients with a primary diagnosis of

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[2]Richard A. Rettig, Ph.D., Policy Analysis, Policy Formulation and End-Stage Renal Disease, Rand Corporation: 1980, p. 8.

[3]United States Renal Data System (USRDS), 1993 Annual Data Report, Table B.1.

[4]Ibid.

[5]Health Care Financing Research Report: End Stage Renal Disease, 1991, p. 60.

diabetes are higher than for any other group ($49,040 versus an average of $41,315).

Finally, we should not overlook the ethnic distribution of the Medicare ESRD population. While African Americans make up 12% of the population of the United States, they accounted for 28% of the Medicare ESRD population on December 31, 1980 and 30% of beneficiaries as of December 31, 1990. There were 15,044 African Americans on dialysis or with a kidney transplant on the former date, compared to 49,827 at the latter date.[6] Many African Americans have limited or inconsistent access to health care throughout their life time and many with end stage renal disease have numerous unmet health care needs with which ESRD providers must grapple.

RECOMMENDATIONS FOR STATUTORY AND ADMINISTRATIVE IMPROVEMENTS IN THE ESRD PROGRAM

The NKF believes that the recommendations set forth below are essential for the continued success and improvement of the ESRD Program. This unique federally supported health care experiment is twenty-two years old and is in need of advancements in the areas of quality improvement and assurance, access, prevention, rehabilitation, reimbursement and scientific research. The substance of these proposals was drawn from the Institute of Medicine study, Kidney Failure and the Federal Government, the findings of the Prospective Payment Assessment Commission, the National Kidney and Urologic Diseases Advisory Board's 1990 long range plan Window on the 21st Century, the National Institutes of Health (NIH) 1993 Consensus Conference "Morbidity and Mortality of Dialysis" and a special study group of the National Kidney Foundation, "Controversies in the Quality of Dialysis Care," previously mentioned. In total, they reflect the Foundation's concern for the ESRD patient and its basic philosophy of "moving from treatment to cure." Some of the recommendations can be implemented by administrative actions and others will require legislative remedy by the Congress.

Prevention

Recent research findings indicate that it may be possible to prevent or delay the progression of kidney failure. On the other hand, health insurers in general, and Medicare in particular, have not promoted preventive health care until recently. The NKF has established an Early Intervention and Prevention Task Force which is developing strategies for implementation among patients who are at high risk for ESRD. We also congratulate Mr. Stark for the interest in new approaches to preventive care which are evidenced in H.R. 1068.

Access to ESRD Therapies

The panel for the IOM study estimated that 93% of the U.S. ESRD population is covered by Medicare for renal replacement therapy. The remaining 7% include those receiving benefits from the Veterans Administration, the Indian Health Service and special State Kidney Programs. Furthermore, the United States has the highest referral rate for ESRD therapy of any industrialized nation. These data would suggest that access to ESRD treatment is not a problem. Such a conclusion, however, may be an oversimplification. Recent studies indicate that there is variability in referral by region of the country and by age. Patients in rural areas often have to travel hundreds of miles for dialysis (three times a week) if they cannot be treated at home.

Access to modality options may also be impaired. In particular access to transplantation is limited because the supply of organs has not kept pace with the growth in the number of patients on the transplant waiting list. Moreover Medicare policies may discourage patients from opting for transplantation. Finally, there has been a marked decline in the percentage of patients on home hemodialysis and the proportion of patients receiving peritoneal dialysis does not approach that in many other countries.

To improve access the Foundation proposes:

1. That information and education programs about choices among various

[6]USRDS, supra, note 3.

treatment modalities be available to all patients without regard to Social Security status.

2. That the 3 year limit on Medicare eligibility be eliminated for ESRD patients who are successful transplant recipients.

3. That benefits for anti-rejection drugs be extended to cover the life of the graft.

4. That new programs be instituted which would increase the availability of organs for transplantation by providing financial incentives for cadaveric organ donation or through removal of financial disincentives for living related donation.

Quality of Care

The NKF believes that the data regarding morbidity and mortality among U.S. dialysis patients are disturbing indicators of a decline in the quality of care in the ESRD Program. Our unadjusted annual mortality rate has risen in the past few years to more than 22%, considerably worse than in other industrialized nations (e.g., Spain, France, Germany, Japan). Despite a recent turn for the better, mortality is still higher than in many other industrialized countries. If we accept hospitalization rates or days per year as apt surrogates for morbidity, then patients over 75 years old and diabetics (the two fastest growing groups in the ESRD Program) consume, respectively, 20% and 22% more resources than the average dialysis patient. The number of Medicare covered hospitalizations increased from 183,500 in 1985 to 283,700 in 1990, an average increase of 9.1% per year. During this period, the total number of inpatient days increased at an average annual rate of 11.1%. This hospitalization experience is an indicator of personal suffering. It also constitutes a growing component of ESRD expenditures.

While there is no single cause for this alarming trend, the experts point to certain factors that contribute to the problem. Some believe that the way dialysis services are delivered, and the relationship between payment levels and patterns of care may have contributed greatly to the decline in quality. Over the past several years there has been a movement toward shorter dialysis sessions, in part based on misinterpretation of early studies. Reduction of hemodialysis treatment time may, however, have had an adverse effect on morbidity and mortality. In reference to the negative impact of reimbursement changes on quality, there is wide spread agreement with the opinion that reduced payments have had a negative effect on outcomes.

As the availability of funds became tighter, dialysis units changed staffing patterns. In the early 1970's, before the Medicare ESRD Program began, most ESRD patients were dialyzed in hospitals by registered nurses and were cared for by a nephrologist during each treatment. There was also intense involvement by experienced renal nutritionists and nephrology social workers with masters degrees. Since that time, but especially since the mid-1980's, there has been an evolution toward treatment in outpatient units, non-hospital based, with less care provided by registered nurses, more involvement by licensed practical nurses and technicians and less interaction with renal nutritionists and masters-level social workers. At the same time the government continued to add to the list of services which dialysis units must provide their patients without making corresponding increases in payment levels. These developments occurred while demographic changes resulted in an ESRD population which requires more, rather than less, care.

With these developments in mind, and from the perspective of the ESRD patient, the NKF makes the following recommendations:

1. That the federal government foster the development and validation of tools to measure the quality of care provided to ESRD patients, based on structure, process, and outcome.

2. That the renal community continue to develop specific quality assurance tools including ones for hemodialysis, peritoneal dialysis and transplantation and that total quality management and assurance be instituted for the program.

3. That all relevant government agencies work with the renal community to put in

place the mechanisms needed to implement quality assessment/quality improvement initiatives for ESRD care.

4. That responsibility for implementation of quality assessment/quality improvement be delineated at the unit level, for state surveyors, for ESRD Networks and at HCFA.

5. That HCFA conduct studies of the feasibility of an incentive reimbursement system for dialysis treatments in which payment is tied to the quality of care delivered.

6. That the reimbursement methodology of HCFA reflect changes in the demographics of the ESRD population that have occurred since the composite rate was instituted.

7. That the methodology for reimbursement be modified to take into account both case mix and acuity levels at individual facilities.

8. In order to handle the diverse needs of an older and sicker ESRD population, reimbursement levels should be sufficient to support adequate staffing levels at dialysis units, both as to staff/patient ratio as well as with respect to staff qualifications.

Rehabilitation

Rehabilitation signifies restoration of physical and mental function to the point that a person can once again engage in family and community activities and enjoy a satisfactory quality of life. Rehabilitation of the ESRD patient may include achieving a level of physical health, strength, and endurance to perform activities of daily living, enjoying hobbies and recreational activities, re-engaging in family responsibilities and returning to school or the work force. For those unable to maintain employment or return to work, rehabilitation may mean redirecting their skills into home or community activities that will enhance their self-esteem.

To enhance rehabilitation, the NKF proposes:

1. That the reimbursement program include incentives for facilities to offer home dialysis and evening shifts for the working patient.

2. That the reimbursement program provide appropriate numbers of qualified professional staff who have the expertise to facilitate rehabilitation.

3. That patients be offered a choice of renal replacement modalities, including transplantation.

CONCLUSION

Ready access to dialysis care and renal transplantation has successfully and effectively prolonged the lives of hundreds of thousands of people. However, the evolution of the Medicare ESRD Program has raised concerns which were not foreseen at its inception. Even though the program has many significant accomplishments, we can do a better job in reducing morbidity and mortality and improving the quality of life of ESRD patients. We therefore urge the Congress to consider implementing the above recommendations. This will help assure that the program continues to serve the needs of those Americans who have End Stage Renal Disease and who will experience kidney failure in the future.

Mr. Chairman, thank you again for the opportunity to appear before the subcommittee. I will be pleased to answer any questions that the subcommittee Members may have.

APPENDIX

Overview and Background of ESRD Program

On October 30, 1972 President Richard Nixon signed PL 92-603 into law, and with it a section which provided that every individual who is medically determined to have chronic renal disease and who requires hemodialysis or renal transplantation for such disease shall be considered as disabled and, therefore, eligible for Medicare. The dramatically concise amendment to the inches thick bill finally addressed the "who shall live and who shall die" argument which had been debated in every possible forum for a decade.

Before the enactment of the 1972 amendment and in the absence of any other formal predictable form of financial assistance, families of patients literally took to the streets selling raffle tickets, clipping coupons from food packages, and seeking outright donations to support dialysis treatment for a loved one. They formed voluntary agencies to help collect funds to buy machines, and to approach the government for assistance. These efforts were reported in hundreds of stories in the press, radio, and television. The public effort was given national attention by a troubling "Life" magazine story which focused on a patient selection process being practiced in Washington State. The article brought the "who shall live and who shall die" issue into millions of homes throughout the country. The situation elicited varying but limited responses from the public, professional societies, volunteer agencies, and state and federal governments.

The so-called 1967 "Gottschalk Report," issued by the White House Bureau of the Budget, which was little noticed at the time, called for a national solution to this perplexing problem. While it did not receive wide circulation it became the Bible for those who were convinced that the ultimate solution was a federally supported program for all patients.

The debate, which culminated in final passage of the Medicare ESRD entitlement, focused on cost, utilization, fairness, the transfer of technology, and the appropriate role of the federal government in health care. In the end, however, the imperative of the life-saving procedures and technology dictated the outcome.

The action of the Congress and of President Nixon had its roots in a combination of ethical imperatives, citizen pressures, evolving technology for life-saving procedures, and pressures for expanded national health coverage.

The second phase in the history of the ESRD Program was the process of implementation. This phase had its beginning in the House/Senate conference committee where cost and utilization were the focus of discussion. To arrive at a projected first year cost and outward estimates the Congress relied upon two sources: transplant and dialysis professionals and the Health, Education, and Welfare Department (HEW) actuaries. The physicians gave sincere but optimistic cost reports ($55 million first year) and conservative estimates of patient populations (level out at below 100,000). The HEW Office of Health Insurance Studies, operating on estimates from the community and statistical models, gave the conference committee its best estimates. Their first year projections had the exceedingly wide range of between $100 million and $500 million. Because of the poor data and the large number of variables, the estimates were no better than "educated guesses."

The process of developing a program had to be placed on a very fast schedule because the implementation date by statute was July 1973 (a short eight months). There was little legislative language as to intent for implementation except:

> The Secretary is authorized to limit reimbursement under Medicare for kidney transplant and dialysis to kidney disease treatment centers which meet such requirements as he may by regulation prescribe. Provided, That such requirements must include at least requirements for a minimal utilization rate for covered procedures and for a medical review board to screen the appropriateness of patients for the proposed treatment procedures.

The Department of HEW set about the task with very little data about severity, age, ethnic factors, associated diseases, numbers of patients and total costs. For example, no one suspected that the number of ESRD patients over 65 (which was about 5% of the total in 1973) would reach 40% of the ESRD population in 1993, or that there would be 160,000

dialysis patients on Medicare at the end of two decades. The result of which as been a twenty-two year process of refinement of policies, regulations and rates by the Congress, the Health Care Financing Administration and the providers.

Unlike almost all government supported health care delivery programs, the ESRD Program experienced rate reductions for facilities and providers. In fact, the reimbursement rate for outpatient dialysis in 1974 dollars has declined more than 60%.

The introduction of new drug coverage added an unforeseen cost element to the program. In 1986 the Congress allowed payment for anti-rejection drugs for transplant patients for up to one year post-transplant. The benefit was extended to three years by the Omnibus Budget Reconciliation Act of 1993. In 1989 recombinant erythropoietin, a synthetic hormone used in treating anemia, was added as a covered item.

Another unforseen development has been the lack of growth in the number of kidney donors, thus affecting the number of patients being transplanted. For example, as of March 15, 1995 there were 28,037 patients waiting for kidney transplants, a number that is expected to increase at an annual rate of 20%. This trend was not anticipated in 1973 or indeed in 1983. A kidney transplant is the treatment of choice for all suitable ESRD patients and, when successful, is cost-effective Over a ten year period transplantation offers an 18% savings from the cost of chronic hemodialysis. Thus, the flat donation rate has had a negative impact on both the patients and program costs.

The final part of this overview concerns trends in research. When the ESRD amendment was enacted into law the Institute at the National Institutes of Health (NIH), which was responsible for basic and clinical investigation concerning kidney disease, was spending $18,127,000 for this purpose, of which $4.6 million was supporting a dialysis research contract program. Ten years later the dialysis contract program received $600,000 in allocated funds out of the $47.4 million appropriated for kidney disease research. By 1992 the support for basic and clinical research in kidney disease had reached $118.4 million with virtually no dialysis research being supported. While this amounts to a seven-fold increase in support of kidney research, Medicare expenditures for ESRD patients in the comparable period grew fourteen times. Fortunately, that trend has been reversed with respect to dialysis research and approximately $1.7 million was directed toward dialysis related clinical research in FY93.

It may be argued that spending for kidney research by NIH is not proportional to the costs allocated for patient care. Although it is clear that the financing of these two separate functions (research and patient care) come about in different ways, and are influenced by varied and dissimilar factors, an effort to maintain research to combat renal disease as a fair fraction of expenditures for care, might help narrow the tremendous gap between the costs of patient care and the commitment to find cures.

Chairman THOMAS. Thank you, Mr. Bowden.

Dr. Lundin, I understand you would be the winner in the show-and-tell contest. I look forward to your testimony.

STATEMENT OF A. PETER LUNDIN, M.D., IMMEDIATE PAST PRESIDENT, AMERICAN ASSOCIATION OF KIDNEY PATIENTS, TAMPA, FLORIDA

Dr. LUNDIN. Thank you, Mr. Chairman.

Mr. Chairman and Members of the Subcommittee on Health, my oral testimony will differ from the written in words, but not in content. As immediate past president of the AAKP, American Association of Kidney Patients, I am gratified to be here today to relate to you the concerns of kidney patients for the future of Medicare's ESRD Program.

For most of us, dialysis has been simply the difference between life and death. Without dialysis, I would have died in 1966. Only because my father could afford to pay for dialysis treatments at over $30,000 per year, I was able to finish college, go to medical school, practice my profession as a kidney specialist, and be here today almost 30 years later.

As you are aware, the ESRD Program was enacted in 1972 to make this uniquely predictable, artificial, and lifesaving therapy available to the many thousands who could otherwise not afford it. I urge you to overlook the media-fostered image of the miserably unhappy dialysis patient as a measure of dialysis. The great majority of us, rather, are content to be alive, and by receiving quality treatments, have been able to do something we value with the time we have left. Given the life-sustaining nature of dialysis and transplantation, it is understandable that any changes in accessibility to the ESRD Program should create concern among its beneficiaries.

There are several points I would like to make to the Subcommittee today. As patients, we are concerned that the transfer of all or even part of the ESRD Program to the private insurance sector could again result in limiting access to care for many deserving patients as was the situation prior to 1972.

In the desire for cost savings, providing dialysis and transplantation services of quality may not always be the primary focus of managed care organizations. AAKP continues to hear from managed care patients with kidney disease as to inconveniences and restrictions of choice and travel. Good business practices do not always coincide with appropriate medical care.

In the future, is it implausible to think that dialysis for an HMO patient could only be received at a dialysis center 100 miles away or a transplant exclusively obtained at one 1,000 miles away where the patient must pay all travel and living expenses? This scenario would mean that only the economically fittest patients with renal disease would survive.

Should we assume that the private insurance sector will willingly assume a larger proportion of these costs, of the costs for these expensive treatments, without looking for such limitations to accessibility? Until we know how managed care organizations are going to deal with these life savings treatments, we urge a more cautious approach as was outlined by some of the speakers earlier.

For the patient with terminal kidney disease, delay of more than a few weeks in getting dialysis or a transplant means death. In addition, we are concerned that oversight for quality will not be a priority in a managed care environment. Most experts acknowledge that insufficient oversight of dialysis care in the past has led to higher mortality rates for dialysis patients in this country compared with Japan and Europe.

Let me point out parenthetically that Dr. Belding Scribbner, who developed hemodialysis with patients for chronic renal disease, learned very quickly what quality was back in the early sixties. Unfortunately in the 10 or 20 years immediately following that, that knowledge was lost. We could all speculate on why that knowledge was lost, but today we have the opportunity to regain it.

As you are aware, HCFA, through the ESRD networks and State facilities, surveys our agencies and with the full cooperation of members of the renal professional community, is moving more effectively to reverse this problem. We feel that this interactive approach to quality supervision should be maintained. More than simply an entitlement program, the ESRD Program is a model for efficient health care delivery and control of medical cost with quality oversight. Even at the $21,000 a year which the reimbursement rate covers for the dialysis patients or at $38,000, if you divide the total costs by dialysis patients, dialysis is cost effective in terms of a real life saved. We fear that this fact will not be appreciated by the private insurance industry today as it was by the Federal Government in 1972.

For patients, I appreciate this opportunity to testify and will be happy to answer questions.

[The prepared statement follows:]

TESTIMONY OF A. PETER LUNDIN, M.D.
AMERICAN ASSOCIATION OF KIDNEY PATIENTS

Mr. Chairman and Members of the Subcommittee on Health, I am pleased to be here today on behalf of the American Association of Kidney Patients (AAKP). My name is Peter Lundin. I am the immediate past president of AAKP and a practicing nephrologist. Moreover, I have been a dialysis patient for 25 years and have had a kidney transplant for the past three years.

The membership of AAKP is concerned about the future of the Medicare ESRD Program and how changes may effect the 200,000 beneficiaries. As a national organization of kidney patients, it is our hope that Congress will ensure the continuation of the very successful ESRD Program, which has covered the expenses of dialysis, transplantation, physician services and immunosuppressive drugs for over 20 years. As you are well aware, dialysis is unique among high-tech medical therapies. Without dialysis or transplantation death will certainly occur, however with treatment, patients can expect long term survival allowing them to lead normal healthy lives.

Given the life-sustaining nature of dialysis treatments and transplantation any change in Medicare payments or policy creates concern among ESRD beneficiaries.

The ESRD program has been and continues to be, a model for future health programs and medical spending. The government, in its efforts to provide a cost-effective method of treatment, has developed quality assurance measurements, maintained a national data system and structured a cost-conscious reimbursement system. Throughout the structuring and continuation of this program, patients' interests have always been balanced with costs in such a way that coverage for these life saving treatments continues to be provided to the growing patient population.

There are several points we wish to make to the Subcommittee today:

1. AAKP hopes that the Medicare ESRD Program will continue in the same capacity as is currently legislated. We are concerned that any move to have patients leave the program and enter managed care plans may lead to difficulties in achieving the current level of care. It is our belief that eliminating or changing the program, before a complete analysis of how new plans would incorporate dialysis and transplant care, could be detrimental to the 200,000 patients.

2. We are concerned that quality assurance levels will be lower in a managed care environment. As you know, the Health Care Finance Administration (HCFA) currently sets certain quality assurance guidelines that are reviewed in the dialysis facilities by the ESRD Networks, thus assuring adequate patient care. As patients, we would not want to see any changes in the tracking of kidney patients and the review of quality guidelines.

3. Discrimination is also a worry to patients. If the Medicare beneficiaries are moved to the private sector, we worry that costs and access could prevent patients from securing services.

4. AAKP wishes to bring to your attention the numerous complaints we continue to receive from kidney patients enrolled in HMO's. Complaints include difficulties in securing transplant services outside the HMO and the ability to choose dialysis facilities and physicians. In an effort to cut costs in a managed care environment, hospital admittance times have been shortened for transplantation. This can lead to only the healthiest patients receiving transplants because the hospital can guarantee a short patient stay. Also, in a managed care situation, dialysis patients may no longer be able to travel for business or pleasure because their destination facility most likely would not be covered in their managed care contract. Because of the numerous patient concerns, we ask that you please consider the impact managed care would have on patients before any type of managed care program is implemented.

Mr. Chairman, we appreciate the opportunity to address your distinguished Subcommittee. I will be happy to respond to any questions or comments any member may have.

Thank you.

Chairman THOMAS. Thank you, Dr. Lundin.

The gentlewoman from Connecticut will inquire.

Mrs. JOHNSON. I thank the panel for your very good comments. Dr. Latos, many would argue that kidney transplantation is the best treatment for many ESRD patients. How do nephrologists interact with other physicians in determining which patients are the best candidates for transplants, and do you have any information about how this interaction changes in a managed care setting or doesn't change in a managed care setting?

Dr. LATOS. The relationship between nephrologists and transplant physicians or transplant surgeons is a very close one, as you would imagine. The recommendations generally, and I think these have already been testified to, are that people really need to be apprised of their relative risks of transplantation.

There are actually only a few categories of people who should never be transplanted: People with active malignancies, certain infections that are ongoing, and virtually all other groups have relative risks, either mild risk or severe risk. And while some practitioners, I believe, tend to dissuade some patients away from transplant, the more appropriate, and I think increasing opinion among nephrologists is that people need to have access to transplant surgeons fairly early in the course of their time on dialysis, even prior to transplantation.

My own experience with managed care has been somewhat biased because we have had some difficulty in getting some managed care programs to have patients referred for transplant consideration until they are already on dialysis.

We have had a very active program in preemptive transplantation and I have personally been involved in the care of about 20 people over the last few years that have been able to receive successful transplantation and have never required dialysis.

So the relationships between nephrologists and those other physicians in the managed care programs need to be examined more clearly, and certainly the role of the transplant surgeon early on needs to be defined.

Mrs. JOHNSON. In your experience, are there any managed care plans that are showing an interest in preemptive transplantation?

Dr. LATOS. I am sorry, I didn't hear the last part.

Mrs. JOHNSON. Are there any managed care plans that are showing an interest in preemptive transplantation?

Dr. LATOS. Not specifically. I don't know that any are totally excluding them by policy. This is not a common practice in the country, although it is regional. Again, it depends on how early the patient gets to the renal care team. If the patient shows up on our door already having advanced uremic symptoms, that is not the time to consider transplantation. Those of us who see patients early in the course of their disease when symptoms are minimal can often get them referred to transplant months and months before they actually become ill enough to require dialysis.

Mrs. JOHNSON. A general question to the panel. This panel, as well as the preceding panel, has talked about the need to improve quality measurement tools. Over what period of time do you think this is possible? I mean, are we talking 6 months, 1 year? Are we

talking 5 years before we will be able to do a better job of measuring quality of care in this area?

Dr. LUNDIN. I think we are just about there. I think the end-stage renal disease networks have a whole plan that the other members can comment on, as well as the State surveyors. I think the cooperation between the U.S. Renal Data System, the ESRD networks, and the State surveyors working cooperatively and hand in hand is just about at the point that they can start to do some of this work that needs to be done.

In fact, they began in July, I believe, of this year with their new programs.

Ms. SIMS. I wonder if I could respond to that. As a member from the renal community of the HSQB and the HCFA Core Indicator Project, I can tell you that I agree with Dr. Lundin that we have made great progress in the last 1½ years. In the contract that was signed between the HCFA and the networks, the work that is being done looking at four quality indicators, the first phase of the report was done in January of this year looking at the four areas that Dr. Rettig referred to earlier. That report has just been made available to the community.

There is a 1995 phase of that process which will include those same indicators looking at another year of data collection, also looking at expansion of that program in 1995 to include peritoneal dialysis patient populations, and we will continue to look at other phases of that program throughout the life of that scope of work contract with those networks.

So I would agree with the previous panel and with Dr. Lundin's comments that we have started to make some real progress in these areas in a collaborative manner between the community and the Federal programs.

Mrs. JOHNSON. Thank you.

Mr. BOWDEN. NKF is about 14 months into a project on quality of dialysis care at this point, and we believe that the time necessary to develop guidelines is being looked at by the actuaries. I think there is pretty wide agreement in the community at this point that Kt/V standards such as those discussed earlier by Mr. Stark are pretty broadly accepted.

At the other extreme, nutrition standards are a long way off, and there is a tremendous amount of research that needs to be done before those standards can be put out. I think the answer to your question is it varies tremendously depending on the area.

Chairman THOMAS. The gentleman from California will inquire.

Mr. STARK. Thank you, Mr. Chairman.

Well, I want to not sound so much like a Johnny-One-Note, but Ms. Sims, you kind of stayed away from the standards. We had a Dr. Owen from Brigham and Women's testify last year that while the precise factors—I am quoting from his testimony—"are uncertain, a major contributing feature is the widespread use of abbreviated dialysis times that do not provide adequate treatment."

The common practice of dialysizing for less than 3 hours in the United States can result in cost savings of up to 25 percent per treatment. However, these cost-effective, short treatment times are associated with a major increase in the relative mortality risk from 1.0 to 2.18.

Recently, we observed that despite a standard established 10 years ago for adequate dialysis, 55 percent of a large cohort of hemodialysis patients received a quantity of dialysis that was associated with greatly excessive death risk.

Now, it seems to me that I am not hearing enough urgency from these witnesses about enforcing some standards that professionals seem to know exist. I mean, you are nodding, Mr. Bowden. I don't know why we can't beat on these people a little bit. It may require government regulation, God forbid, but somebody ought to say, this is a minimum, and anybody who doesn't do it that well ought to be kicked out of the program or not paid.

I would just like to urge you all, I know it is going to be tough on some of the people you work with or for, but it is a standard we know, or you all know, and I just would hope that we could be—however this comes out, whether you do it managed care or whether you do it fee-for-service, that we take the standards and start to, if you will pardon me, punish the people who don't live up to them. Maybe they are not perfect, but they are good.

The other thing that I am hearing is a 3.7-percent increase. Now, that is only one-half of the loaf. ProPAC recommended that the base rate is too high, so you can't—in a sense, can't have it both ways here, that you want a 3.7-percent increase but you don't want to raise the base rate. Those things, to me, go together. I guess the third comment is this issue of extending the time for private payers.

Nobody is suggesting that we do private payers permanently until people get to be 65, right? Because you are scared that the insurance companies will end the benefit, right? OK.

Now, I think you are flirting with disaster here. You want to keep pushing the private insurers, say let's go from wherever it is now, 18 months or 24 months to 30 months, because you get almost twice as much reimbursement, right? The private guys pay 80 percent more than Medicare. That is the reason they want to extend the private pay.

Now, I would be for extending it forever except if we required that every insurance plan in the country have the benefit. You got me signed up right now. Let's require every health insurance plan in the United States to make it a benefit and pay it up through age 65, at which point Medicare would take over. I will sign onto that in a New York minute, but then Dr. Lundin is going to worry that people who even have a hint of kidney problem will never get hired, that the employers—because it will kick their insurance up.

So somehow we have got to find—it isn't quite right, and what I am sensing, not from any one of you in particular, is that the providers want to keep inching a few more months of private care because that is a few more months of double rate, and at some point you are going to break that camel's back and then the private insurers are going to stop carrying it as a benefit. I don't know where that is, but I hope we could find a better solution than just extending private pay until we find out. Because when we find out that suddenly people are canceling the benefit, we are going to wish we hadn't gone that far.

So I am going to urge you to find another way to get a little more reimbursement than to keep pushing the private pay, because I think we are flirting with a disaster that we don't want.

I am going to urge you to set a minimum standard, because I think you can. Maybe it is not 1.2, but you can set one that—below which no one dare go. I think you help the patients a lot by doing that. And then we can see maybe whether we can provide more—because my time is expired, but you may want to respond.

Ms. SIMS. I wonder if I could address your first comment. We have, to this point, not supported minimum standards because we feel like they will be interpreted as minimum standards.

Mr. STARK. Above which no one would go?

Ms. SIMS. Exactly. Exactly. But we have supported the work that has been done on the core indicator project which has looked at quality core indicators, in other words, red flag areas that you would want to look at, the patient's outcomes, in four areas, and that is adequacy being one of them and using that number, anemia, hypertension, and albumin or nutrition, and I think another problem with the standard as proposed currently is that there are other factors that need to go with it.

That is, looking at nutrition, there are many studies right now that say it is not an independent factor. Also, I think that we have already seen lately that the standards continue to be elevated by the community itself, so to legislate a number would be a problem; and in fact, again, it would become a minimum, not something that people would strive for.

So that has been our big concern with standards. I think the work that has been done on those quality core indicators has taken a much more appropriate tact so far. It has looked at quality from the research. It is literature-based indicators and it has also provided data back in a very quick turnaround to the community that is, although it is nationally specific and network specific, it allows—the scope of work contract calls for work being done in those facilities specifically where their patients are, against those national core indicators, and then looking at ways under quality improvement for those facilities to start to work with the patient specific data.

Mr. STARK. At some point we ought to be able to set a minimum. No dialysis could be the standard if you say that is a minimum. I hear what you are saying, but it would seem to me there ought to be a floor below which—I am sorry, Mr. Chairman.

Chairman THOMAS. No. I just share the concern that establishing a floor then becomes a ceiling. The core concept is one we should look at. Does the gentleman from Nebraska wish to inquire?

Mr. CHRISTENSEN. Yes. Thank you, Mr. Chairman.

Ms. Wish, earlier you mentioned a study that you have done on EPO, and I wondered if any of your studies reflected the financing arrangement. I am told that in paying providers, a lump sum is how some providers are being paid, and I wanted to know if, in determining the optimal financial solution to the dialysis centers, maybe a monthly composite rate has been looked at.

I am told that by using bundling versus a pay-as-you-go, that we may be causing higher rates of illness, possibly causing hospitaliza-

tion in the long term. I just wanted to hear your comments on that and if any of your studies have reflected that.

Ms. WISH. When EPO was first reimbursed, it was set up as a flat fee, that all providers got the same amount of money regardless of the dosage. Medicare felt that was one way to control the cost of EPO. HCFA's studies have shown that patients were significantly underdosed and we believe there was a profit motivation there. There was a very good opportunity to make money on the flat fee reimbursement at the time.

I believe that some of those studies were skewed a little bit based on the fact that it was a new drug and providers and practitioners had very little experience with it, and there were a lot of serious reservations about starting the drug at high levels.

So there were a lot of facilities that legitimately gave the patients low doses initially until they could get a handle on what kind of symptoms the patients had, whether they had seizures, whether they had massive problems with hypertension, and so forth.

When the drug was first available at the $40 per dose level, a lot of facilities did start off with lower doses and then increased the dosage as they became more comfortable with the drug and found out more about the side effects or lack thereof of the side effects. At the same time that the dosages were starting to increase, Medicare changed the payment to $10 per 1,000 units administered.

From the time the payment mechanism was changed, EPO dosages increased significantly because, at that point, people could appropriately prescribe the amount of drug that the patient needed to get them up to the appropriate hematocrit level.

So a couple things happened at the same time. The payment methodology changed about the same time that providers felt more comfortable with giving the drug and found out about what kind of side effects the patients did or did not have.

I think right now, the average hematocrit has increased. It isn't quite at the national level to the targeted range between 30 and 36 where we would like it, but it is going in the right direction. I think that if the payment methodology was changed back to a flat sum by bundling it into the dialysis payment, there would be a real danger that patients would be underdosed, especially coupled with the fact that we haven't had basically an increase in our dialysis treatment rate in about 20 years. Because Medicare's dialysis payments just keep going down in real dollars, facilities have got to cut somewhere and they have got to find some way, and I think that bundling EPO payments into the dailysis payment would provide people a very easy target to try to underdose EPO. Bundling EPO payments into the dialysis payment would not be good for patients.

Mr. CHRISTENSEN. Do you have any kind of estimate on how much of the total cost is being reimbursed to the manufacturers in this area.

Ms. WISH. How much is being reimbursed to manufacturers?

Mr. CHRISTENSEN. Of the total cost on EPO, how much is actually going back, is being reimbursed. Is there any specific figure, do you know? I mean, I think it is very important that we keep in mind the total cost of the drug, and I am wondering if the actual total cost is being reimbursed.

Ms. WISH. The bundling method doesn't exist right now. But the cost—the reimbursement rate we get is 80 percent of $10 per thousand units, and the cost that most providers pay is just a very small fraction below that. One statement that was made in prior testimony alluded to the fact that the monopoly status that Epogen has right now on EPO will expire within the next couple years, and that is not true. It is my understanding that Amgen will remain the only supplier of EPO for at least another 10 years.

Mr. CHRISTENSEN. Thank you, Mr. Chairman. Man I have one more question?

Chairman THOMAS. Sure.

Mr. CHRISTENSEN. We are running out of time but it is for Dr. Latos. Would you explain to me the ESRD networks and who runs these networks?

Dr. LATOS. That is very appropriate. The end-stage renal disease network organization was actually established in approximately 1978. At that time there were 32 networks, I believe, whose job it was to provide oversight and feedback to dialysis practitioners, facilities, as well as nephrologists, nurses, and other staff.

It was funded solely through Medicare and HCFA at that time. Several years ago, the network system was revamped and now there are, I think, 17 networks—19 networks, and these are all funded, by the way, based on a 50-cent-per-treatment basis, so that the dialysis facilities pay into the funding for the network organizations.

The role of the network organizations has actually increased over the years. It has become very important to the practitioners and the facilities. Feedback is provided on a regular basis, and it was already commented that the core indicators project will be a very, very valuable and powerful tool in changing practice patterns where they need to be changed.

Mr. CHRISTENSEN. Thank you.

Thank you, Mr. Chairman.

Chairman THOMAS. As a followup to one of the questions, I believe, Mrs. Sims, in your testimony you said we possibly could extend the secondary payer to 24 months but not longer. Ms. Wish, I believe yours was 24 to 30 months. The gentleman from California indicated that there is a drop-dead point. Is the difference between 24 and 30 months that factor, or is it that you take it in stages to see where we go?

Ms. Sims, what if it was extended to 30 months rather than 24 months?

Ms. SIMS. I couldn't hear the last part of your question.

Chairman THOMAS. If it was extended to 30 months rather than 24 months. You indicated that you thought 30 months was too far.

Ms. SIMS. I didn't—we basically stuck with the number 24 to this point. We do not support it being extended indefinitely, which as Mr. Stark pointed out is not necessarily being suggested right now. I think we would be negotiable on a fixed time. We are concerned about employer group health plans and benefits to those patients.

Ms. WISH. I agree as well. We are concerned, as Mr. Stark mentioned, that we don't know what could happen if the Medicare ESRD secondary payer provision became indefinite. We feel that a small incremental increase is the most appropriate way to go,

which is why we feel that anywhere between 24 and 30 months would be OK. Anything beyond that, we are just too concerned about the ramifications.

Ms. SIMS. I would also like to go back and comment on something Mr. Stark said, I didn't get a chance, and although Ms. Wish could probably more helpfully address this, I am aware of private payers who have negotiated Medicare rates so that it is not our understanding at this point that if you have patients with extended private pay, that the facility is getting any more money because they are private pay. We have heard of specific examples where the private insurer has negotiated a same rate.

Ms. WISH. I agree that that is true, that the private payers are getting much more sophisticated. In the past they really didn't know. They probably had a very small percentage of their patients that were on dialysis and the bills just went through, and they really were not aware of what they were paying.

The managed care providers, in particular, are getting much more sophisticated about this and some of them are either negotiating Medicare rates or below Medicare rates. This is very scary to us because it is very difficult right now, dealing with a low Medicare reimbursement rate, and with the great move toward managed care, we are really concerned that we will be in a situation where we would be forced to take dialysis payment rates that are even significantly lower than the Medicare rates.

Chairman THOMAS. Which puts more weight on our rate setting because we clearly have a direct impact on the private sector.

Dr. Lundin, do you mind if I ask you some personal questions?

Dr. LUNDIN. Not at all.

Chairman THOMAS. You indicated that you began dialysis in the midsixties.

Dr. LUNDIN. That is correct.

Chairman THOMAS. My understanding is that you had a kidney transplant?

Dr. LUNDIN. No. I began on hemodialysis. I spent 25½ years on hemodialysis.

Chairman THOMAS. So you have not had a kidney——

Dr. LUNDIN. I had a kidney transplant 3 years ago.

Chairman THOMAS. Three years ago, and obviously, it was successful?

Dr. LUNDIN. Yes.

Chairman THOMAS. Are you on dialysis now?

Dr. LUNDIN. No. The kidney is working, after 6 weeks of not working, so——

Chairman THOMAS. What led to the decision and the timing?

Dr. LUNDIN [continuing]. You might ask the question why I didn't have a transplant before.

Chairman THOMAS. That was what I was asking.

Dr. LUNDIN. My experience in seeing friends who went off to get a transplant with the promise that if it didn't work, they would be back on dialysis, most of them never made it back on dialysis when it didn't work. So there was—for many years, transplant was sort of a Russian roulette in effect. With the advent of cyclosporine, it has improved substantially. After 25½ years of dialysis, one gets

a little tired of doing the same thing all the time, so it was time to try another therapy.

Chairman THOMAS. Your decision is kind of like my 4/5 lumbar area. They are getting better at it and if I can still wait around, I am going to wait as long as I can.

We are talking about, obviously, quality of life before your transplant and after the transplant is significantly changed. So you waited, but now you are glad you had the transplant?

Dr. LUNDIN. First of all, I don't know that the quality of life was—in some ways it is different in that you are not restricted to a machine, but I was able to go to college, medical school, play basketball, many things on dialysis that I can't do today, although I am almost 30 years older. That may be the explanation.

Chairman THOMAS. When we say that some patients are probably not good candidates for transplants, is that a timing factor, that had we had the capability for a transplant and the organ available at the same time? Or, that at an earlier age, they would have been candidates?

Setting aside the availability of sufficient organs, is it reasonable to say that if we had the timing and the ability to increase the potential for transplants, that virtually everyone at one time on a time progression would be a candidate for transplants?

Dr. LUNDIN. Well, because of the major surgery involved with transplant compared to dialysis and the immunosuppressive drugs which have their own level of toxicity, it becomes increasingly risky for older patients, patients with other medical complications to undergo that and survive.

As I said, it took 6 weeks for my transplant to finally work, and at the state I was in, I doubt very seriously if the kidney had not worked that I would have made it back to dialysis. And that 6 weeks was a very debilitating time of course.

Chairman THOMAS. Well, clearly if you have various infections, because of the immunology, you wouldn't be able to do it, but I am just trying to get a feel for the significant increase in transplants, and then the subsequent reduction in dialysis over the next several years, but I am getting some resistance.

Dr. LUNDIN. No. The availability of donors is quite clearly a problem.

Chairman THOMAS. That is the key.

Dr. LUNDIN. Yes. If there were more donors, then certainly most of the younger people today would opt for a transplant.

Dr. LATOS. If I might comment, Mr. Chairman, I think Dr. Lundin's hesitancy to undergo transplant for many years is no surprise to many of us who have also taken care of people, and the real risks in the days gone by that immunosuppressive agents and the programs, we had to counter the rejection episodes, which occurred virtually 100 percent of the time, were not very good, and patients who got treated for rejection with very high doses of prednisone did not do well.

Even 20- and 25-year-olds did very poorly with repeated episodes of rejection. It was only with the advent of cyclosporine that the early severe rejections have been decreased, that many patients are able to undergo transplant much safer.

There is another point that I think needs to be used for word of caution here is that the experience is not uniform, but it is very clear that some managed care programs are hesitant to have patients undergo transplantation. The policies are not written in many situations. There are intrinsic policy issues that have to do with referrals. Patients get transplanted in one program and then in the midst of a rejection episode are told that they now must transfer their care to another managed care program because the employer has changed.

That doesn't happen—that doesn't have to take place too many times within a dialysis center and patients are going to say, wait a minute, I don't think I want to do that. It is a real problem. I am not sure how widespread it is but it is a factor that needs to be looked at as well.

Chairman THOMAS. We are dealing with a whole set of psychological concerns as well as physiological, and if you add any trauma to that, it makes it very difficult. Is that what you are saying?

Dr. LATOS. Absolutely. The stress, as Peter mentioned, of going through a rejection or a nonfunctioning transplant is substantial. People who are on dialysis know what they have. Good, bad, or indifferent, they know. They have done it for months, they have done it for years, and for many individuals, especially if they have undertaken some type of physical rehabilitation program along with it, can do pretty well and many can do what they need to do with their lives. And that risk of transplant is uncertain enough that they may not be willing to take it.

Dr. LUNDIN. Mr. Chairman, if I might, the reason I stayed on dialysis for so many years is because it is a very predictable therapy. If you have good access, it works. It is a matter of sticking to one successful treatment after another.

I might point out again to Dr. Scribbner, who is Dr. Blagg's mentor, that the very first patient with chronic liver failure put on hemodialysis lived for 11 years, even though those first number of years they didn't know how long to dialyze the patient and what to do in terms of other medical therapy, and one of the original patients is still alive today, exclusively on hemodialysis over 34 years later.

Chairman THOMAS. What about mobility in terms of the ability to travel in dialysis, especially with managed care and restrictions with——

Dr. LUNDIN. Yes. That is going to be a problem. Today, there are many dialysis centers around the country and around the world that, if you plan early enough, you have the opportunity to go. I have spent 6 months in Germany on a sabbatical. I have spent a month in Taiwan getting dialysis and traveled extensively around the world as a dialysis patient.

Ms. SIMS. I wondered if I could just go back to the transplant issue. I thought Mrs. Johnson asked a good question earlier. I am a transplant clinician at the University of Virginia and I will tell you that we have seen patients who we would like to evaluate in our program who cannot be referred in for after 1 year of dialysis, although we would like to preemptively transplant them in our program and that is something we have done very well.

Certainly, there are managed care programs, HMOs right now, that just simply are not referring those patients in. It may be a small number right now, but I think those are patients who are not on that continuum that you asked about. There are some patients who, because of their comorbid diseases, just will never be candidates.

There are patients who need a trial on dialysis to see how they are going to do before they are candidates again. The waiting time is 2 years or longer for kidneys right now. But there are patients who must be on dialysis for over 1 year in some programs before they can even be evaluated. It really lengthens their waiting time to almost 3 years.

Mrs. JOHNSON. As you watch the development of managed care in the next year or two, I hope you will get back to us on this subject. I consider managed care an evolving form of delivering medical services, and in other areas, I have seen enormous change of focus toward more preventative or permanent solutions, so I am not surprised that you aren't seeing it yet in this area, but I would hope that you would begin to see it. If you stumble across any other evidence, I would be interested in that, and I am very interested in your most recent comments.

Thank you.

Dr. LATOS. Mr. Chairman, I feel an urgent need to clarify an issue for this Subcommittee, if I may, now or at your convenience, that has to do with this standard that has been talked about and this dose of dialysis, this thing called Kt/V. I think it is very important that the Subcommittee understand what that represents.

The Kt/V is a mathematical number that is an attempt to define a dose of dialysis, and there are many factors that contribute to that dose, none the least of which is the length of time that an individual stays on dialysis for a given treatment.

And although factors such as the type of dialyzer, the length of minutes one dialyzes, the adequacy of blood flow, many things are beyond the control of the provider group, the physician, and the nurse, that actually are going to encompass a dose of dialysis. If patients, for whatever reason, choose to come off dialysis sooner or they have vascular access that does not work properly, then it is sometimes difficult to actually deliver that dose.

Reflecting a little bit further on the comments about standards, the practice guideline that has been developed, and I was part of the committee that actually wrote that practice guideline, is a guideline, sir. It is not a standard, and it is very important that we focus on that. The data that we have published that suggests that 40 percent or somewhere in that range of dialysis patients may not be getting the proper amount, I suggest will be changing because the community is now much more aware of the need to provide good dialysis for a proper length of time. I think the practices already are changing, and the data that we see this year I suspect will be much different than it was 1 year ago or 2 years ago.

Chairman THOMAS. I thank the panel very much. One last question.

Mrs. JOHNSON. Could I just clarify? Are you saying to us, Dr. Latos, that the guideline is working well and that precise standards could actually not work in the patient's interest?

Dr. LATOS. Yes to both those. There are many studies that have been published over the last couple of years that talk about the number of Kt/V, and the RDA guideline was designed to define not the absolute minimum but sort of a range that would assure a good outcome. We are not able to equate that number, which is still an evolving number, to a standard.

If we were to set a Kt/V, for example, of 1.2, there well could be some practitioners that would decrease the amount of dialysis to achieve only 1.2. Mr. Stark asked whether or not we want to develop a floor below which no one should fall, and we are supportive of trying to do that. I am not sure the science allows us to define that number at the present time. It is certainly in the range of 1.2 or thereabouts.

Chairman THOMAS. Dialysis is a medical procedure. It is not changing oil.

Dr. LATOS. That is correct. There is no magic dose of penicillin that treats pneumococcal pneumonia either.

Chairman THOMAS. All right. I thank the panel very much.

We would call our last panel, Mr. Berger and Mr. Thiry, is it, I believe?

Mr. THIRY. Yes.

Chairman THOMAS. Thank you.

As I have indicated to the other panels, your written testimony will be made a part of the record and you can, for your 5 minutes, inform us any way you see fit. Doctor Berger.

STATEMENT OF EDWARD E. BERGER, PH.D., VICE PRESIDENT, GOVERNMENT RELATIONS, NATIONAL MEDICAL CARE, INC., WALTHAM, MASSACHUSETTS

Mr. BERGER. Thank you, Mr. Chairman, Members of the Subcommittee. I appreciate the opportunity to come here and speak to you today on behalf of National Medical Care.

The positive achievements of the ESRD Program have been well documented in prior testimony today. The Federal guarantee of coverage to those with ESRD has certainly fostered the rapid development of a dialysis and transplantation service system more than adequate to meet the needs of all Americans with ESRD.

With respect to dialysis service, it has done so with a record of cost control unequaled in the recent history of the U.S. health care system.

Over the years, however, and this is the focus of my testimony, the program's guarantee of coverage has evolved into a set of policies which segregate ESRD providers and patients from the mainstream of developments in the private health care sector and which artificially insulate private insurers from responsibility for ESRD.

The resulting disproportionate reliance on the public sector for funding and for management has, over the long term, had a variety of deleterious effects on the ESRD Program, and we have some proposals as to how those might be addressed going forward.

Most immediately, dialysis providers and patients have been rendered excessively vulnerable to public budgetary concerns in a time

of great and legitimate concern over the rising cost of health care. Because dialysis uniquely lacks some form of automatic adjustment for inflation and because we have seen over the last decade a series of budgetary reviews, all done in the context of efforts to control Medicare spending, reduce Medicare spending, reduce overall government spending under Gramm-Rudman-Hollings, we are paid just about the same amount of money today as we were in 1983 when the composite rate was first put into place.

Most authorities who have studied the subject believe that Federal reimbursement policy has been an important factor in limiting or reducing the quality of care available to ESRD patients and that all reasonable sources for efficiency gains have already been fully exploited by providers.

We think it is terribly important, therefore, that Congress turn its attention to this problem, and we urge on the Subcommittee the view that an automatic annual adjustment inflation for dialysis services comparable to that which is already in place for virtually every other class of Medicare provider be instituted.

At the same time, we believe that the Medicare Program has both the right and the obligation to demand that dialysis facilities develop and implement effective outcome-focused quality assurance programs to monitor the quality of care along the critical dimensions that dialysis patients need to live and to prosper. The model for such programs has been fully developed in the literature on continuous quality improvement and is described in detail in the Institute of Medicine's 1990 study, Medicare: A Strategy for Quality Assurance.

I would like to suggest that the special restrictions in the length of the Medicare ESRD secondary payer period, and other existing rules insulating the private sector from involvement with ESRD, should be removed. These rules have been critical in insulating us from the creative adaptations which dominate the private health care sector and keep us segregated from improvements in the nature of medical case management and cost-efficient delivery of care.

Finally, we believe that the conflicting incentives that are created by the diversity of Medicare reimbursement methodologies which apply to dialysis facilities should be rationalized.

Without going into detail, the most obvious case in point is the conflict in incentives created by the difference between the dialysis composite rate, which is for some package of services comprehensive and prospective, and the erythropoietin payment methodology, which is dose related, retrospective, if you will.

There are many other examples in addition to EPO which might be given, but we believe that the combination of these two in the facility creates conflicting incentives which detract from the efficient overall utilization of scarce health care resources for ESRD patients, and we think that that is an issue that should be addressed.

Thank you very much.

[The prepared statement follows:]

The Special Restriction on the Length of the Medicare ESRD Secondary Payer Period, and Other Rules Insulating the Private Sector From Involvement With ESRD, Should Be Removed.

Disproportionate reliance on the public sector for ESRD coverage has relieved private insurers from having to deal with the clinical and cost management of the ESRD patient. As a result, the development of models for the cost-efficient clinical management of the ESRD patient, a population at least theoretically well-suited for managed care, is far behind similar development in clinical areas of more immediate concern to the private payer community. While Medicare appears ready to implement an ESRD capitation demonstration project, that effort is limited and will not bear policy fruit for some time; the natural evolution of the private insurance marketplace would be a far more dynamic engine for development and testing of alternative models for management of ESRD care. The isolation of the ESRD program from the forces shaping the development of the larger health care system have deprived dialysis patients and providers of exposure to the variety of innovative and potentially valuable models for service delivery, care management, quality assurance, and risk-sharing which have been evolving in recent years in the private health care sector.

Congress should remove restriction on length of time for private insurance to be primary to Medicare for ESRD patients. This will give ESRD providers a better payer mix, save the Medicare program a meaningful amount of money each year, (CBO est $800 million in the budget period) and help integrate ESRD clinical management into the mainstream of development of the emerging and more cost-effective health care system. It could be accomplished without any harm to beneficiaries, particularly in conjunction with basic insurance market reforms addressing portability, pre-existing condition exclusions, etc.

Congress should also actively pursue other changes to encourage rather than discourage integration of the clinical management of ESRD patients into the mainstream of the private health care sector. Broader opportunities for ESRD patients to participate in HMO risk contracts would support this goal, as would demonstration projects for a variety of capitation models and/or voucher systems.

The Conflicting Incentives Created by Diverse Medicare Reimbursement Methodologies Which Apply To Dialysis Facilities Should be Rationalized.

Finally, while the dialysis composite rate was an early example of how a prospective payment system could create incentives for providers to behave more efficiently, and dialysis providers have been extraordinarily creative in finding efficiencies to absorb the inflation they have experienced in the last 12 years, the totality of Medicare payment rules applicable to dialysis providers today institutionalizes a welter of perverse incentives which undercut overall cost control efforts and which discourage optimal deployment of clinical resources. Reimbursement policy for human recombinant erythropoietin (EPO) is a case in point.

EPO, an artificial form of a hormone produced by healthy kidneys and essential to red blood cell production, is administered with close to 90% of all dialysis treatments, yet it is reimbursed separately on a dose-related basis. There is, then, an economic incentive for providers to use more as opposed to less EPO. Consistent with that incentives, HCFA data from facility billings shows that the average dose of EPO administered in the last 3-4 years has skyrocketed, from approximately 2,700 units when the present payment system was implemented to about

4,500 units by the end of 1994. Patient hematocrits, the measure of red blood cell count typically used to monitor the effectiveness of EPO therapy, have improved only marginally in this same time frame - certainly in no way proportionate to the increase in dose (and cost) of EPO.

At a reimbursement rate of $40 per 1,000 units, Medicare today spends more than $40 per dialysis treatment for EPO. This is almost one-third of the Program's average cost for a dialysis treatment, and the amount continues to grow inexorably without significant incremental benefit to patients. Anemia control is an important clinical dimension in care of the dialysis patient, and EPO is a valuable and effective tool in an anemia control program. But this investment is arguably highly inefficient, whether viewed narrowly in terms of maximizing the clinical effect of EPO or, more broadly, in terms of the overall clinical quality of ESRD patient care. A more rational and unified set of incentives for providers would likely produce a more efficient pattern of allocation of limited provider resources.

very thoughtful job of this nor did we in working with them 3 years ago. The world is very different today.

The final chart is just to get to the concerns in this area where as HMOs grew over the last 5 or 6 years in every other chronic disease state except dialysis, there were huge concerns about how pregnant women, particularly high-risk pregnant women, would be taken care of. The data couldn't be more clear that in a managed care plan, after managed care plan you have a lower rate of premature births and this includes the Medicaid population.

In the area of AIDS, again, you had huge and very legitimate concerns about how managed care would take care of these very expensive, often employed, high-dollar patients. If you go to southern California where there are more of these patients employed than anywhere else, you will see that many of the AIDS advocates point to the best care systems being those that are managed by managed care.

Managed care is no panacea. There will be mistakes; there will be abuses. But with the right volume of patients, there is a level of up front investment and a level of vigorous monitoring of quality that simply doesn't exist in a fragmented fee-for-service system.

Thank you.

[The prepared statement and attachments follow:]

Testimony of
Kent Thiry
President and CEO, VIVRA

before the
House Ways and Means Committee
Subcommittee on Health

Hearing on
Medicare End Stage Renal Disease Program

April 3, 1995

I would like to start my testimony today by thanking Chairman Bill Thomas for inviting me to testify on managed care for Medicare patients with End Stage Renal Disease (ESRD). I am Kent Thiry, President and CEO of Vivra, a New York Stock exchange listed company, headquartered in Burlingame, California. We operate over 150 kidney dialysis centers in 24 states, including California, Texas, Pennsylvania, Georgia, Louisiana, Virginia, Florida, Michigan and Illinois through a subsidiary company, Community Dialysis Centers. Vivra provides dialysis care to over 9,000 patients (one out of 20 in the country), making us the second largest provider of dialysis care in the country.

Summary

For patients with chronic disease states, the Medicare fee-for-service system is a clinical and economic tragedy. The system provides huge incentives for providing too many services at too late a point in patient care while simultaneously putting immense structural obstacles in front of anyone who would like to invest in preventative care.

The ESRD program in Medicare is no exception. In fact, it is probably the most extreme example of the immense human and economic waste caused by Medicare fee-for-service because it is likely no other patient population has as much of its reimbursement coming from Medicare fee-for-service.

I am here today to make one simple plea -- put more of these patients into the private sector so that:

1. More of them will enjoy the dramatically improved quality of care they would receive in a managed care setting.

2. The government will save $1 - 2 billion over 5 years

3. The country's overall health care costs will be lower within 3-4 years.

4. The government will be spared another blow to its operating credibility with the public, because otherwise it will be embarrassed by study after study showing the patients it "manages" die faster, are less likely to be employed, and cost more.

I will address the following issues in turn:

* Magnitude of the Issue
* The Basic Prevention Concept
* Real-life Examples
* Magnitude of the Opportunity
* Our Policy Recommendations

Magnitude of the Issue

The Medicare fee-for-service approach for serious chronic diseases is bad health care. The graph on the next page is a crude indicator of the power of managed care on the mortality side of the quality question. It is crude because it uses gross mortality, which does not adjust for differences in age, sex, race, etc. that may exist between the HMO population and others.

There is a new "Adjusted Mortality" methodology, however, which does adjust for several of the key patient-specific variables. Most of the government sponsored networks around the country prefer this measure, as do most thoughtful clinicians and analysts.

The economic issues are also large. In the advisory announcing this hearing, it was stated that this year there are approximately 200,000 Medicare beneficiaries with ESRD and that Medicare is spending $8 billion on this program, or $38,900 per beneficiary. These figures used by the Committee are considerably lower than our estimates, perhaps because some expenditures are not included and/or because we estimate there were only 190,000 dialysis patients in 1994. We believe the total national average cost of Medicare non-HMO coverage in 1994 was $56,070 per patient. The national cost of non-HMO care for ESRD patients has been growing at a considerable pace and saw almost a 20% increase from 1991 when the annual ESRD patient costs were $44,413. To make even a more significant comparison, the Medicare non-HMO care cost in California in 1994 was $62,636 versus a Medicare HMO in California where cost was only $35,000. This information is reflected on the next graph in my testimony.

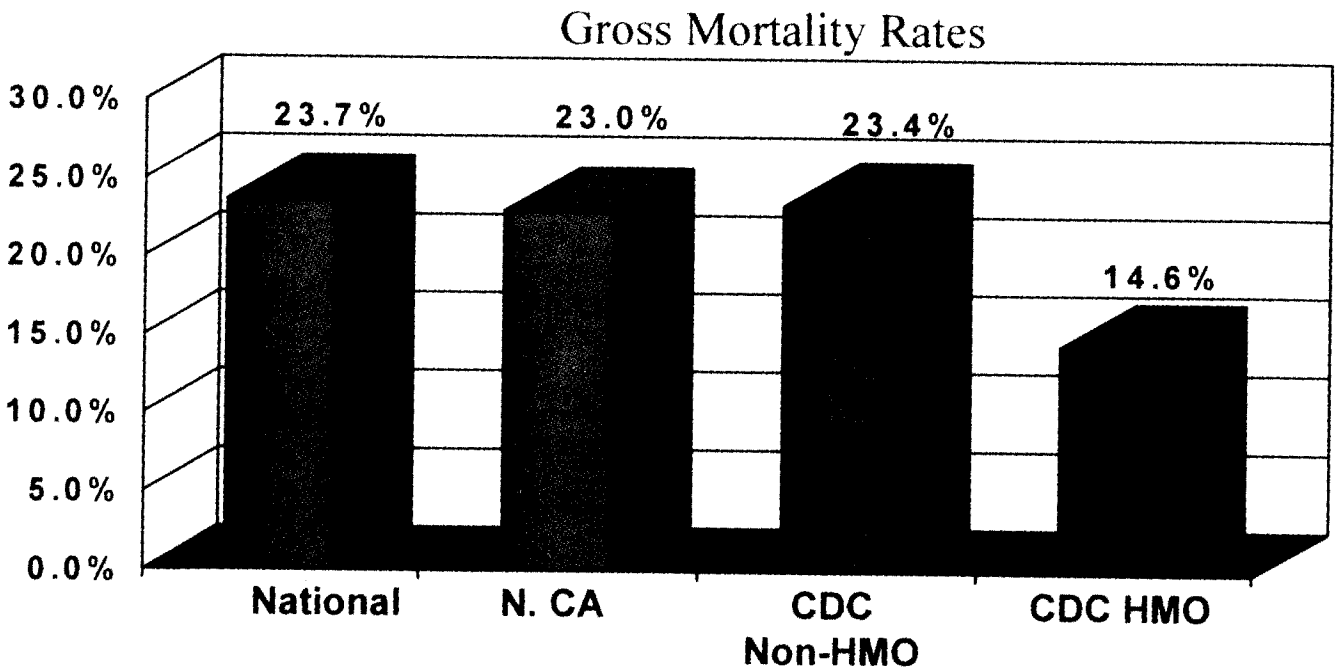
Which costs are increasing most rapidly? And independent of which national average cost per patient is correct, what is the biggest area of cost difference across different patient populations?

The largest drivers of ESRD cost increases over the last five years (and, if unchecked, the most likely drivers of increases for the next five years) are hospital costs and EPO (a drug). Depending upon whose numbers you use, hospital costs represent 20 to 45% of total costs. No matter whose numbers you use, dialysis is one of the few chronic disease states where annual hospital days per patient are increasing. And again, no matter whose numbers you use, managed care leads to significantly fewer hospital days per patient year as is shown in the graph on the following page.

With severe chronic disease states you cannot achieve lower hospitalization rates by "cutting corners" or by withholding care. Any good clinician will tell

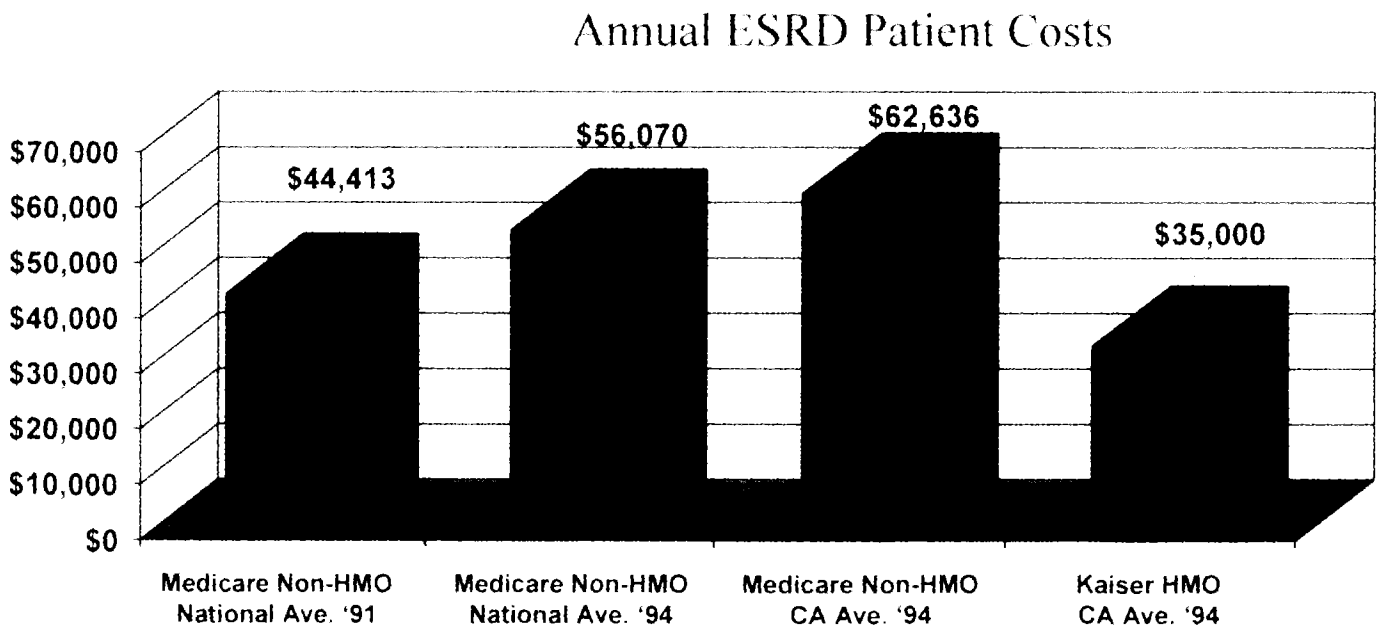
Quality of Life...

The mortality rate for HMO dialysis patients is 30% lower than the national rate, Northern California rate, or CDC Non-HMO rate.



Costs...

In 1994, Kaiser's annual dialysis costs per patient were 44% lower than Medicare's average California cost, and 21% lower even than Medicare's '91 national average cost.



you that if you do, then that patient will be back in the hospital bed sooner and sicker. Any good Medicare HMO executive will tell you that most of their enrollees (and an even higher percentage of their enrollees with chronic conditions, since the economic benefits of an HMO are more powerful for them), do not switch plans often, and so they are very sensitive to the multiple-year cost implications of any care approach.

Equally significant are the indirect expenses. Most dialysis patients who were working stop, because of the trauma and inconvenience associated with the beginning of dialysis and the ongoing disruption caused by the care pattern and regular hospitalizations.

The Basic Prevention Premise

Our premise not complicated, it is common sense. It is not theoretical, it is being proven every day in the actual real world of patient care. It will keep people healthier.

Our premise is that the private sector/managed care system will invest more and more effectively in prevention than Medicare fee-for-service.

This is true whether you assume most care givers are noble humanitarians or medical mercenaries, because for a chronic disease state they both want to do the same thing, namely delay the onset of the disease itself and prevent complications and extreme deterioration once the disease is in place.

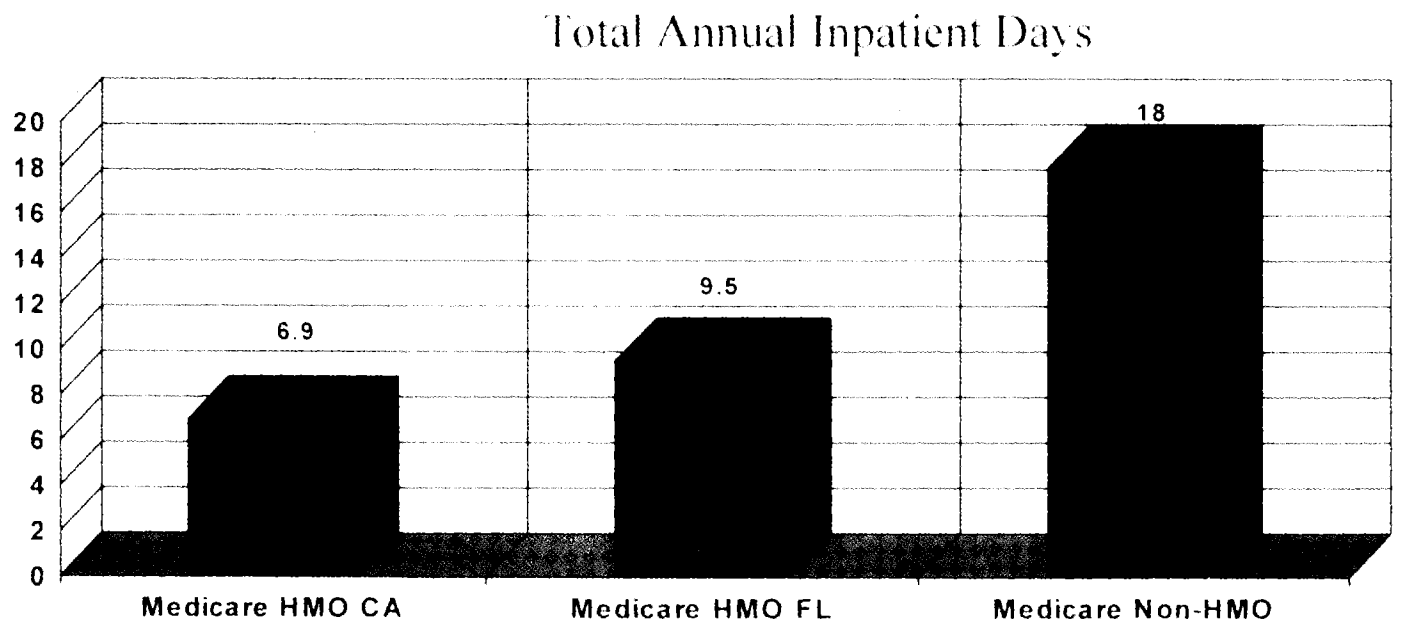
The economic incentives motivate the mercenary. But please understand your fee-for-service system makes things basically impossible for the humanitarian. Some of our patients would be better off if you reimbursed for more social work, dietetic work, homecare, and patient education. As a citizen I do not advocate your loosening the reimbursement restrictions in any of these areas because some providers would abuse the situation and work to the maximum allowed for all eligible patients. But the current system makes it impossible for the caregivers to make the larger investment for the particular patients who would benefit.

The soul of managed care lies in discretion around established baseline standards. Health Care Financing Administration (HCFA) fee-for-service is genetically wired for rigidity, not discretion.

When there is unified multi-year accountability of the total quality and total cost of a patient population, medical magic can and does happen. For patients costing an average of $150,000 to $250,000 each, who have thrice-weekly contact with their caregiver, the private sector/managed care system will put in place the unified, long-term accountability with discretion.

Quality of Life...

California and Florida HMO dialysis patients spend 50-60% less time in the hospital than the average Medicare Non-HMO dialysis patient.



Real-Life Examples

First I will provide three non-dialysis anecdotes, since non-dialysis areas ar dramatically more advanced in applying these basic truths of preventative c and working out the operating bugs.

We at Vivra are also in the diabetic care business. We know that rates of diabetes re-admission (meaning the same person being re-admitted) are low higher managed care areas than in low ones. This is because a greater investment is made on the "soft" side of patient education, care manageme and early identification of emerging problems, often by purchasing our ser

The next two examples are portrayed in the graph on the next page of my statement. The graph reinforces the powerful congruence of cost and quali objectives in "high prevention potential" situations. Private sector AIDS patients enjoy lower mortality and lower health care costs, primarily due to lower hospitalizations. Pregnant women avoid the cost, trauma, and long-t issues associated with premature births, with the obvious societal benefits.

Let's turn to some equally powerful dialysis examples:

1. Delaying Onset of Dialysis. Earlier specialist intervention could slo down kidney deterioration for many patients. Even a six month dela yields immense individual and societal benefits. Payers and provide experienced with capitation have "early warning systems" based on pharmaceutical prescriptions and other indicators which allow them t focus on these patients. They also have management processes whic eliminate the specialist's fear of antagonizing referral sources. This several hundred million dollar issue in itself.

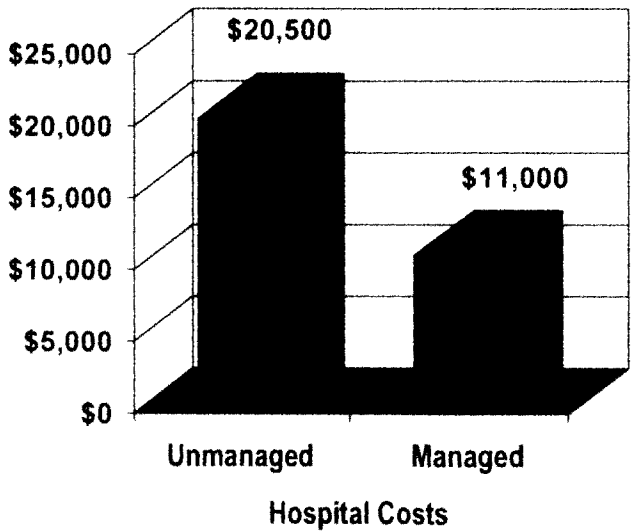
2. Quality Dialysis Initiation. A well managed pre-dialysis patient has simple "access device" placed in their arm though a simple out-patie procedure. This is done well before they need dialysis so their body time to accept it. When their kidneys ultimately fail, they simply be outpatient dialysis.

   Poorly managed patients are not similarly prepared. They will appe the emergency room and require a multi-day inpatient admission to surgically implant a larger and less clinically desirable access device.

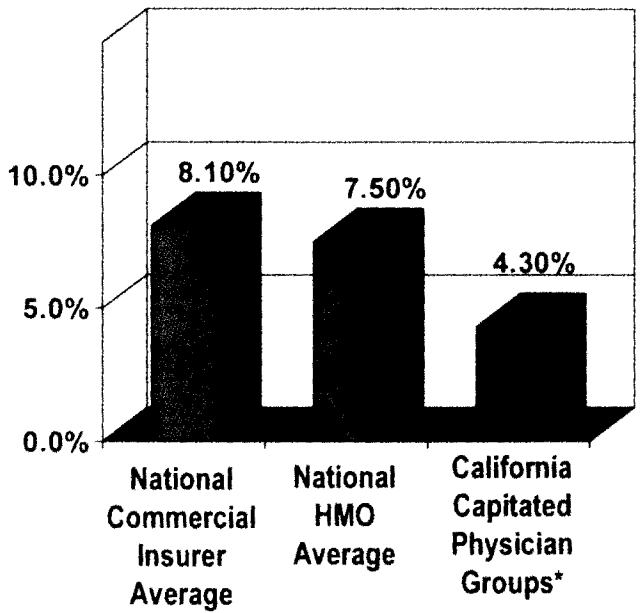
   The latter situation costs anywhere from three to six times more. Th patient is less likely to continue working. The patient suffered far m clinical trauma.

   The incident of this latter situation varies by a factor of 10 in differe markets, and in general is already less frequent in high managed car areas due to the spillover benefits of managed care affecting general behavior.

Treatment Costs per AIDs Patient



Premature Birth Rate



* $400 million in revenues

3. Surgeon Selection Surgical and surgically related costs are 5 to 20% of patient costs. They are important to patient care because they are important to the patient retaining good "access" between the dialysis machine and the blood system. Surgical quality differs dramatically by surgeon. Low quality surgeons are high cost surgeons because their patient's accesses perform less well during dialysis and fail more quickly, requiring additional procedures.

   The private sector and managed care give nephrologists the data required to compare surgeons, and the surgeons get an unambiguous message as to the consequences of low quality.

4. Patient Education and Proactive Support. This can have an immense impact, as has been dramatically demonstrated with pregnant women in some Medicaid programs. Some patient populations require far more education and support than others. These are often the same populations who end up with the most complications and the highest annual expenses.

   The private sector will negotiate customized rates for these patients, supporting the larger investment requirement up front in exchange for the rigorously monitored downstream returns. Again, this is not theoretical -- we already see capitated Ob/Gyn rates for Medicaid patients that are a multiple of those for commercial patients. The provider demands the higher rates because there will be more work. The for-profit payer agrees to the higher rates because it knows the downstream savings will exceed the up-front investment. The patient and society benefit.

The list of examples could go on and on. What I would like to highlight is the:

* Alignment of economic and clinical incentives (including multiple-year agreements)

* Common sense

* Magnitude of the quality and cost improvements -- they are dramatic, not incremental

* Fact that a bureaucracy which is well-intentioned but structurally incapable of the requisite creativity, nimbleness and discretion will fail to achieve these improvements. They inevitably fall back on compliance to either administrative procedures which do not powerfully correlate with quality outcomes, or they boldly venture out with actual clinical parameters which are so crude that thoughtful providers are appalled. Finally, the bureaucracy never does what it takes to provoke exciting improvements, namely take patients away from bad physicians by providing referring physicians with compelling data or by eliminating them from a provider panel.

Magnitude of the Opportunity

We can delay onset. We can increase the percentage of patients who work. We can reduce complications and hospitalizations. We can do a lot, not a little, in all these areas.

The current centralized fee-for-service system has had a 22 year experiment. It would be difficult to imagine a more disappointing cost and quality performance. Please give us a chance, buy giving us a customer who can enter into meaningful and decisive discussions on real-world quality and cost per performance.

Our Policy Recommendations

To provoke private sector/managed care leadership in improving the ESRD program, we recommend:

1. **Test Us.** Extending the period patients remain on their private sector insurance from 18 months to 30 months.
2. **Free Choice.** Allowing Medicare beneficiaries with ESRD to enroll in HMOs.
3. **Fair Choice.** Grant ESRD patients the same COBRA continuation of health care rights as other employees.

I'll elaborate on each of these:

The benefits of managed care flow to the patient in the form of better quality of life and to the patient's insurer in reduced cost only if that insurer practices managed care. A problem arises with ESRD managed care in the fact that three months after diagnosis of ESRD a patient becomes eligible for Medicare. If an ESRD patient has private insurance, that private insurance remains the primary payor for 18 months. Because managed care relies on a significant initial investment of resources in the patient which would be recouped later in patient care, private insurers have little financial incentive to make that initial investment in managed care for their ESRD patients when Medicare will take over after 18 months. This then all but eliminates the financial incentive for insurers to manage the ESRD patient's care. To remedy this situation, we propose extending from 18 months to 30 months the period that private insurance remains the primary payer.

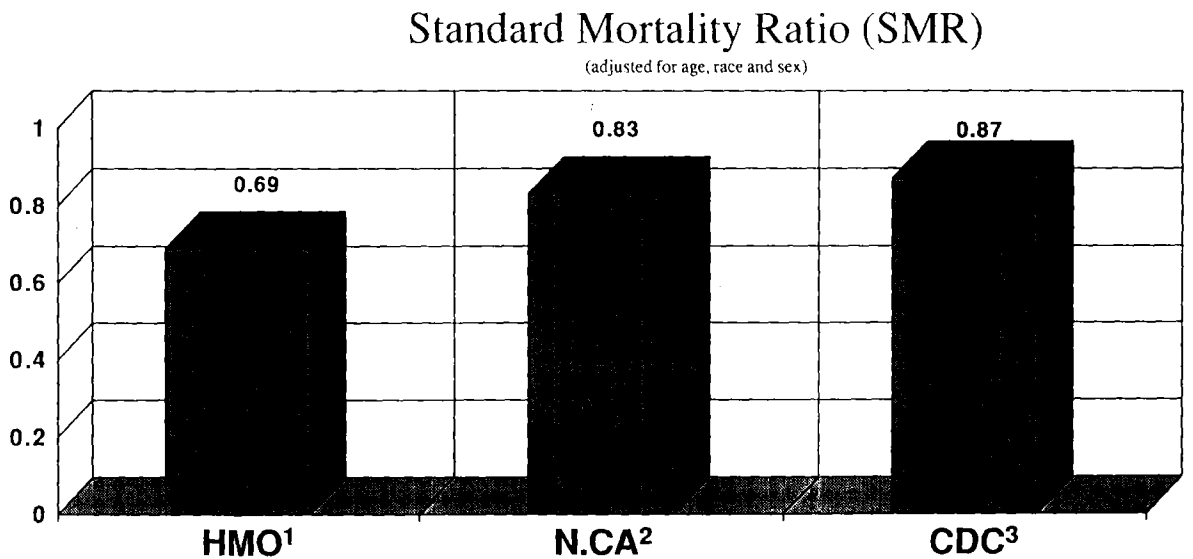
This is not a unique proposal. Last year, all of the comprehensive health care reform proposals (except for the Gephardt proposal) would have increased the period to 24 months in which private insurance would be primary. We believe that 30 months is more likely to encourage managed care and result in more significant savings to Medicare. The overall cost to insurers will be: a) minuscule as it will be taken from one payer (Medicare) and spread across thousands, and b) not proportional to the increase in months, because costs per patient will decrease over time. In going to a 30 month period for insurance as primary payer, it would be important to also write into law that insurance policy limits could not be reduced for ESRD. Limits are not generally applied to other chronic diseases, and ESRD should be no exception.

The benefits of managed care for ESRD patients are obvious. However, the country's largest insurer -- the Medicare program -- prevents ESRD patients from enrolling in an HMO after the advent of ESRD. While an ESRD patient who is already enrolled in a Medicare HMO may remain in it after the onset of ESRD, Medicare rules actually prevent individuals from choosing HMO care after the advent of ESRD. This rule no longer makes sense and ESRD patients should be permitted to enroll in managed care. This policy is especially perverse as Medicare HMOs grow. Many seniors will not join if they must change physicians. As HMOs grow, more physicians will become involved. Once a patient's physician is affiliated with a plan the patient can directly benefit from the superior pharmaceutical benefits and co-pay arrangements, which are economically significant for chronically ill patients.

Finally, as a result of being eligible for Medicare after three months, the Federal courts have held, despite HCFA's arguments to the contrary, that ESRD patients are not eligible for COBRA continuation of their private health insurance after leaving employment. If an ESRD patient could maintain COBRA coverage, the private insurance would be the primary payer. Another reason for permitting this COBRA coverage is that current case law is not clear with regard to whether dependents of ESRD patients are eligible for COBRA coverage when the ESRD patient becomes eligible for Medicare. HCFA's advocacy on this issue should not go unnoticed.

Quality of care...

Dialysis patients in HMOs experience lower standard mortality rates than patients in traditional fee-for-service plans.



[1] Kaiser of Northern California, CDC facility survey, 1994.
[2] Trans-Pacific Renal Care Network Annual Report, 1990.
[3] CDC company-wide average, 1994.

Chairman THOMAS. Mrs. Johnson will inquire.

Mrs. JOHNSON. Thank you for your very interesting testimony. Mr. Thiry, how do you account for the fact that some of the preceding panelists really had no sense that managed care was contributing to quality or managed care was doing a good job of both quality and cost reduction in dialysis, and particularly they focused on the insecurity that managed care would create for dialysis patients. In other words, all the negative arguments and none of the positive arguments. Why is the community that is most involved in delivering this care so unaware of the kinds of advances that you note?

Mr. THIRY. Dialysis patients that are in managed care probably only represent about 3 to 4 percent of the total. If you are running one center or a few centers, you have an exceptionally small number of patients. That also means the payers with whom you are dealing have a very small number of patients and therefore they probably aren't doing anything thoughtful with respect to dialysis because they only have four or five of them and after 18 months they turn them over to the government for the rest of the person's care life.

We are active in Florida and southern California, working with a small number of HMOs who have a sufficient number of dialysis patients so that it makes sense for them to allocate a lot of management time. We, all by ourselves, have about 600 managed care patients. That is probably a multiple of what anyone else other than national medical care is working with on a day-to-day basis. Not only do we care for 600 HMO patients, but they are concentrated in a couple of geographic areas.

Mrs. JOHNSON. So the news just hasn't spread yet.

Mr. THIRY. They literally are not dealing with managed care or thoughtful managed care. They may be dealing with thoughtless management care, exactly as they describe.

Mrs. JOHNSON. Your experience is in HMOs, which isn't an organization of managed care that maximizes the ability to manage. Are you aware of more flexible PPOs and organizations like that that also deliver managed care getting into dialysis?

Mr. THIRY. We have received our first phone calls from them and made our first phone calls to them only in the last 6 months, again, because of the same volume issue. There is tremendous opportunity to work within the PPO, POS industry.

Mrs. JOHNSON. Could you clarify for me again the volume issue, why is it other plans don't have to deal with the volume issue?

Mr. THIRY. If I have 150,000 enrollees in Cincinnati and x number of them are dialysis patients and x is a very small number, I will first deal with AIDS, asthma, allergy, oncology, Alzheimer's, and so forth, before I get to dialysis because it is such a small number of patients and I only have them for a short time.

Mrs. JOHNSON. Thank you.

Chairman THOMAS. The gentleman from Nevada.

Mr. ENSIGN. Thank you. Dr. Berger, you mentioned an inflation adjuster. Do you know what we would currently be spending if we had an inflation adjuster all along in relation to the dollars per year that we are spending on ESRD today?

Mr. BERGER. There are two components that have not been traditionally adjusted for inflation. One is the physician monthly capita-

tion, and in the last year that has been folded into the physician payment system and will be adjusted. The remaining one is the dialysis system. I don't know, given the number of Gramm-Rudman-Hollings freezes and other specially legislated freezes and suspensions, what the actual difference would have been between 1983 and 1985 had there been the same sort of mechanism in place, no.

Mr. ENSIGN. If we built in an inflation adjuster, it would seem to me that advances in technology that would save costs would preclude the government from saving these costs.

Mr. BERGER. Congress has asked the Prospective Payment Assessment Commission to look at dialysis facility reimbursement and to make an annual recommendation and it has done so for 3 years. In doing that, it looks at the actual trend to the best it can calculate in the inflation, the costs of labor and other goods that dialysis providers have to buy.

It also looks at provider efficiency gains and at the net effect of new technology. It comes up with a single composite from those three factors which is its recommendation in terms of those quantitative numbers that are available for an annual change.

I think that is almost precisely comparable to the way in which the ProPac recommendation for hospital reimbursement is made, and we would certainly be very happy to see those elements factored in.

Mr. ENSIGN. So that would be acceptable to you on the inflation adjuster?

Mr. BERGER. Absolutely. Not just a pure blank check for some financial indicator; no.

Mr. ENSIGN. Thank you, Mr. Chairman.

Chairman THOMAS. The gentleman from Nebraska.

Mr. CHRISTENSEN. Mr. Thiry, in your written testimony you talk about the extension of COBRA benefits. Did you want to expand on that or not?

Mr. THIRY. The reasons for advocating are the same reasons that we advocate in general putting more of these patients in the private sector. In that particular scenario it seems especially unfair that ESRD patients are not having the same right of choice that other employees have. But our basic motivation is the same.

Mr. CHRISTENSEN. OK. I tend to agree with most of your testimony and appreciate your time here today. Thank you, Mr. Chairman.

Mr. THIRY. Mr. Chairman, you asked a question earlier about breakthrough investments which could radically improve the quality and reduce the cost of dialysis care. I believe some of those are out there.

I just recently received the highest quality investment opportunity in a wearable kidney, truly the best one I've seen. It is not going to get funded because even if it ends up working, it would cost several million dollars and a few years of development. Yet no one is confident under the current reimbursement system that the government will be able to do an effective, long-term cost analysis and weigh in the up front investment versus the downstream costs of managing those patients. I would submit that there is a definite chilling effect. This particular venture would radically alter the economics of my business in a way that will be very bad for my

shareholders, but it is a development I would welcome. That won't happen with the way the system works today.

Chairman THOMAS. I would expand the question and ask, if you have a wearable kidney and you have those kinds of expenses up front under a managed care structure or you have a transplant where you wouldn't continue—say, the success rate is very high and we have sufficient organs—why would any managed care operation on a capitated basis make the investment in fixing that problem given the high mobility that people have today in terms of their chances of moving on, having been fixed by you at great expense to provide a very handsome profit margin on a capitated basis to some other plan? Where is the incentive for you to make that decision?

Mr. THIRY. I would submit that if and when there are a lot of dialysis patients in the private sector, even an unethical company would be absolutely unable to underperform their competitors in terms of doing early transplants. Every thoughtful clinician knows that doing early transplants is a key to effective care in this area. Just as there are emerging key indicators in asthma allergy, and AIDS, and so forth, in dialysis you would be slitting your own neck as a proprietor of your own business to cut corners in that area.

Chairman THOMAS. In the long run?

Mr. THIRY. Correct.

Chairman THOMAS. You are in it for the long run.

Mr. THIRY. I am sure there are companies that are not, but the short run is getting shorter as employers are getting much more rigorous every month in the data they are demanding from providers.

Chairman THOMAS. Dr. Berger, that is why in your testimony you say that you would remove any month's period. We discussed with the earlier panel going from 18 to 24 or to 30. If I recall, your testimony indicated that you would leave it open ended.

Mr. BERGER. Leaving it open ended is where the logic of the analysis takes it. Mr. Chairman, we are knowledgable and sympathetic to some of the concerns that were voiced earlier, and we would be very pleased to have the Subcommittee look at those concerns to see whether there are some reasonably simple ways of alleviating them. But the logic of the problem, of the isolation of this program from the developing mainstream of the American health care system, is as Kent has said, to see to it that the private sector bears its fair share of the burden.

This is not a matter of trying to dump responsibility that is rightfully the public sector's on to the private sector, but rather to bring the distribution more into line with what is in fact conventionally found elsewhere in the health care system.

Chairman THOMAS. Perhaps the solution lies not narrowly within the public months relationship, but in the larger area of reforming health insurance which is offered and denied?

Mr. BERGER. Certainly, the package of what we are always told are almost universally agreed upon health insurance reforms having to do with portability and preexisting conditions would go a long way to alleviating the concerns expressed earlier.

Chairman THOMAS. One of the concerns I have in dealing with payment structures is that oftentimes you find to a certain extent

choices dictated by the payment method, especially in skilled nursing facilities—home health care areas that are growing rapidly, they are the last fee-for-service bastion. I am concerned that if we begin to make changes in structures, we do not create any opportunity for choices based upon a payment schedule rather than the efficacy of the choice toward the patients.

Any additional questions? I thank the panel very much for your participation and the Subcommittee hearing is adjourned.

[Whereupon, at 1:10 p.m., the hearing was adjourned.]

[Submissions for the record follow:]

Statement of Amgen Inc. to House Ways and Means Subcommittee on Health on Medicare End-Stage Renal Disease Program

Amgen Inc. is pleased to submit this statement for consideration by the subcommittee and inclusion in the record of the April 3, 1995 hearing on the Medicare end-stage renal disease (ESRD) program. As the manufacturer of EPOGEN® (Epoietin alfa), an important part of the treatment of many dialysis patients, Amgen closely follows trends in the cost and quality of the ESRD program. The company's observations are informed by its experience during almost a decade of participation in efforts to improve the clinical status and quality of life of Americans who depend on kidney dialysis to survive. Amgen strongly believes that focusing on quality of outcomes in dialysis patients and aligning incentives and payments around these outcomes is the best way to control costs and benefit patients.

BACKGROUND

Amgen is the U.S. (and the world's) largest independent biotech company.

Amgen, headquartered in Thousand Oaks, California, is the largest independent biotechnology company in the world. Since its founding in 1980, the company has spent $1.2 billion dollars on research and development, with emphasis on finding new treatments for diseases for which current therapeutic interventions are inadequate. Last year, the company was awarded the National Medal of Technology, an award established by Congress in 1981 to recognize technological achievement. Amgen is the only biotechnology company ever to receive this tribute.

Epogen is a breakthrough application of genetic engineering for dialysis patients.

In 1989, the Food and Drug Administration approved for marketing Amgen's first product, EPOGEN. First cloned and developed by Amgen scientists, EPOGEN is a biopharmaceutical product with the same amino acid sequence as natural erythropoietin, which is produced by healthy kidneys and acts to stimulate the maturation of red blood cells.

Kidney failure almost always results in anemia because the kidneys no longer produce adequate amounts of erythropoietin. Before the availability of EPOGEN, most dialysis patients were severely anemic, reflected in low hematocrit readings. Hematocrit is the ratio of red blood cells to total blood volume; low hematocrit readings are associated with increased morbidity and poor quality of life. Indeed, prior to 1989 many dialysis patients were dependent on blood transfusions to survive. Since the introduction of EPOGEN, blood transfusions to combat the

anemia of renal failure have become unnecessary, and the quality of life of dialysis patients has improved significantly.

The Medicare payment experience for EPOGEN illustrates the importance of establishing and maintaining incentives for proper patient outcomes.

Shortly after EPOGEN was approved for marketing, the Health Care Financing Administration (HCFA) established a policy to pay for it as an add-on to the prospective payment rate for dialysis services. (While the product is also covered by Medicare when administered in physicians' offices or dispensed for self-administration to qualified dialysis patients, most EPOGEN is administered to dialysis patients at the end of the dialysis session by injecting it into the venous access route).

The rate set in 1989 was a flat $40 per EPOGEN treatment for most patients, regardless of the amount administered. In setting the rate, HCFA assumed that average doses would reach 5,000 units per administration, the average for patients in Amgen's phase III clinical trial. While it was always understood that the vast majority of dialysis patients would eventually receive EPOGEN therapy, HCFA also assumed that, as with most new products, the use would grow gradually.

In retrospect, it is clear that those assumptions (which Amgen shared at the time) failed adequately to reflect the financial incentives created by the payment mechanism. By mid-1990, the Office of Technology Assessment (OTA) and the HHS Office of Inspector General (OIG) had reported to this subcommittee that the doses were significantly lower than anticipated, to the detriment of patients. The OIG report concluded that the effect of the flat rate reimbursement system was windfall profits to dialysis facilities and recommended that Medicare pay for EPOGEN based on actual doses administered.

Congress in the Omnibus Budget Reconciliation Act (OBRA) of 1990 changed the reimbursement methodology from the flat rate to $11 per thousand units administered. In OBRA 1993, the payment amount was reduced to $10 per thousand units. Doses, which had averaged 2700 units in 1990, are currently averaging about 4400 units per administration, enabling more patients to achieve hematocrit levels within the FDA-approved target range of 30-36 percent. Amgen data suggest that nearly all dialysis patients for whom EPOGEN therapy is indicated now receive it, but only approximately 65 percent have hematocrits within target range. This means that doses for some patients are still inadequate and that closer clinical management of iron stores and other factors should be encouraged, as discussed below. (Since HCFA's reimbursement guidelines require a hematocrit reading below 30 to initiate EPOGEN therapy, it is unlikely that patients who are not anemic are being treated.)

COST AND QUALITY OF MEDICARE ESRD PROGRAM

Costs per beneficiary of ESRD program to Medicare have risen at a rate lower than the rest of the Medicare program.

The subcommittee has indicated its intention to examine trends in Medicare spending on the ESRD program. Amgen's first observation on this subject will no doubt be echoed by a number of witnesses at the hearing: It is clear that on a per beneficiary basis, the rate of growth in spending for this program over the past 10 years has been relatively moderate. Indeed, the aggregate increase in program expenditures per ESRD beneficiary since 1985 (34%), is dramatically lower than the increase over the same period in the average Medicare benefit payments per enrollee (108%). (Source: 1994 Green Book)

Amgen has contributed to the effort to restrain the rates of increase in Medicare spending. Influenced by extensive discussions with HCFA officials, Amgen set the price for EPOGEN in 1989 at $10 per thousand units, well below the average European price ($15) set by its licensee. The U.S. list price has never been increased in the intervening years, and it remains on average 34.4 percent lower than the European price and 68 percent lower than the price in Japan. Adjusting for inflation, Amgen's list price for EPOGEN has declined by 21.4 percent since 1989.

The introduction of EPOGEN and -- more recently -- the progress achieved in bringing hematocrit levels into target range also contribute indirectly to cost control in the ESRD program. Dialysis patients receiving EPOGEN have been found to develop fewer comorbid conditions that require inpatient hospital treatment. Since inpatient costs account for almost half of all Medicare payments for dialysis patients, adequately managing anemia could result in reductions in outlays. A recent study conducted by the Johns Hopkins School of Medicine and HCFA found that patients on EPOGEN are less likely to have heart failure, angina, myocardial infarction, depression and strokes than patients not receiving the drug. The study also concluded that use of EPOGEN may be associated with fewer overall hospital admissions and fewer days spent in the hospital. (Powe et al., JASN, 1994: 4:1455-1465).

The current reimbursement rate for EPOGEN provides some incentive to providers to increase doses if the patient's hematocrit is not within the target range. (As discussed in more detail below, it is important that iron stores be monitored carefully to insure that the lowest effective dose is used.) Some have suggested that the Medicare payment rate should be reduced or folded into a composite or capitation rate for dialysis. These suggestions should be rejected. If the incentives to properly dose were reduced, removed, or reversed, hospitalization costs could rise and--at the extreme--transfusions could return as the treatment of choice for anemia due to renal failure. This, of course, would lead to additional costs for

treating blood-borne infections, and patients would risk development of antibodies, increasing the chances that a kidney transplant would be rejected. These additional costs would likely wipe out any anticipated savings associated with changing the payment rate/method for EPOGEN.

Focusing on the quality of care of dialysis patients provides the greatest return on the Medicare investment in its ESRD program.

Any careful observer of the ESRD program would note a growing concern about the quality of care delivered to ESRD patients, particularly those dependent on dialysis. The ESRD mortality rate in the United States is reported to be the highest in the industrialized world. The National Institutes of Health, the Institute of Medicine and the National Kidney Foundation have all expressed concern and made recommendations regarding the adequacy of dialysis and the morbidity and mortality of dialysis patients.

Last year, HCFA launched a Core Indicators Project to measure how key clinical parameters are being managed. HCFA is also developing quality screens for care of dialysis patients. The first of these to be implemented deals with management of the anemia of chronic renal failure. These efforts should be encouraged, although it may never be possible to assure high quality using only the power of the payor to survey and certify providers.

There is a strong correlation between Medicare reimbursement policy and the quality of delivered care to ESRD beneficiaries. To focus on cost minimization without a corresponding investment in quality assurance would result in short-term savings at the cost of long-term costs and absolute reductions in the quality of life of a particularly vulnerable group of beneficiaries.

Since such extraordinary efforts are being taken to extend the length of the lives of ESRD patients, it would be unfortunate indeed if the quality of those lives was allowed to deteriorate through neglect or inadvertence. Amgen has supported, financially and through participation of its staff, the development by the Rand Corporation of a Kidney Disease Quality of Life Instrument which could assist researchers in measuring the impact of various therapies. In addition, the company has sponsored a Life Options Program, which identified barriers faced by dialysis patients attempting to achieve more normal lifestyles, including returning to work. The program is now seeking ways to surmount those barriers.

The Ranking Minority Member of the subcommittee, Mr. Stark, has introduced a bill (H.R. 1067) to require renal dialysis facilities to meet certain standards relating to the adequacy of dialysis as a condition of payment. This is a step in the right direction. It also would be appropriate to monitor more closely how anemia is managed in dialysis patients. In addition to appropriate use of EPOGEN, such monitoring should require that patient iron stores are maintained at a sufficient

level to allow optimal development of red blood cells. In other words, no amount of EPOGEN will cure the anemia of a patient who is allowed to become severely iron-deficient.

CONCLUSION AND RECOMMENDATIONS

The Medicare ESRD program is remarkable in that it keeps 200,000 Americans alive regardless of their social or economic status. Even successful programs can usually be improved, but the Congress should beware of "improvements" in the ESRD program that put patient quality of life at risk. Amgen recommends that the Congress:

- Resist changes in payment policy to effect short-term savings; any reduction in payments could result in additional long-term costs.
- Continue to support HCFA's efforts to monitor the quality of care provided to ESRD patients.
- Require that patients receive adequate dialysis and that their hematocrits be appropriately maintained to control anemia, as a condition of payment for dialysis and EPOGEN.

TESTIMONY OF BAXTER HEALTHCARE CORPORATION

COMMITTEE ON WAYS AND MEANS
SUBCOMITTEE ON HEALTH
U.S. HOUSE OF REPRESENTATIVES

HEARING ON THE MEDICARE END-STAGE RENAL DISEASE PROGRAM
APRIL 3, 1995

I. INTRODUCTION

Baxter Healthcare Corporation appreciates the opportunity to submit written testimony to the Subcommittee on the Medicare End Stage Renal Disease (ESRD) program in connection with its hearing on April 3. We applaud the Subcommittee for its efforts in evaluating this program and examining other alternative payment and administrative approaches for the management of this chronic condition.

Baxter is a subsidiary of Baxter International, Inc., a publicly traded company headquartered in Deerfield, Illinois. Through its Renal Division, Baxter manufactures and distributes a full range of hemodialysis and peritoneal dialysis equipment and supplies to the renal community. Baxter has pioneered many of the technological breakthroughs in dialysis that have enabled hundreds of thousands of patients to survive and live quality lives despite chronic renal failure. Baxter believes it is critical that this vulnerable patient population continue to receive access to quality care and integrated, comprehensive services. Over the years, we have had the opportunity to listen to and work closely with all interested members of the renal community, including physicians, providers, suppliers, payers, professional associations, and most importantly, patients. It is based on this perspective that we offer these comments.

We believe strongly that the Medicare ESRD program generally has been successful in meeting the needs of patients with chronic renal failure. We feel equally strongly, however, that the program can be significantly improved in terms of quality of care, patient satisfaction and cost-effectiveness. There is much we have learned since the inception of the Medicare ESRD benefit twenty three years ago, and the time to apply these lessons, we believe, is now.

Recently, there has been a great deal of examination and discussion regarding current and alternative payment policies for the ESRD program, both within and outside of the context of broader Medicare reform. While many of the proposed Medicare reform initiatives will require a long-term analysis and evaluation, we believe that several initiatives can be implemented now that can improve beneficiary options and encourage the renal community to further adopt and implement certain managed care mechanisms. These mechanisms, we believe, will promote improved patient quality, provider accountability and cost-effective care.

Our recommendations do not suggest a total overhaul of the ESRD system, nor do we endorse a rapid movement of the entire ESRD program to a capitated payment methodology. Rather, we believe that the endorsement of certain integrated delivery system principles, such as the concept of "disease management," coupled with incremental changes in the current payment and reimbursement system offer the potential for improved quality of care, greater system efficiency and lower total costs.

II. THE ESRD PROGRAM TODAY

As it is currently structured, the Medicare reimbursement system, through its focus on the treatment of and payment for acute, isolated services, discourages integrated care for patients with ESRD. Medicare reimburses facilities for services strictly related to dialysis based on a prospectively determined composite rate; ancillary supplies and services are

covered under a fee-for-service methodology; outpatient physician services are subject to a separate monthly cap; and inpatient care is reimbursed under the applicable DRG classification. An inevitable yet unintended consequence of this fragmented approach is that providers are encouraged to manage only that portion of the patient's care for which they are responsible. Decisions may be made without collaborating with other health care providers and without fully taking into account their impact on the entire disease process. Due to this lack of integration and multidisciplinary management, which are becoming commonplace in the private sector, continuity of care for ESRD across care settings has not occurred. Patients themselves have not received the benefits of an integrated, coordinated care system.

III. THE IMPORTANCE OF INTEGRATED CARE

Through Baxter's involvement in the development and distribution of products to treat other chronic, high cost disease states (including cancer and hemophilia), we have seen the successful application of "disease management" principles and integrated delivery system models in other contexts. We believe that these principles and models represent equally viable approaches for addressing the special needs of the ESRD population. Under some chronic disease management models, for example, providers are given the flexibility and are charged with the accountability of managing the patient's disease from the onset of diagnosis, when well-informed decisions can be made regarding modality of treatment and site of care. These models encourage prevention and treatment that will provide maximum effectiveness and efficiency at the time of onset of illness. As with other chronic illnesses, and as other hearing witnesses have confirmed, intensive disease management of ESRD at an early stage is critical. Unlike a traditional acute managed care model where the focus is typically on avoiding overutilization, an integrated disease management model strives to ensure that patients are not underserved. Under this model, patients receive comprehensive care that helps minimize many of the more costly complications arising from a lack of intervention and provider coordination.

We believe that <u>any</u> initiative that is developed for the ESRD population must include some form of case management that focuses on coordination of care and encourages collaboration among all providers of the health care team. In working with providers and patients to create optimal home care therapy solutions for ESRD patients, we have seen first-hand the challenges of creating and managing a comprehensive care plan encompassing the clinical, psychosocial and economic needs of these individuals. We applaud the American Nephrology Nurses Association endorsement of a comprehensive nurse case management approach to the ESRD population and we encourage the further development and refinement of these types of initiatives. This endorsement is consistent with the position of the Renal Physicians Association. In any chronic disease management approach, we support the role of the nephrologist as the primary care physician who is responsible for the overall management of the ESRD patient's care.

IV. INTEGRATED CARE AND PATIENT INVOLVEMENT

We believe that moving in the direction of a chronic disease management model for ESRD also will give patients the opportunity to actively participate in their care and make meaningful, well-educated choices regarding their treatment. In our experience, the more active the patient is in his or her therapy, the more likely the patient is to adhere to the treatment plan. This has a positive impact on patient outcome. A chronic disease management program promotes active patient involvement through aggressive case management, which includes patient/family education, regular follow-ups and supportive services. These activities help decrease the incidence of complications and, for a significant number of patients, minimize the utilization of expensive services in costly acute or subacute care settings.

V. *QUALITY AND COST-EFFECTIVENESS IN AN INTEGRATED CARE SYSTEM*

We concur with many of the concerns raised by members of the renal community regarding the potential impact of cost-containment objectives in a managed care setting. On the other hand, we believe an integrated disease management approach that is properly supported by an appropriate payment policy can align the quality and cost-containment concerns of all parties involved. Through a capitated payment methodology or other comparable global system, the clinical team responsible for the care of the ESRD patient will work to minimize costly complications, prevent unnecessary hospitalizations and ensure the proper prescription and administration of life-sustaining therapy.

An integrated disease management approach that is properly supported by an appropriate payment policy can be an effective means of controlling costs. The quality concerns of the patient and provider and the cost-containment focus of the payer or employer can be aligned to produce the optimal clinical result. ESRD services are already subject to a modified capitated system under the composite rate methodology. This methodology has been viewed as a relatively effective means of controlling program costs. The monthly capitation for physicians also has proven to be an effective cost-controlling mechanism for physician outpatient care. Significantly, cost increases in the program are primarily related to non-dialysis, non-capitated services. A global capitated method that encompasses all services provided to ESRD patients -- from the time of diagnosis throughout the course of therapy -- will properly align incentives to encourage appropriate utilization from all providers and will thereby minimize total illness costs, rather than just component costs of the disease.

VI. *RECOMMENDATIONS*

We believe that to properly implement integrated disease management initiatives in the ESRD program, certain incremental changes should be made in the current program. First, we recommend that Congress lift the current restrictions or barriers that prevent ESRD patients from electing to enroll in managed care programs. Under the current system, an ESRD beneficiary is prohibited from enrolling in a Medicare prepaid health plan, unless that individual is already a member of such a plan at the time his or her kidneys fail. This restriction deprives ESRD beneficiaries of a meaningful choice of care available to other Medicare beneficiaries and prevents managed care plans from gaining the valuable experience necessary to apply disease management concepts to this population. Significantly, managed care plans have demonstrated that they will make the initial investment of resources in the patient through optimal disease management if this investment can be realized through greater cost savings over the long term.

In addition, given the unique nature of the ESRD program and the complex medical, technological and social demands facing ESRD patients and the providers that care for them, we recommend that Congress encourage the development of specially qualified ESRD delivery systems by allowing greater flexibility in the types of integrated delivery models that are eligible to care for these patients. Under the current regulatory structure, an ESRD patient must disenroll from the health plan of his or her choice at the end of the Medicare secondary payer period if that health plan does not have a contract with HCFA. If more patients are allowed to remain in their networks, we believe managed care plans will be more inclined to make the initial investment in the prevention, early identification and case management of this population -- all necessary and critical elements in the successful treatment of ESRD patients. Greater flexibility will allow patients already enrolled in managed care networks to maintain existing physician relationships and remain in these delivery systems throughout the duration of their illness.

Baxter strongly supports the efforts of HCFA in implementing a demonstration project to assess the impact of a capitated payment system for ESRD patients. We agree with members of the renal community that the demonstration will provide valuable insights in the development of broader changes to the current ESRD payment policy. Nevertheless, we

believe it would be unwise to delay implementing the relatively simple initiatives described above until a final analysis and evaluation of that demonstration is achieved. Our desire to construct a perfect system should not prevent the introduction of logical reforms that can produce benefits immediately. The demonstration which was originally targeted to be completed by 1998, has already been significantly delayed and will not be completed until the 21st century.

We also believe it is unwise to rely on one demonstration project to evaluate the impact of a capitated payment system on ESRD services. As currently structured, the demonstration itself fails to capture patients prior to the eighteen month Medicare secondary payer period and therefore does not allow a plan to manage the patient from the onset of diagnosis when critical decisions must be made regarding treatment and modality. We also believe that equally valuable information can be obtained from monitoring the experience of a number of creative integrated financing and delivery models that are already in place and successfully providing care to ESRD patients. Foregoing the exploration of innovative and comprehensive approaches for managing this chronically ill population until after the demonstration is unwise and unnecessary. Therefore, we encourage the Subcommittee to apply the experience and lessons we have learned from the private sector to spur further debate and to help formulate policy changes for the future. In implementing any of these changes, we recommend that appropriate attention be devoted to educating both the patient and provider communities about the underlying principles and objectives of a chronic disease management approach.

Finally, Baxter recognizes that concerns have been expressed by patient and provider representatives that quality assurance measures must be included in any approach or initiative that is adopted to protect the interests of this highly vulnerable patient population. We share these concerns. We believe there is a legitimate role for the government to define baseline standards applicable to both the public and private sectors. We support HCFA's efforts and encourage the implementation of mechanisms to provide for careful oversight to measure performance. We look forward to the opportunity to work with HCFA to help achieve these goals.

STATEMENT OF DIALYSIS CLINIC, INC. TO THE SUBCOMMITTEE ON HEALTH OF THE HOUSE WAYS AND MEANS COMMITTEE

Dialysis Clinic, Inc. (DCI) is a not-for-profit organization based in Nashville, Tennessee. DCI was established in 1971 in an effort to ensure that medical decisions for individuals with End-Stage Renal Disease (ESRD) would be made on the basis of patient need instead of on the basis of investment returns. DCI currently provides dialysis services to more than 6,000 ESRD patients at over 90 outpatient dialysis units throughout the continental United States. DCI is active in kidney transplantation and operates three independent organ procurement agencies. DCI also has affiliations with numerous major universities and teaching hospitals throughout the United States in an effort to continually improve the care provided to individuals with ESRD. We applaud the interest of the Subcommittee on Health of the House Ways and Means Committee for individuals with ESRD and the Medicare ESRD program and appreciate the opportunity to submit comments for the Subcommittee's consideration.

Although the viability of a shift towards managed care for ESRD is currently a topic receiving great attention, DCI feels that the ESRD program's experience with managed care is insufficient to make major programmatic changes at this time based upon perceived benefits of managed care in this area. However, DCI feels that several areas of the Medicare ESRD program deserve attention and would like to take this opportunity to address several of these areas. Briefly, these areas are: (i) providing funding for quality of care programs; (ii) maintaining Epogen® as separately reimbursable; (iii) extending Medicare's secondary payer status to 24 months; and (iv) providing inflation updates for dialysis providers;.

Funding for Quality of Care Programs

DCI feels that maintaining and improving the quality of care provided to individuals with ESRD is of paramount importance. By continuously striving for increased quality of care, DCI feels that complications associated with ESRD and dialysis can be reduced while simultaneously making dialysis treatments less burdensome and more effective for individuals with ESRD. DCI has data that relates the quality of care to the incidence of hospitalization. This data demonstrates that improving the quality of care in dialysis units reduces the incidence of hospitalization, thus reducing the cost to the Medicare program.

DCI encourages the development and use of quality assurance programs such as the ESRD Health Quality Improvement Program and urges Medicare to support this program and similar programs through funding. DCI feels that outcome focused quality assurance programs will result in elevating the standard of care provided to individuals with ESRD and provide a benchmark with which to evaluate the care provided by dialysis providers. The benefit of such programs will aid not only individuals with ESRD through higher quality care, but also aid the Medicare ESRD program through cost savings associated with greater efficiencies.

Epogen® (EPO) Reimbursement

In the course of receiving dialysis treatments, individuals with ESRD often times require the administration of certain drugs. The cost of some of these drugs are included in the dialysis composite rate while others are separately reimbursable by Medicare. One such drug that Medicare currently reimburses separately from the composite rate is EPO. DCI strongly believes that Medicare should continue to separately reimburse providers for EPO supplied to individuals with ESRD. While including EPO in the composite rate may save Medicare money in the short run, the adverse effects which would result from such a shift will far outweigh the monetary savings realized.

One of the side effects of ESRD is that the kidneys often times cannot produce erythropoietin, a glycoprotein necessary for the production of red blood cells. As a result, individuals with ESRD often contract anemia which leads to other medical complications. However, the use of EPO, a synthetic version of erythropoietin, allows the body to produce red blood cells, thus avoiding anemia and the resulting complications. Medicare currently reimburses EPO on the basis of actual doses administered. At present, this rate is $10 per 1,000 units of EPO. DCI feels that the current reimbursement mechanism ensures that individuals who require EPO will receive the drug.

To the extent EPO is included in the dialysis composite rate, some providers may have a disincentive to provide EPO to individuals with ESRD who would benefit from its use. Since providers will receive the same rate regardless of whether EPO is used, many providers may elect to not administer EPO and save the cost otherwise associated with procuring the drug. To the extent the patient contracts anemia which leads to other complications, the cost of such complications will be borne by another provider (such as a hospital); ultimately Medicare will incur the cost of such complications.

As a result, not only will it be more cost effective for Medicare to reimburse EPO in the first instance, but by removing any element of cost justification on the part of providers, individuals with ESRD will be guaranteed to receive medically necessary treatments integral to their care.

Extension of Coordination Period

Under the current Medicare ESRD program, once an individual is diagnosed with ESRD and becomes Medicare eligible (after a 3 month waiting period), Medicare assumes secondary payer responsibility for the individual's dialysis expenses for an 18 month coordination period. During this period, the individual's employer group health plan or other private insurance assumes the primary responsibility for the individual's dialysis related expenses. DCI feels that extending the duration of this coordination period from 18 months to 24 months will result not only in a benefit to the Medicare ESRD program, but also a benefit to individual's with ESRD.

Requiring private insurers to remain primary payer for an additional 6 month period will result in several distinct benefits. First, the extension of this period will allow Medicare to save approximately $25,000 per patient. With approximately 60,000 new patients undergoing dialysis each year, the savings associated with such a change would be substantial. These savings can be used to fund programs such as quality assurance programs and inflation updates for dialysis providers, all of which will benefit the Medicare ESRD program, dialysis providers and individuals with ESRD.

Secondly, requiring private insurers to remain primary payer for an additional 6 month period will require these insurers to assume a greater responsibility for the care and treatment of their enrollees with ESRD. Under the current system, the short period of responsibility (18 months) for enrollees with ESRD provides private insurers little incentive to maximize efficiencies. This situation occurs because unlike the health care costs of other enrollees which can be recouped over time, enrollees with ESRD require costly treatments continually during this period which will not be recouped over time. However, extending this period will provide insurers with more of an opportunity to increase their efficiency through beneficial relationships with dialysis providers in an effort to better manage their enrollees with ESRD.

As a corollary, requiring private insurers to assume an increased responsibility for the care of their enrollees with ESRD will likely result in the expansion of managed care relationships between insurers and dialysis providers. The proliferation of individuals with ESRD who are covered by managed care programs from the current low percentages will generate greater amounts of data with which to evaluate the feasibility and benefits, if any, of shifting the Medicare ESRD program from a fee-for-service model to a managed care model.

In favoring a longer coordination period for individuals with ESRD, DCI recognizes that too long a coordination period would be counterproductive and work to the detriment of individuals with ESRD. Faced with the possibility of unduly long periods of responsibility, many employers or private insurers might be reluctant to become associated with individuals with ESRD because of the high costs associated with caring for such individuals. This reluctance might hinder the ability of individuals with ESRD to shift employment or obtain replacement health coverage. Consequently, DCI feels that a 24 month coordination period would achieve the desired shift in responsibility without endangering the ability of individuals with ESRD to obtain employment or health coverage.

Inflation Updates

DCI feels that updating the dialysis composite rate to reflect the impact of inflation will enable dialysis providers to continue providing the highest quality of care possible to individuals with ESRD. The composite rate dialysis providers receive for dialysis treatments is at approximately the same rate as existed when Medicare first established the composite rate in 1983. Although dialysis providers have suffered inflationary effects since that time, the dialysis composite rate has remained constant.

Medicare is the primary payer for the vast majority of ESRD patients. Consequently, the composite rate for dialysis treatments establishes the parameters of providers' revenues. The failure of Medicare to grant dialysis providers inflation updates has resulted in a situation where providers' per treatment revenue has remained constant, yet per treatment costs have increased consistent with the rate of inflation.

While the composite rate for dialysis has remained insulated from the effects of inflation, the operational costs of providers have not fared so well. Costs such as salaries, benefits, dialysis supplies and equipment have increased because of inflation and technological advances, and providers have been forced to absorb such increases. Aggravating this situation is the fact that items which Medicare historically reimbursed separately, such as albumin, mannitol and oxygen use, have been bundled into the dialysis composite rate, further increasing the costs of dialysis providers. It has been estimated that providers' costs will increase 3.7% in the next year. However, since providers have not received corresponding increases in revenues to offset the inflationary effects on their costs, providers must attempt to provide the same level of care for ESRD patients on reduced margins. In time, this tightening of the gap between revenues and costs will force many providers to make adjustments in an effort to maintain their facilities. Such adjustments will likely change the dynamic of access to services and the nature of the services provided. DCI believes that most dialysis providers already have cut costs as much as possible and that further cuts in response to inflationary pressures will compromise the quality of care these providers provide.

Providing annual inflation updates to the dialysis composite rate not only will allow providers to continue to provide the quality of care ESRD patients require and deserve, but it will also grant dialysis providers the same consideration Medicare grants to other Medicare providers. Since the services provided to ESRD patients are equally important as the services provided to other Medicare beneficiaries, inflation adjustments to the dialysis composite rate should be equally available to dialysis providers.

DCI would like to thank the Subcommittee of Health for its kind consideration of the issues we have addressed in this statement and express our willingness to assist the Subcommittee in increasing the benefits the Medicare ESRD program generates for individuals with ESRD.

STATEMENT OF DONALD K. GALLION, SR. SUBMITTED TO THE SUBCOMMITTEE ON HEALTH OF THE COMMITTEE ON WAYS AND MEANS HEARING ON MEDICARE END-STAGE RENAL DISEASE PROGRAM APRIL 3, 1995

My daughter, Elizabeth A. Greeson, was a healthy, insured working mother of one son. However, near the end of her second pregnancy, Elizabeth began to experience complications, including taking on excess fluid. Her son, Matthew was born by "C" Section on July 15, 1988. Elizabeth remained in intensive care for many weeks, full of fluid. The doctor in charge at that time, treated Elizabeth with pills, in an attempt to dry up the fluid. This medication did not work and in the end, the fluid build-up damaged her heart. To make things worse, Elizabeth was later diagnosed with LUPUS.

After Elizabeth's employer-provided insurance paid out thousands of dollars under the COBRA Act, Elizabeth was placed on Medicare because of her end-stage renal disease-related disability.

Elizabeth was required to travel approximately thirty miles round trip to Atlanta, Georgia, every Monday, Wednesday and Friday to receive dialysis treatment. She was informed by her doctor that she would have to continue traveling to the Peachtree Dialysis Center in order to continue to be provided care by her physician, Dr. Donna Craig. I did not know until after Elizabeth's death that Dr. Donna Craig owned 20% of Peachtree Dialysis Center. Also, this dialysis center was controlled by one man in Florida who owned centers within the states of Florida, Georgia and California.

After Elizabeth's death, I requested that the Inspector General of Atlanta, Georgia, investigate the Peachtree Dialysis Center. This request was made after I had been informed by the center's staff that Elizabeth was not being properly dialyzed. Congressman Mac Collins (GA-3) and I did not know until June 1994 that an unannounced inspection was conducted by Georgia Regulatory Services, during November 1993. During this inspection, the Peachtree Dialysis Center was cited for sixteen violations. Furthermore, I later learned that during 1991, 1992 and 1993, this center was cited by Georgia Regulatory Services while HCFA took no action and apparently ignored these violations.

My CONCERN is the lack of regulatory oversight of these dialysis centers; and the failure to protect the patients.

My MOTIVATION is the death of my daughter, Elizabeth A. Greeson, who was a patient of the Peachtree Dialysis Center.

After her death, I looked very closely into that center and discovered that it had been in repeated violation of regulatory standards, while NO action was taken by HCFA or Georgia Regulatory Services.

As was the case for Elizabeth, most dialysis center patients have expended their private insurance and are receiving government coverage through the End-Stage Renal Disease program. These centers make an enormous amount of money from this federal government program. If the regulatory agencies in charge fail to protect the American people, who are paying for these programs? Who will protect them? WHO IS ENSURING THAT THE REGULATORS DO THEIR JOB?

Why has it been so difficult for me to get information? I can only assume there may be something to hide.

How can we correct this situation, before other unsuspecting dialysis patients are subjected to this substandard life-threatening mistreatment?

In my daughter's name, I want to improve the regulation of these centers. I am asking that the following changes be made to make these centers operate safely and professionally.

1. Require all dialysis centers under Medicare, to provide services on a 24 hour basis; seven days per week; and 365 days per year.

2. Require all centers to have a trained, registered nurse on duty at all hours. A kidney doctor should be on call on a twenty-four hour basis.

3. Require all dialysis centers to have a coronary program in effect twenty-four hours per day. Properly trained personnel should be on duty to handle emergency coronary problems.

4. Require all dialysis centers to provide beds that can be used when a patient is forced to be removed from the dialysis machine before being fully dialyzed. Once this patient regains the ability to be placed back on the machine, then this patient would be fully dialyzed before leaving the center. If the patient is too sick to be fully dialyzed, then it would be the responsibility of the center to have this patient transported to a nearby hospital.

5. Require State Regulatory Services to inspect these centers on a six month schedule. HCFA should be required to enforce any corrections needed to correct violations. Centers that continue to violate the regulatory requirements, should be closed.

Congressman Mac Collins has spent a great deal of time meeting with me, because he understands just how serious this dialysis center problem has become. I urge each Member to support Congressman Collins and pass dialysis patient protection legislation.

Thank you for your support.

Options for Improving Cost Effectiveness of Medicare End Stage Renal Disease (ESRD) Program by Increasing Organ Donation

Submitted to the Hearing Record of the
House Ways and Means Subcommittee on Health of
April 3, 1995

By

Carol Beasley, Managing Director
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Introduction and Overview

Work done by HCFA confirms that if more end-stage renal disease (ESRD) patients could receive kidney transplants, rather than relying on hemodialysis, their quality of life would improve and the Medicare ESRD program would save money, an estimated $42,000 per patient transplanted.[1] Therefore it would be worth investing resources to increase kidney donation.

Work done by The Partnership for Organ Donation in collaboration with eight organ procurement organizations (OPOs) and hundreds of hospitals in the United States confirms that only about one third of the medically suitable potential organ donors actually donate organs.[2] By identifying all potential donors and asking families to donate in a systematic and sensitive manner, donation could substantially increase. Furthermore, most potential donors are found in a relatively few large hospitals, which allows interventions to be focused and efficient. Our work confirms that there is substantial opportunity to increase donation by focusing on a few hospitals and implementing a systematic donation process. Some thoughts on how Medicare could facilitate effective donation practices follow:

General Guidelines:

To have the desired impact on organ donation, any programs or policies initiated by Medicare should be guided by the following principles:

- Use performance measures and quality assurance approaches. Organ donation lends itself well to a quality assurance approach. Large hospitals could be required to analyze their donor potential and to track donation outcomes for all suitable cases. This should be done with an established medical record review methodology. OPOs can be helpful in carrying out and analyzing medical record review.

  As a rule of thumb, any acute care hospital with more than 350 beds should have a medical record review at least annually; and hospitals with between 150-350 beds should review their donor potential and performance at least every two years.

  One option is to require a specified performance level – maybe 50% realization of potential organ donors – and those major institutions that

fall below the benchmark, should be required to develop donation protocols as a high priority.

- Focus on modifiable elements in the organ donation process that have been shown to correlate with higher rates of donation,[3] specifically:
  - Protocols to ensure early identification and referral of all potential organ donors to organ procurement organizations (currently about a third of eligible families are not asked -- despite required request policies).
  - Requiring OPO procurement coordinator participation in family request, along with trained hospital staff
  - Clear explanation of brain death to families, and raising donation only after the family has been informed of death (decoupling).

- Strategically target those hospitals most likely to care for potential donors typically large hospitals (greater than 150 beds) that are trauma centers and are affiliated with medical schools.[4]

Perspectives on Using Economic Incentives to Encourage Organ Donation:

The Partnership urges caution in applying direct financial incentives. So far, the reaction of the public and health professionals[5] to financial incentives for organ donation has been at best lukewarm. It is essential to preserve public trust in the donation and transplantation system, and financial incentives have the potential to erode this.

Financial incentives at the hospital level could exacerbate public fears that potential organ donors receive less attentive medical care, or that a black market in organs could be operating in the U.S. Members of ethnic minority groups are especially likely to harbor these concerns, potentially depressing even further the low rate of organ donation among ethnic minorities.[6]

Options for Structuring Economic Support for Organ Donation

While caution is called for, there may be a strategy for targeting financial support to remove *institutional disincentives* for organ donation, particularly in those large hospitals with significant donor potential that are not transplant centers. Large hospitals, especially public hospitals caring for significant numbers of indigent or underinsured patients, seldom have the resources to devote to improving organ donation practices. The public would benefit from supporting the adoption of good organ donation practices in these hospitals.

Grants could be offered to support the creation of in-house teams to diagnose donation performance and institute effective donation protocols. Continuing funding could be contingent on documenting significant gains in donation effectiveness. Because donor potential is concentrated, grants could be targeted to the largest 500-600 hospitals in the United States, enabling access to 70 percent or more of all the potential donor cases in the country.

To facilitate the administration of these grants, the following provisions could be made:

- Focus initially on hospitals with 350 beds or more. If limiting the program further is a consideration, support could be restricted to those hospitals that are <u>not</u> also solid organ transplant centers, since transplant centers presumably have some inherent incentive to improve organ donation performance.
- Create a very simple application process by requiring minimum criteria to be met, for example: documented medical record review showing a minimum of 10 potential organ donor cases in the prior year.

- Provide a standard grant of $5,000-$10,000 with a set of guidelines about how the funds are to be used, rather than asking each hospital to design a program individually.

The other area in which to consider financial incentives is living kidney donation. Living kidney donation has a number of advantages over cadaveric donation, including more control over the scheduling of surgery, and close tissue matching when blood relatives donate. A preliminary pilot study[7] suggests that there is wide variation in practice around living donation. Many believe that lack of financial coverage for family members' time away from work operates as a powerful disincentive to donate. HCFA might consider a pilot program to identify more accurately the current financial disincentives in the system, and test the impact of providing some financial support to living donors.

The Partnership for Organ Donation has extensive experience in working with hospitals to improve organ donation. We would welcome the opportunity to provide input to the design of any program intended to increase the effectiveness of our organ donation system in the United States.

References:

[1] Eggers, Paul, "Comparison of Treatment Costs Between Dialysis and Transplantation," Seminars in Nephrology, 12:3, May 1992, pp 284-289

[2] Gortmaker, et al, "Organ Donor Potential and Performance: The Size and Nature of the Organ Donor Shortfall." Unpublished draft

[3] Helander et al, "Standards of Practice Needed to Ensure Effective Donation Process," Abstract presented February 1994, Society of Critical Care Medicine

[4] This finding comes from a study funded by the Division of Organ Transplantation. Results have not yet been published, but preliminary data are available on request to The Partnership for Organ Donation

[5] Altshuler and Evanisko, "Financial Incentives for Organ Donation: The Perspectives of Health Care Professionals," Letter published in JAMA, April 15, 1992

[6] "The American Public's Attitudes Toward Organ Donation and Transplantation," conducted for The Partnership for Organ Donation, Boston, MA, February, 1993.

[7] Survey on living kidney donation conducted at the American Society of Nephrology meeting, October 1994 by The Partnership for Organ Donation

TESTIMONY OF LISA R. KORY, BSN, RN, CPTC
TRANSPLANT RECIPIENTS INTERNATIONAL ORGANIZATION, INC.

Transplant Recipients International Organization, Inc. (TRIO) welcomes the opportunity to comment on the Medicare End Stage Renal Disease Program.

TRIO is a member supported organization with 3,000 Members world-wide (32 national and 2 international Chapters). TRIO was founded in 1983 to support patients waiting for organ transplants, individuals who have been transplanted, their family members, and the families of organ donors. Our mission is to provide accurate and timely information on all aspects of the transplant process, including:

- to be there on a one-to-one basis for these individuals throughout the time of hospitalization before and after transplant;
- to provide a community of interested individuals who understand what the candidates and recipients and their family members, and donor family members have gone through;
- to serve as a national voice on transplant issues; and
- to increase donor awareness.

Who better to comment on the ESRD Program than those who have experienced renal failure, life while on dialysis and the life-saving benefits of kidney transplantation.

The following comments outline TRIO's position regarding the privatization of the ESRD Program, proposed increases in the primary payer status, the need for increased organ donation and the life-enhancing benefits of organ transplantation.

Privatization of the ESRD Program

TRIO understands the importance of deficit reduction and fiscal responsibility but primarily, we are concerned for the welfare of ESRD patients. Despite recent testimony regarding the cost-effectiveness of managed care, it is unclear whether or not the ESRD Program could be replicated by managed care facilities and still provide quality care with unlimited access and without regard to economic status or race.

While dialysis is a costly therapy, it is important to point out that dialysis costs have remained stable over time. In his 1992 study, "Comparison of Treatment Costs Between Dialysis and Transplantation," Paul Eggars, of HCFA, indicates that payment per dialysis in 1989 was around $125, representing a 61% reduction in inflation adjusted dollars from the payment level in 1974 ($138)[i]. In their study "Cost-effective care and endstage renal diseases: A billion dollar question," Roberts et.al., discovered that home dialysis, as an alternative to in-center dialysis treatment, produced a savings of $7,000 to $8,000 per life-year[ii].

Privatization of the ESRD Program is not necessarily the answer to reducing costs. Alternatives to in-center dialysis; the most cost-effective being home dialysis and transplantation, need to be fully explored. Given the profit of in-center treatment and the financial incentive for doctors to recommend in-center hemodialysis however, it may be difficult to alter prevailing medical opinion.

Since its inception in 1972, the ESRD Program as administered by HCFA, has treated **all** eligible ESRD candidates without regard to age, sex, race or religion. Prior to 1972, ESRD care was characterized by inequities, with hospital boards deciding who would, and wouldn't, receive the life-saving benefits of dialysis. It is all too possible that an analogous situation would exist under an ESRD system controlled by managed care providers. In short, managed care providers would be the "gate-keepers," providing coverage to a limited number of ESRD patients while excluding older ESRD populations and those with limited financial resources. Faced with rising costs of treating ESRD patients, managed care providers will have greater incentive to reduce expenditures, perhaps by limiting ESRD for those populations at greater risk of hospitalization or those populations unable to afford rising premiums.

Given the steady ESRD patient population growth (9% annually), the aging of the ESRD population and the level of comprehensive specialized care required, the multi-billion dollar costs of ESRD are comprehensible. Continued protection from rising inflation, forthcoming analysis of ESRD capitation studies, and the exploration of alternatives to in-center dialysis, will serve to slow rising costs and reduce Medicare expenditures.

Primary Payer Provision

TRIO supports the current system, with Medicare as secondary payer for 18 months. Undoubtedly, extending the secondary payer provision from 18 to 30 months would reduce Medicare costs in the short-term; however, these gains would most likely be offset by the negative impact on ESRD patient life-style and care.

If coverage were not dropped altogether, some combination of measures would be implemented to reduce expenditures. In all likelihood, employers would be unwilling to hire ESRD patients or those predisposed to ESRD, such as diabetics and minorities. Lower reimbursement rates would be implemented, with some insurers eliminating ESRD coverage outright. And, in some instances, we fear that an extension could serve to drive private insurance costs even higher, leaving individuals with no choice but to drop their coverage. In each one of these cases, ESRD patients would revert back to Medicare with potentially greater health problems, requiring even greater government expenditures.

Government involvement with the ESRD program ensures the extension of benefits to all in need of care. Extending the primary payer provision makes economic sense, but the decision to reduce costs should be tempered by the resultant negative effects on patient care. These may include:

- loss of coverage for those who want to work and utilize private insurance;

- the possibility of reductions in Epogen dosing as insurers reduce reimbursement levels; and
- premature death for those patients who loose or can't afford coverage.

Organ Donation

Organ transplantation is in part a victim of its own success. With improvements in technology more and more patients become candidates for life-saving kidneys, livers, hearts, lungs and other vital organs. Tragically however, 8 people die each day while on the waiting list. Simply put, a rising demand in transplants and a flat supply of adequate donors means a severe shortage in organs for transplantation.

There are nearly 40,000 people waiting for an organ transplant, with greater than 28,000 awaiting a healthy kidney. In addition, there are 500 children waiting to benefit from transplantation. Half of these children will die, and every thirty minutes another child will be added to the pediatric waiting list[iii]. **The need for increased organ donation can not be stressed enough!**

Transplantation as a Cost-Effective Alternative

Numerous studies have been conducted that compare the long-term costs of dialysis and transplantation. In many cases, when looked at over a period of between 7 to 10 years, transplantation has been the least costly option for treating ESRD patients.

With the advent of cyclosporine, and other immunosuppressive drugs, the survival rates of kidney recipients have shown a marked improvement. According to data provided by the United Network for Organ Sharing (UNOS), in 1993, the first-year survival rates for living donor recipients was 93.8%.

Paul Eggers, in the aforeto mentioned study, concluded his findings with the following comments,

> The results of this study confirm the widely held belief that kidney transplantation is, over time, a less costly alternative to maintenance dialysis. The high initial cost of transplantation is recovered in about 4.5 years (3 years for a living-related donor) with a net discounted savings of about $42,000 over a 10 year time frame. To the extent that transplantation may result in superior patient survival rates and a higher quality of life, the results would more forcefully favor transplantation as the preferred renal replacement therapy. Combined with the better quality of life assumed to result from transplantation, it appears that transplantation is the preferred alternative for ESRD patients both from a medical as well as an economic perspective (288)[iv].

TRIO is not encouraging a doing away of the ESRD program, and we concede that older individuals currently on dialysis are not necessarily adequate candidates for transplantation. With proper incentive however, kidney transplantation for a significant number of dialysis patients is realistic and would reap benefits that exceed current ESRD costs.

We urge the Congress to consider implementing our recommendations which will help assure that the ESRD Program continues to serve the needs of those Americans in saving them from premature deaths and provide them with the opportunity for a second chance to lead productive and more rewarding lives.

Transplant Recipients International Organization, appreciates the opportunity to provide comments on the ESRD Program. We have seen first-hand the benefits of this program and encourage your continued support. We would be happy to speak with the Members of the Subcommittee for any further clarifications or recommendations.

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[i] Eggers, Paul, "Comparison of Treatment Costs Between Dialysis and Transplantation," Seminars in Nephrology, Volume 12, No. 3 (May), 1992: pp 284-289.

[ii] Tousignant, Pierre, et.al., "Transplantation and Home Hemodialysis: Their Cost-Effectiveness," Journal of Chronic Disease, Volume 38, No. 7, pp 589-601.

[iii] UNOS, March 31, 1995

[iv] Eggers, Paul, "Comparison of Treatment Costs Between Dialysis and Transplantation," Seminars in Nephrology, Volume 12, No. 3 (May), 1992: pp 284-289.