S. HRG. 106–685

KIDNEY DIALYSIS PATIENTS: A POPULATION AT UNDUE RISK?

HEARING

BEFORE THE

SPECIAL COMMITTEE ON AGING UNITED STATES SENATE

ONE HUNDRED SIXTH CONGRESS

SECOND SESSION

WASHINGTON, DC

JUNE 26, 2000

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KIDNEY DIALYSIS PATIENTS: A POPULATION AT UNDUE RISK?

MONDAY, JUNE 26, 2000

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, DC.

The committee met, pursuant to notice, at 1:32 p.m., in room 628, Dirksen Senate Office Building, Hon. Chuck Grassley, (Chairman of the Committee) presiding.

Present: Senators Grassley, Breaux, and Wyden.

OPENING STATEMENT OF SENATOR CHARLES E. GRASSLEY, CHAIRMAN

The CHAIRMAN. I want to begin by thanking Senator Breaux and other members who will be along for taking time out of their busy schedule to attend a very important hearing. In addition, we have had a lot of witnesses, both within government and outside of government, that have taken time out of their busy schedule to be with us to study this issue, to give us their analysis of the situation, both from the standpoint of a consumer, as well as those who have studied what the problems are and what some of the solutions to the problems are. Their testimony will greatly assist the committee in doing our best to address the quality of care that kidney dialysis patients receive.

And for those of you who came just to listen, we thank you for your interest in this. Our committee usually ends up with a full committee room of people and those of you who maybe are not in here yet, we apologize for the room not being larger.

This hearing focuses on the quality of care of close to 300,000 patients on kidney dialysis throughout the country. In spite of the excellent care many dialysis facilities provide, the committee's investigation has found evidence of poor treatment, as well. Shoddy treatment of people with kidney problems under any condition is inhumane. Bleeding to death is never acceptable, like John Floyd Martin of Florida, who was left to bleed to death when a technician went to take a phone call and failed to properly connect him to the dialysis machine.

It is important that taxpayers receive the quality of care that ought to be given in exchange for their dollars. But most important is the quality and safety of patient care and the quality of the patient's life.

Now, we have a chart here that I would like to refer to. Chart A is here and it shows that 300,000 or more end stage renal disease patients represent .8 percent of the Medicare population but

account for 5.2 percent of the total Medicare outlays. That adds up to about $12.8 billion annually.

The largest portion of dialysis patients are those who are 65 and up. Of particular concern to this committee is the fact that this population continues to increase at the rate of 7 to 8 percent per year. This is largely due to the growth in the elderly American population. While it is gratifying that more and more people are living longer, there are increasing concerns about the ability to serve this growing dialysis population and serve it well.

Although each kidney dialysis patient is extremely vulnerable, I am particularly concerned about the elderly, who are, of course, the focus of our committee, the Committee on Aging. They are the most vulnerable and least able to recover financially or emotionally or medically if they do not receive the best quality of care that medical science has to offer.

Our first witness, Dr. Bays, will describe the differences in his quality of life on dialysis depending upon the care that he receives. With less dialysis, Dr. Bays was sick every day, had no quality of life, and was resigned to dying within 3 years. Now, by nocturnal home dialysis, he has regained his life and expects to live a full and complete life.

The next witness, Mr. Smith, will describe his experiences with dialysis and transplants over a 23-year period of time. He will describe the marked decline in the skill of dialysis staff and how this almost cost him his life. The committee staff have interviewed numerous other dialysis patients with similar stories but too many to come in here and speak to us in person.

At this point let me say how much I appreciate the willingness of Dr. Bays and Mr. Smith to testify. They must dialyze to live. That fact alone has discouraged many patients interviewed by this committee from coming forward today to publicly testify.

So I understand the courage that it takes for them to be here today. Therefore I want to make it clear that retaliation against congressional witnesses is a crime. I intend to use all tools available to me to ensure that there is no retaliation against either of these witnesses for their testimony today.

Today this hearing will examine several issues related to quality of care for kidney dialysis patients. First we will examine the role of the Health Care Financing Administration and the 18 network organizations and how well each carries out their responsibilities to oversee the kidney dialysis program.

As of 1999, the Health Care Financing Administration surveyed only 12 percent of existing dialysis facilities. This, of course, is a dramatic drop from 1993, when more than half of the facilities were surveyed. It is extremely important that the delivery of care is reviewed periodically to ensure that patients receive the best possible care.

Next we are going to review several quality issues, including adequacy of dialysis, reuse of dialyzers, and training of technicians. Other than some voluntary guidelines that exist, there is a distinct lack of rules addressing these issues and other dialysis issues. The committee recognizes that medical science and research are at the heart of many of these issues. However, one purpose of this over-

sight hearing is to determine the extent of the medical research and the consensus within the medical community on these issues.

Also, the purpose of this committee's investigation is to encourage a consensus on dialysis issues. Much research has been conducted over the years with little resolution. It may be time to ensure that the proper research is conducted that will expedite resolution of these important health care issues.

Adequacy of dialysis refers to the amount of time that patients spend in dialysis. This is a period in which the patient's blood is circulated out of the body through the dialyzer for cleansing and returned to the body free of toxins. Many patients have raised concerns that they are subjected to kind of a Jiffy Lube approach where they are rushed through that process. In other words, some patients believe that longer dialysis can produce increased quality of life and longer life. It has been suggested that some facilities are driven by the profit motive and little concern about patients' health. It is suggested that these facilities schedule as many patients as possible to collect Medicare payments.

Let me hasten to add at this point that I recognize that there are many excellent providers of dialysis in this country. I have an Iowa constituent who has told me of the wonderful care that he has received at a facility in Iowa. However, this committee has reviewed numerous studies worldwide about the adequacy of dialysis. Although there are many studies that address this issue, there is no clear definitive work. Moreover, there are no clear standards enforced by the Health Care Financing Administration or the Networks. These are serious matters that must be addressed.

Another important issue is reuse of dialyzers. The United States is the only industrialized Nation that reuses dialyzers to a large extent. One report shows that approximately 85 percent of all dialysis facilities reuse dialyzers. A dialyzer, which acts as a patient's artificial kidney, is a critical part of the dialysis process. To the extent that the dialyzer is unsafe in any way, patients are at risk. Again there is no clear definitive consensus on this issue in the United States and we encourage that consensus be made as soon as possible.

In addition, much evidence exists about the decline in skilled staff who work with kidney dialysis patients every day. Approximately 20 years ago registered nurses were the primary caregiver in dialysis clinics. Today most of the staff are made up of lesser skilled technicians. As a result, it is imperative that adequate training is provided to these technicians for dealing directly with patients' lives.

Once again there is no established requirement nationwide with regard to the level and content of the training of dialysis staff. Patients like Professor Robert Sollod, Professor of Psychology at Cleveland State University, who is a dialysis patient, have had to resort to putting up signs just to get a minimum of safety. And we have a copy of Dr. Sollod's sign over here that he keeps in his dialysis station just to remind staff to wash their hands. It says, with a picture of the hands, "Please be sure that your hands are clean, that you have new gloves before working on me or with tubes containing my blood. Thanks for your consideration." Now in summary, there is a lack of oversight of the dialysis industry. This, cou-

pled with serious quality issues that remain unresolved in the United States, leaves a vulnerable kidney dialysis population at risk.

It is with these thoughts in mind that the committee convenes this hearing. My hope is that these hearings will be constructive and I look forward to hearing the testimony of today's witnesses to address these issues.

Now we have an opportunity to hear an opening statement from my friend and colleague and faithful cooperator in the work of this committee, Senator Breaux.

STATEMENT OF SENATOR JOHN BREAUX

Senator BREAUX. Thank you very much, Mr. Chairman, and thank you once again for putting together a panel of witnesses which I expect fully to be very informative and hopefully help us find some solutions to the problems of inadequate inspection of the dialysis facilities around the country.

We have over 304,000, I think at last count, people in this country who participate in the end stage renal dialysis program that Medicare pays for. My own State of Louisiana has the highest percentage of people who are facing this illness of any state, second only to the District of Columbia, in the entire country. It is interesting that while the number of patients reflects less than one percent of the total Medicare patients, it does account for over 5 percent of the total outlays or money being spent to provide this very important service. It is almost a $13 billion annual cost for the end stage renal dialysis program.

That is a very large amount of money and I think our job here in the Congress is to make sure that we are doing everything to see that the quality of service that that $13 billion is paying for is world class and I think that it is.

Are there problems? Of course. Can it be improved? Yes. And the purpose for us being here today is to look at ways in which we can make it work better than it has been in the past.

I do want to say I think, and others will agree, that it does provide a service that is incredibly important and that by and large, when people have this type of treatment presented to them, they can know that it is being done properly.

I think that it is interesting that HCFA, which it does on so many occasions, basically contracts out with the States to do the inspection. And I know that there are some States—my own is one of them—that has been particularly strapped financially and it is a question of whether the States have the capacity to perform the inspections and whether this is not something that HCFA should be doing themselves. So I think the witnesses will be able to help us find answers to some of these questions.

I want to make part of the record, Mr. Chairman, a well thought out letter that we received from Racineas Medical Care commenting on the hearings today and the recommendations that they have made, which they would like to have made part of the record. I think they are the nation's largest provider, support provider for these facilities and I think the comments that they have made are well taken and we are pleased to have them and I would ask that it be made part of the record.

The CHAIRMAN. Without objection, they will be part of the record.

And we are glad to hear from all sides on any issues and any suggestions. Even the weeks that follow this meeting, we will be glad to listen to points of view.

Thank you, Senator Breaux.

Now it is my pleasure to introduce the first panel. I have already referred to Dr. Bays and Mr. Brent Smith as being two kidney dialysis patients—Dr. Bays, a retired Dentist from Georgia. And Mr. Smith has been a 23-year veteran of dialysis and kidneys transplants and he is from Arizona.

Then we have studies on the end stage renal disease quality of care by the General Accounting Office and the Inspector General of the Department of HHS. Representing the Health and Human Services Inspector General is the Deputy Inspector General, George Grob, and representing the General Accounting Office is Dr. William Scanlon, Girector of Health Financing and Public Health Division.

So we are going to start with Dr. Bays and then Mr. Smith and then Dr. Scanlon and then Mr. Grob. Then we will have questions when we are all done.

Would you proceed, Dr. Bays.

STATEMENT OF W. KENNETH BAYS, D.D.S., DIALYSIS PATIENT, PELHAM, GA

Dr. BAYS. I am a retired Dentist 72 years old who practiced from 1952 until 1995. In August 1995 I was diagnosed with a massive cancer of the liver. At the time, I was semi-retired and living in North Georgia. Having practiced dentistry over 43 years, I was very aware of——

The CHAIRMAN. I think we are going to have to have you——

Senator BREAUX. Move that mike a little closer to your mouth.

The CHAIRMAN. Yes, I think about like that.

Dr. BAYS. OK, good. I am sorry.

I was very aware of educating patients and offering different treatment options. It had always been my belief and practice that the patients themselves had the right to final determination of their treatments. I was about to find the concept of patient education and patient determination would not exist in the world I was about to enter.

Other than a loss of my kidneys, my treatment for cancer was successful. I was, however, not prepared for what was coming next. It was much later before I understood the treatment options and choices available to me. I, of course, was entering into the very difficult world of the dialysis. In this world of dialysis, even though I am a Dentist and understand medical terms, I was appalled to find that dialysis patients have no right of self-determination. Never before had I been in a position where treatment options were not offered, much less explained.

Vascular access is the key to proper dialysis. Without the proper working access, you cannot dialyze a patient. I was referred to a vascular surgeon. There was no preceding exam or discussion of treatment. I was just set up for surgery. A vortex graft was put in instead of an A-V fistule. The graft is a treatment of last choice. I was now becoming fully involved in the wonderful world of num-

bers and dollars. I was just another money cow with a market value of $100,000.

I next went to the nephrologist in Georgia, who turned me over to his physician's assistant. I tried to get some information but was cutoff with the remark, "Patients who have never been sick have a hard time accepting."

I was taken on a walk through the clinic and my treatment was set up on a time slot basis so as to maximize the number of patients per day. I was dialyzed twice a week. As a result of inadequate treatment, my back itched as if there were a thousands mosquitos biting it. This was due to a buildup of phosphorus. This caused me to rub my back raw on the door facing. I had to force myself to eat, as well as watch my diet and fluid intake carefully. I also was taking eight times the normal dose of blood pressure medications because of the buildup of toxins.

I was sick all the time. Dialysis was hell. The cramping, changes in blood pressure, and the pain of being roto-rooted with a needle the size of a 10-penny nail by untrained personnel made me a nervous wreck. The cramping and changes in blood pressure were a result of removing the fluid from the blood too fast. I was at this facility for 7 months. I do not wish to name the facility in particular because this is a systematic problem with the industry.

I had to go to South Georgia on business so I set up an appointment at the Michell County dialysis facility. This facility is a branch of the Archbold Hospital in Thomasville, GA. Archbold is a nonprofit public hospital.

As of that day, I moved into a different world of medicine and the caregivers were nurses trained in dialysis. My doctor, Dr. Merrill Hicks, a nephrologist on rounds, stopped to talk. He explained to me that home dialysis existed. He further explained to me if I would do my part, I would have to take very few medications and would not have any diet restrictions. I now dialyze six nights, 8 hours at a time, a week.

I have been on dialysis for 3 years. The total cost of my care is substantially less than that of thousands of patients. I have become a productive member of society again. I expect to live a normal life within the confines of my impairment. I am one of the very fortunate few that had the means to get adequate treatment.

Approximately 2 years ago I became involved with Network 6. I was first on the consumer committee and then next on the board of directors. The board consists of 18 industry members and two patients. I found out very quickly that network was constructed for the betterment of the industry. One of the primary problems the network was concerned with was the noncompliance of patients and how to handle them. There is one in particular I remember quite well. A patient wanted to continue working. This interfered with the clinical scheduling so he was judged noncompliant.

The statistics that are collected by the network are, in my opinion, a joke. If you want to get the true data, you should get it from the back of the machines and compile it by a central computer. Wal-Mart keeps track of tens of thousands of items from thousands of stores. It would be child's play to create a data base of dialysis patients from the data collected from the machines. It is my belief this would upset the gravy train if it was done.

I never reuse a dialyzer. Reuse, according to the literature, degrades the efficiency of dialyzers to remove large, more toxic particles and the chemicals affect the proteins in the dialyzer to produce toxins.

Dialyzers are labeled single use only but as far as I can find by researching the literature, companies that make dialyzers have no protocol for reuse and only post warnings as to the problems of reuse. Also, the literature confirms reuse causes high mortality and more hospitalization, therefore, increasing the suffering to the patients and increasing the cost to the government.

My greatest fear is that my facility may be forced out by the for-profit companies. If this happens, I would lose my only supply and support. It would be back to the Jiffy Lubes 2½ to 3½ hours, three times a week.

A patient who has a lot of toxins and is very anemic has greatly diminished mental and physical abilities. They must have proper treatment to return them to a normal state in order to be able to educate them and get them involved in their rehabilitation. Thank you.

The CHAIRMAN. Thank you, Dr. Bays.

Now Mr. Smith.

STATEMENT OF BRENT SMITH, DIALYSIS PATIENT, CHANDLER, AZ

Mr. SMITH. Mr. Chairman and members of the committee, thank you for inviting me to testify today.

My exposure to the dialysis industry began in 1973, 2 weeks before my 18th birthday. A year later I received my first transplant, which was from my mother. Two months later, the kidney failed due to infection and I returned to dialysis.

In 1977 I received a second transplant from my grandmother. This transplant succumbed to complications in 1990. I returned to dialysis in the fall of that year. Soon after, it became all too clear that the entity providing treatment, its administration, the support staff and the standard procedures with which I was familiar had changed drastically.

The major concerns of dialysis patients fall within the following interrelated components. I have provided more detail in a longer statement submitted for the record. They are as follows: adequacy of dialysis, competency of patient care technicians, knowledgeable and disciplined nursing staff, facilities and technology, which is the machines, and accountability.

The adequacy of my prescribed treatment relies heavily on me, my discipline with regard to diet and food restrictions, and my oversight of my own dialysis treatment. Because I am very disciplined in my care, I can allow the dialysis machines to do their work. I have worked to become very knowledgeable in what is needed for my care. Other patients who are less familiar with the dialysis process are very vulnerable.

One of the areas that that needs to be addressed by research is adequacy of dialysis. I can only tell you from my personal experience that with the amount of time I dialyze, the better I feel. When I dialyze 4 hours each session, I feel better. When treatments have been shortened in the past, over time my energy levels are de-

pleted. In addition, complications may appear from fluid restrictions, such as higher blood pressure and shortness of breath. I and other patients feel very lethargic and have little appetite at all. I can only conclude that the amount of time on dialysis is a factor.

Second, in the year I started dialysis, the caregivers were mainly nurses from the top graduating classes, as well as medical students and other medical technicians. Almost every technician had a college degree and every technician had previous medical experience.

Today I see technicians with only a high school diploma. In Arizona a manicurist is subject to more licensing than a dialysis technician is.

When I first returned to dialysis, I had technicians handle my blood and my life who were convicted criminals, strippers and refrigerator technicians. The ratio of patients to technicians, at times, is now five or six patients to every technician. This is not safe and it does not work.

A main worry for dialysis patients is vascular access. A patient recently told me of a treatment where it took eight attempts by technicians to initiate her treatment—eight sticks by 16 gauge needles. Not only is this painful but it increases the risk of infection and could destroy that access. There are limits to vascular access with each patient. When vascular access runs out, a patient can no longer dialyze and may surely die. Many other patients have told me of similar occurrences.

Another example of training deficiencies among dialysis technicians stems from my personal experience. In 1994 I suffered an extended period of appetite and weight loss. As part of my routine assessment prior to each dialysis session, I explained that I had not been eating properly. I reported this for almost 4 months. The food I was eating did not provide me with sufficient potassium for my prescribed potassium bath. During the fourth month, during the third hour of a 4-hour treatment, I suffered a cardiac arrest attributable to the low potassium in my system. The attending technician did not recognize this problem. Another technician took over to attempt resuscitation until the paramedics arrived.

Upon arrival, emergency room records reflected a potassium level of 2.9, well below the 3.5 recommended range. Discharge summary records show fibrillatory arrest secondary to hypokalemia, which is low potassium. The dialysis technicians did not correlate the loss of my appetite with the low potassium bath. The seriousness of the problem and possible results were never brought to my attention or to the attention of my charge nurse, the dietitian or even my physician. This event was completely preventable.

In addition to the competency and training of dialysis staff, I believe that the staff must be knowledgeable and disciplined. I have witnessed instances where floor nurses lacked familiarity with the machines and their functions. These are complicated machines that stand between life and death of dialysis patients. Lack of knowledgeable staff exposes patients to dangerous circumstances.

Moreover, lack of discipline or failure to pay attention is a primary source of incidents affecting patient care. On one occasion soon after my return to dialysis, staff drained off too much fluid from me during dialysis. This exposed me to a crash in my blood pressure and loss of consciousness. I am aware of another instance

where a patient bled to death because no one was watching while the patient's blood inadvertently drained into a trash can while the patient slept.

It is instances like this that cause me to do everything in my power to stay awake throughout my 4-hour dialysis and try to watch every move of the staff attending to me and to watch the fluctuations on the dialysis machines.

Worn, older, and overused machines are not as effective or as efficient.

One of the most important aspects of patient care relates to the relationship with the dialysis staff. Staff must be accountable to the level of care provided to patients. They must demonstrate strict adherence to set policies and procedures. Appropriate discipline must be administered for breach of policies and procedures. This is a life and death situation. In my experience, technicians are rarely written up forminor or major infractions involving patient care. I have seen technicians ignore the glove policy, exposing patients to possible infection, and I have seen technicians reading magazines while attending to other patients.

In closing, throughout my life I have strived to avoid the label "dialysis patient" and the stigma associated with it, yet today I appear before you in a public forum as a dialysis patient because of the importance of the issues being discussed here. Patients can and do lead purposeful lives. However, it has become an increasing burden to do so. Monitoring a technician's abilities during every treatment week after week is a tremendously stressful undertaking for a dialysis patient. Enduring the limits and inadequacies of the present system of dialysis compound the already difficult treatment into an intolerable, unjustifiable and inexcusably frustrating experience.

My purpose today in appearing before this committee was to present the life of a dialysis patient to you. It is my life and that of many others. We live it every day. You cannot possible understand it unless you are a dialysis patient. I sincerely hope you or a loved one will never experience it but I do, with dignity and all due respect, implore you to do something about it. Thank you.

[The prepared statement of Mr. Smith follows:]

Special Committee on Aging
Hearing on End-Stage Renal Disease
Statement of Brent Smith
June 26, 2000

Mr. Chairman and Members of the Committee. Thank you for inviting me to testify today.

My name is Brent Smith. My exposure to the dialysis industry began in 1973, two weeks before my 18th birthday. A year later, I received my first transplant which was from my mother. Two months later, the kidney failed due to infection, and I returned to dialysis. In 1977, I received a second transplant from my grandmother. That transplant succumbed to complications in 1990. I returned to dialysis in the fall of that year. Soon after, it became all too clear that the entity providing treatment, its administration, the support staff, and many of the standard procedures with which I was familiar had changed drastically.

Over the last ten years, as a patient, I have witnessed the gradual decline in competency of those given the responsibility of my care. In my view, efficiencies intended to enhance the financial position of the providing companies expose patients to great risk and may even hasten their demise. This trend continues and worsens each years as providing companies focus on bottom line management and not patient care.

The major concerns of dialysis patients fall within the following five interrelated components. I have provided more detail in a longer statement submitted for the record. They are the following:

- Adequacy of dialysis
- Competency of patient care technicians
- Knowledgeable and disciplined nursing staff
- Facilities and technology (machines)
- Accountability

Adequacy of Dialysis

The adequacy of my prescribed treatment relies heavily on me, my discipline with regard to diet and fluid restrictions, and my oversight of my dialysis treatment. Because I am very disciplined in my care, I can allow the dialysis machines to do their work. I have worked to become very knowledgeable in what is needed for my care. Other patients who are less familiar with the dialysis process are very vulnerable.

One of the areas that needs to be addressed by research is adequacy of dialysis. I can only tell you my personal experience with the amount of time I dialyze. When I dialyze four hours each session, I feel better. When treatments have been shortened in the past, over time my

energy levels are depleted. In addition, complications appear from fluid retention, such as higher blood pressure and shortness of breath. I, and other patients, feel lethargic and have little appetite. So, I can only conclude that the amount of time on dialysis is a factor.

Competency of Patient Care Technicians

Second, in the year I started dialysis, the care givers were mainly nurses from the top graduating classes, as well as medical students, and other medical technicians. Almost every technician had a college degree, and every technician had previous medical experience.

Today, I see technicians with only a high school diploma. In Arizona, a manicurist is subject to more licensing than a dialysis technician. When I first returned to dialysis, I had technicians handle my blood and my life who were convicted criminals, strippers, and refrigerator technicians. The ratio of patients to technicians, at times, is now 5 or 6 patients to every technician. This is not safe, and it doesn't work.

A main worry for dialysis patients is vascular access. A patient told me recently of a treatment where it took eight attempts by technicians to initiate her treatment - eight sticks by 16 gauge needle! Not only is this painful, it increases the risk of infection and could destroy that access. There are limits to vascular access with each patient. When vascular access runs out, a patient can no longer dialyze and can die. Many other patients have told me of similar occurrences. These examples, involving poorly trained, unsupervised technicians include the following:

- target weight miscalculations that could cause blood pressure decline. On one occasion, staff miscalculated the projected amount of fluid to remove from me by a significant margin. When this happens, a patient feels extremely weak and lightheaded at best. At worst, a patient can severely crash, losing consciousness with a blood pressure far lower than levels needed to maintain life. Also, patients experience excrutiatingly painful cramping, and treatments will be shortened because the patients cannot withstand additional treatment.
- too much or too little heparin, the blood thinning agent. Too much heparin thins the blood and could lead to the patient's inability to clot blood; so they could bleed to death. Too little heparin allows the blood to clot in the machine and stop the flow of blood back to the patient.
- placement of a dialyzer on the wrong machine for the wrong patient. This is a potentially fatal error.
- Disregard for the Universal Antiseptic Code, the protocol that protects both patient and technician alike from infectious germs, viruses, and bacteria. This is one of the largest and most common reasons patients are hospitalized.

Another example of the training deficiency among dialysis technicians stems from my personal experience. In 1994, I suffered an extended period of appetite and weight loss. As part

of my routine assessment prior to each dialysis session, I explained that I had not been eating properly. I reported this for almost four months. The food I was eating did not provide me with sufficient potassium for my prescribed potassium bath. During the fourth month, during the third hour of a four hour treatment, I suffered a cardiac arrest attributable to the low potassium in my system. The attending technician did not recognize this problem. Another technician took over to attempt resuscitation until the paramedics arrived. Upon arrival, Emergency Room records reflected a potassium level of 2.9, well below the 3.5 recommended range. Discharge Summary records showed fibrillatory arrest, secondary to hypokalemia, which is low potassium. The dialysis technician did not correlate the loss of my appetite with the low potassium bath. The seriousness of the problem and possible results were never brought to my attention or to the attention of the charge nurse, the dietitian, or my physician. THIS EVENT WAS COMPLETELY PREVENTABLE.

Knowledgeable and Disciplined Nursing Staff

In addition to competency and training of dialysis staff, I believe that the staff must be knowledgeable and disciplined. I have witnessed instances where floor nurses lacked familiarity with the machines and their functions. These are complicated machines that stand between life and death of dialysis patients. Lack of knowledgeable staff exposes patients to dangerous circumstances. Moreover, lack of discipline or failure to PAY ATTENTION is a primary source of incidents, affecting patient care. On one occasion soon after my return to dialysis, staff drained off too much fluid from me during dialysis. This exposed me to a crash in my blood pressure and loss of consciousness. I am aware of another instance where a patient bled to death, because no one was watching, while the patient's blood inadvertently drained into a trash can while the patient slept. It is instances like this that cause me to do everything in my power to stay awake throughout my four hour dialysis and try to watch every move of the staff attending me and to watch the fluctuations on the dialysis machine.

Facilities and Technology (Machines)

Not all facilities where I have dialyzed have been well maintained. Too often poorly trained or overworked staff will choose speed over substance in attending to patients. Worn, older, overused machines are not as effective and efficient. One problem in dialysis is the way dialyzers are reused. Even though they are labeled for "single use only" many are reused in this country as much as 30-50 times. I do not reuse dialyzers. However, as a patient advocate of many years, I have observations and experiences with regard to reuse of dialyzers from other patients. The efficiency of the dialyzer can decrease as much as 20% over the span of reuse. In turn, it is as if the patient's treatment time has been reduced by 20%. No adjustments are ever made to compensate for this loss. As a result, the patient's lab reports get worse as the patient's condition gets worse. Moreover, many patients aren't aware that they don't have to reuse dialyzers and that the mortality level is higher with reuse. I know of one woman who could only reuse eight times before she felt very bad.

In addition, I have been told by staff that Medicare pays for a new dialyzer after each session. However, my experience is that dialyzers are used as much as 30-50 times. In fact, facilities have had to establish elaborate procedures to clean, sterilize, and catalogue dialyzers to ensure that patient receives their own dialyzer during sessions. I am aware of one technician who processed one patient's dialyzer bar code and passed and approved all other patient bar codes on that basis. This violated the procedural rules and, of course, exposed patients to potential harm.

Accountability

One of the most important aspects of patient care relates to their relationship with the dialysis staff. Staff must be accountable for the level of care provided to patients. They must demonstrate strict adherence to set policy and procedure. Appropriate discipline must be administered for breach of policy and procedure. This is a life or death situation. In my experience, technicians are rarely written up for minor or major infractions, involving patient care. I have seen technicians abuse the glove policy, exposing patients to possible infection. I have seen technicians reading magazines while on duty rather attending to patients. I have seen technicians engage in distracting conversations when inserting or removing needles from people.

In all my years on dialysis, I have never seen a government surveyor review a facility where I have dialyzed. In fact, I am unaware of any surveys of any facilities where I have dialyzed. I am greatly concerned as a dialysis patient about oversight of this industry.

In closing, throughout my life I have strived to avoid the label, "dialysis patient," and the stigma associated with it. Yet, today I appear before you, in the public forum, as a dialysis patient, because of the importance of the issues being discussed here today. Patients can and do lead productive, purposeful lives. However, it has become an increasing burden to do so. Monitoring a technician's abilities during every treatment, week after week, is a tremendously stressful undertaking for a dialysis patient. Enduring the limits and inadequacies of the present system of dialysis compound the already difficult treatment into an intolerable, unjustifiable, and inexcusably frustrating experience.

My purpose today in appearing before this committee was to present the life of a dialysis patient to you. It is my life, and that of many others. We live it every day. You cannot possibly understand it. I sincerely hope you or a loved one will never experience it, but I do implore you to do something about it.

Thank you.

The CHAIRMAN. Thank you, Mr. Smith.
Now Dr. Scanlon.

STATEMENT OF WILLIAM SCANLON, PH.D., DIRECTOR, HEALTH FINANCING AND PUBLIC HEALTH DIVISION, GENERAL ACCOUNTING OFFICE, WASHINGTON, DC

Dr. SCANLON. Thank you, Mr. Chairman and Senator Breaux. I am pleased to be here today as you examine the quality of care provided to Medicare beneficiaries with end stage renal disease and consider options for improving its oversight. These patients are a very vulnerable group. They are often elderly and afflicted with other conditions, such as severe diabetes, and several times a week the vast majority must visit a dialysis facility for life-sustaining blood cleansing treatments. Safe and competent treatment is critical because with patients this sick, there is little room for error.

In response to the committee's interest we have examined what is known about the quality of ESRD care and oversight activities. The report on our findings has been released today. We found that there is little evidence on whether dialysis facilities are complying with Medicare's quality of care standards and consequently, no assurance that patients using a given facility will receive adequate quality care.

There are signs that the average quality of care for ESRD patients may, however, be improving. Mortality rates and hospitalizations have declined and measured clinical indicators of quality have improved. However, this does not provide the assurance that significant quality of care problems do not exist in some facilities.

Our uncertainty is due to the fact that there has simply been too little oversight of dialysis facilities to determine if they are complying with quality standards. The reviews that have taken place indicate that there are enough quality problems that exist that we should be taking steps to adequately assess quality in individual facilities.

Over the last 7 years, as you have indicated, there has been a dwindling frequency of onsite surveys. These unannounced inspections, which are the primary tool for ensuring that facilities meet Medicare's quality standards, were conducted at only 11 percent of facilities in 1999, compared to more than 50 percent in 1993.

As the number of surveys declined, the proportion of surveys that identified serious problems was increasing. In 1993, 6 percent of facilities were found to be out of compliance with Medicare standards. This figure rose to 15 percent in 1999.

A facility that is out of compliance has problems that are serious enough that unless corrected, the facility will be terminated from participation in the Medicare program. The most common types of problems identified included lack of adequate procedures to safeguard the health and safety of patients, the failure to meet standards governing the reuse of dialyzers and supplies and the lack of adequate patient care plans. Problems like these can be life-threatening. For example, improper procedures for reusing dialyzers can expose patients to microbial contamination and dangerous levels of a germicide used to clean the dialyzers. HCFA has recognized that the infrequency of inspections may be compromising patient care

and has requested a nearly threefold increase in the funding for dialysis facility surveys.

HCFA is also attempting to make more effective use of the resources available by using information on clinical outcome measures to assist in the process of identifying which facilities to survey. While we believe this approach has merit, we are concerned that the measures being used by HCFA in pilot testing may not be sufficiently strong predictors of compliance with Medicare standards and that there needs to be consideration of other factors to select facilities for inspections. A thorough evaluation of the pilot that HCFA is undertaking should be completed before encouraging states to use outcome data to drive their survey selection processes.

We also believe that the oversight process could be strengthened if the state survey agencies and the ESRD Networks would share information about complaints and known quality of care problems at specific facilities. The 18 ESRD Networks are contractors to HCFA responsible for improving safety and quality of dialysis facilities. HCFA has not consistently encouraged coordination between these two groups and, in some cases through conflicting policy interpretations, has actually impeded it.

As a result, neither state agencies nor the Networks have a clear picture of what the other is finding and are able to take advantage of that information to target or otherwise modify their activities.

We see increased communication as a way to help identify which facilities are most likely to need attention and encourage better and more consistent cooperation and information-sharing between state agencies and ESRD Networks. We are encouraged by HCFA's positive response to our recommendations and yet mindful of the challenges involved in carrying them out.

Identifying where the problems are is only one half of what needs to be done. Getting them corrected and keeping them corrected is the other half. HCFA's current enforcement authority does not provide strong incentives for dialysis facilities to stay in compliance with Medicare standards. The threat to terminate a facility from Medicare is sufficient to bring nearly all problem facilities back into compliance with the standards but they do not necessarily stay that way. Because of the infrequency of inspections, it is difficult to determine how quickly or how often the facilities fall out of compliance. But in every state we visited during this review, we found instances in which facilities that had corrected their problems were found to have serious problems shortly thereafter.

For example, a Texas facility cycled in and out of compliance over a 9-year period while developing numerous plans of correction. On many occasions, the deficiencies were so severe that they put the health and safety of the facilities' over 200 patients in immediate jeopardy. In 1999, the deficiencies included not providing care necessary to address patients' medical needs, not complying with physicians' orders and not following up on adverse incidents. It took more than 4 months and two revisits from the state before the facility came back into compliance. However, when the state conducted another survey 4 months later, the facility was again out of compliance.

In the past, this committee has examined a similar problem with respect to nursing home care and nursing homes that cycle in and

out of compliance with quality standards. The Congress had created a broad range of penalties to help encourage nursing homes to stay in compliance with standards. We found that the sanction most likely to encourage staying in compliance—monetary penalties—was infrequently used and we urge that it be applied much more frequently in appropriate situations.

HCFA lacks comparable authority for sanctioning dialysis facilities. We believe that Congress should consider whether granting such authority could reduce the likelihood of these yo-yo patterns of compliance and noncompliance evident in the Texas example.

Mr. Chairman, this concludes my statement and I would be happy to answer any questions that you or members of the committee may have and we also are ready to assist the committee in the future in monitoring progress in guaranteeing quality of care to this very vulnerable group of Medicare beneficiaries.

[The prepared statement of Mr. Scanlon follows:]

United States General Accounting Office

GAO

Testimony

Before the Special Committee on Aging, United States Senate

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MEDICARE QUALITY OF CARE

Oversight of Kidney Dialysis Facilities Needs Improvement

Statement of William J. Scanlon, Director
Health Financing and Public Health Issues
Health, Education, and Human Services Division

GAO/T-HEHS-00-136

Mr. Chairman and Members of the Special Committee:

I am pleased to be here today to discuss what is being done to assure that the care provided to the more than 280,000 Medicare patients being treated for End Stage Renal Disease (ESRD), also known as kidney failure, is adequate and safe. Several times a week, the vast majority of these patients visit a dialysis facility for life-sustaining blood cleansing treatments. Caring for these patients is one of Medicare's biggest costs—with spending per patient equaling 6 to 7 times the average. These patients are often elderly and afflicted with other conditions, such as diabetes. Safe and competent treatment is critical, because with patients this sick, there is little room for error.

Responsibility for overseeing the quality of ESRD care rests with the Health Care Financing Administration (HCFA), the agency that administers Medicare. HCFA's oversight takes two main forms. First, HCFA pays state agencies to conduct unannounced inspections of dialysis facilities. These inspections, commonly called surveys, are designed to determine whether dialysis facilities are complying with quality-of-care standards. Second, HCFA pays organizations called ESRD networks to conduct quality improvement activities at the nation's 3,800 dialysis facilities and gather data on various outcomes, such as patient mortality rates.

You asked us to evaluate how well HCFA's processes for monitoring the quality of dialysis services are working. In response, we have completed a report that is being released at this hearing. My statement today will highlight some of the key points in that report.

In summary, the oversight of dialysis facilities has several weak links. As a result, there is little assurance that facilities are routinely complying with Medicare's quality of care standards, which protect patients' health and safety. Our report highlights problems in three main areas. The first is the dwindling frequency of on-site surveys. The number of facilities surveyed has been dropping each year since 1993, even though the surveys show that facilities are becoming increasingly likely to have one or more serious deficiencies. The second problem is that HCFA's enforcement approach does not provide strong incentives for dialysis facilities to stay in compliance with Medicare requirements. HCFA's threat to terminate a facility from Medicare is sufficient to bring nearly all noncompliant facilities into compliance, but many soon slip out of compliance again. At present, they face no penalty for this behavior. Third, state agencies and ESRD networks often do not share information about complaints and known quality-of-care problems at specific facilities. As a result, neither has a clear picture of what the other is finding and is unable to take advantage of that information to target or otherwise modify its own activities. Our report recommends changes to address all three problems. HCFA has reviewed these recommendations and agrees with them.

BACKGROUND

To stay alive, a patient with ESRD must receive either a kidney transplant or regular kidney dialysis treatments. Such treatments use a machine to do the kidneys' job of

removing impurities from the blood. If performed improperly, such treatments can contaminate patients' blood, causing serious complications and even death.

Kidney dialysis is a big business. The number of Medicare patients receiving kidney dialysis has increased more than 20 times since coverage began in 1973. To accommodate this demand, more facilities have opened. Since 1993, for example, the number of facilities has grown an average of 6 percent per year. Medicare's payment for a dialysis treatment is a fixed rate per treatment that has remained essentially unchanged for more than 15 years. For facilities that aim to maximize profits, such fixed payment rates can create incentives for efficiencies but also can be an incentive for underservice. Inspection surveys and other monitoring plans are needed to help ensure thatcost-cutting does not lead to substandard services.

HCFA has established a set of 11 quality-of-care standards, commonly called "conditions of participation," that dialysis facilities are required to meet. The conditions of participation are designed to ensure that facilities safely provide quality care. They cover such areas as the physical environment of the facility, the adequacy of patient care plans to address medical needs, and the qualifications of the staff that provide dialysis services. Inspection surveys are designed to determine whether facilities meet these standards. They are conducted by state agencies, typically health departments, under contract with HCFA.

HCFA also contracts with 18 ESRD networks that work with facilities to improve the quality of dialysis services provided to Medicare beneficiaries. These ESRD networks collect data on key clinical indicators and provide individual facilities with regional performance data on these indicators, so that each facility can compare its performance with other facilities. Because networks are staffed and governed by dialysis providers and others with expertise in dialysis, they also provide technical support to help facilities improve their performance on clinical indicators. The networks also conduct quality improvement projects dealing with specific aspects of dialysis, handle complaints regarding patient care, and assist patients in finding dialysis providers.

MOST FACILITIES GO YEARS BETWEEN SURVEYS FOR COMPLIANCE WITH HCFA STANDARDS

When a dialysis facility is certified to treat Medicare patients, nearly a decade may elapse before it receives another HCFA-funded survey. Two factors are at work. First, the total number of HCFA-funded surveys has declined substantially since 1993. Second, a greater portion of these surveys must go for inspections of new facilities. The number of new facilities entering the program has grown each year, and each new facility must receive a survey before it can begin participating in Medicare. As a result of these factors, while about 1 of every 2 existing facilities received a recertification survey in 1993, only about 1 in 10 received a recertification survey in 1999.

While the number of surveys is going down, the proportion of surveys that find major problems is increasing. In 1993, 6 percent of facilities surveyed were cited for not meeting a condition of participation; that figure rose to 15 percent in 1999. A condition-

of-participation deficiency means that the problems found are serious enough that, unless corrected, the facility's participation in Medicare will be terminated by HCFA. Because so few facilities actually receive a recertification survey in a given year and surveys are not performed on a random basis, it is not clear whether this increased percentage is indicative of all facilities. Nevertheless, it is cause for concern.

The most common types of deficiencies included lack of adequate operational rules and patient care policies to safeguard the health and safety of patients, the failure to meet standards governing the reuse of dialyzers and supplies, and lack of adequate patient care plans. Deficiencies such as these can be life-threatening. For example, improper procedures for reusing dialyzers can expose dialysis patients to microbial contamination and dangerous levels of the germicide used to clean the dialyzers.

HCFA has recognized that the infrequency of on-site inspections may be compromising patient care, and it has requested a nearly threefold increase in the funding for dialysis facility surveys—from $2.2 million in fiscal year 2000 to $6.3 million in 2001. Such an increase, according to HCFA, will ensure that ESRD facilities are surveyed at least every 3 years. However, the extent to which any increased on-site survey efforts will be effective in improving quality also depends on how well HCFA systems (1) get facilities to correct deficiencies and maintain compliance with standards, and (2) make use of available information to target its on-site survey resources. As I will discuss, both these areas need improvement.

ENFORCEMENT PROCESS GIVES FACILITIES LITTLE INCENTIVE TO SUSTAIN COMPLIANCE

HCFA relies on termination from Medicare—or, in reality, the threat of termination—as its only tool for bringing deficient facilities into compliance with standards. HCFA officials view this threat as an effective method for achieving compliance. Before a facility can be terminated, it has an opportunity, essentially a grace period, to correct its deficiencies or develop acceptable plans of correction. Of the 481 facilities confronted with at least one condition-of-participation deficiency since 1993, only three have been terminated for not correcting it.[1]

We found that the problem was not getting facilities to comply, but assuring that they stay compliant. If a facility slips out of compliance again, it can avoid a penalty by once again coming into compliance during the next grace period. Because of the infrequency of recertification surveys, it is difficult to determine how quickly and how often facilities fall out of compliance. It also means that a facility that becomes deficient again could remain so for a very long time. Analysis of HCFA's survey database suggests that facilities do tend to have repeat deficiencies. Of those facilities with four or more surveys, 38 percent that had deficiencies on their most recent survey were also deficient in at least one of the same areas on their prior survey. More than half of them had two or more repeat deficiencies. For example, a Texas facility cycled in and out of compliance

[1] An additional facility voluntarily withdrew from Medicare because of the threat of termination.

over a 9-year period while developing numerous plans of correction. On many occasions the deficiencies were so severe they put the health and safety of the facility's 227 patients in immediate jeopardy. In 1999, the deficiencies included not providing care necessary to address patients' medical needs, not complying with physician orders, and not following up on adverse incidents. It took more than 4 months and two revisits from the state before the facility came back into compliance. However, when the state conducted another survey 4 months later, the facility was again out of compliance. At the time of our review, state agency officials were exploring enforcement options under state licensing authority.

In the past, this Committee has examined a similar problem—nursing homes that cycled in and out of compliance with quality standards. The Congress has allowed HCFA a broad range of penalties to help encourage nursing homes to maintain compliance with standards. For example, for nursing homes HCFA has authority to levy monetary penalties and stop Medicare payments to deficient nursing homes, but neither of these options can be applied to dialysis facilities. Effective options for dealing with chronically deficient dialysis facilities do not exist.

As we have stated in our reports to you on nursing homes, monetary penalties in particular create a strong incentive for nursing homes to remain free of severe or repeated deficiencies. Today's report on ESRD suggests that the Congress may wish to consider granting HCFA the same sanctioning authority to dialysis facilities as it has for nursing homes.

HCFA does already have authority to impose monetary penalties for facilities failing to maintain compliance with requirements in one aspect of quality of care, but the agency has decided not to use this authority. Specifically, HCFA can assess financial penalties on facilities that do not properly reprocess and reuse dialyzers, the filters that clean a patient's blood. Reprocessing dialyzers incorrectly can lead to such problems as exposing a patient's blood to dangerous levels of the germicide used to clean the dialyzers. The Congress authorized HCFA to impose penalties on such facilities even if they subsequently corrected their deficient procedures, which may provide a stronger incentive than the threat of termination to remain compliant with the quality requirements.

So far, HCFA has not exercised this authority. HCFA officials believe doing so would be difficult, because the agency could only recoup payments for specific services affected by the lack of compliance. However, many of the important reuse standards relate to processes and procedures that affect almost all patients in a facility. Our state-level reviews showed instances in which surveyors were able to identify specific days on which facilities were out of compliance with requirements that affected all patients in a facility. Application of the sanction appears feasible in these instances. As a result, our report recommends that HCFA develop procedures to make use of this authority.

EFFORTS AND OPPORTUNITIES TO IMPROVE ON-SITE INSPECTIONS

Ideally, the facilities that are most likely to be deficient will be targeted for more frequent inspections. We looked at what is done to identify the dialysis facilities most in need of oversight. HCFA is taking some steps to use outcome measures to identify facilities to survey. While this approach has merit, it also has limitations that remain to be addressed. We do see immediate opportunities for HCFA to facilitate the sharing of information between state regulators who conduct the inspections and ESRD networks that gather information for individual facilities to better target surveys. Sharing information on complaints and known quality-of-care problems could help target inspections where they are needed most.

The approach HCFA is developing to assist in targeting surveys involves the use of certain patient outcome measures reported to ESRD networks, Medicare claims processing contractors, and the Centers for Disease Control and Prevention. In May 2000, as part of a pilot project, HCFA created profiles of these measures for facilities in seven states. The profiles were based on information HCFA obtained from dialysis facilities on such indicators as the degree to which dialysis treatments remove impurities from the blood and the degree to which patients' anemia is controlled.

Because the facility profile project is in the process of being tested, we did not comprehensively evaluate it. However, a major concern is whether the outcome indicators being used are a strong predictor of noncompliance with Medicare standards. In the states we visited, we found cases in which facilities had above-average scores on these indicators but were found to have serious deficiencies during surveys or complaint investigations. These deficiencies included such things as lack of knowledge of basic medical and dialysis practices like anemia management, infection control, and water purity. Accordingly, we recommended that HCFA complete an evaluation of the pilot project results before it encourages states to use outcome data as a key factor in selecting facilities for on-site inspections.

More immediately, sharing ESRD networks information on complaints and known quality-of-care problems at specific facilities with state agencies could strengthen the oversight process. HCFA has not consistently encouraged this coordination, and in some cases, through conflicting policy interpretations, has actually impeded it.

By sharing information and knowledge, ESRD networks and state agencies can create a more complete picture of ESRD facilities. The networks and agencies have different information about facilities. ESRD networks have information on the clinical aspects of the care in facilities and also may be more aware of recent staffing and management changes, patient complaints, and the results of quality improvement initiatives. In contrast, state survey agencies may have more detailed information about facilities' systems, such as those for infection control and reprocessing dialyzers.

HCFA's current policy allows networks to share facility-specific information with state survey agencies to aid in the certification process. However, HCFA regional offices that

oversee network and survey agency activities have not applied this policy consistently. As a result, the level of coordination and information sharing varies dramatically across regions, and in most cases little has taken place. Most HCFA regional offices restrict networks from sharing facility-specific information and support ESRD networks when they deny requests by state survey agencies for such information, saying that federal confidentiality restrictions prohibit this sort of exchange. In contrast, with the knowledge of its HCFA regional office, the ESRD network in Texas began providing facility-specific information to the Texas Department of Health after the state passed a licensure law for dialysis facilities in 1996. More recently, early this year, some HCFA regional offices have begun efforts to facilitate the communication and exchange of information, including facility-specific performance information, between ESRD networks and state agencies. Because we see increased communication as a way to help identify which facilities are most likely to need attention, we recommended that HCFA encourage better and more consistent cooperation and information sharing between ESRD networks and state survey agencies.

In commenting on our report, HCFA officials agreed with our recommendations and indicated that steps were being taken to implement them. For example, HCFA stated that they would develop the necessary regulations and procedures to implement sanctions for facilities that do not meet quality standards for dialyzer re-use. HCFA also stated that steps were under way to clearly delineate responsibilities of state survey agencies and ESRD networks that would encourage cooperative information sharing to help identify poor-performing facilities.

This concludes my statement. I will be happy to answer any questions you may have.

GAO CONTACTS AND ACKNOWLEDGMENT

For future contacts regarding this testimony, please contact JanetHeinrich at (202) 512-7119 or Frank Pasquier at (206) 287-4861. Individuals who made key contributions to this testimony included Margaret Buddeke, Timothy Bushfield, Stanley Stenersen, and Mark Ulanowicz.

Related GAO Products

Medicare Quality of Care: Oversight of Kidney Dialysis Facilities Needs Improvement (GAO/HEHS-00-114, June 23, 2000).

Nursing Homes: Additional Steps Needed to Strengthen Enforcement of Quality Standards (GAO/HEHS-99-46, Mar. 18, 1999).

Nursing Homes: Stronger Complaint and Enforcement Practices Needed to Better Ensure Adequate Care (GAO/T-HEHS-99-89).

Medicare Dialysis Patients: Widely Varying Lab Test Rates Suggest Need for Greater HCFA Scrutiny (GAO/HEHS-97-202, Sept. 26, 1997).

Medicare: Data Limitations Impede Measuring Quality of Care in Medicare ESRD Program (GAO/HEHS-97-137R, July 11, 1997).

Medicare: Enrollment Growth and Payment Practices for Kidney Dialysis Services (GA0/HEHS-96-33, Nov. 22, 1995).

(201070)

The CHAIRMAN. Thank you, Dr. Scanlon.
Now Mr. Grob.

STATEMENT OF GEORGE GROB, DEPUTY INSPECTOR GENERAL, OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Mr. GROB. Good afternoon, Mr. Chairman and Senator Breaux.

The systems intended to protect vulnerable dialysis patients from harm and to assure and promote improvements in the quality of their care have some serious shortcomings. Fortunately, there are easy, practical solutions to quickly address the more fundamental weaknesses and some promising new approaches that, in the long run, will not only strengthen the safeguards for the patients but increase the efficiency and the efficacy of the care provided to them.

Today the Office of Inspector General is releasing two reports which analyze the system's weaknesses and which provide a detailed comprehensive set of recommendations to address them. I cannot describe everything in these reports today but will briefly summarize them.

First, to put things in perspective, the renal dialysis industry and the Health Care Financing Administration have in recent years brought about significant improvements in the treatment of renal disease, as measured, for example, by the adequacy of the dialysis rendered to patients, an improvement from 43 percent in 1993 to 74 percent between 1993 and 1998. Other measurable improvements have been made, as well.

However, in the course of our study we found serious problems where patients were put at risk due to inappropriate treatment, including exposure to a toxic disinfectant administered directly through a patient's bloodstream and a drug overdose resulting in prolonged bleeding.

The shortcomings of the protective and quality assurance systems are obvious. In 1995, 20 percent of all facilities had not been surveyed within 3 years. This has risen to 44 percent in 1998, and 10 percent had not been surveyed within 6 years. Performance measures already available and used to track quality of care on a broad regional scale are not used to hold individual facilities accountable for the care that they provide.

The complaint system is unreliable. Patients have little incentive and inadequate knowledge to use it. Medical injuries are not systematically monitored. The two main contractors responsible for oversight of the system, Renal Disease Networks and the state survey and certification agencies, seldom work in concert on any aspect of quality assurance. Assessment and accountability of both is minimal. Public disclosure of survey results and the findings related to individual facilities is also limited.

We have made a complete set of recommendations to address the problems and highlighted some promising approaches used by two of the Networks to raise the level of care for kidney disease patients. The Health Care Financing Administration has prepared a plan of action that is quite responsive to our findings and recommendations. The most immediate need is to increase the frequency of facility surveys, for which HCFA has requested the necessary funding. Longer-term improvements will result from atten-

tion to the performance and accountability of individual facilities, as measured by clinical and administrative factors. The problems can be corrected and care for these patients can be better than it is.

That concludes my testimony and I will be happy to answer questions.

[The prepared statement of Mr. Grob follows:]

External Quality Review:

DIALYSIS FACILITIES

Testimony of

George F. Grob
Deputy Inspector General
for Evaluation and Inspections

Hearing Before:
Senate Special Committee on Aging

June 26, 2000

Office of Inspector General
Department of Health and Human Services
June Gibbs Brown, Inspector General

Testimony of
George F. Grob
Deputy Inspector General
for Evaluation and Inspections
Department of Health and Human Services

Good afternoon Mr. Chairman and Members of the Committee. I am George F. Grob, Deputy Inspector General for Evaluation and Inspections, in the Office of Inspector General (OIG), U.S. Department of Health and Human Services. I am pleased to testify at today's hearing on dialysis facilities. My testimony will focus on Medicare's system for the external quality review of these facilities.

Mr. Chairman, the Health Care Financing Administration (HCFA) has made important strides in using performance measures to help encourage improvements in the quality of care. However, the overall system has major shortcomings. It conducts little enforcement to ensure compliance with minimum standards that help protect patients from harm. The system is fragmented, in that End Stage Renal Disease (ESRD) Networks and State survey agencies, HCFA's two main contractors responsible for quality oversight, rarely coordinate their efforts to foster patient protections. And, fundamentally, the system lacks accountability both on the part of the individual facilities and on the part of the contractors.

These findings, along with appropriate recommendations, are contained in two reports which we are issuing today. These reports also contain the plan of action which HCFA has prepared to address the issues we have raised.

External Quality Review Is Important

Many dialysis facilities and corporations conduct their own internal quality monitoring and improvement projects. However, in order to protect patient safety, it is essential that an external oversight system exists to provide objectivity and public accountability that internal quality reviews lack. We present four key factors that underscore the need for external oversight in dialysis facilities.

Instances of poor care. In the course of our review of documents, we came across several examples where patients were put at risk due to inappropriate treatment. For example, we learned of a case where a patient was exposed to a toxic disinfectant directly through his bloodstream, and another case where a patient received an overdose of a drug that resulted in prolonged bleeding.

Vulnerable patient population. There are over 230,000 dialysis patients, and the population is growing at a rate of 7 percent a year. Many dialysis patients are elderly and suffering from other complicated illnesses such as diabetes and hypertension.

Variation in the quality of care. Performance data reveal that a substantial portion of patients nationwide do not achieve the clinical outcomes recommended by clinical practice guidelines. For example, 20 percent of hemodialysis patients did not meet clinical guidelines for the minimum dose of dialysis (as measured by a $Kt/V \geq 1.2$). And, 41 percent of hemodialysis patients did not meet the

guidelines for the management of anemia (as measured by a hemoglobin level that met or exceeded 11-12 gm/dL). Similarly, scientific studies suggest widespread variation in the quality of care patients receive in facilities. One study in particular showed that facilities differ in mortality rates, and that higher mortality rates were correlated with facilities that provided less adequate doses of dialysis.

Marketplace pressures. The dialysis industry has grown significantly in recent years. Moreover, through a series of mergers and acquisitions, there has been increased consolidation in the ownership of the facilities. Along with growth and consolidation, the dialysis treatment environment is characterized by at least three other increasingly prominent forces: increased competition for patients, heightened concerns to contain costs, and increased difficulty in finding and retaining experienced nurses and technicians in an increasingly competitive marketplace.

HCFA's External Review Bodies

HCFA relies upon two main entities to oversee the quality of care in dialysis facilities: the ESRD Networks and the State survey agencies. The 18 regional Network organizations, governed primarily by renal professionals associated with facilities in the Network's region, perform multiple functions mostly oriented around collegial efforts to promote improvement in the quality of care and to respond to complaints lodged by patients, staff, and others. The State agencies, typically within State departments of public health, perform a more regulatory role and have greater authority. The States conduct Medicare certification surveys of facilities and investigate complaints, both in accordance with the Medicare Conditions for Coverage for dialysis facilities. Our report assessed the role of both entities in the oversight of dialysis facilities.

Our Inquiry

Our findings come from multiple sources of information. We surveyed all 18 Networks and interviewed over half, and visited several. We analyzed several Network complaint logs and Network responses to complainants. We also analyzed HCFA's database on State survey agencies, observed a State survey of a dialysis facility, and interviewed staff at several State survey agencies. Throughout our inquiry we interviewed HCFA staff and various stakeholders and reviewed pertinent Federal documents and scientific literature.

We structured our inquiry around a framework that we have used in other studies to help assess the overall effectiveness of an external quality review system. For a comprehensive and effective external quality review system, all components need to be adequately addressed. The framework contains four elements: use of standardized performance measures, response to complaints, on-site surveys, and response to medical injuries.

FINDINGS

The Major Strength of the System Is its Use of Performance Measures to Foster Improvements in the Quality of Care.

HCFA's use of performance measures is well worth noting. Since HCFA began collecting performance measures on a national sample of patients in 1994, the data have shown considerable improvement. For example, HCFA's data show the percentage of patients achieving adequate dialysis according to clinical guidelines (a URR ≥to 65 percent) increased from 43 percent in 1993 to 74 percent in 1998.

Yet, the Current System of Oversight Falls Short in Several Key Aspects.

Performance measures are rarely used to hold individual facilities accountable. HCFA does not require Networks or States to collect a set a of facility-specific performance data to monitor the performance of individual facilities. Without facility-specific data it is difficult for Networks and States to identify poorly performing facilities that require intervention. In some instances, Networks have access to facility-specific data either because they collect them on their own or through other research efforts. Even if a Network is able to identify a facility performing well below accepted standards, Networks have little enforcement authority to ensure compliance and are reluctant to share such information with States who have more authority. Networks are reluctant to share data with the States because they fear that States will misinterpret the data and will be unable to protect the data from public disclosure. Networks believe eventual public disclosure will undermine their collegial relationships with the facilities. Currently, no data are readily available to the public on a facility-specific basis either by HCFA, Networks, or States.

The complaint systems serve as unreliable means for identifying and resolving quality-of-care concerns. Three major barriers inhibit individuals from lodging complaints. First, dialysis patients may find it difficult to complain about an individual or facility providing treatment that their lives depend upon for fear of retribution. Second, patients may lack an understanding of the technical aspects of care and may not know when to complain. Third, staff of dialysis facilities face significant deterrents to lodging complaints; such actions could put their jobs at risk and brand them as a trouble-makers, thereby jeopardizing future employment in the field.

Network officials are aware of and often sympathetic to these barriers. But, in general, their policies and practices make the barriers even more imposing. First, they tend to discourage confidential complaints by stopping investigations short if complainants are unwilling to allow their names to be disclosed to the facility in question. Networks reported that it is difficult for them to investigate complaints fully without disclosing the complainants' names to the facility. Second, about half of the Networks require grievances to be in writing, before they take any action, unless they involve life-threatening situations, even though HCFA policy states that such an approach is unnecessary. Third, Networks, and even more so the States, conduct little outreach to inform, let alone encourage, patients or staff to use the complaint system. The information that the Networks provide tends to be limited to posters sent to facilities and information packets sent to new patients who are usually overwhelmed with information at that early stage.

States and Networks conduct few on-site investigations of complaints concerning the quality of care. In 1998, State survey agencies conducted about 250 on-site investigations; the Networks, about 35 for over 3,000 facilities nationwide.

The complaint system also may be bogged down with information requests drawing resources away from more serious problems. We examined 9 Network complaint logs for 1998 and found that these 9 Networks combined received over 700 complaints. However, the majority of these complaints did not involve quality-of-care concerns. About 45 percent were actually requests for information and 13 percent involved concerns expressed (typically by staff) about disruptive patients. Of all the complaints, 25 percent concerned service quality (e.g., temperature of facility, waiting times, friendliness of the staff) and 15 percent technical quality (e.g., clinical care, adequacy of equipment).

Networks and the States rarely work together to handle complaints, resulting a fragmented system. Working single-handedly, neither the States nor the Networks can tap the full potential of a complaint system that effectively addresses quality-of-care concerns. Through their board membership, Networks have important clinical expertise in nephrology that gives them substantial ability to assess and follow-up complaints regarding the adequacy of clinical care. But the Networks have little authority to enforce corrective actions. The States, on the other hand, have enforcement authority for violations of the Medicare Conditions for Coverage, but tend to lack the clinical expertise concerning renal care. The Networks do refer to the State agencies complaints concerning the Medicare Conditions. We found that in 1998 each Network referred, on average, three complaints to the States. But the Networks report that the State agencies do not routinely inform them of the results of complaint investigations or even whether they conducted an investigation. Similarly, Networks themselves do not tend to be any more forthcoming in informing the States of their own investigations. And, Networks and State agencies seldom undertake combined complaint investigations about the quality of care.

Medicare certification surveys play a limited role in ensuring facilities meet minimum standards. The elapsed time between Medicare surveys is increasing. Facility, Network, and State agency staff viewed Medicare surveys as an important part of external oversight. However, we found that in 1995 20 percent of all facilities were not surveyed within 3 years; by 1998, that increased to 44 percent. Ten percent of facilities had not been surveyed in 6 years or more by the end of 1998.

Partly as a result of the low frequency of surveys, State survey agencies have difficulty maintaining the expertise of surveyors. Network and State officials stressed that dialysis surveys are highly technical, requiring knowledge not only of water treatment processes but also of the complexities of dialysis treatment. As dialysis surveys become less frequent, surveyors are increasingly hard pressed to maintain their familiarity with dialysis facilities, let alone keep pace with technological advances.

The Medicare Conditions for Coverage for dialysis facilities provide an inadequate foundation for accountability. Established in 1976, the Conditions fail to reflect major changes in the delivery of dialysis services, in the organizational auspices of dialysis facilities, and in the concepts of quality oversight and quality improvement. The Conditions fail to hold the facility governing body and the medical director sufficiently accountable for the quality of care, and they fail to require facilities to

report facility-specific data, to conduct quality improvement programs, and to monitor patient satisfaction.

Medical injuries are not systematically monitored. Medical injuries are attributable to the care provided to the patient. Such injuries can happen even in the best of health care facilities. HCFA does not require the Networks, the State agencies, or facilities to identify and analyze medical injuries attributable to the care provided to the patient as opposed to the patient's underlying condition. Without such a system, an important opportunity to identify problems is missing.

Networks and State Survey Agencies Are Not Held Accountable for Their Effectiveness.

Assessment of Networks' performance is minimal. Although HCFA receives regular information from Networks, it provides little substantive evaluation and feedback to them. For instance, HCFA does not hold Networks accountable for how facilities fare on performance measures. HCFA's most formal mechanism for evaluating the Networks is the year-end evaluation questionnaire that the project officers complete and send to the central office. In our review of the completed questionnaires for 1998, we found that they consisted of multiple-choice questions and few contained any elaboration.

Assessment of State survey agencies' performance is also minimal. HCFA has few means to evaluate the content or quality of the surveys the State agencies conduct on behalf of Medicare. HCFA no longer validates surveys. Recently, HCFA eliminated this in favor of periodically observing State surveyors' performance and offering advice and assistance as applicable. While the latter approach has potential and may well involve some useful informal assessment and feedback to the State surveyors, we found no evidence of substantive evaluation and feedback to the States on such key matters as the effectiveness of the surveys, the skill of the surveyors, and the adequacy of collaboration with the Networks

Public disclosure is limited. HCFA offers no readily accessible public information (e.g., on the Internet) on any Network or State actions taken by either Networks or States to protect the public. All Networks have websites, but they vary significantly in the amount and type of information that they post. None publishes any information on complaints received and investigated at a particular facility or on any corrective actions pending against a particular facility. Similarly, little information is readily available on the performance of States. Survey results are available only upon request and are difficult to interpret. Results are not routinely posted on the Internet or in facilities.

RECOMMENDATIONS

We urged HCFA to provide leadership to address the shortcomings we have identified. In doing so we suggested that HCFA (1) steer external oversight of the quality of dialysis facilities so that it reflects a balance between collegial and regulatory modes of oversight, and (2) foster greater collaboration between the Networks and State survey agencies. Toward that end, we offered the following specific recommendations.

Holding Individual Dialysis Facilities More Fully Accountable for the Quality of Care.

Conditions for Coverage. The current Conditions are close to a quarter-century old. It is time to update and reinforce them as a tool for holding dialysis facilities accountable for the quality of care they provide. We recommend that HCFA revise the current Conditions so that, at a minimum, they: strengthen the accountability of the dialysis facility governing body, reinforce the accountability of the dialysis facility medical director for patient care, require facilities to report electronically on standardized performance measures determined by HCFA, require dialysis facilities to conduct their own quality improvement program, require dialysis facilities to establish internal systems for identifying and analyzing the causes of medical injuries and medical errors, and require dialysis facilities to monitor patient satisfaction.

Facility-Specific Performance Data. Facility-specific measures should be used to encourage facilities to improve the quality of care and to help ensure facilities meet minimum standards. HCFA should identify a core set of performance indicators to collect regularly on all patients from facilities. HCFA, with input form the professional community and from patients and patient advocates, should determine a new core data set of clinical data that will be used to help assess the quality of care provided by facilities. Using these data, HCFA should disseminate comparative facility-specific reports to facilities, Networks, State survey agencies and the public containing all the performance indicators. The data should be available to facilities to support internal quality improvement activities, to Networks to support regional quality improvement activities and to identify outliers for further review, to State survey agencies to help guide and inform the survey process, and to the public to foster public accountability. We emphasize that HCFA's posture toward performance data should be that if they are worth collecting, they are worth disclosing.

Complaint System. HCFA needs to work with the Networks and the State survey agencies to establish an effective complaint system that reflects eight key elements we outline in the report: accessibility, objectivity, investigative capacity, timeliness, responsiveness to complainants, enforcement authority, improvement orientation, and public accountability. HCFA should conduct pilot projects to test ways in which the Networks and the State survey agencies could work together to create such a complaint system that is integrated. HCFA should also develop a common instrument that facilities and others could use to assess patient satisfaction. For many patients, an anonymous response to a patient satisfaction survey may serve as a safer vehicle for expressing concern than a formal complaint to a facility, Network, or State agency.

On-site Certification Surveys. Routine, on-site surveys are important to help ensure that facilities comply with minimum standards outlined in the Medicare Conditions for Coverage. HCFA should determine an appropriate minimum cycle for conducting Medicare certification surveys of dialysis facilities. In addition, HCFA should conduct pilot tests to determine the potential of Network and State joint initial certification visits of dialysis facilities. We recognize that at the time of initial reviews few patients are receiving treatment at the facility and therefore major problems rarely are uncovered. However, we think that initial reviews provide an opportunity for the Networks and States to work together cooperatively without the pressures associated with a for-cause investigation.

Medical Injuries. The Institute of Medicine recently called for a mandatory national system for reporting of such adverse events in hospitals and other health care facilities. Given that dialysis

treatments are paid for primarily by Medicare funds, and that HCFA has the major responsibility for the external quality oversight of the facilities, dialysis facilities are an ideal candidate for testing this kind of reporting system. HCFA could facilitate the development of publicly accountable means for identifying serious medical injuries and analyzing their causes. The system should provide for the analysis of adverse events and for any necessary corrective actions at the facilities involved.

Holding the Networks and State Survey Agencies More Fully Accountable for Their Performance in Overseeing the Quality of Care Provided by Dialysis Facilities.

Distinctive role of Networks and States. Policy guidance delineating the distinctive roles of the Networks and State survey agencies in quality oversight and providing direction on how they should collaborate is needed. HCFA should clearly state that the Networks serve as its primary agents in fostering continuous quality improvement in the care provided to dialysis patients, but yet must also support enforcement efforts. Similarly, it would be helpful for HCFA to clearly state that the State survey agencies serve as HCFA's primary agents in enforcing compliance with the Medicare Conditions for Coverage, but also must support improvement opportunities. HCFA can convey this in two ways. For Networks, their contracts, particularly in the section explaining HCFA's Health Care Quality Improvement Program, would seem to be a particularly appropriate vehicle. For the State agencies, the annual budget call letter would appear to be the most appropriate forum. At a minimum, the Networks and State agencies should be held accountable for collaboration in the following four areas: (1) sharing facility-specific data, (2) sharing State survey results, (3) working together in addressing complaints, and (4) consulting one another in their respective areas of expertise.

Accountability of Networks. Networks can be held more accountable in two ways. First, HCFA should develop, with input from the Networks, a system for performance-based evaluations of the Networks. Given the development of increasingly sophisticated performance measures, it is reasonable to use them as key references in assessing the Networks' own performance. HCFA has already moved in this direction with the Medicare Peer Review Program. Second, HCFA should increase public disclosure of information on the Networks. Such disclosure can be particularly important in helping the media, advocates, patients, and other interested parties understand how Networks handle complaints and use performance data to improve dialysis care. In the process, it reinforces the point that publicly-funded Networks are accountable to the general public as well as to HCFA.

Accountability of the State survey agencies. State agencies can also be held more accountable in two ways. First, HCFA needs to better assess the State surveyors. One way this can be accomplished is to observe more State surveys. This provides HCFA with the opportunity to provide direct feedback to surveyors and can be more instructive and timely than validation surveys. However, because of the technical nature of these surveys, it may be difficult for HCFA personnel to develop and maintain the expertise to constructively assess State surveys. In this regard, HCFA should consider developing a small group of contracted, experienced dialysis surveyors that it could draw upon to periodically observe State surveys as well as to investigate complaints as needed. Second, HCFA should increase public disclosure of information on the States survey agencies. Particularly relevant would be information on the number of surveys conducted, the specific facilities surveyed, the type of deficiencies found, and the corrective actions taken. As with the Networks,

HCFA could post this and other pertinent information on its own website or call for the States to post it on their own, or even post it within the facilities as is the case for nursing homes.

We presented our recommendations in the context of the current oversight system in which HCFA relies upon the Networks and State survey agencies. We believe that this system has the potential to provide effective oversight if HCFA moves in the direction we call for. We want to stress that while HCFA has authority and leverage, it must approach the Networks and State agencies as partners who contribute to and share a commitment to high-quality dialysis care. We also want to stress that external oversight must be conducted in ways that minimize the regulatory burden on dialysis facilities and seek to complement the facilities' own internal quality review efforts.

HCFA has developed a comprehensive plan of action which we regard as responsive to our findings and recommendations. The plan outlines HCFA's actions for each of our recommendations. Most notably, HCFA's commits to collect and disclose facility-specific performance data, increase on-site surveys, revise the Conditions for Coverage, and strengthen the complaint process.

This concludes my testimony, and I welcome your questions.

The CHAIRMAN. Thank you very much.

I have questions of all of you and I am sure that Senator Breaux will, as well. And I would encourage you, if I ask a question of one person and somebody has something to add to it or another point of view on the same question, to signal your intent and I will be glad to include other people in the response.

Dr. Bays you referred to yourself and other dialysis patients as "money cows with a market value of $100,000." What do you mean by that?

Dr. BAYS. Dialysis patients are routinely sold. In other words, being that the dialysis industry is not covered by the Stark law, a physician can sell his patients. The clinics, the companies routinely sell patients to each other. In other words, it is like commodities. And being a patient, they are locked into a geographic area and there is nothing they can do about it.

So this is, to me, one of the major problems, is the dialysis community should be put under the Stark law, like all other physicians are. That is the No. 1 thing. And No. 2 is that we think that Microsoft has a monopoly; Microsoft does not really have a monopoly. Some of these for-profit companies have a total monopoly because they control the production of dialyzers, production of the machine, down to the services, down to control of the geographic area. So they control it completely.

Does that explain what I am talking about?

The CHAIRMAN. Yes, very much so.

Dr. Bays, you describe your experience at the first dialysis center that you went into, and these were your words, as hell. Can you elaborate on the quality of care you received there?

Dr. BAYS. Well, in other words, whenever dialysis started out, like he referred to with the nurses and everything like that, which I think the main focus on dialysis should be educating the patients as to what is proper care. And the second thing is self-care or home care because the dialysis patient is on dialysis for the rest of their life; most of them are. Transplantation is a thing for some people but most of them, it is not and it is not a permanent cure.

Therefore, the faster they can dialyze you, the more money they can make. So they run you through just as fast as they can and give you the minimum amount of care to keep you alive for a certain length of time.

Does that explain it?

The CHAIRMAN. Yes, thank you very much.

Now I want to ask Mr. Smith a question. This is something that I did not have a chance to think about until just today because my staff just learned of this today, that your dialysis facility made calls to you about your testimony today while you were on dialysis. Could you tell me about that telephone call?

Mr. SMITH. Well, I believe it was Friday I walked in the facility and the head of the nursing staff there asked me if I would receive a phone call from the Vice President of the company. I asked her if it would be all right if I called her after I got off the machine or the next day and she said no, she would like to talk to you now.

So about 15 minutes after I was on the machine, the phone did ring and I got a call from her and it was basically that she had seen on the website that I was going to be testifying today. She

was questioning a few of the things I was going to say and she then asked me if I would release my medical records for the company to release what my dialysis clearances were and that kind of stuff. I told her no, if somebody had a question about my clearances, they could ask me.

And I am not sure if there was a subliminal threat of some sort or whatever, but she then went on to say that the chairman of the board of the company would be calling me Wednesday when I get back. So I do not think they are going to be congratulating me on this.

The CHAIRMAN. Well, you were on dialysis at the time. How did that call affect you or how does it affect you today?

Mr. SMITH. Well, the general policy for myself is if somebody wants to talk to me about the quality of care, I do not talk while I am sitting in the chair of a dialysis machine. It puts them at an advantage and I will not discuss it. But it kind of looked at this point in time like I really was not given much of a choice.

And just from the physical aspect of it, of course your blood pressure is going to go up and it affects your run entirely.

The CHAIRMAN. What happens if you are asked to leave the facility where you now get dialysis?

Mr. SMITH. I have been asked to leave the facility where I am.

The CHAIRMAN. How recently were you asked to leave?

Mr. SMITH. Paragraph about 2 years ago. They consider me a troublemaker and a whistleblower, if you will, because I ask them to do their job, the job that they are paid to do.

The problem is 90 percent to 99 percent of dialysis patients, like the doctor was saying, are not educated in what they are supposed to get. They are not aware or made aware of the care that they are supposed to be getting.

There is also the intimidation factor. As a patient advocate for about 6 months, I could not get patients to talk because they are so afraid of what the technicians are going to do to them that they just do not say anything.

The CHAIRMAN. And being in the situation where you are, without dialysis, obviously death is just around the corner and then being intimidated about that is even further stress that I presume causes some health problem.

Mr. SMITH. Absolutely. But personally, after 20 some years, I am not intimidated easily. So it is not just me; it is the other patients. The other patients get intimidated very easily and it does affect their care.

The CHAIRMAN. In my opening statement I talked about the law that protects congressional witnesses, so I hope if there is any retaliation against you that you will inform me.

Mr. SMITH. Absolutely.

The CHAIRMAN. Mr. Grob, what is the process to get a complaint investigated by a state agency, as opposed to a network?

Mr. GROB. A complaint can be made in either case. They can be made, as they are in nursing homes, through the survey and certification agencies, but they can also be made through the Networks. So there is a dual avenue, if you will.

One of the deficiencies that we found in the system is a failure to take advantage of the great potential that is there because the

people who work for the Networks have a very high level of knowledge of dialysis care and the people who do the survey and certification have knowledge of the quality control systems. And if we could only put the two together, they could probably do a lot better job of responding to these complaints.

The CHAIRMAN. Why do Networks require written complaints, as opposed to HCFA not requiring them?

Mr. GROB. I do not think they should be requiring the written complaints. I think that would discourage——

The CHAIRMAN. But they evidently do.

Mr. GROB. They evidently do; that is right. And they may require identification of the person filing the complaint, as well. And, as the last witness said, we noticed in doing our reports, as well, that some of the patients were feeling intimidated and nervous about making complaints. In my opening statement I made a remark about how the patients really do not have the incentive to make complaints. That was probably a milder version of the statement that they may feel intimidated—they have to sign things; they have to identify themselves.

The CHAIRMAN. Dr. Scanlon—and then I will go to Senator Breaux—why doesn't the threat of termination keep dialysis facilities in compliance for more than a short period of time? And what sort of recommendations does your agency have for addressing the problem?

Dr. SCANLON. Mr. Chairman, the threat of termination has no teeth because each facility is given an opportunity to return to compliance before the termination actually occurs. And invariably, facilities take advantage of that. In terms of almost 500 actions that threatened termination, only three facilities were ever terminated in the last 5 years.

The lack of incentive is associated with the fact that there is no cumulative history that is supplied when one is reviewed and when the action to terminate is initiated. You are given the same opportunity to come back into compliance as if you had never had another problem in the past.

So it is our sense that there is no cost to a facility to be out of compliance. And in fact, there is even less of a risk to facilities today because surveys are going to occur so infrequently that a facility may remain out of compliance for a considerable period of time before it is detected and before they have to engage in producing a plan of correction.

The CHAIRMAN. Senator Breaux.

Senator BREAUX. Thank you very much, Mr. Chairman. Thank you, members of the panel.

I take it that HCFA has the authority to impose monetary fines. Did not Congress give them the authority to——

Dr. SCANLON. HCFA does not have that authority with respect to dialysis facilities. They do have the ability to withhold Medicare payments when there are problems associated with dialyzer reuse and they actually are allowed to recoup Medicare payments that have been made when they are associated with dialyzer reuse.

Senator BREAUX. On your statement on page 4, "Congress authorized HCFA to impose penalties on such facilities."

Dr. SCANLON. Right. It is in the case of dialyzer reuse and HCFA has——

Senator BREAUX. Only in that case?

Dr. SCANLON. Right. HCFA has said that they find the imposition of those penalties or the recouping of funds too difficult because they have to be recouped only for the patients that are affected by the deficient procedures. So we feel——

Senator BREAUX. So we gave them authority to impose penalties for dialyzer reuse but not for other problems?

Dr. SCANLON. Not for failure to comply with other conditions of participation; no, Senator.

Senator BREAUX. That is one of the stupidest things we have done in a while.

The CHAIRMAN. You are right.

Senator BREAUX. We wrote a law that spelled out that we can impose a penalty for dialyzer reuse but for nothing else that goes wrong?

Dr. SCANLON. That is correct, Senator. And also with respect to the Networks, there are provisions where the Networks have some flexibility in terms of the sanctions that they impose for lesser deficiency, but when a deficiency is serious, only termination is their option.

Senator BREAUX. It just points out something that I have been arguing about for a very long time—the ultimate micromanagement of the Medicare program by the Congress, to get down to that small of an act of Congress for that specific a violation but not to give someone the authority to look at the whole thing. It boggles my mind.

So I guess your recommendation is because the penalty is like the sledgehammer approach, if you are not running a good program, the only thing we have the ability to do is withhold certification, so it does not occur very much.

Dr. SCANLON. That is correct, Senator. A penalty that is so severe is very rarely going to be imposed and I do not think we would be comfortable if it was imposed very frequently. Something intermediate creates the incentive to try to avoid the penalty because you know it is going to be imposed.

Senator BREAUX. OK. Under the current rules and regulations, 131,000 pages under Medicare, do we have to have another act of Congress to give them the authority to do something short of decertifying a facility?

Dr. SCANLON. I am afraid you do.

The CHAIRMAN. Senator Breaux, that is one of the things that I think I have concluded, and I am going to come to you and ask you for your help, what we need to do in that area and I do not know how difficult it will be to do but I think we need to take a look at it.

Senator BREAUX. It may be the only Medicare reform we do all year.

The CHAIRMAN. Well, I support your approach on Medicare reform but I do not think we will get there this year, but we will get there sometime.

Senator BREAUX. How does the penalty provisions for failure to comply with standards compare in the dialysis facilities to the situ-

ation with the nursing homes, which this committee has looked at before, when you find a violation in a nursing home?

Dr. SCANLON. I think the most important difference is the ability in the nursing home area to impose a monetary penalty. Even though, as we have talked before in prior hearings, monetary penalties have not been imposed very often in the nursing home area, part of that was due to some of the administrative difficulties that HCFA was having in using that sanction.

They have had more resources this year, the ability to use more administrative law judges, and hopefully some of those administrative problems will be resolved and we will be able to identify whether or not monetary penalties will be an effective technique in the nursing home area. But that, I think, is the principal difference between nursing homes and dialysis facilities.

Senator BREAUX. Tell me, either Mr. Grob or Mr. Scanlon, who can tell me about the Networks? What are they supposed to do and how do they work or how are they supposed to work?

Mr. GROB. The Networks actually sponsor a lot of improvement projects for the facilities in their regions and they also gather clinical and other data to gauge the effectiveness of the operations of the clinics.

The key thing here is that they do do that and there has been a set of measures that have been used, for example, to demonstrate that the care overall has improved. But what is lacking is that they do not use that same approach for individual facilities or for individual physicians or for the care of an individual patient. And of those three, probably the individual facility is the key.

So they might be issuing reports that things are going great in the region but if you wanted to know how a particular facility is doing, you would have trouble finding that out and there might not be the goals established for that facility that the facility will be held to. Yet it should be possible to that. In fact, some have tried that and it does seem to bring about——

Senator BREAUX. Do the people in the Networks work for Medicare?

Mr. GROB. The people in the Networks, they are contracted by Medicare to do the work but they are experts from the dialysis industry.

Senator BREAUX. Now, do they inspect the facilities or just look at the overall information coming out of a collective group of facilities?

Mr. GROB. It is more the latter than the former. The inspections are done by the state survey teams.

Senator BREAUX. Are we duplicating the effort here? Is there not some way of combining the work that Networks do with inspectors and have one more efficient operation?

Mr. GROB. That would be the absolute best thing that we could do. We really think that both approaches, which we have here—you do have the survey and cert inspections and you do have the Networks—they are both good. Either one alone would not be so good but you have both of them and we think we should do more with both of them, especially at the individual facility level. There are some really good opportunities for on-hand cooperation.

For example, I mentioned the resolution of complaints. It is also possible to strengthen the way surveys are conducted, by getting more information from the renal Networks about what is happening in individual facilities.

There is a lot more that could be done about getting these two groups working more closely together. They do not overlap what they do. So if you can get them working more closely together, you are going to get a better product out of it. It is going to be much better.

Senator BREAUX. Well, is there any way to compare the state of this industry, this treatment as far as quality, 10 years ago to what it is today? Are we better off today with the type of treatment or are we about the same or are we going in the wrong direction?

Mr. GROB. Overall, I do not think there is any question but that the efficacy of the treatment has improved. There seems to be no question about that from the point of view of the clinical guidelines.

However, I think from the point of view of the service to the patient in the facility and the failure to really get control over medical errors when they occur or complaints when they are registered, I think that those areas are very deficient.

And I would like to take, if you do not mind, the opportunity to elaborate on the question you asked about comparison to the nursing home industry, because I think there are two other differences.

In the nursing home industry, you have the survey and certification reviews approximately once a year. There is no timeframe for these facilities. As we said now, only about half of them get it even once every 3 years and some even less than once every 6 years.

The other thing is if you wanted to check into a nursing home, you could go to HCFA's website and they will have a program there where you can look up any nursing home by name and you can find out the results of the survey and certifications the last three or four times they were given but you cannot get that information at all about any of these ESRD facilities.

Senator BREAUX. Oh, we do not have that information on the website?

Mr. GROB. It is not there.

Senator BREAUX. So you cannot compare them to nursing homes. Before, you could go off and you can find more information about a toaster oven than you could about some medical facilities—find out how often it breaks and how much it costs to repair it and which ones are reliable and which ones are not. The nursing home industry now has that, working with HCFA, has put that on the Internet and made it available to everyone just to be able to check, and you are saying we do not have that type of system for the dialysis programs?

Mr. GROB. That is exactly right.

The CHAIRMAN. Is the information available so it could be put on line?

Mr. GROB. There are fewer surveys, so from that point of view, there is less information. However, these Networks do gather a lot of information for the regional dialysis facilities, so there is facility-specific information that is available. In fact, if I may go even fur-

ther here, the idea would be to use at the facility level some of the techniques that are being used at the regional level to promote an improvement in care. Facilities ought to be able to compare how well they do with respect to other facilities, previous periods of time, things like that, and other people ought to be able to compare them and goals ought to be set. And if you did those things, I think, in connection with strengthening the survey process, I think it could be done. I think you could see a real improvement here.

The CHAIRMAN. So you think there would be information available that could be put on line here.

Mr. GROB. Yes.

The CHAIRMAN. And it would be available through an agency that contracts with Medicare.

Mr. GROB. Yes. Both the surveyors and the networks are contractors of the Health Care Financing Administration. Now, I think everyone agrees that the performance measures and the other data need to be improved and HCFA is planning to do that. I think the industry recognizes that and has some of its own initiatives.

Senator BREAUX. It is clear, too, and I think the Chairman would agree with me that if you have that information out there to the public, it is an incentive to the providers to do a better job.

Mr. GROB. Exactly.

Senator BREAUX. Because they know their record is out there, like a nursing home's record, with all the good features and all the negatives. People are going to shop and compare.

Mr. GROB. That's right.

Senator BREAUX. If you have that information out there, there is going to be a real incentive to make sure we are doing a better job because we are going to get reported on.

Mr. GROB. Exactly.

Senator BREAUX. What I am hearing then is inadequate sufficiency of inspections and an inadequate range of tools with which to penalize the operator for deficiencies that need to be addressed.

Mr. GROB. Yes.

Senator BREAUX. Dr. Bays and Mr. Smith, I do not have any other questions but I would certainly like to thank you very much.

Dr. BAYS. Well, I am on the network and the first thing you have to realize is that information on networks is voluntarily sent to the network from the clinics. There is no way that they check the authenticity of the data. I have seen the data and to me, it is a joke. The way they measure adequacy is also a joke. It is taking their word for it.

We have the ability now, this electronic age, to get the true data and get it from the back of the machines. Unfortunately, the network is run by the industry, it is staffed by the industry, has volunteers, and it is like letting the fox watch the henhouse.

We have gone from a mortality rate in the United States of 10 percent to 25 percent. The rest of the civilized world has a mortality rate of less than 10 percent and those facts speak for themselves.

Senator BREAUX. Mr. Smith, do you have a comment?

Mr. SMITH. Senator, I would like to take one step back to the facility level and the information that is being gathered and reported. There is absolutely no incentive at the facility level for them to re-

port mistakes that happen. There is incident report, I think it is called, that they never write. So the information that they are going to get is going to be false to begin with.

Senator BREAUX. It is like confession time. They are not going to confess.

Mr. SMITH. You can gather up all the data about how great the units are doing when it comes to the patient care relationship because mistakes are never made or never recorded. They are never reported.

Senator BREAUX. You know, it is interesting. I was reading about the numbers in the health care system in the country and we all think we have the finest in the world. I continue to think we do but these numbers I saw in one of the magazines just a few minutes ago was that $334 is the amount of money spent in the country of Oman for a person per year on health care and Oman ranks No. 8 in the world for overall fairness and quality of the health care.

The United States, on the other hand, spends $3,724 per year per person on health care and we rank 37th in the world on the quality of our health care system. So it is not just a question of spending money. It is a lot more and hopefully we are making progress.

Thank you very much. I thank the panel.

The CHAIRMAN. I think Dr. Scanlon also wanted to add something to your last comment, Senator Breaux.

Dr. SCANLON. I just wanted to add that while I agree completely with the power of information and how we really should be moving to focus on clinical outcome data, a note of caution in terms of how long it may take us to get there is also in order. For example, as we did our work and we looked at the different networks, and we found extreme variability in terms of both the quantity and quality of information they were collecting about a facilities performance.

As Mr. Smith has indicated, there are reasons to believe that patient care information is not always being reported and there are issues of accuracy of reporting.

As we start to use this information, I think we have to be even more concerned about errors that may appear in the data and to have the methods in place to make sure that we have accurate, reliable data, and we do not have those today.

So I think while we would like to use patient outcome and clinical data to measure how well a facility is doing, it is going to potentially be a while before we can be there on a national basis.

The CHAIRMAN. I have three questions I want to ask. Let me announce that Senator Breaux and I may have some questions that we will submit for answers in writing, but also other members who could not come may want to do that, as well, so I want to ask you to do that in 2 weeks.

Dr. Bays, you stated in your testimony that you have concerns about reuse of dialyzers and you do not reuse them yourself in your hemodialysis at home. What is your greatest concern about reuse?

Dr. BAYS. Well, the greatest concern—there are several concerns with it. One of them, a dialyzer is like an oil filter, basically the same thing as your car. When you have an old oil filter, the thing that filters out gets stopped up. These little pores in this dialyzer

get stopped up and the things that you do not get out—you talk about urea, that is mildly toxic in the body. The beta–2 microglobulins, the phosphorus and other factors are the ones that should be removed.

Another thing is the chemicals that are used in reuse. The major one is peracetic acid and if you will look at it, peracetic acid is a fairly nasty animal. In other words, if you spill some on you the precautions are that you are supposed to get your clothes off. If you get some on your shoes, you throw them away. If you inhale it, it can be fatal.

And this dialyzer is like an old garden sprayer. If you take a garden sprayer and you put some weed killer in it and you rinse it and you wash it and you do everything you want to it and then you put some insecticide in it, it will still kill your shrubbery when you use it.

The CHAIRMAN. Well, that is what is wrong.

Dr. BAYS. That is simply the basic thing there.

Then also, the chemicals change the proteins, the blood that is in there, and they form toxins. This all documented in the literature.

The CHAIRMAN. Thank you.

Now I would ask Mr. Smith a question and that is in regard to your own experience with the effect of your having cardiac arrest because of high and low potassium levels. I would like to have you explain what happened to you there and exactly what you and your family were told at the hospital about the reasons.

Mr. SMITH. Well, I think there were two distinctly different stories from the providers if I had died and since I lived. I mean if I would have died, they would have just told them that it was just simply that this happens in dialysis. This is just part of being a dialysis patient.

But since I lived, I really was not told anything. I was told I had low potassium but there was no investigation as to what caused it that I am aware of, other than my own. And I believe by looking back at the records like I did and talking with the doctor and going back over my chemistry through the labs, I pretty much figured out what had happened.

So again if I can conclude, there are two different stories, one had I died, and I did not really get much of a story since I lived.

The CHAIRMAN. And my last question, Dr. Bays, is about the part of your testimony where you told me that the first facility that you went to, the technicians were "untrained personnel with no medical background." How could you tell this? But, more importantly, if you were going to voice a concern or other people voice a concern about an untrained technician, do patients feel comfortable complaining about the quality of their care or the people who are working with them?

Dr. BAYS. The first thing, I did not realize they were untrained until I went to the second facility and really understood. It was inconceivable to me, as a professional man, that a person would be untrained and unskilled. I knew they were unskilled but it was inconceivable to me that—say if you had an accident and you went in the hospital. You assume in the emergency room that the one that that is going to put in the catheters and fluids in you is skilled

in doing it. You just assume this. So you cannot visualize what exists.

Plus the fact that you have to realize this, and most people do not understand this, that a person who is very anemic and very uremic has greatly diminished mental and physical abilities. I mean your IQ drops down quite drastically.

You go into a dialysis center and just sit back and look at those patients. They are very lethargic. They really do not have the mental ability—I know this sounds strange to you—to really make intelligent decisions. It is only whenever they—it is basically like concentration camp victims. They are very easy to control and they do not have the—their main thrust is on keeping alive. I know this sounds strange to you that this would happen in this country.

The CHAIRMAN. What about patients being willing to complain about the quality of care that they receive?

Dr. BAYS. Well, there are two things there you have to realize. You remember if you are on the verge, the end, you realize that if you miss two or three dialysis treatments, you are going to die. Plus the fact is just think of somebody there and you do not want to make them mad because they have this needle as big as a 10-penny nail; they can make you behave.

I know this may sound strange to you. I know when I was on a network, they would get these complaints. See, they have to send in the name and patients would not send in their names because the first thing a network does is send the name back to the facility to work it out.

So if you are in a position where you will die if you do not behave, then you are going to behave. I do not know if this makes sense to you or not. Until you are in this position, you really cannot understand.

The CHAIRMAN. And we appreciate that.

Thank you all very much for your testimony. We appreciate your cooperation and hopefully Senator Breaux and I will come up with a program that will help some of these situations not to be repeated.

Now I am going to call our second panel of witnesses. We have Terry Bahr, President of the National Renal Administrators Association. We have Dr. William F. Owen, President of the Renal Physicians Association. Then we have Dr. Jay Wish, President of the Forum of End Stage Renal Disease Networks, and Dr. Jeffrey L. Kang, Health Care Financing Administration.

We will take your testimony in the way that I introduced you, so that will be my left to my right. Mr. Bahr.

STATEMENT OF TERRY BAHR, PRESIDENT, NATIONAL RENAL ADMINISTRATORS ASSOCIATION, RESTON, VA

Mr. BAHR. Thank you, Chairman and members of the committee for allowing us to present testimony.

I am an Administrator from Scripps Dialysis Center. We operate two freestanding dialysis units in La Jolla, CA. I am also currently the president of the National Renal Administrators Association. It is a voluntary organization for professional managers representing freestanding and hospital-based facilities.

Looking at the ESRD program for almost two decades, Medicare reimbursement in both real and inflation-adjusted dollars, has been while dialysis has been improving quality of care to 300,000 patients. USRDS and HCFA 1999 data demonstrate that dialysis facilities have been improving mortality, as well as improving adequacy of dialysis and anemia management. These are two key dialysis quality measurements for the ESRD patient.

We strongly believe that dialysis providers are continuing to make progress in improving quality in our facilities and Medicare must do a better job of reimbursing dialysis facilities so that we can continue to improve patient outcomes.

The Medicare Payment Advisory Commission, MedPAC, essentially agrees with NRAA and the renal community. They recommend HCFA annually review the composite rate paid to dialysis facilities because only the largest dialysis providers are currently being reimbursed more than their cost. Further improvements in quality will entail more resources. This is an intensive process requiring staff to do more patient care services, education and monitoring.

MedPAC would agree that dialysis facilities are about as productive and efficient as possible. Therefore, it is unrealistic to expect dialysis facilities to be able to do more at the current Medicare reimbursement levels.

Unfortunately, HCFA has no authority to update the annual composite rate, as it does for all other Medicare providers.

NRAA would urge members of this committee to join Senators Frist and Conrad in introducing legislation to support MedPAC's recommendations to increase payments for dialysis facilities by an additional 1.2 percent in the year 2001 and add an annual increase, inflation adjustment, for the dialysis providers beginning in 2002.

NRAA has supported HCFA in its efforts to improve quality initiatives, including the current ESRD Clinical Performance Measures Project. These projects have provided dialysis facilities with specific data on how well each facility is doing in improving adequacy of dialysis and anemia management. USRDS, funded by NIH, provides facilities also with specific profiling data for their facilities.

NRAA would like to suggest several improvements within the ESRD program. HCFA should do a better job of ensuring state surveyors are well trained understand the dialysis regulations. HCFA should require greater collaboration between the 18 ESRD Networks and the state surveyors. I think we heard about that earlier today and it is nonexistent in my State of California.

HCFA should require the state surveyors in general to survey dialysis facilities at least every 3 years, taking the limited resources that are currently available and focusing on facilities who have lower outcomes or have problems which would free them up to improve those facilities.

There are other ways in which HCFA can help the renal community. HCFA should be required to respond in a more timely fashion to issues that are critical to the industry. An example recently, HCFA took almost a year to get answers to the renal community on how to deal with ESRD patients in skilled nursing facilities. These patients were in the skilled nursing facility, and could not come to the dialysis unit.

It took 3 years for HCFA to tell us what they would do on reimbursement for doppler flow studies. We heard about vascular access and that is a very key point to dialyzing a patient well. It took 3 years for an answer and the answer was not what we wanted to hear.

HCFA should allow dialysis providers to utilize and reimburse new technologies. Instead, it is all considered part of the composite rate.

HCFA should require better coordination between the different departments of HCFA. The recent reorganizations, a number of reorganizations, have left us finding more questions and who to talk about any specific issue than any answers that have come from them.

HCFA should be given the authority to require physicians to physically see their patients at least two times a month in their unit or in their office. Currently that is not the case.

Having made all of the above recommendations, we would still say the best way to monitor and improve quality to ESRD patients in a dialysis facility is to use the existing ESRD network structure in collaboration with the state inspectors. Dialysis facilities should have to report data on renal community consensus outcomes to their network and the networks should have to report specific data back to the facilities and target the below average facilities for improvement. We have found in the renal administrators group that this type of system works best for turning facilities around.

We have been very supportive of all the quality and continuous quality programs developed, including DOQI and KDOQI. We continue to have AAMI reuse of dialyzer regulations, support for their workshops and meetings and education. And that is the end of my testimony.

[The prepared statement of Mr. Bahr follows:]

NATIONAL RENAL ADMINISTRATORS ASSOCIATION

Senate Special Committee on Aging

Testimony
of the
National Renal Administrators Association

Presented by
Terry Bahr
President, NRAA

June 26, 2000

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Good morning Mr. Chairman and Members of the Special Committee on Aging. My name is Terry Bahr, and I am the Administrator at Scripps Dialysis Center, which operates --- free-standing for-profit dialysis facilities in LaJolla, California. 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 half of the dialysis units in this country which provide dialysis services to a majority of Medicare End-Stage Renal Disease (ESRD) 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 to the ESRD patients in our dialysis facilities in the most cost effective manner. The association is also dedicated to educating our membership on complying with all of Medicare's rules and regulations.

We are delighted to have the opportunity to participate in this important hearing on the Medicare ESRD program. Our testimony will focus on: (1) NRAA's position on quality of care provided by Medicare's ESRD program, (2) HCFA's oversight of the program, (3) NRAA's suggestions for improvements within the ESRD program, and (4) the association's numerous initiatives directed at improving the quality of care dialysis patients receive.

Medicare ESRD Program Is Successful, Cost Effective and Improving Quality of Care

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. The Institute of Medicine, in its landmark study entitled, ***Kidney Failure and Medicare Program***, concluded that, "It (i.e. Medicare's ESRD program) 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), ***1999 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, nominal spending per patient per year actually decreased by 0.2% in 1997 and in the past several years there has been little or no growth in per patient spending.

Despite almost two decades of declining Medicare reimbursement both in real and inflation adjusted dollars, dialysis providers have been improving the quality of care to the estimated 300,000 ESRD Medicare beneficiaries in this country. The USRDS ***1999 Annual Data Report*** demonstrates that dialysis facilities have been improving mortality rates. Also, the ***1999 Annual Report on ESRD Clinical Performance Measures Project,*** published by HCFA, shows steadily improving numbers on the adequacy of dialysis and anemia management, two key measures of quality of care for dialysis patients.

However, the NRAA strongly believes that if dialysis providers are to continue making progress in improving quality of care in their facilities Medicare needs to do a better job of reimbursing dialysis facilities for providing the treatments that lead to improved outcomes.

Need to Include An Annual Inflation Formula to Medicare's Dialysis Payments

The Medicare Payment Assessment Commission (MedPAC) essentially agrees with the NRAA's and renal coalition's position. MedPAC, in their ***March 2000 Report to the Congress***, recommends that HCFA annually review the composite rate paid to dialysis facilities because currently all but the largest dialysis providers are being reimbursed by Medicare at a payment rate that is **less** than their costs. Further improvements in quality will entail more resources as improving quality is an intensive process requiring staff to do more in terms of patient education, monitoring, services and rehabilitation.

MedPAC would agree that dialysis facilities are about as productive and efficient as possible and therefore it is unrealistic to expect dialysis facilities to be able to do more at current Medicare reimbursement levels.

Unfortunately, HCFA has no authority to annually update the composite rate, as it does for all other Medicare providers. However, Congress could mandate that they be required to do so.

The NRAA would urge members of this committee to join Senators Frist and Conrad, in introducing legislation to support MedPAC's recommendations to increase payments to dialysis facilities by an additional 1.2% in 2001 and require HCFA to provide an annual inflation update to dialysis facilities, beginning in 2002.

HCFA's Oversight of the ESRD Program

The NRAA has supported HCFA's efforts to improve quality through their Continuous Quality Improvement (CQI) Initiatives, including the National Anemia Study, Core Indicator Study and now the ESRD Clinical Performance Measures Project. These projects have provided dialysis facilities specific data on how well each facility is doing in improving the adequacy of dialysis, anemia and other quality measures. The USRDS, funded by the NIH, also provides facility specific profiling data. The association believes that these types of profiling data have significantly improved the quality of care in facilities.

NRAA's Suggestions for Improvements Within the ESRD Program

While the NRAA believes HCFA has made an honest effort to help improve quality of care in dialysis facilities, the association would like to make the following recommendations for additional improvements:

1. **HCFA should do a better job of ensuring that the state surveyors are well trained and understand the dialysis regulations.** In some states the surveyors are very knowledgeable but in others they do not understand the ESRD regulations and as a result sometimes unfairly cite dialysis facilities because they have misinterpreted the rules. Lack of adequate training also frequently results in variations and inconsistencies in interpreting the guidelines among the states which creates unjustified problems for providers with facilities in more than one state.

2. **HCFA should require greater collaboration between the 18 ESRD Networks and state survey agencies.** This would help target the limited resources available to helping problem dialysis facilities improve the quality of care in their facilities.

3. **HCFA should require the state surveyors in general to survey dialysis facilities every three years.** The state agencies should identify problem dialysis facilities and target them for more frequent inspections. For dialysis facilities that have been found to provide good quality care, the state surveyors should only conduct brief surveys in the next third year survey, so that they can spend the bulk of their time on the problem facilities.

There are other ways in which HCFA could assist the renal community in improving quality care.

1. **HCFA should be required to respond in a more timely fashion to issues that are critical to the ESRD industry.** For example, it took HCFA well over a year to respond to the association's request for guidance and clarification of the rules concerning ESRD Medicare beneficiaries in skilled nursing facilities (SNFs), due to the implementation of the SNF prospective payment system. Another example was the renal community's request for continued separate reimbursement for doppler flow studies. It took HCFA three years from the time of our first meeting with them on this issue to publish a program memorandum which we now find unacceptable. The NRAA members have a steady stream of questions for HCFA on reimbursement issues that directly or indirectly affect quality of care. HCFA should have to respond to such questions within thirty days rather than the months and sometimes years before answers are given.
2. **HCFA should allow dialysis providers to utilize and be reimbursed for new technologies instead of continually claiming that they are already included in the composite rate paid to dialysis facilities.** The latest example concerns doppler flow studies, which are used to measure the dialysis vascular access. If the vascular access is blocked or in any way narrowed it is very difficult to adequately dialyze a patient. Instead of establishing a national policy on the medical justification for separate reimbursement for doppler flow studies, HCFA is leaving it up to each local fiscal intermediary, according to their Program Memorandum Transmittal AB-00-44. As a result, some patients' care will be compromised because the local intermediary has not made a decision on when or if reimbursement will be made. Dialysis facilities cannot afford to provide this service without separate reimbursement given that the composite rate paid to dialysis facilities has essentially been frozen for the past two decades.

3. **Require better coordination between the different departments of HCFA that handle ESRD issues.** The latest reorganizations have resulted in such fragmentation that it is very difficult to know who in HCFA is handling an issue and to get all the necessary players at HCFA to coordinate their policies. This fragmentation has also led to confusion and lack of clarification on what Medicare's rules are which in turn means that dialysis facilities have to spend too much time on administrative issues which detracts from their time spent on improving quality of care.

4. **HCFA should be given the authority to require physicians to physically see their patients at least two times a month in the dialysis unit or in their offices.** Physicians should also be required to participate in patient care planning on a monthly basis for unstable patients and every six months on stable patients in order to qualify for their monthly capitation fee.

Having made the above recommendations, the NRAA would still say that the best way to monitor and improve quality of care of ESRD patients in dialysis facilities is to utilize the existing ESRD Network structure. Dialysis facilities should have to report data on renal community consensus outcome measures to their Network and the Networks should work with facilities that are below the average for their area, state or nationally to improve the care their patients receive. Renal administrators have found that this system works best in turning problem facilities into facilities that provide their patients with first rate care.

NRAA's Initiatives to Improve Quality of Care for Dialysis Patients

The NRAA has taken many steps since the inception of the association to improve the quality of care in dialysis facilities. **First, the NRAA has worked with other organizations in the renal community to reach consensus on how to improve quality of care by establishing quality measurement guidelines.** The best examples of this are the establishment of the Dialysis Outcome Quality Initiatives known as DOQI and KDOQI, which spell out for the first time guidelines for measuring adequacy of dialysis, and establishes other outcome measure guidelines. NRAA not only participated in the development of these outcome measures but has had several speakers at spring and annual meetings educate renal administrators on how to implement these outcome guidelines.

Secondly, the NRAA allots considerable time at each spring and annual conference to having a variety of experts educate the membership on the newest quality standards. For example, when new water quality standards are established by the American Association of Medical Instrumentation (AAMI), the NRAA had someone from the organization speak about the new standards. The association has also helped sponsor AAMI workshops on water quality standards for dialysis facilities. The association also regularly has experts talk about re-use of dialyzers and one of our members has begun the first partnership with a company to centralize the cleaning and sterilizing of re-used dialyzers which is hoped will prove to be a cost effective and quality enhancing program for re-using dialyzers. Another NRAA member is currently participating in a research project on re-use.

Thirdly, as compliance with Medicare's numerous and complex rules is another key to improving quality of care, the NRAA undertook to develop a compliance manual for dialysis facilities. The association is now selling its compliance manual to administrators and others in the renal community and has held two compliance workshops, with more to follow.

Fourthly, the association has helped improved cost data collection. The NRAA has also had a long standing interest in improving the data supplied on Medicare cost reports and annually holds cost report workshops. The NRAA has been credited by MedPAC with improving the quality of data reported on cost reports. This is important because without accurate cost data, policy makers cannot make good recommendations on adequate reimbursement for dialysis care. Without adequate reimbursement dialysis facilities cannot continue to improve quality of care for their patients.

Conclusion

Again, the association thanks the committee for the opportunity to present our recommendations for improving quality of care in dialysis facilities and HCFA's oversight of the ESRD program. I would like to conclude by stressing to the committee that without adequate funding of dialysis facilities, providers cannot continue to improve outcomes and reduce mortality rates, which are the true measures of quality of care for ESRD patients. The NRAA urges the members of this committee to join with Senators Frist and Conrad in support of an annual inflation update being added to Medicare's reimbursement for dialysis facilities to help achieve this goal. At this time I would be pleased to answer any questions that you might have.

The CHAIRMAN. Thank you, Mr. Bahr.
Now Dr. Owen.

STATEMENT OF WILLIAM F. OWEN, JR., M.D., PRESIDENT-ELECT, RENAL PHYSICIANS ASSOCIATION, ROCKVILLE, MD

Dr. OWEN. Senators, good afternoon. I am Dr. William Owen, Jr. I am president-elect of the Renal Physicians Association. The RPA is the national representative for physicians engaged in the study and management of patients with renal disease and our goal is to ensure optimal care under the highest standards of medical practice. I am a nephrologist in Durham, NC and the Director of Duke Institute of Renal Outcomes Research and Health Policy. Thank you for allowing our participation in these hearings to identify opportunities to enhance patients outcomes and satisfaction through improved oversight, accountability and quality of care in the end stage renal disease program.

The RPA has long supported appropriate oversight and accountability of providers, nephrologists and allied health professionals and payers of ESRD services in the context of quality of patient services. The RPA views the routine measurement of clinical outcomes as the infrastructure of quality. These outcomes should be tied to achievable expectations of performance that have the potential to enhance the quality and quantity of patients' lives and meet their physical and emotional needs. All this should be achieved, of course, recognizing fiduciary responsibility to the payers of the End Stage Renal Disease Program.

Examples of the RPA's commitment to quality of dialysis services includes our development and dissemination of clinical practice guidelines for nephrologists, dialysis units and patients. We were the first to offer minimum standards for the amount of hemodialysis and expanded these, offering best practices for dialyzer reuse. Moreover, the RPA assumed a substantial partnership role with the Health Care Financing Administration in translating the guidelines into national performance measures. Recognizing an opportunity to expand health literacy for patients and providers, the RPA developed a sentinel practice guideline offering guidance for both and shared decisionmaking about initiating and discontinuing dialysis.

Other relevant initiatives include the development and distribution of recommendations for the minimum frequency of physician visits to a dialysis unit, a description of the scope of work for a dialysis unit's medical director, and a documentation tool for fulfillment of the scope of work under the nephrologist's monthly capitated payment.

The RPA has developed and distributed position papers on multiple topics, including end stage renal disease patient protections in managed care organizations, in which safeguards for this vulnerable patient population are articulated; support for the exclusion of end stage renal disease patients from managed care plans until greater patient protection is implemented and the AAPCC is adjusted and principles for dialysis unit accreditation and certification that urge review at a regular frequency and that focus on patient outcomes, rather than simple operational processes.

The RPA has taken the lead in organizing dialysis stakeholders to develop interventions to enhance ESRD patient safety. Also, the RPA has taken a proactive position to minimize racial inequity in the ESRD program by sending a letter to all our members reminding them to meet patients' reasonable expectations for renal transplantation. Last, the RPA supports efforts by other societies to develop minimum uniform criteria for staff training and credentialing in dialysis units.

The RPA feels that the 18 End Stage Renal Disease Networks are the best equipped to serve as our public quality oversight partner. The RPA favors the Networks first, because of their greater depth of experience in quality oversight for ESRD patients; second, the multidisciplinary leadership of nephrologists, nurses, social workers, nutritionists and patients; and last, a regional organization that recognizes geographic variations in care and oversight.

The RPA acknowledges HCFA's quality oversight role but feels that its size and fiduciary mission may complicate quality improvement strategies. Similarly, state health departments have substantial competing tasks that confound their role.

Although the RPA favors the ESRD Networks for quality oversight, we recognize opportunities to improve their quality management.

The principles of our recommendations are first, that performance measures for providers and physicians should be actionable and linked to patient outcomes. Second, the performance of nephrologists and individual dialysis units should be routinely monitored. Third, minimum levels of performance should be defined and monitored using quality assurance strategies and achievement above these minimum benchmarks facilitated using continuous quality improvement methods.

Fourth, accountability should be maintained and demanded. Fifth, outcomes should be compared between providers and appropriate results should be offered to patients. Six, greater coordination of efforts between oversight agencies is needed. And last, adequate funding is needed to support all of these activities.

To minimize interpretive vagaries and enforce durable improvement, the RPA feels that these principles are best realized as a legislative mandate, such as our ESRD continuous quality improvement legislative proposal.

Again we thank the Special Committee on Aging for this opportunity to offer our approach for improving patient outcomes within the ESRD program. We look forward to being a continued resource to you and to this Congress. Thank you.

[The prepared statement of Dr. Owen follows:]

Testimony before the Senate Special Committee on Aging

On Medicare's End Stage Renal Disease Program

Submitted by the Renal Physicians Association

June 26, 2000

The RPA is the national representative for physicians engaged in the study and management of patients with renal disease, and our goal is to ensure optimal care under the highest standards of medical practice. RPA appreciates the opportunity to provide written testimony to the Special Committee on Aging, and our organization is available as a resource to Committee as it continues its review of the quality of care provided to the nation's End Stage Renal Disease (ESRD) patients. RPA's testimony will discuss our positions on the issues raised by the Committee in its request for input, primarily focusing on regulatory oversight of the ESRD program, and in the context of those positions will offer recommendations for improvement where appropriate.

Overview and History

The RPA has long supported appropriate oversight and accountability of providers, nephrologists, allied health professionals, and payers of ESRD services in the context of quality of patient services. The RPA views the routine measurement of clinical outcomes as the infrastructure of quality. These outcomes should be tied to achievable expectations of performance that have the potential to enhance the quality and quantity of patients' lives and meet their physical and emotional needs. All this should be achieved recognizing fiduciary responsibility to the payers of the ESRD Program.

Examples of the RPA's commitment to quality of dialysis services includes our development and dissemination of clinical practice guidelines for nephrologists, dialysis units, and patients. We were the first to offer minimum standards for the amount of hemodialysis and expanded these offering best practices for dialyzer reuse. Moreover, the RPA assumed a substantial partnership role with HCFA in translating the guidelines into national performance measures. Recognizing an opportunity to expand health literacy, the RPA developed a sentinel practice guideline offering guidance for shared decision making about initiating and discontinuing dialysis. Other relevant initiatives include the development and distribution of recommendations for the minimum frequency of physician visits to the dialysis unit, a description of the scope of work for a dialysis unit medical director, and a documentation tool for fulfillment of the scope of work under the nephrologist's monthly capitated payment. We would be pleased to provide any of these documents at the Committee's request.

RPA Positions on Quality Oversight and Improvement

Regarding the specific issues under review by the Special Committee, the RPA has developed and distributed position papers on the following topics in recent years: 1) ESRD patient protection in managed care organizations in which safeguards for this vulnerable patient population are articulated, 2) support for the exclusion of ESRD patients from managed care plans until greater patient protection is implemented and the AAPCC is adjusted, and 3) principles for dialysis unit accreditation and certification that urge review at regular frequencies and that focus on patients' outcomes, rather than operational processes. The principal thrusts of these three positions are summarized as follows, and the complete documents are appended to this testimony:

ESRD Patient Protections in Managed Care - RPA believes that in order to protect the rapidly expanding managed care population in the United States, particularly vulnerable sub-groups such as those with ESRD, legislation establishing patient protections must be enacted. At a minimum, patient protection legislation should include provisions ensuring access to specialty care, use of reasonable criteria for utilizing emergency services, confidentiality of medical records, and protection for providers against interference with medical communications and improper incentives. Foremost, the system must define and evaluate processes of enrollment and care where the patient and family understand the ramifications of a particular decision. RPA acknowledges that when cautiously and appropriately administered, managed care can provide enhanced efficiencies of care delivery. However, patients often get lost in the fray of efficiency and fall victim to a well-intended but flawed system. The physician must remain the patient's advocate in an increasingly sophisticated system. Early prevention can often save both costs and morbidity. For chronically ill patient populations such as those with ESRD or those with conditions that are often precursors to ESRD such as diabetes and hypertension, the limitations inherently present in managed care can have a tangibly negative effect, including reduced quality or loss of life.

ESRD Patient Participation in Managed Care Plans – Currently, RPA opposes a repeal of Section 1876 of the Social Security Act, which specifically prohibits Medicare ESRD beneficiaries from participating in managed care plans. However, the issue of ESRD patient participation in managed care plans has recently come under increased scrutiny, and therefore RPA believes this subject merits reevaluation. In order for ESRD patients to safely participate in managed care plans, the RPA believes that: (1) A quality oversight program must be implemented that includes continuous quality improvement methodologies such as clinical practice guidelines, clinical performance measures, and integrated information systems. Quality improvement processes should encompass the current ESRD Network system and should focus on actual implementation of CQI methodologies at both the Network level and the facility level. A national committee should be established to oversee these CQI efforts. Legislative proposals should include emphasis on patient surveys and outline the critical success factors needed for QI implementation at the network and dialysis facility level; (2) Modification of the AAPCC must occur first as many of the other

difficulties occurring in Medicare managed care flow from inadequate reimbursement for these groups of patients. Appropriate adjustment for case-mix variability that provides sufficient reimbursement for both complex and relatively stable ESRD patients will allow the sponsors of these delivery systems to provide an expanded level of benefits to vulnerable patients while maintaining fiscal viability; and (3) Any legislative proposal to repeal the 1876 prohibition must be delayed for a minimum of two years to allow for full implementation of the CQI oversight program and modification of the AAPCC. In the event that the CQI and AAPCC proposals are not implemented, the ban must not be repealed.

Improving the Dialysis Facility Accreditation and Certification Process - The RPA supports the accreditation, certification and licensure of dialysis facilities as a visible means of ensuring accountability, and in order to accomplish these functions appropriately, increased federal funding is necessary. The RPA believes that an appropriate accreditation and certification system will emphasize use of evidence-based quality improvement methodologies that use outcomes data to enhance facility processes. Within the current governmental framework exist several alternative solutions with the potential to improve the outlook for dialysis facility accreditation. One possibility involves legislative modification of the statutes that govern certification of facilities providing services to Medicare beneficiaries. By adding dialysis facilities to the list of provider types for whom certification is statutorily required (currently nursing homes and home health agencies), ESRD facilities would be assured that their certification surveys and re-inspections would both occur within a defined timeframe. Considering the highly vulnerable nature of the patient population being served by these facilities, and the potential therapeutic and economic benefits of improving care to these individuals, enactment of legislation expanding the list of Medicare providers requiring timely certification appears to be a reasonable and cost-efficient method of improving dialysis facility accreditation. The ESRD Network organizations offer another avenue for improving dialysis facility accreditation using an existing governmental agency. By providing deeming authority for certification to the Networks, HCFA would be engaging organizations that are already in contact with the nation's dialysis providers and already heavily involved in the business of improving the quality of care to ESRD patients. The territorial orientation of the network system would easily allow for consideration of regional differences as necessary. As the Networks already serve a vital role as a catalyst for improvement for the nation's dialysis facilities, providing deeming authority to these entities would seem to be a natural extension of their current mission. The Networks are responsible for ensuring 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.

For these reasons, the RPA feels that the eighteen ESRD Networks are best equipped to serve as our public, quality oversight partner. In summary, we favor the ESRD Networks because of their: 1) greater depth of experience in quality oversight for ESRD patients, 2) multidisciplinary leadership of nephrologists, nurses, social workers, nutritionists, and patients, and 3) regional organization that recognizes geographic variations in care and oversight. The RPA acknowledges HCFA's quality oversight role, but feels that its size and

fiduciary mission may complicate quality improvement strategies. Similarly, state health departments have substantial competing tasks that confound their role.

Recommendations

Although the RPA favors the ESRD Networks for quality oversight, we recognize opportunities to improve their quality management, and have accordingly developed the following recommendations for enhancement of the quality of delivered ESRD care. To minimize interpretive vagaries and enforce durable improvement, the RPA feels that these recommendations are best realized as a legislative mandate, such as our ESRD Continuous Quality Improvement legislative proposal.

1) **Performance measures for providers and physicians should be actionable and linked to patients' outcomes.**

2) **Performance of nephrologists and individual dialysis units should be routinely monitored.**

3) **Minimum levels of performance should be defined and monitored using quality assurance strategies, and achievement above these minimum benchmarks facilitated using continuous quality improvement methods.**

4) **Accountability should be maintained and demanded.**

5) **Outcomes should be compared between providers, and appropriate results should be offered to patients.**

6) **Greater coordination of efforts between oversight agencies is needed.**

7) **Adequate federal funding is needed for these activities.**

Conclusion

The RPA commends the Special Committee on Aging for addressing issues surrounding the quality of care delivered to the nation's ESRD patients. We appreciate the opportunity to provide input to your efforts, and look forward to working collaboratively with the Congress to advance the goal of continuous quality improvement in the ESRD program.

APPENDIX A

Adopted by the RPA/ASN Board of Directors, 1/23/99

RPA/ASN POSITION ON ESRD PATIENT PROTECTIONS

EXECUTIVE SUMMARY

RPA/ASN believe that in order to protect the rapidly expanding managed care population in the United States, legislation establishing patient protections must be enacted. At a minimum, patient protection legislation should include provisions ensuring access to specialty care, use of reasonable criteria for utilizing emergency services, confidentiality of medical records, and protection for providers against interference with medical communications and improper incentives. Foremost, the system must define and evaluate processes of enrollment and care where the patient and family understand the ramifications of a particular decision. Meaningful legislation should also include well-defined processes for quality improvement, information dissemination, and grievance resolution, protections against provider deselection, and out-of-network access, or Point-of Service (POS).

BACKGROUND

If the managed care population in the United States maintains a steady rate of growth into the next millennium as expected, it will become increasingly important that meaningful patient protections are put into place to ensure that patient health outcomes are not adversely affected by sometimes troubling managed care strategies. Recent studies indicate that while fewer than one in seven Americans with private insurance were insured by a managed care organization (MCO) less than ten years ago, today nearly three of every four Americans with private insurance are enrolled in some form of managed care. Including Medicaid and Medicare beneficiaries, there are now more than 140 million Americans covered by managed care.

RPA/ASN acknowledges that when cautiously and appropriately administered, managed care can provide enhanced efficiencies of care delivery. However, patients oftentimes get lost in the fray of efficiency and fall victim to a well-intended but flawed system. The physician must remain the patient's advocate in an increasingly sophisticated system. Early prevention can often save both costs and morbidity. For chronically ill patient populations such as those with End-Stage Renal Disease (ESRD) or those with conditions that are often precursors to ESRD such as diabetes and hypertension, the limitations inherently present in managed care can have a tangibly negative effect, including reduced quality or loss of life.

As Congress looks to address the shortcomings of managed care, we believe that certain patient protection principles of fundamental importance must be included as part of any legislative effort to reform the managed care industry. At a minimum, patient protection legislation should include provisions ensuring access to specialty care, use of reasonable criteria for utilizing emergency services, confidentiality of medical records, and protection for providers against interference with medical communications and improper incentives. Other critical success factors include well-defined processes for quality improvement, information dissemination, and grievance resolution, protections against provider deselection, and out-of-network access, or Point-of Service (POS). RPA/ASN

believes that patient welfare and the right of physicians to provide optimal care must remain paramount within any legislative vehicle. Any compromise of those principles is unacceptable.

NECESSARY PATIENT PROTECTIONS

Access to Specialty Care

One of the most fundamental components of any managed care plan should be a guarantee of the patient's right to see a specialist with the training and experience to diagnose and manage a patient's specific medical needs. If a plan does not have an appropriate specialist in the network, it should provide for an outside referral to such a specialist, at no additional cost to the patient. The cost of delayed care may ultimately be greater than prompt care.

A common complaint with managed care organizations is that patients must make multiple requests for a referral before seeing a specialist. As a result, it can sometimes take months before an appropriate treatment plan is set in place. For patients with chronic conditions, the inability to provide timely referrals and treatment can have ramifications that last a lifetime. Such managed care policies governing access to specialty care have critical consequences for pre-ESRD and ESRD patients. Delays in the scheduling of diagnostic testing and late referrals may increase the rate of progression to chronic renal failure requiring dialysis and transplantation for patient survival. These delays can potentially become life-threatening. Late presentation of a patient with renal insufficiency restricts the nephrologists' ability to stabilize the patient's condition and provide an optimal level of care, which can delay the need for dialytic intervention or transplantation.

Similarly, because managed care organizations tend to contract with a limited number of physicians to provide dialysis, there would likely 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. ESRD patients are inherently different from other health plan enrollees. Because of the life-threatening nature of their disease, ESRD patients can not be treated in the same manner as other managed care enrollees who are healthier and not in constant need of a physician's care. It seems doubtful that large health plans would take this geographic factor into account when enrolling physicians in their dialysis panels.

Therefore, RPA/ASN believes that enrollees with life-threatening, chronic, degenerative or other serious conditions that require specialized care should be provided access to an appropriate specialist or sub-specialist capable of providing quality care for that condition. If a plan does not have a participating specialist for a condition covered under the plan, the plan must refer the patient to a non-participating specialist at no additional cost. Should an enrollee have a chronic illness that requires specialty care over a long period of time, the specialist must be allowed to become the enrollee's principal care provider, thus eliminating unnecessary referrals. MCOs should have a procedure to allow individuals with serious illnesses and ongoing needs for specialty care to receive that care from a specialist -- one who will coordinate all care for that individual.

Emergency Services

Coverage of emergency care services should be based on a "prudent layperson" standard. Simply put, use of a "prudent layperson" standard would prevent the insurer, regardless of diagnosis, from denying coverage for emergency care if a "prudent layperson" would have considered the symptoms

life-threatening. This "prudent layperson" standard would prevent insurers from utilizing narrowly defined categories of diagnoses when providing coverage for emergency services, and thus enable a person with an average knowledge of health and medicine to seek emergency treatment when they have a condition believed to be life-threatening.

While many managed care organizations may oppose the use of a broader definition of emergency care, implementation of a "prudent layperson" standard would encourage patients experiencing life-threatening symptoms to seek diagnosis and treatment when they might otherwise resist doing so for fear of incurring a substantial medical bill. As a result, physicians and other health care professionals would be able to treat these conditions before more serious and costly interventions are necessary.

Protection of Providers against Interference with Medical Communications And Improper Incentives

RPA/ASN firmly believes that no health plan should in any way interfere with oral and written communication between the physician and the patient. This is particularly important in the case of medical treatments that may be available for certain conditions but are expensive, require new technologies, or not regularly approved by the plan. Such protected communications should include the discussion of the patient's health status, medical care, or treatment options, provisions of the plan's utilization review requirements, or discussion of any financial incentives that may affect the treatment of the enrollee. Such prohibitions of physician-patient communications, commonly known as a "gag clauses" serve no purpose in achieving optimal health care outcomes.

Similarly, RPA/ASN believes that any patient protection legislation must include a provision prohibiting financial relationships between the insurer and the health care professional that may act as an inducement to reduce or limit medically necessary care provided to the patient. A health plan's use of financial incentives to promote efficient health care delivery via controlled utilization must not result in the withholding of medically necessary care. All medically appropriate therapeutic and diagnostic alternatives must be presented as options in keeping with the physician's primary role as patient advocate. We believe that any financial arrangement that furnishes a disincentive for providing the highest quality should be eliminated.

Quality Improvement

Managed care plans should be required to establish and maintain programs to monitor the quality of health care provided, especially with regard to at-risk or chronically ill patient populations, such as those with ESRD. Such a quality improvement program should use data based on both performance and patient outcomes. Plans should report certain standard information to state agencies and the public with accordance with uniform standards. This information should include at a minimum: utilization data, demographic data, morbidity and mortality rates, disenrollment statistics and satisfaction surveys, and quality indicators.

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 MCOs, maintenance of such an effective oversight program may be problematic. Quality improvement systems are critical to the proper delivery of dialysis care. Managed care organizations may have neither the capabilities nor the disposition to provide the intensive quality agenda already being pursued by the ESRD program.

RPA/ASN believe that ideally a quality improvement process should be reiterative, with results funneled back to providers of service to facilitate enhanced performance. Such a reiterative process that recycles outcomes data back to providers of service would encourage renewed assessments of performance benchmarks, and thus foster continuous quality improvement.

Information Dissemination and Confidentiality Concerns

It is the opinion of the RPA/ASN that legislation enacted to provide patient protections must establish minimum requirements for information dissemination by health plans to enrollees. This information must address issues such as patient rights, restrictions on payments, restrictions on access to specialists, out-of-area coverage, emergency services, premiums, benefits, treatment options, covered services, patient satisfaction, grievance procedures and the results of appeals. Additionally, insurers should be required to disseminate that information in easily understood terms so that their patients can compare the different plans and make informed choices that fits their individual needs. The purpose of such information is to facilitate the beneficiary's choice of insurer.

We also believe that in addition to the information outlined above, plans should also be required to provide procedural advice concerning cost-sharing requirements, how to obtain authorization for services, and how to get referrals to providers who may not be in the network. In other words, patients ought to have enough information at their fingertips to navigate the system without frustration and failure.

While RPA/ASN firmly supports dissemination of health plan information, we also believe that the implementation of procedures to safeguard the confidentiality of individually identifiable medical records represents a fundamentally important component of any patient bill of rights. While it is our understanding that concerns have been raised in the medical research community over the potentially dampening effect confidentiality provisions may have on research, we do not believe that these perceived competing concerns are impossible to adjudicate. Therefore, we are of the opinion that confidentiality policies compliant with all state and Federal requirements regarding medical record privacy should be included in any patient protection legislation.

Out of Network Access/Point of Service Option

In order to ensure that patients are able to receive care commensurate to their need, health plans which at the time of enrollment restrict the choice of health care professionals must establish a mechanism to allow patients to go out-of-network for treatment. Such a mechanism, often known as a point of service (POS) option, ensures that the plan have an option for the enrollee to receive benefits by a nonparticipating health care professional for an additional reasonable premium

The presence of such a vehicle providing out-of-network access can be especially crucial to achieving positive health outcomes for chronically ill patient populations. For those patients with chronic, degenerative diseases such as arthritis, diabetes or ESRD, the importance of maintaining continuity of care with the subspecialist who is not only trained to treat their condition in general but is also specifically familiar with the patient's personal history cannot be overestimated.

Provider Selection and Due Process

RPA/ASN believe that health plans should be required to establish protocols that address provider selection and allow for due process for health care professionals terminated from network

participation. Such provisions would prohibit discrimination against providers when selecting for a network, set forth procedures for reasonable notice of termination, allow for review of the information leading to the termination, and outline rights of appeal for such terminated participants.

As with several of the other patient protection principles addressed above, this issue can be of particular significance to nephrologists, who treat what is arguably the sickest patient population in the Medicare universe. In addition to the high risk and high cost of treating ESRD patients, patient compliance is an important a success factor in treating ESRD. The nephrologist's ability to affect a positive result is highly contingent upon the patient's cooperation. The confluence of these circumstances could foster an environment where subspecialists treating chronically ill patients would be subject to deselection.

Grievance Procedures

RPA/ASN believe that insurers must establish meaningful internal and external grievance procedures to act as a final "backstop" in ensuring adequate patient protections. Internally, procedures should establish the patient's right to appeal denials of care and to voice concerns regarding the health plan, and should require the plan to have appeals heard in a timely manner by appropriately credentialed individuals. Externally, for cases of sufficient seriousness or beyond an established monetary threshold, individuals must have access to an external, independent body with the capability and authority to resolve such grievances. Such a body for ESRD patients must include nephrologists.

Under current law enrollees are allowed to appeal their health plan's decision with regard only to the denial of care through an internal process. Such a system gives the insurer the right to decide what care should or should not be provided. We believe that a more appropriate process of appeal would address all aspects of the plan's services, including complaints regarding the quality of care, choice and accessibility of providers, and network adequacy. A two-stage appeal process should be implemented, with requirements initially for a review panel of non-involved providers, and an independent body in the second phase. A written explanation of each phase must be provided and timely decisions are required.

RECOMMENDATIONS

1. RPA/ASN's firmly believes that purposeful reform of the managed care industry is necessary to protect the exponentially growing number of participants in managed care plans, especially those with chronic illnesses such as ESRD.

2. RPA/ASN believe that legislation in this area that addresses the following fundamental issues will accomplish such reform.

   - **Access to Specialty Care** – RPA/ASN believes that enrollees with life-threatening, chronic, degenerative or other serious conditions that require specialized care should be provided access to an appropriate specialist capable or providing quality care for that condition. Frequently, patients in managed care must make multiple requests before seeing a specialist. For patients with chronic conditions, the inability to provides timely referrals and treatment can have ramifications that last a lifetime, particularly for pre-ESRD and ESRD patients. Delays in the scheduling or diagnostic testing and late referrals may increase the rate of progression to chronic renal failure requiring dialysis and transplantation for patient survival. These delays can be potentially life-threatening.

   - **Emergency Services** – Coverage for care should be based on a "prudent layperson" standard. The use of a "prudent layperson" standard would prevent the insurer, regardless of diagnosis, from denying coverage of emergency care if a "prudent layperson" would have considered the symptoms life-threatening.

   - **Protection of Providers against Interference with Medical Communications and Improper Incentives** – RPA/ASN firmly believes that no health plan should interfere with oral and written communication between the physician and the patient. Such protected communications should include the discussion of the patient's health status, medical care, or treatment options, provisions of the plans utilization review requirements, or discussion of any financial incentives that may affect the treatment of the enrollee. Similarly, patient protection legislation must include a provision prohibiting financial relationships between the insurer and the health care professional that may act as an inducement to reduce or limit medically necessary care provided to the patient.

   - **Quality Improvement** – Managed care plans should be required to establish and maintain programs to monitor the quality of health care provided, especially with regard to at-risk or chronically ill patient populations, such as those with ESRD. Quality improvement programs should use data based on both performance and patient outcomes.

   - **Information Dissemination and Confidentiality Concerns** – Patient protections legislation must establish minimum requirements for information dissemination by health plans to enrollees. Information must address issues such as patient rights, restrictions on payments, treatment options, restrictions on access to specialists, out-of-area coverage, emergency services, premiums, benefits, covered services, patient satisfaction, grievance procedures, and the results of appeals.

   - **Out of Network Access/Point of Service Options** – Health plans which at the time of enrollment restrict the choice of health care professionals must establish a point of

service (POS) option, a mechanism to allow patients to go out-of-network for treatment. The presence of such a vehicle providing out-of-network access can be especially crucial to achieving positive health outcomes for chronically ill patients such as those suffering from ESRD. The importance of maintaining continuity of care with the subspecialist who is not only trained to treat their condition in general but is also specifically familiar with the patient's personal history cannot be overestimated.

- **Provider Selection and Due Process** – Health plans should be required to establish protocols addressing provider selection and allow for due process for health care professionals terminated from network participation. Such provisions would prohibit discrimination against providers when selecting for a network, set forth procedures for reasonable notice of termination, allow for review of the information leading to termination, and outline rights of appeal for such terminated participants.

- **Grievance Procedures** – Insurers must establish internal and external grievance procedures to ensure adequate patient protections. Internally, procedures should establish the patient's right to appeal denials of care and to voice concerns regarding the health plan, and should require the plan to have appeals heard in a timely manner by appropriately credentialed individuals. Externally, for cases of sufficient seriousness or beyond an established monetary threshold, individuals must have access to an external, independent body with the capability and authority to resolve such grievances.

Congress should maintain passage of patient protection legislation as its highest priority.

APPENDIX B

RPA Principles on ESRD Patient Participation in Managed Care

RPA opposes a repeal of Section 1876 of the Social Security Act, which specifically prohibits Medicare ESRD beneficiaries from participating in managed care plans. The issue of ESRD patient participation in managed care plans has recently come under increased scrutiny, and therefore RPA believes this subject merits reevaluation. Results of recent studies conducted by HCFA, while still awaiting rigorous validation, fail to confirm that ESRD patients would experience adverse outcomes in managed care delivery systems. Other relevant literature indicates that vulnerable patient groups such as those with ESRD would require special treatment in managed care settings. This divergence of data demonstrates a need for further study of these issues.

As noted in the RPA/ASN Position Paper on "Managed Care and Nephrology", legislative proposals that focus on the subject of allowing ESRD patients to enter managed care environments must address the following issues:

1. A quality oversight program must be implemented that includes continuous quality improvement methodologies such as clinical practice guidelines, clinical performance measures, and integrated information systems. Quality improvement processes should encompass the current ESRD Network system and should focus on actual implementation of CQI methodologies at both the Network level and the facility level. A national committee should be established to oversee these CQI efforts. Legislative proposals should include emphasis on patient surveys and outline the critical success factors needed for QI implementation at the network and dialysis facility level.

2. Public and private sector funding must be obtained to support this initiative, including contributions from private plans covering ESRD patients during their 30 month waiting period for entrance into the Medicare ESRD program, and contributions to Network activities by the Medicaid program.

3. ESRD patients must have access to the level of specialty care necessary to treat their condition.

4. ESRD patients must be afforded the following protections if and when they are allowed to enter managed care: a. receive easy to understand marketing information; b. receive information on plan enrollment and disenrollment; c. access to a prudent layperson standard for emergency medical care; and d. access to an efficient and effective appeals process.

5. Modification of the AAPCC must occur first as many of the other difficulties occurring in Medicare managed care flow from inadequate reimbursement for these groups of patients. Appropriate adjustment for case-mix variability that provides sufficient reimbursement for both complex and relatively stable ESRD patients will allow the sponsors of these delivery systems to provide an expanded level of benefits to vulnerable patients while maintaining fiscal viability. RPA suggests including an analysis of the potential impact of AAPCC changes with specific emphasis on determining what level of risk for providers is appropriate and how this level of risk will affect the treatment of the sickest ESRD sub-populations. Such an analysis should also address a study of Medicare patients not part of the ESRD program, and AAPCC methodologies outside the ESRD milieu.

6. The nephrologist's ability to function autonomously within the current system must be preserved. This autonomy should maintain the nephrologist's freedom in clinical decision making and foster the nephrologist's position as the leader of the renal care team.

7. The nephrologist's ability to negotiate contracts, achieve appropriate reimbursement for their services, and develop relationships with the other essential participants in a capitated payment system must be preserved.

8. The outcomes from HCFA's ESRD Managed Care Demonstration Project must be considered in developing a legislative policy that affects ESRD patient enrollment in managed care.

9. Any legislative proposal to repeal the 1876 prohibition must be delayed for a minimum of two years to allow for modification of the AAPCC and full implementation of the CQI oversight program. In the event that the AAPCC and CQI proposals are not implemented, the ban must not be repealed.

APPENDIX C

REVISED DRAFT, 3/2000

Adopted by the RPA/ASN Board of Directors, 4/14/97

RPA/ASN POSITION ON IMPROVING ACCREDITATION OF DIALYSIS FACILITIES

Executive Summary

The RPA/ASN supports the accreditation, certification and licensure of dialysis facilities as a visible means of insuring accountability, and that in order to accomplish these functions appropriately, increased federal funding is necessary. The RPA/ASN supports public and private sector efforts to accredit and/or certify dialysis facilities provided an appropriate process and methodology are established and provided the renal community has appropriate and reasonable participation. The RPA/ASN believe that an appropriate accreditation and certification system will emphasize use of evidence-based quality improvement methodologies that use outcomes data to enhance facility processes. The RPA/ASN believes that legislation should be enacted to expand deemed certification, with appropriate safeguards, to include ESRD providers, and that the certification process must be unified among the various levels of government to avoid duplication and eliminate unnecessary expense to dialysis facilities.

Background

Over the past decade, the number of Americans requiring treatment for End Stage Renal Disease (ESRD) has experienced significant continual growth. According to data released by the Health Care Financing Administration (HCFA), more than 361,000 patients were receiving treatment under the Medicare program for ESRD (as of 12/31/97), with an approximate annual rate of growth of 8 percent. Consistent expansion of the kidney failure patient population heightens the challenges facing the nation's renal care community in their efforts to provide the highest possible level of care to an extremely vulnerable group of patients.

A key component of high quality ESRD patient care is the availability of accredited facilities providing dialysis services. However, the current accreditation process has often worked against optimal dialysis facility availability. Improvements in the accreditation process are needed to enhance patient convenience and therefore facilitate compliance, which is arguably equal to or more important in the treatment of chronic kidney disease than any other medical condition. Increasing access to dialysis facilities and thereby reducing the hardships that excess travel time places on patients is critically important to improving outcomes. Patient non-compliance invariably jeopardizes the adequacy of their dialysis and leads to infection, increased co-morbidities and ultimately loss of life. Financially, non-compliant dialysis patients escalate the burden on an already stressed health care system by increasing the likely necessity of emergency dialysis, surgery, and hospitalization. However, as dialysis centers become more accessible, treatments become less burdensome on patients' time, more economical, and more conducive towards the maintenance of a predialysis lifestyle and employment, with improved patient outcomes.

On a positive note, the issue of dialysis facility accreditation has garnered the attention of health care policymakers in recent years, and as a result several efforts are underway to examine and enhance the methodologies under which this accreditation occurs. Foremost among these initiatives is a 1997 study performed by The Lewin Group and Johns Hopkins University in response to a HCFA RFP to review the Medicare survey and certification process for dialysis facilities. Included among the study's recommendations were:

- The success of the accreditation process is dependent upon increased funding, and reallocation of those funds.
- Increased uniformity of the inspection process is necessary, with particular emphasis on frequency and training of inspectors. The goal for inspection frequency should be once every 1-2 years, and implementation of uniform processes for collection and analysis of outcomes data and data sharing must be established.
- Accreditation survey content must be standardized.
- Communications and cooperation from all stakeholders in the process is necessary.

Complimenting the Lewin study is a HCFA sponsored effort to develop a dialysis facility-specific data report for use by state surveyors. This project is intended to fulfill a legislative mandate set by the Balanced Budget Act of 1997 (BBA '97) to develop a method for assessing the quality of care delivered to Medicare's ESRD beneficiaries, and was managed under contract by the Colorado Foundation for Medical Care (CFMC). The initiative seeks to use existing databases to develop user-friendly facility-specific profiles based on an outcome-oriented approach. Other HCFA activities in this area include the Agency's ongoing efforts to continually improve ESRD care through the ESRD Core Indicators Project and its Health Care Quality Improvement Program. Finally, the Office of the Inspector General (OIG) issued a report on the Medicare certification process that, while primarily focusing on hospitals and nursing homes, does confirm the lack of resources available for dialysis facility certification and accreditation.

RPA/ASN strongly supports the accreditation, certification and licensure of dialysis facilities as a necessary and visible method of insuring public accountability, and as such we believe the public sector efforts to examine these issues represent a positive step toward improving dialysis facility accreditation. However, we continue to believe that the current process is fraught with problems and compromises the ability of nephrologists to provide the highest level of quality patient care possible. This paper will discuss the current accreditation system and its limitations, and analyze both the merits of improving accreditation within the current governmental framework, and the potential of private accreditation of dialysis facilities. Further, the paper will offer recommendations on how to ensure accountability using this methodology, and discuss the accreditation process and its effect on renal care delivery.

Dialysis Facility Accreditation: Current Situation

Under the current system, dialysis facilities are accredited through a federally-funded block grant program intended to ensure that institutions and agencies providing care to Medicare and Medicaid beneficiaries meet all federal health, safety and program standards. Federal funds are provided to each state. State surveying agencies then conduct on-site surveys, which are randomly monitored by federal surveyors. This fragmented execution of the certification process is the source of many of the current system's difficulties. Two significant problem areas are the irregular distribution and dispersal of federal funds and the inconsistent, "patchwork" nature of the actual surveying process,

both circumstances being a function of 50 separate state government entities carrying out certification duties.

One result of budgetary constraint and enormous expansion of the health care industry is the lack of financial resources to achieve appropriate licensure of institutions serving the Medicare/Medicaid population. Out of the pool of money provided to each state for inspection of facilities providing care to these beneficiaries, the states are responsible for certifying or accrediting a wide range of health care providers. Included on this list are home health agencies, nursing homes, ambulatory surgical centers, rural health clinics, and numerous others, in addition to dialysis facilities. To further exacerbate the accreditation outlook for institutions providing ESRD services, inspection of two of the provider types on the list, home health agencies and nursing homes, is statutorily required and therefore must be performed before any other surveys take place. As a result, ESRD facilities are competing with all of the other types of institutions providing care to Medicare/Medicaid beneficiaries (about ten provider types) for the funds remaining from the federal certification grant to each state. Consequently, new dialysis facilities can sit idle for months before receiving their initial certification, and existing centers often go years between their subsequent inspection surveys. Patient care is jeopardized by forcing chronically ill recipients of dialysis services to travel significant and unnecessary distances to receive treatment while a nearby center awaiting accreditation sits unutilized (thus reducing patient compliance), or by allowing problems that do arise at previously accredited, "good" facilities to remain uncorrected.

The current system also often allows the quality of the surveys that do occur to be compromised. Lack of uniformity in the training and education of the surveyors causes great variability in the caliber of inspections from state to state. While the dialysis facility certification process in some states is a positive and educational exercise that fosters the development of effective processes of patient care at the institution, in other states accreditation inspections can be arbitrary and punitive, and contrary to the needs of the local kidney patient population. A common complaint is that the primary training of the inspectors performing surveys at dialysis facilities is geared towards inspecting nursing homes or home health agencies, rendering the inspectors uninformed about the nuances of dialytic care. Some dialysis unit medical directors have noted that surveyors unfamiliar with renal care processes will often focus on issues peripheral to dialysis delivery while ignoring the more critical elements of ESRD services, or will cite the facility for "violations" that do not reflect deviation from the state regulations governing ESRD facilities.

In spite of the efforts of HCFA and the state regulatory agencies to ensure that providers of dialysis services receive both initial accreditation and recertification on a timely and intelligent basis, the current system is at best inconsistent and at worst reduces the adequacy of the patient's dialytic care. The RPA/ASN believes that it is appropriate to explore new methods of accrediting the nation's dialysis facilities, whether through the framework of the present governmental system or through the use of private accrediting bodies (under the Medicare deemed status program). Accordingly, RPA/ASN is supportive of HCFA's efforts to review the requirements and methodologies associated with the accreditation and certification of dialysis facilities.

Use of Existing Structures

Within the current governmental framework exist several alternative solutions with the potential to improve the outlook for dialysis accreditation. One possibility involves legislative modification of the statutes that govern certification of facilities providing services to Medicare beneficiaries. By adding dialysis facilities to the list of provider types for whom certification is statutorily required (currently

nursing homes and home health agencies), ESRD facilities would be assured that their certification surveys and re-inspections would both occur within a defined timeframe. Considering the highly vulnerable nature of the patient population being served by these facilities, and the potential therapeutic and economic benefits of improving care to these individuals, enactment of legislation expanding the list of Medicare providers requiring timely certification appears to be a reasonable and cost-efficient method of improving dialysis facility accreditation.

The ESRD Network organizations offer another avenue for improving dialysis facility accreditation using an existing governmental agency. By providing deeming authority for certification to the Networks, HCFA would be engaging organizations that are already in contact with the nation's dialysis providers and already heavily involved in the business of improving the quality of care to ESRD patients. The territorial orientation of the network system would easily allow for consideration of regional differences as necessary. As the Networks already serve a vital role as a catalyst for improvement for the nation's dialysis facilities, providing deeming authority to these entities would seem to be a natural extension of their current mission. The Networks are responsible for ensuring 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.

Advantages of Private Accreditation of Dialysis Facilities

The concept of private sector accreditation of health care providers serving Medicare beneficiaries is time-tested and valid, and would provide substantial benefit to the ESRD community. The federal government acknowledged the merits and benefits of this licensure method when it created the Medicare deemed status program. A key factor in granting an accrediting body deeming authority is HCFA's determination that the organization's standards are equivalent to or more stringent than federal health, safety and program regulations. Once the deeming authority has been granted to providers serving the Medicare ESRD population and the public/private sector partnership has been forged, significant benefits would be realized, including:

- Private accrediting organizations would assist the federal government in the enormous task of certification of new dialysis facilities and re-certification of existing ones, greatly reducing both the backlogs in these areas and federal regulatory expenditures.
- Improved quality of patient care would invariably result from the higher standards in some areas that accrediting organizations would bring to the process and an overall cross-fertilization of accrediting methodologies.
- Private sector resources would produce inspectors well-trained in the specifics of ESRD care, leading to a reorientation of the certification process towards an educational model that would foster facility development.
- Participants would reap economic benefit as the costly delays previously experienced in opening new dialysis facilities would be eliminated; the possibility that Medicare will enact user fees for certification in the future increases the potential for cost savings.
- Providers of ESRD care would be granted access to the same types of accreditation that other health care providers have utilized for years.

Accountability and Unification

In order to earn HCFA deeming authority, the RPA/ASN believes that an applicant dialysis facility accrediting organization must demonstrate accountability for its actions, and develop appropriate methodologies and standards. In addition to demonstrating that its standards are equivalent to or more stringent than HCFA standards, the applicant should develop a comprehensive reporting mechanism and establish a framework for a partnership with HCFA and the National Renal Coalition. Among the elements of the partnership should be:

- Notification of survey schedules to HCFA.
- Random inspections of a percentage of accredited facilities by HCFA for validation by qualified inspectors.
- Reports to HCFA on dialysis facilities with demonstrated deficiencies, particularly regarding water treatment and reuse, as these activities are often the source of deficiencies.
- Notification to HCFA of any dialysis facilities whose processes pose a danger to the patient's health or public safety.
- Notification to HCFA of all newly accredited dialysis facilities, and all facilities whose accreditation has been denied or suspended.

To develop appropriate survey methodologies and standards, the RPA/ASN believes that it is necessary to incorporate multidisciplinary input from all members of the national renal community. The methodologies and standards developed should be as scientifically valid and as clinically relevant as possible, with a clear link to continually improving facility performance and thus positively affecting patient outcomes. Additionally, the surveys should be as non-intrusive as possible.

One of the common complaints about the current process relates to the duplication among the various jurisdictions certifying dialysis facilities, and opponents of private accreditation feel that it will result in an additional layer of expense. Therefore, a crucial element to the success of private accreditation efforts is the unification of the certification process so that licensure criteria of all affected governmental entities (national, regional, state, local) are satisfied. It is the opinion of the RPA/ASN that the criteria for granting HCFA deemed status to dialysis facilities must be designed in such a way to meet the standards of the other governing bodies and avoid duplication of certification efforts. HCFA oversight of the accreditation process is needed to ensure public accountability and allow the unification of the process so that state licensure requirements can be eliminated. Unifying the survey and certification process will help eliminate the duplication and additional expense, simplify multiple governmental standards, and ease the regulatory burden on providers of ESRD services while improving patient outcomes. Precedent does exist for recognition of HCFA-approved accrediting bodies for state licensure purposes. The states of Oregon and Florida have recognized the Commission on Office Laboratory Accreditation (COLA) for licensure of physician office laboratories (POLS).

Recommendations

1. The accreditation or certification of dialysis facilities is a visible mechanism of insuring public accountability. Therefore, RPA/ASN supports accreditation and certification, as well as licensure, of dialysis facilities.

2. RPA/ASN believe that in order to achieve appropriate accreditation and certification of the nation's dialysis facilities, increased federal funds be provided to HCFA by Congress, and reallocation of those funds by HCFA must be considered.

3. RPA/ASN believe that as methods for enhancing the accreditation and certification of the nation's dialysis facilities are evaluated and developed, evidence-based quality improvement methodologies that use outcomes data to enhance facility operations should be emphasized.

4. RPA/ASN supports the development and enactment of legislation that would expand deemed certification for ESRD providers, with appropriate safeguards.

5. Public and private sector efforts to accredit and/or certify dialysis facilities can be supported provided an appropriate process and methodology are established and provided the renal community has appropriate and reasonable participation.

6. If multiple entities and both public and private entities accredit or certify dialysis units, these efforts should be substitutive rather than duplicative. Private sector initiatives to accredit or certify dialysis facilities, subject to oversight by HCFA, must replace the Medicare certification process and the state licensure process, the former under the Medicare deemed status program.

7. The process for developing accrediting standards should be undertaken with appropriate input from all involved parties, including the member organizations of the National Renal Coalition, the regional ESRD Networks, and representatives or designees from HCFA.

8. The methodologies, standards, and measures established by both public and private sector entities to review and accredit dialysis facilities should be scientifically valid, defensible, uniform, and as non-invasive and non-intrusive as possible. Both public and private sector accreditation/certification initiatives should be subjected to reasonable cost benefit analyses.

The CHAIRMAN. Thank you, Dr. Owen.
Now Dr. Wish.

STATEMENT OF JAY WISH, M.D., PRESIDENT, FORUM OF END STAGE RENAL DISEASE NETWORKS, MIDLOTHIAN, VA

Dr. WISH. Good afternoon. The Forum thanks Senators Grassley and Breaux and the Special Committee on Aging for the opportunity to testify regarding the oversight of Medicare's End Stage Renal Disease Program. My name is Jay Wish. I am President of the Forum of ESRD Networks. I am an academic nephrologist from Cleveland, OH and I am on the faculty of Case Western Reserve University. I have been involved in the Network program since 1980 and I am currently Chairman of the Medical Review Board of Networks 9 and 10. My appearance before you today as a spokesperson for the ESRD Networks is symbolic of the fact that all 18 Networks are governed, through their boards of directors and medical review boards, by volunteer renal professionals and patients whose only agenda is to ensure that a high level of care is delivered to patients with ESRD.

The 18 ESRD Networks are independent, nonprofit corporations which contract with HCFA to oversee the quality of care delivered to Medicare ESRD beneficiaries. The Networks' responsibilities are defined by their scope of work, which specifies activities in quality improvement, data collection and analysis, and community outreach. The geographical boundaries of the Networks are illustrated on the first poster.

The Forum is a nonprofit corporation whose purpose is to facilitate communication among the Networks, between the Networks and HCFA, and to represent the Networks to the renal community and to other organizations, such as the U.S. Senate. The Forum is funded by annual dues from the Networks and by contracts with HCFA to perform specific functions, such as an information clearinghouse, the organization of certain national meetings, and the administration of some national work groups, all of which promote the quality of care delivered to Medicare ESRD beneficiaries.

The 18 ESRD Networks work directly with providers to improve the quality of care that is delivered to ESRD beneficiaries. Because their peers respect the volunteer professionals on the medical review boards of the Networks, facilities tend to buy into the Networks' quality agenda. The Networks are able to identify better performing facilities and then expert their successes to the other facilities in the region through workshops, publications, and site visits.

The Forum endorses the dual oversight model with state survey agencies operating in a regulatory mode to enforce minimum standards of patient care mandated by the conditions of coverage and the Networks working in a nonpunitive, collegial, quality improvement mode to stress education, data analysis and targeted interventions to bring all providers up to a higher level of patient care and outcomes.

Medicare regulations require that a Network facility relationship exist and that all Medicare-certified ESRD providers participate in Network activities. Each Network interacts with facilities in several ways: by providing quality oversight, by implementing facility-

specific quality improvement projects, by sharing facility-specific data and regional comparatives with the respective facilities, acting as a clearinghouse for information and resources, and by conducting educational seminars and regional meetings.

Networks perform specific activities to facilitate the improvement of patient care processes and outcomes at the facility level. These include but are not limited to participating in the National ESRD Clinical Performance Measures Project, conducting focussed quality improvement projects and special studies, managing information and providing profile reports to facilities and other providers, processing patient grievances and addressing patient concerns, and conducting educational activities, including seminars, workshops, newsletters, videotapes and distribution of printed materials.

Over the last 6 years since the inception of what is now known as the National ESRD Clinical Performance Measures Project, there have been statistically significant improvements in clinical outcomes likely attributable to Network quality improvement initiatives. The areas most improved include, in the next poster, hemodialysis adequacy. As you will see, 74 percent of hemodialysis patients had a mean URR, which is urea reduction ratio, the target for adequacy of dialysis, of greater than 65 percent in 1998, compared to only 43 percent in 1993, and in anemia management, which is on the next poster, you will see that if you use your target hematocrit of 30 percent as your quality improvement criterion, then 78 percent of patients had a hematocrit above this level in 1998, compared to only 46 percent in 1993.

Some of the most significant recent activities of the Forum of Networks have included collaborating with the Renal Physicians Association and the National Patient Safety Foundation in the development of a patient safety committee to investigate and reduce medical errors in dialysis facilities; designing a national quality improvement project addressing vascular access which, as you have heard, is the lifeline for renal patients and something that really does need to be focussed on at the national level; assisting HCFA in the development of a patient orientation package to be distributed to each new ESRD beneficiary; and surveying Networks regarding their renal transplant assessment activities.

The Forum agrees that the current ESRD oversight model is not perfect. The Forum has recommended an increase in the frequency of facility surveys by the Medicare state surveyors to ensure that providers are meeting the conditions of coverage. Texas and Ohio, for example, have instituted dialysis facility licensure programs to fund the cost of more frequent surveys. Texas does every facility every 3 years and Ohio does every facility every year, but it costs the facility the licensure fee to cover the cost of these site visits.

The conditions of coverage need to be updated to include more rigorous facility staffing and personnel training requirements. However, the dual oversight model with the state surveyors having a quality assurance focus and the Networks having a quality improvement focus is fundamentally sound and should not be discarded.

With the volunteer expertise that resides in the medical review boards and an evolving powerful data infrastructure, the Networks

are an invaluable resource that continually brings the quality of patient care to a higher level.

That concludes my testimony and I would be happy to answer any questions.

[The prepared statement of Dr. Wish follows:]

FORUM OF ESRD NETWORKS
TESTIMONY FOR SENATE SPECIAL COMMITTEE ON AGING

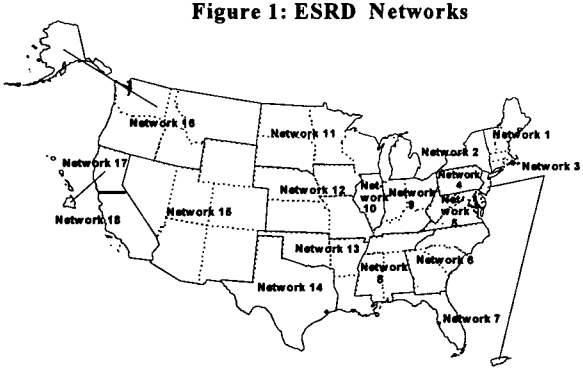
PRESENTED BY JAY WISH, MD
PRESIDENT

Introduction

The Forum of ESRD Networks (Forum) appreciates the opportunity to testify before the Senate Special Committee on Aging regarding the oversight of Medicare's End-Stage Renal Disease (ESRD) Program. The Forum is an organization representing all 18 ESRD Networks. The Forum facilitates the exchange of information and ideas among the 18 Networks, renal related organizations and the Health Care Financing Administration and serves as a clearinghouse for the distribution of material to support the improvement of care delivered to patients with ESRD.

The 18 ESRD Networks are independent non-profit corporations established to oversee the quality of care provided to Medicare ESRD beneficiaries. The Networks' contract with HCFA is defined by the scope of work, which specifies activities in quality improvement, data collection/analysis and community outreach. The geographical boundaries of the Networks were re-configured by HCFA in 1988 and are illustrated in Figure 1 below.

Figure 1: ESRD Networks



e Forum is pleased to provide the following responses to questions posed by Senators Grassley and Breaux.

1. Description of the Forum of ESRD Networks

The Forum is incorporated as a 403C non-profit corporation in the state of New York. The bylaws of the Forum specify that the purpose of the corporation is to "serve as a forum in which assistance, advice, information, ideas, and policy proposals may be exchanged between and among the Networks and the Health Care Financing Administration (HCFA) and its agencies, and other renal care organizations." In 1995, HCFA recognized the value of the Forum of ESRD Networks in providing a clearinghouse for information with relevance to Network quality oversight activities, evolving practice guidelines, patient educational materials, and Federal legislative/regulatory changes which impact the ESRD program. As a result, HCFA provided funds to create the Forum of ESRD Networks Clearinghouse as a support office and information distribution center for the ESRD program. The Forum Clearinghouse office, located in Midlothian, Virginia has acted as a liaison between the Networks, HCFA, and prominent renal organizations and works to facilitate an improvement in the care received by ESRD patients by supporting Network data collection/analysis and quality improvement activities. The Forum office currently consists of one full-time administrator and one part-time assistant. As part of its clearinghouse activity, the Forum office:

- Maintains a web site on the Internet that outlines Forum activities and provides links to the 18 individual Networks as well as to other renal web sites;
- Provides an annual report summary of the 18 individual Network annual reports;
- Provides support to the national ESRD Clinical Performance Measures (CPM) Project;
- Maintains a library of resources to support Network activities including practice guidelines, patient educational materials, nephrology journals, and materials from other renal professional and patient organizations.

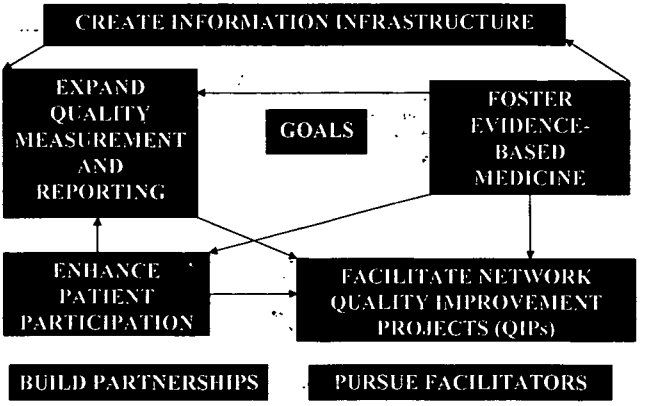
By obtaining consensus on issues of importance to the quality of care of ESRD beneficiaries, the Forum is able to effectively represent the ESRD Networks. The Forum's membership consists of one physician representative, the Medical Review Board chairperson, and the Executive Director from each ESRD Network organization.

The Forum's goals are:

- To foster the improved delivery of care to Medicare ESRD beneficiaries through the Networks' comprehensive quality improvement program;
- To create and maintain an information infrastructure that supports quality improvement activities at the provider level;
- To assist Networks in identifying the areas where the greatest opportunities for improvement exist so that interventions can be most effectively targeted;
- To promote the use of the evolving information infrastructure to accumulate evidence that can be used as a basis for clinical practice guidelines.

These goals are supported by a strategic plan designed to promote a quality measurement and reporting agenda (Figure 2).

Figure 2: Forum Strategic Plan



The Standardized Information Management System (SIMS), a national information infrastructure that supports Network quality improvement activities, was implemented this year (2000). Designed by the Networks, the renal community and HCFA, SIMS was designed to:

- Electronically link all 18 ESRD Networks with HCFA;
- Transfer ESRD data collection forms electronically to HCFA central office;
- Provide standard data elements, data definitions and reporting/analysis tools.

The Forum actively promotes continuous quality improvement activities among the Networks to facilitate outcomes improvement within dialysis facilities and renal transplant centers. The Forum partnered with HCFA to increase hematocrit levels for ESRD patients in the National Anemia Cooperative Project. This project improved the processes of anemia management by:

- Providing facilities with a continuous quality improvement manual with a focus on anemia management;
- Providing facilities with an algorithm for the treatment of anemia;
- Providing facilities with their respective facility-specific profiles on hematocrit and erythropoietin usage.

The Forum was awarded a contract by HCFA in 1999 to develop and administer the national ESRD CPM Project. This project began in 1992 as the Core Indicators Project and involves the annual collection by the Networks of clinical data from a random sample of ESRD patients to assess patterns of care. In 1998, following e publication of the National Kidney Foundation's Dialysis Outcomes Quality Initiative (DOQI) clinical practice guidelines, evidence-based clinical performance measures were derived and provided the basis for the

evolution from the Core Indicators Project to the ESRD CPM Project. The CPMs currently used include adequacy of dialysis, anemia management, nutrition, vascular access for hemodialysis patients, and hypertension management for peritoneal dialysis patients. The annual data feedback reports obtained from these projects are important tools in assessing patient care processes and outcomes on a national and regional level and identifying opportunities for improvement.

2. Description Of Mechanisms By Which Networks Ensure Quality Of Care

The 18 ESRD Networks work directly with ESRD providers to improve the quality of care provided to ESRD beneficiaries. The ESRD Networks do not provide direct patient care. With volunteer leadership by nephrologists, transplant surgeons, nurses, social workers, dietitians, administrators and patients, Networks engage providers to improve patient care processes and outcomes through a non-punitive paradigm. By collecting and analyzing process and outcomes data, Networks collaborate with providers to identify opportunities for improved care and to design measurable quality improvement initiatives. Strict conflict of interest rules apply to assure an objective and impartial review process.

A Board of Directors that provides oversight of Network operations and assures compliance with contractual requirements governs each Network. Each Network has a Medical Review Board (MRB), a multidisciplinary group that directs its quality improvement efforts. All Networks have a structured mechanism to assure patient input and involvement. Patients are represented on the Networks' Boards of Directors and Medical Review Boards.

The current system of external oversight of the ESRD program includes the Networks and state survey agencies. The state survey agencies operate in a regulatory mode to hold providers accountable to the minimum standards mandated by the Conditions of Coverage. The Networks, through their governance by professionals who are associated with individual providers, have expertise on dialysis treatment that the state survey agencies lack. The Networks' collegial orientation stresses education and improvement objectives rather than enforcement of minimum standards.

Through an information infrastructure that has developed over 20 years, the Networks are able to identify clinical trends at the provider, region, state, and Network level and to develop and implement targeted interventions to effectively improve care.

Networks have established channels for coordinating and collaborating with other agencies and organizations to avoid duplication of efforts and to build upon the expertise of many groups. These include HCFA, State Health Department and Survey Agencies, Peer Review Organizations and renal related professional groups such as the Renal Physicians Association (RPA), American Society of Nephrology (ASN), National Renal Administrators Association (NRAA), American Nephrology Nurses Association (ANNA), National Kidney Foundation (NKF), and American Association of Kidney Patients (AAKP).

3. Description Of Relationship Between Networks And Facilities

Medicare regulations require that a Network-facility relationship exist and that all Medicare certified providers participate in Network activities. These relationships are maintained, enhanced and supported by a mutual interest to improve care and assure quality. Each Network interacts with facilities in several ways:

- Providing quality oversight;
- Implementing facility-specific quality improvement projects;
- Sharing facility specific data and regional comparatives with the respective facilities;
- Acting as a clearinghouse for information and resources;
- Conducting educational seminars and regional meetings.

Although Networks have traditionally assumed a quality improvement role, working in a confidential relationship with providers to educate and improve outcomes through a systems focus, occasionally a provider will not respond to a collegial Network approach. In such cases, a Network may assume more of a quality assurance role by conducting a site visit, requiring a plan for corrective action, referring the problem(s) to the state survey agency, and/or recommending to HCFA that sanctions be imposed.

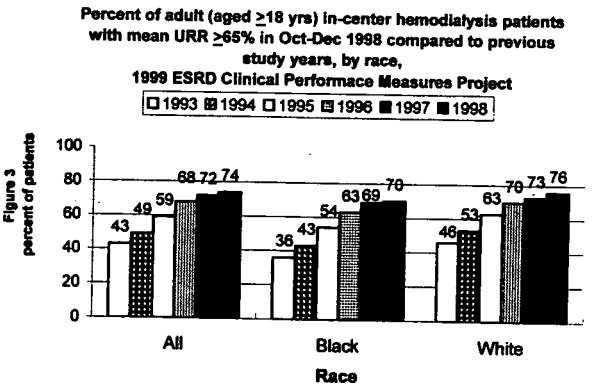
4. Description Of Processes The Networks Undertake To Ensure That Facilities Are Providing Proper Care.

Networks perform specific activities to facilitate the improvement of patient care processes and outcomes at the facility level. These include, but are not limited to:

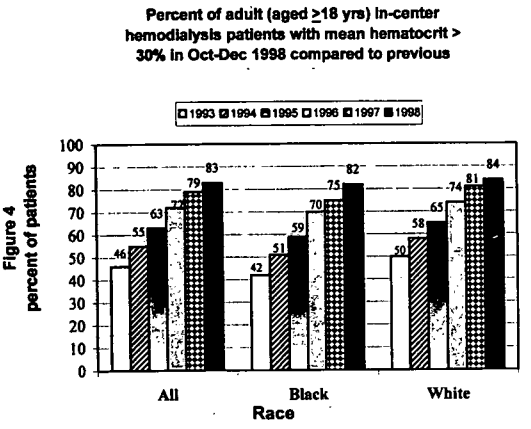
- Participating in the national ESRD Clinical Performance Measures Project;
  - Raises level of awareness by facilities of measure domains and outcomes
  - Provides benchmarks of performance that facilities can use as targets
- Conducting focused quality improvement projects and special studies;
  - Addresses regional variations in processes and opportunities for improvement
  - Engages expertise of Medical Review Board regarding evidence-based methods
- Managing information and providing profile reports;
  - Drives internal quality improvement activities at the facility level
  - Identifies areas for targeted intervention
- Processing patient grievances and addressing patient concerns;
  - Fosters communication between patients and providers
  - Mediates conflicts to achieve satisfactory resolutions for patients and providers
  - Identifies patterns of care which may require intervention activities
- Conducting educational activities including seminars, workshops, newsletters, videotapes, and distribution of printed materials.

The Network program has fostered a national improvement in the four areas of care monitored by the national ESRD CPM Project (adequacy of dialysis, anemia management, hypertension, nutrition). Due to Networks' participation since the project's inception, national and Network specific data are available on care provided to ESRD patients. Over the last 6 years, the CPM project has demonstrated statistically significant improvements in clinical outcomes, likely attributable to Network quality improvement activities. Areas most improved include:

- Hemodialysis Adequacy (Figure 3):
  - 74% of hemodialysis patients had a mean URR ≥ 65% in 1998 compared to 43% in 1993.
  - The difference between Caucasian and African-American patients receiving adequate dialysis was 6% in 1998 compared to 10% in 1993.



- Anemia Management (Figure 4):
  - 78% of hemodialysis patients had a mean hematocrit > 30% in 1998 compared to 46% in 1993.
  - The difference between Caucasian and African-American patients with hematocrit > 30% was 2% in 1998 compared to 8% in 1993.



These changes demonstrate the positive effects of the partnership between Network and facility staff on the care received by ESRD patients.

Networks conduct quality improvement projects (QIPs) to assess and improve the outcomes of care. QIPs are a continuous process, using data on processes and outcomes of care to recognize opportunities to improve care and to develop measurable improvement initiatives. Examples of Network quality improvement projects include:

- Improving influenza and hepatitis B vaccination rates;
- Increasing the placement of arteriovenous fistulae in hemodialysis patients;
- Improving surveillance for stenosis of arteriovenous grafts;
- Improving adequacy of hemodialysis;
- Increasing the frequency of measurement of peritoneal dialysis adequacy;
- Improving anemia management.

Working one-on-one with Network quality improvement staff and Medical Review Board experts allows the facility staff to improve the care delivered to patients. The Networks are able to achieve buy-in from facilities hich understand that:

- Network staff are trained in the principles and application of continuous quality improvement (CQI);
- Network Medical Review Board members are highly respected practitioners with considerable clinical experience;
- Network's data infrastructure offers facilities data tracking tools that they may not otherwise have;
- Networks recognize and praise high performers.

Each Network collects data from dialysis facilities regarding patient demographics, co-morbid conditions, process and outcome indicators, patient events and deaths, and facility characteristics. These data are validated and analyzed by the Medical Review Board and can be used to improve patient care by:

- Supporting facility quality improvement projects;
- Targeting facilities for Network intervention activities;
- Evaluating Network-wide quality improvement projects;
- Driving the development of health care policy specific to ESRD;
- Identifying predictors of morbidity and morality;
- Entering the medical literature to become part of the evidence basis for the development or updating of clinical practice guidelines.

Networks also provide community outreach services to renal professionals, patients and family members. Using a variety of educational venues and information distribution methods, Networks impact the lives of patients by:

- Conducting patient-focused seminars and conferences;
- Providing rehabilitation information (exercise programs, vocational educational materials, job placement programs) to providers and patients;
- Addressing patient grievances and family concerns;
- Assisting transient patients in finding dialysis services.

Networks are a significant provider of information to facilities. Networks house and regularly distribute information to facilities regarding:

- Evidence-based medicine including clinical practice guidelines and care paths;
- Disaster preparedness;
- FDA alerts;
- Centers for Disease Control and Prevention guidelines and recommendations;
- Patient education materials;
- National ESRD CPM Project annual reports, highlight reports and supplemental reports.

Many Network staff are trained in conflict resolution and mediation and provide facilities with an accessible resource to discuss handling challenging patients. Many Networks house a library that contains patient education videos and materials that are available to facilities and patients on request.

All Networks convene meetings directed at bringing together facility personnel to discuss on-going and emerging clinical issues. Sites for these meetings are chosen based on accessibility and convenience in order to attract a large number of participants. These meetings may offer incentives such as continuing education credits.

Meeting topics are determined regionally by a planning committee composed of all stakeholders with the goal f improving processes of care. Recent meeting topics have focused on:

- Patient safety and medical errors;
- Adequacy of dialysis;
- Vascular access;
- Managing anemia;
- Dealing with challenging patients.

5. Forum Initiatives Directed At Improving The Quality Of Care Dialysis Patients Receive

The Forum's role in improving the quality of care received by ESRD patients is through enhancing the effectiveness of the 18 Networks. Interventions by the Networks have led to a significant improvement in the percentage of patients receiving adequate dialysis as demonstrated by data from the national ESRD CPM Project cited above. Opportunities for improved dialysis adequacy continue to exist and all Networks will focus on this area for their 2000–2001 quality improvement projects. The standards for dialyzer reuse are specified in the Conditions of Coverage for Medicare-approved dialysis facilities and are enforced by state surveyors. The Conditions of Coverage currently in effect do not specify standards for dialysis facility staffing ratios and training.

The Forum has assumed a leadership role in identifying new initiatives that enhance the effectiveness of the Networks in improving patient care. The Forum's activities are driven by its strategic plan (Figure 2). Appendix 1 summarizes the 1999-2000 accomplishments of the Forum in each of the strategic plan domains. Appendix 2 summarizes the current activities of the Forum in each of the strategic plan domains. Some of the most significant activities include:

- Collaborating with the Renal Physicians Association and National Patient Safety Foundation in the development of a Patient Safety Committee to investigate and reduce medical errors in dialysis facilities;
- Designing a National Quality Improvement Project addressing vascular access;
- Participating on the Public Reporting and State Surveyor Committees addressing the public release of data;
- Assisting HCFA in the development of a patient orientation package to be distributed to each new ESRD beneficiary.
- Partnering with the Renal Physicians Association to rank and implement the NKF-DOQI guidelines at the provider level;
- Surveying Networks to report on renal transplant assessment activities;
- Participating in the Renal Physicians Association's development of "Shared Decision-Making in the Appropriate Initiation and Withdrawal from Dialysis" clinical practice guideline.

Conclusion

The increasing visibility and credibility of the Forum and the ESRD Networks in the national landscape are due, in large part, to their long-standing and unwavering advocacy for improved ESRD patient outcomes through the plication of continuous quality improvement methodologies and the development of an appropriate data frastructure. This advocacy is untainted by the agenda of any single professional constituency, and its success

is limited only by the commitment that all stakeholders have to the process. Through their clearinghouse activities, the Forum and the ESRD Networks foster evidence-based medicine, increasing provider awareness of clinical practice guidelines and other literature that may improve the quality of patient care. Although opportunities for improvement continue to exist, the dramatic increase in the percentage of patient receiving adequate dialysis and achieving target hematocrit levels over the past 6 years demonstrates the ability of Networks to effect change. With the volunteer expertise that resides within the Medical Review Boards and an evolving powerful data infrastructure, the Networks are an invaluable resource that continuously brings the quality of patient care to a higher level.

For additional information on the ESRD Networks or the Forum, please contact:

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Appendix 1: Forum Accomplishments

GOALS	1999-2000 ACCOMPLISHMENTS
Provide Leadership	
Create Information Infrastructure	• Implemented Standardized Information Management System (SIMS) • Continued to develop and formalize United States Renal Data System (USRDS) relationship • Collaborated in the development and testing of a facility data system • Actively sought to communicate with the private sector industry
Expand Quality Measurement and Reporting	• Participated on National ESRD CPM Project committees and subcommittees • Merged the CPM and Core Indicators Projects • Disseminated and implemented the NKF-DOQI clinical practice guidelines • Participated in the "Shared Decision Making in the Initiation and Withdrawal of Dialysis" clinical practice guideline • Encouraged organizations, such as Council of American Kidney Societies, to actively seek and take the lead in a research venture with an academic medical center • Began to established relationship with National Patient Safety Foundation and RPA in the development of a patient safety committee • Received HCFA contract to survey Networks on transplant data and referrals • Supported Networks 1 & 11 collaboration with RPA to prioritize clinical practice guidelines
Foster Evidence-Based Medicine	• Circulated CQI articles to MRB Chairs • Encouraged Forum representatives to speak at national meetings to update the community on the Forum's current activities and positions • Used Forum Clearinghouse to gather information
Enhance Patient Participation and Strengthen the Hand of Consumers	• Received HCFA contract to develop committee to recommend a standardized new patient packet

Create Public-Private Partnerships	• Developed CPM Initiative with HCFA, RPA, NKF • Supported the renal community's (RPA/ASN/FORUM) implementation of NKF-DOQI project • Maintained RPA relationship and share committee representation • Supported the Forum Clearinghouse as a partner with HCFA • Evaluated the need for & type of information applicable for public release • Explored private sector accreditation • Researched expanding state surveyor agency collaboration • Distributed Core Indicators and Anemia QIPs • Initiated and encouraged the growth of existing partnerships with dialysis chains • Established relationship with renal magazines to published Network accomplishments and projects
Facilitate Health Professional Education	• Held regular MRB chair meetings • Encouraged Forum representatives to speak at national meetings on behalf of Forum and Networks • Developed liaison with RPA and ASN • Pursued joint initiative with RPA to support "Teach the Teachers" program

Appendix 2: Current Forum Activities

GOALS	2000 CURRENT ACTIVITIES
Provide Leadership	
Create Information Infrastructure	• Pursue facility data system collaboration with HCFA • Developing and formalizing USRDS relationship • Exploring data collection of difficult patients • Final implementation of Standardized Information Management System
Expand Quality Measurement and Reporting	• Participating on national ESRD CPM Project committees and subcommittees • Encouraging Network level reporting in support of quality improvement • Participating in the development of a Patient Safety Committee with RPA • Pursuing liaison with National Patient Safety Foundation through the Patient Safety Committee • Revising the Medical Records Model • Surveying Networks on transplant data, referrals and outcomes
Foster Evidence-Based Medicine	• Circulating CQI articles to MRB Chairs • Encouraging Forum representatives to speak at national meetings to update the community on the Forum's current activities and positions • Using Forum Clearinghouse to gather information • Collaborate with RPA to research physician level measures using evidence-based medicine
Enhance Patient Participation and Strengthen the Hand of Consumers	• Participating on the New Patient Packet Committee to distribute uniform information to patients

Create Public-Private Partnerships	• Supporting Dr. William Owen's initiative to develop a "Modifying Errors Noted in Dialysis Trial" proposal • Maintaining RPA relationship and share committee representation • Supporting the Forum Clearinghouse as a partner with HCFA • Evaluating the need for & type of information applicable for public release • Expanding state surveyor agency collaboration • Initiate and encourage the growth of existing partnerships with dialysis chains • Providing representation on Robert Wood Johnson End of Life Committee • Providing representation on State Survey Committee and Public Reporting committee of HCFA
Facilitate Health Professional Education	• Holding regular MRB chair meetings • Encouraging Forum representatives to speak at national meetings on behalf of Forum and Networks • Developing liaison with RPA and ASN • Pursuing joint initiative with RPA to support "Teach the Teachers" program
Facilitate Network Quality Improvement Projects (QIPs)	• Standardizing QIP activities and distribute document describing the differences between outcomes research and quality improvement • Documenting the success of Network QIPs • Develop partnership with renal magazines to publish QIP abstracts and Network activities • Supporting Networks 1 & 11 Prioritization QIP in conjunction with RPA

End Stage Renal Disease (ESRD) Network Program Annual Report Summary 1998

Prepared by the Forum of ESRD Networks
Midlothian, VA

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Annual Report Summary

INTRODUCTION

The national End Stage Renal Disease (ESRD) program which extends Medicare benefits to cover the high cost of medical care for most individuals suffering from ESRD was created in October 1972 through the passage of Section 2991 of Public Law 92-603. Modifications to the ESRD program were enacted by Congress four years later in order to improve cost effectiveness, ensure the quality of care provided under the program, encourage kidney transplantation and home dialysis, and increase program accountability. This legislation, PL 95-292, authorized the establishment of ESRD Network areas and Network organizations, consistent with criteria determined by the Secretary of the Department of Health and Human Services. The legislation mandated 32 geographic areas and organizations, but in 1987 Congress reduced the number to the existing 18 Networks (see front cover). This report summarizes the annual reports submitted by these 18 Network organizations for calendar year 1998.

ESRD POPULATION & CHARACTERISTICS

Although the ESRD population is less than 1% of the entire U.S. population it continues to increase at a rate of 7%-8% per year impacting all races, age groups and socioeconomic standings. Because the ESRD Network Organizations cover all 50 states plus Puerto Rico, Saipan and the U.S. Virgin Islands, much variation is seen in both the overall population and the ESRD population. While California (Networks 17 & 18) has the largest state population, the state of Georgia has the largest population on dialysis. At the end of 1998 there were 248,845 patients being dialyzed and 87,301 were newly diagnosed (Appendix A). As seen in Appendix B, Washington, DC had the highest incidence rate, 804.78 per million, while Alaska had the lowest at 109.12 per million. Of the U.S. territories, American Samoa has the lowest incidence rate with only 144.94 cases per million population. Although the incidence in some states has fallen slightly, the overall incidence and prevalence of ESRD continues to rise nationally. Appendix C displays the incidence data for 1997 and 1998 by Network. The national average incidence rate has risen to over 317 cases per million population and the overall ESRD prevalence counts have more than doubled since 1988 (USRDS 1999).

The Forum of ESRD Networks aggregated data obtained from the ESRD Networks to calculate both state and national incidence rates for 1998 (Table 1 and Appendix B). Included in the count were all new ESRD patients, both dialysis and transplant, as well as all non-Medicare patients reported to the Networks.

Incidence rates are calculated by dividing the number of new cases by the general population. The U.S. Bureau of Census estimated population for July 1, 1998 was used in the calculation.

TABLE 1
ESRD INCIDENCE RATES BY NETWORK
CALENDAR YEAR 1998

Network based Patients' Residence	Initiated ESRD Therapy	General Population	Incidence Rate Per Million Population
1	3,473	13,429,862	257.34
2	6,201	18,175,301	341.07
3	4,100	12,093,393	339.03
4	4,577	12,745,054	358.81
5	5,550	14,260,433	376.57
6	6,833	19,024,662	356.69
7	5,192	14,915,980	348.02
8	4,421	12,534,712	352.70
9	6,889	21,045,187	327.34
10	4,395	12,045,326	364.87
11	5,863	21,142,576	277.07
12	3,554	12,592,792	282.22
13	3,649	10,253,983	355.86
14	6,323	19,759,614	320.00
15	3,677	14,704,096	250.00
16	2,179	11,694,384	186.33
17/18*	10,425	34,137,356	305.30
Total	**87,301**	**274,554,711**	**317.97**

Source: Forum of ESRD Networks
*Networks 17 and 18 have been combined to incorporate the state of California. Hawaii and American territories are included

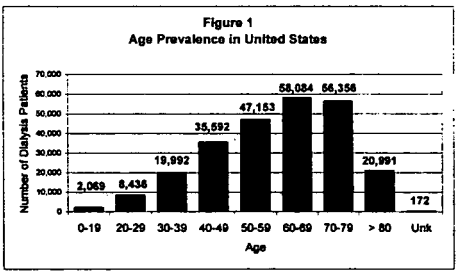
- **AGE**

In 1998 a majority of the ESRD patients were between the ages of 60 and 79 with the pediatric population remaining relatively small with less than one percent of the ESRD population under 20 years old (Table 2 and Figure 1). This same age distribution can be seen in the incident population (Appendix D).

TABLE 2
PREVALENCE OF DIALYSIS POPULATION BY AGE AND NETWORK
DECEMBER 31, 1998

Network	0-19	20-29	30-39	40-49	50-59	60-69	70-79	≥80	Unk	Total
1	50	266	688	1,086	1,528	2,142	2,637	1,209	0	9,606
2	163	595	1,516	2,761	3,685	4,294	4,104	1,711	0	18,829
3	93	349	886	1,556	2,292	2,768	2,531	919	0	11,394
4	96	324	843	1,590	2,087	2,934	3,287	1,224	0	12,385
5	145	481	1,309	2,442	3,082	3,690	3,471	1,109	136	15,865
6	136	790	1,975	3,481	4,838	5,431	4,395	1,403	1	22,450
7	96	437	1,061	1,903	2,480	3,269	3,491	1,531	0	14,268
8	108	551	1,210	2,272	2,907	3,479	2,952	956	0	14,435
9	157	572	1,429	2,405	3,019	4,076	4,237	1,443	13	17,351
10	117	341	844	1,550	1,951	2,504	2,684	997	3	10,991
11	93	507	1,107	2,088	2,726	3,297	4,000	1,683	0	15,501
12	93	320	744	1,294	1,643	2,149	2,307	983	0	9,533
13	79	418	914	1,720	2,147	2,615	2,083	723	0	10,699
14	189	729	1,632	3,057	4,028	4,793	3,888	1,155	3	19,474
15	102	339	874	1,373	2,013	2,414	2,251	687	3	10,056
16	75	258	546	901	1,139	1,352	1,385	542	0	6,198
17	72	366	896	1,661	2,281	2,723	2,715	1,175	13	11,902
18	205	793	1,518	2,452	3,307	4,154	3,938	1,541	0	17,908
Total	2,069	8,436	19,992	35,592	47,153	58,084	56,356	20,991	172	248,845
% Total	1%	3%	8%	14%	19%	23%	23%	8%	0	

Source: 1998 Network Annual Reports



Source: 1998 Network Annual Reports

- **RACE**

While the vast majority of ESRD patients are white, the number of Blacks and Native Americans with ESRD is disproportionately high compared to the U.S. population. While Black Americans comprise 13% of the population they make up 38% of the total ESRD population and Native Americans establish less than 1% of the US population and 2% of the ESRD population. Network 6 has a large population of Blacks and Network 15 is home to a large number of Native Americans. Appendices E and F present tables comparing the prevalent and incident ESRD population by race and Network.

- **DIAGNOSIS**

The leading cause of renal failure in the United States is diabetes. Table 3 and Figure 2 categorize prevalent dialysis patients by primary diagnosis. A list of primary causes for ESRD can be found in Appendix G.

TABLE 3
PREVALENCE OF DIALYSIS POPULATION BY PRIMARY DIAGNOSIS AND NETWORK
DECEMBER 31, 1998

Network	Diabetes	Hypertension	GN	Cystic Kidney	Other[1]	Unknown[2]	Total
1	3,452	2,335	1,577	471	1,760	11	9,606
2	6,622	4,531	2,862	636	2,476	1,702	18,829
3	4,601	2,921	1,902	524	1,292	154	11,394
4	4,632	3,392	1,745	419	2,187	10	12,385
5	5,731	5,193	2,449	685	1,140	667	15,865
6	8,139	7,346	2,403	694	2,706	1,162	22,450
7	5,005	4,644	1,882	656	1,614	467	14,268
8	5,239	5,120	1,751	571	1,754	0	14,435
9	7,052	4,124	2,757	577	2,824	17	17,351
10	3,787	3,601	1,414	297	1,800	92	10,991
11	6,071	4,151	1,873	485	2,354	567	15,501
12	3,723	2,604	622	554	1,680	350	9,533
13	4,262	3,730	1,364	409	669	265	10,699
14	9,136	4,744	2,477	677	2,397	43	19,474
15	5,009	1,669	1,413	511	1,044	410	10,056
16	2,433	1,065	1,182	496	741	281	6,198
17	5,017	2,621	2,342	562	1,347	13	11,902
18	7,458	4,948	2,616	477	2,409	0	17,908
Total	**97,369**	**68,739**	**34,631**	**9,701**	**32,194**	**6,211**	**248,845**
%	**39.1%**	**27.6%**	**13.9%**	**3.9%**	**12.9%**	**2.5%**	

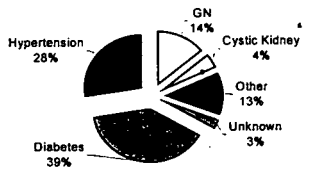
Source: 1998 Network Annual Reports
[1]Other refers to those primary causes listed in Appendix G
[2]Unknown refers to causes both unknown and unreported

As shown by Figure 2, diabetes represented 39% of the prevalent dialysis patient population in 1998. Hypertension followed with 28%, glomerulnephritis with 14% and other causes accounted for 13% of the dialysis population with 3% of patients having an unknown primary cause. The percentage of patients with a primary diagnosis of diabetes is up slightly by 1% since 1997. With similar results, Appendix H illustrates the primary diagnosis of incident patients by Network. While diabetes is the

most common cause of ESRD it is prominently the cause of ESRD in women while hypertension is most common cause of ESRD in men (USRDS 1999).

Given the diverse patient populations seen within each geographic region it is surprising that there is little variation between the Network populations with respect to the diagnosis of their prevalent populations. All Networks reported diabetes as the primary cause of renal failure in 1998 but Network 15, at 50%, had the highest percentage of patients with this primary diagnosis. Network 8 joined the Networks in this category in 1998 by reporting a lower percent of their total patients with a primary diagnosis of hypertension.

Figure 2
Prevalent Dialysis Patients by Primary Diagnosis
December 1998



- **GENDER**

In 1998, males represented over half of the ESRD incident and prevalent population, 53% and 52% respectively. With the exception of Networks 6 and 8, all Networks reported a higher ratio of males to females (Appendices I and J).

- **TREATMENT MODALITY**

Today, ESRD patients have a variety of choices for outpatient renal replacement therapy. They have the option of dialyzing at home, in a hospital-based facility, or an independent facility offering treatment. Some transplant centers, in addition to providing kidney transplants, offer dialysis services. Appendices K and L display the number of patients in each Network by modality.

Table 4 lists Medicare ESRD providers by type of service offered by Network. As expected based on patient populations, Network 6 has the largest number of dialysis providers (314) and Network 16 has the smallest number of providers (96).

While in-center hemodialysis is the predominate modality choice, changes are occurring in peritoneal dialysis (Appendix M). Continuous cycling peritoneal dialysis rose between 1997 and 1998 in most Networks. In-center peritoneal dialysis fell in all Networks as did CAPD (Appendix N).

TABLE 4
MEDICARE ESRD PROVIDERS BY TYPE OF SERVICE AND NETWORK
DECEMBER 31, 1998

Network	Total	Transplant	Dialysis	Hospital[1]	Independent[1]
1	122	15	118	40	78
2	183	14	181	101	80
3	109	3	108	48	60
4	208	14	189	39	150
5	246	15	240	48	192
6	314	10	308	25	283
7	230	7	226	15	211
8	253	12	246	15	231
9	250	16	244	52	192
10	118	8	116	34	82
11	258	20	249	113	136
12	193	18	182	50	132
13	212	18	203	32	171
14	263	20	247	13	234
15	175	14	166	30	136
16	96	5	93	32	61
17	143	9	136	29	107
18	213	17	203	18	185
Total	3,586	235	3,455	734	2,721

Source: National Listing of Medicare Providers Furnishing Kidney Dialysis and Transplant Services, January 1999
[1] Hospital and Independent counts are included in the total dialysis count.
Note: Detail does not add to total because most transplant centers also provide dialysis services and are counted again as dialysis providers.

According to the annual facility surveys conducted by the Networks, 13,212 transplants were performed at 235 transplant facilities within the United States during 1998. Of these transplants, 8,859 were from cadaveric donors while 3,498 were from living related donors and 825 from living non-related donors. Cadaveric donors represent 67% of transplants performed, but due to decreases in the availability of cadaveric donors, the percent of living and living unrelated donor transplants have increased in recent years and in 1998 represented 33% of all transplants performed. The number of patients waiting for a kidney transplant is listed in Appendix O.

Table 5 and Appendix P list the number of transplants performed by Network. Networks 11 and 14 had 20 transplant centers each. Network 11 performed the largest number of transplants in 1998, 1,375. Network 3 performed the least number of transplants, 314 and had the least number of transplants by living related donor.

TABLE 5
KIDNEY TRANSPLANTS BY NETWORK
CALENDAR YEAR 1998

Network	Total Transplants	Cadaveric Donor	Living Related Donor	Living Unrelated Donor	Unknown
1	628	339	221	68	0
2	841	549	242	50	0
3	314	214	87	13	0
4	832	671	141	19	1
5	853	467	249	137	0
6	788	573	188	27	0
7	663	536	108	19	0
8	671	454	175	42	0
9	972	731	241	0	0
10	557	350	207	0	0
11	1,375	818	420	137	0
12	657	461	157	39	0
13	393	275	98	20	0
14	954	681	228	45	0
15	629	368	188	44	29
16	445	278	134	33	0
17	662	444	167	51	0
18	978	650	247	81	0
Total	13,212	8,859	3,498	825	30

Source: 1998 Facility Survey, Medicare Providers

NETWORK DESCRIPTION

The start of 1997 marked the 20th year of the ESRD Network program. The program began in 1977 when HCFA published the final regulations establishing 32 Network Coordinating Councils to administer the newly funded ESRD program. With only 40,000 dialysis patients receiving care in 600 facilities, the Networks' responsibilities focused on organizational activities, health planning tasks, and medical review activities.

By 1987 the ESRD program encompassed over 100,000 patients and 1,800 facilities administering renal replacement therapy. At this time, Congress consolidated the 32 Networks into 18, redistributing and increasing their geographical areas as well as their program responsibilities. Funding mechanisms changed when Congress mandated that $ 0.50 from the composite rate payment from each dialysis treatment be allocated to fund the Network program. In 1988, HCFA began contracting with the ESRD Networks to meet their legislative responsibilities. These contracts placed greater emphasis on quality improvement activities and standardizing approaches to quality assessment. Networks still collected and analyzed data for quality improvement, but health-planning functions diminished.

The Networks began working on a new three year Scope of Work (SOW) in July 1997. The contract established a new ESRD Network Organization Manual that allowed HCFA to efficiently modify some requirements of the ESRD Network program while enabling Networks to better understand contract responsibilities.

The impact of the new manual is more significant to the daily operations of the Networks. As specified in the Scope of Work, each Network is responsible for conducting activities in the following areas:

1. Quality Improvement
2. Community Information and Resource
3. Administration
4. Information Management

HCFA contracts require each Network to have an Executive Director, a Director of Quality Improvement, and a Director of Data Management as well as other necessary staff to fulfill the contract obligations. The role of the Executive Director is to coordinate the activities of the Network. The Quality Improvement Director coordinates quality-related requirements and creates and implements quality improvement projects. The Data Manager's role is the accurate recording and transmission of data between the facilities, the Network, and HCFA.

In addition to these staff, Networks employ other individuals to accomplish contract responsibilities. Though these positions vary from Network to Network, additional staff in the areas of quality improvement and data are essential for the coordination of the many Network activities. Table 6 shows the type, number and percent of staff employed by each Network.

TABLE 6
NETWORK STAFF BY TYPE, NUMBER AND PERCENT
DECEMBER 31, 1998

	Administrative		Quality		Data		Patient Services		
Network	#	%	#	%	#	%	#	%	Total Staff
1	3	33%	2	22%	3	33%	1	11%	9
2	3	30%	2	20%	4	40%	1	10%	10
3	4	36%	2	18%	5	46%	0	0%	11
4	3	37%	2	25%	3	37%	0	0	8
5	4	37%	3	27%	4	27%	1	9%	12
6	3	27%	3	27%	5	46%	0	0%	11
7	2	22%	2	22%	4	44%	1	11%	9
8	2	25%	2	25%	3	37%	1	13%	8
9/10	5	39%	2	15%	4	31%	2	15%	13
11	2	18%	3	27%	4	37%	1	9%	11
12	3	43%	2	29%	2	29%	0	0%	7
13	2	22%	2	22%	4	45%	1	11%	9
14	3	27%	4	37%	3	27%	1	9%	11
15	2	25%	2.5	31%	2.5	31%	1	12%	8
16	2	29%	1.5	21%	3.5	50%	0	0%	7
17	3	30%	3	30%	3	30%	1	%	10
18	3	37%	1	13%	4	44%	1	13%	9

Source: 1998 Network Annual Reports

As seen in Table 6, Networks operate with a relatively small number of employees for the size of the ESRD patient population served. The patterns of staffing are similar across the Networks, with respect to the number of staff assigned to functional categories but still reflect regional variations. Over seventy percent of the Networks have patient services staff while the other Networks handle these

responsibilities through their quality improvement or administrative personnel. The staff classification areas above are for calculation purposes only and often do not indicate the true nature of staff work duties. Due to the small staff size in the Networks an administrative assistant may be responsible for supporting the quality improvement staff a portion of the time and the data staff the other time.

Network staff are supported by a variety of committees with volunteer members from within the Network area. Each Network is required by contract to specify appropriate roles and functions for these committees and each is required to have the following:

- **Network Council:** A body composed of renal providers in the Network area that is representative of the geography and the types of providers/facilities in the entire Network area as well as at least one patient representative. The Network Council serves as a liaison between the provider membership and the Network.

- **Board of Directors (BOD):** A body composed of representatives from the Network area including at least one patient representative. The BOD (or executive committee) supervises the performance of the Network's administrative staff in meeting contract deliverables and requirements and maintains the financial viability of the Network.

- **Medical Review Board (MRB):** A body composed of at least one patient representative and representatives of each of the professional disciplines (physician, registered nurse, social worker, and dietitian) that is engaged in treatment related to ESRD and qualified to evaluate the quality and appropriateness of care delivered to ESRD patients.

- **Any other committees** necessary to satisfy requirements of the SOW. These committees are designated by the Network and/or BOD and may include, but are not limited to patient advisory, grievance, organ procurement, transplant, finance, and rehabilitation.

HCFA NATIONAL GOALS AND NETWORK ACTIVITIES

The 1997 Scope of Work outlines four goals to provide direction to the national ESRD Network program. These goals outline the basic functions of the ESRD Networks and are used to direct the Network daily activities. Each Network tailors their activities to meet and exceed HCFA expectations.

The four goals for 1998 are:

1. Improving the quality of health care services and quality of life for ESRD beneficiaries;
2. Improving data reporting, reliability and validity between ESRD facilities/providers, Networks and HCFA;
3. Establishing and improving partnerships and cooperative activities among and between the ESRD Networks, Peer Review Organizations, State Survey Agencies and ESRD facilities and providers; and,
4. Evaluating and resolving grievances.

These goals and how the Networks accomplished them are discussed below.

GOAL ONE: IMPROVING THE QUALITY OF HEALTH CARE SERVICES AND QUALITY OF LIFE FOR ESRD BENEFICIARIES

■ QUALITY IMPROVEMENT PROJECTS

The Networks are required to conduct Quality Improvement Projects (QIPs) to assess and improve the outcomes of care provided to ESRD beneficiaries. Quality improvement, as defined in the Scope of Work is "a continuous process, using information from data on processes and outcomes of care to recognize opportunities to improve care and to develop measurable improvement initiatives." A QIP is a collaborative effort between Networks and health care providers and/or beneficiaries, which results in a measurable improvement of outcomes. The Dialysis Outcome Quality Initiative (DOQI) clinical practice guidelines published in the fall of 1997 provide the foundation for Network QIPs. Each QIP submitted to HCFA for approval must fit into one of four broad categories. These are adequacy of dialysis, anemia, prevention, and vascular access. Table 7 and Appendix Q show the types of Quality Improvement Projects implemented by each Network during 1998.

TABLE 7
QUALITY IMPROVEMENT PROJECTS
CALENDAR YEAR 1998

Network	Title
1	Increasing the Utilization of Permanent Access in Incident Hemodialysis Patients Improving Influenza Vaccination Rates
2	Improving Peritoneal Dialysis Adequacy Measures Early Detection of Venous Stenosis in AVG's to Prevent Thrombosis
3	Vascular Access Cooperative Anemia
4	Adequacy of Dialysis Early Referral to Nephrology Care
5	Improving the Adequacy of Hemodialysis Dialysis in ESRD Network 5 Improving Influenza Vaccination Rates
6	Improving Influenza Vaccination Rates Improving Hepatitis B Vaccination Rates Peritoneal Adequacy
7	ESRD Hepatitis B Vaccine Study Cooperative ESRD Vascular Access
8	Hemodialysis Adequacy Improving Peritoneal Dialysis Adequacy in Network 8
9/10	Peritoneal Dialysis Prescription Adequacy Hemodialysis Central Venous Catheter
11	A Systems Based Approach to Quality Improvement Strategies for Managing the Continuum of Care in the ESRD Patient
12	Vascular Access Quality Improvement Project Improving Hepatitis B Vaccination Rates
13	Early Detection of Venous Stenosis in AVG's to Prevent Thrombosis Adequacy of Hemodialysis
14	ESRD Immunization Cooperative Project
15	Peritoneal Dialysis Adequacy Improving Influenza Vaccination Rates
16	Reducing the Rate of Hemodialysis Access Infection
17	Improving Adequacy of Hemodialyis Patients in Northern California ESRD Patients
18	Vascular Access: Increasing & Maintaining AV Fistulae Improving Hepatitis B Vaccination Rates

Source: 1998 Network Annual Reports

In addition to their QIPs, Networks promote improved quality through:

- Participating in the collection of Dialysis Outcomes Data (Core Indicators Project);
- Conducting special projects and studies;
- Encouraging patient vocational rehabilitation programs;
- Providing educational opportunities and materials;
- Collaborating with Peer Review Organizations on state specific quality initiatives; and
- Providing technical assistance to state survey agencies.

■ CORE INDICATORS PROJECT

The ESRD Core Indicators Project is a product of the joint efforts between HCFA, the Forum of ESRD Networks, Networks, and other members of the renal community. Implemented in July 1994, the project collects data on measurable treatment outcomes to generate national and Network-specific data that reflects care provided to ESRD patients. The purposes of the core indicators project are to:

- Assist ESRD providers in improving care delivered to dialysis patients;
- Compare the prevalence of important clinical characteristics for adult patients; and
- Identify opportunities to improve care.

The four areas of care monitored by the core indicators are:

- Adequacy of dialysis measured by urea reduction ratio (URR);
- Anemia management measured by hematocrit;
- Hypertension measured by pre/post dialysis diastolic and systolic blood pressure; and
- Nutritional status measured by serum albumin.

Annually, each Network validates the dialysis patient population within its geographic area. After the process is complete, a census report is produced for HCFA containing such items as name, gender, etiology of ESRD, Social Security Number, and date dialysis was initiated for every hemodialysis and peritoneal dialysis patient alive within the calendar year. HCFA then selects a random sample of in-center hemodialysis and peritoneal patients. In 1998, the sample consisted of 8,838 in-center hemodialysis patients and 1,650 peritoneal dialysis patients (Tables 8 & 9). Once a random sample of patients is chosen, HCFA then uses data specific collection forms to obtain core indicators data. Networks collect and enter each patient form into a standardized data file ensuring the data are correct. Once all the data are collected, HCFA analyzes the core indicators data and provides feedback reports to the Networks which, in turn, are distributed to dialysis providers.

Tables 8 and 9 illustrate the sample number of in-center hemodialysis and peritoneal patients within each Network that was taken at the end of 1998. As noted the sample ranges from 2.5% to 9.4% for hemodialysis patients.

TABLE 8
1998 CORE INDICATORS PROJECT
NUMBER OF ADULT (≥ 18 YEARS) IN-CENTER HEMODIALYSIS PATIENTS BY NETWORK AND SAMPLE SIZE
DECEMBER 1998

Network	Number of Hemodialysis Patients December 1998	Sample Size
1	8,181	485
2	16,701	497
3	9,509	489
4	11,170	492
5	13,982	494
6	19,544	498
7	12,333	493
8	14,163	495
9	13,958	494
10	9,275	488
11	12,949	494
12	7,788	485
13	9,594	489
14	17,745	498
15	8,788	488
16	5,033	472
17	10,386	490
18	15,945	497
Total	217,044	8,838

Source: 1999 ESRD Core Indicators Report

TABLE 9
1998 CORE INDICATORS PROJECT
NUMBER OF ADULT (≥ 18 YEARS) PERITONEAL DIALYSIS PATIENTS BY NETWORK
SAMPLE DECEMBER 1998

Network	Sample Size	Network	Sample Size
1	74	11	115
2	99	12	88
3	77	13	75
4	70	14	98
5	88	15	70
6	163	16	76
7	71	17	70
8	102	18	117
9	126		
10	71	Total	1,650

Source: 1999 ESRD Core Indicators Project

Figure 3
Percent of adult (aged ≥18 yrs) in-center hemodialysis patients with mean Kt/V ≥ 1.2, by Network, in Oct-Dec 1998, 1999 ESRD Clinical Performace Measures Project

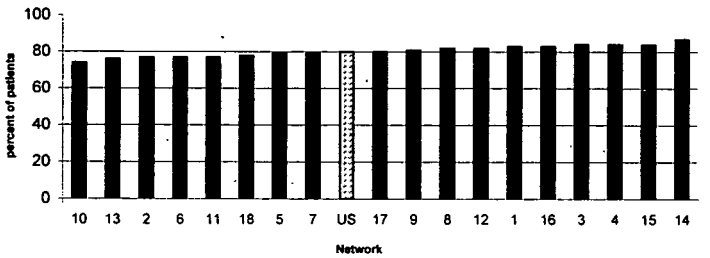
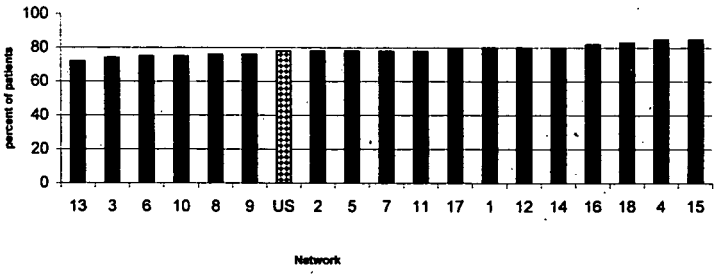


Figure 4
Percent of adult (aged ≥18 yrs) in-center hemodialysis patients with mean hemoglobin > 10 gm/dL, by Network, in Oct-Dec 1998, 1999 ESRD Clinical Performace Measures Project



The above figures (Figures 3 & 4) report findings for two of the core indicators, adequacy of dialysis and anemia, for the adult, in-center hemodialysis patients. These data are representative of the patients included in the 1998 core indicators sample. Using data collected on each selected patient, average values for adequacy of dialysis was calculated by Kt/V (a specific calculation factoring in patient size, time of treatment and dialyzer clearance). The percent of patients receiving adequate hemodialysis is displayed in ascending order by Network and for the U.S. Figure 3 shows the percentage of patients with a Kt/V $\geq$ 1.2. The threshold used in reporting, Kt/V $\geq$1.2, is the minimum acceptable level set forth by the DOQI Clinical Practice Guidelines. Figure 4 illustrates the percentage of patients with hemoglobin > 10 gm/dL varied among the Networks, ranging from 72% to 85%.

Each year that the Core Indicators Project has been performed, there have been statistically and clinically significant improvements made in hemodialysis adequacy and anemia management. See ESRD Core Indicators Reports for more details.

■ SPECIAL STUDIES AND PROJECTS

Networks develop special studies to examine issues specific to each Network area and patient population. While these studies are often limited to only one Network area, some projects are developed to incorporate multiple Networks.

Examples of Network special studies are provided below as well as Appendix R:

- Network of New England Clinical Indicator Project (Network 1)
- Network Core Indicators Monitoring (Network 2)
- ESRD Emergency Preparedness Resources for Pennsylvania and Delaware Dialysis Facilities (Network 4)
- Vancomycin Resistant Enterococcus (VRE) (Network 5)
- Familial Clustering of End-Stage Renal Disease in HIV-Associated Nephropathy (Network 6)
- Evening Dialysis Study (Network 7)
- The Physician Activity Report (Network 9/10)
- Transplant Reviews (Network 11)
- Pre-ESRD (Network 15)
- Northwest Renal Mortality Report (Network 16)
- 1998 Pacific Island Core Indicators Follow-Up (Network 17)
- Heparinization Practice Project (Network 18)
- Cooperative National Study of Renal Decisions (CONSORD) (Networks 5, 8, 11, 18)

■ VOCATIONAL REHABILITATION

Networks are responsible for assisting providers in defining or establishing rehabilitation goals for referring suitable candidates to vocational rehabilitation programs. Networks study the patterns of patient employment within the Network area. They maintain and distribute vocational rehabilitation information to providers and patients. The vocational rehabilitation information includes dialysis shifts available after 5 pm, job placement programs, exercise programs, and educational materials.

Networks are contracted to report the number of patients between 18 and 55 years who are referred for vocational rehabilitation and the number of patients in this age category who are employed or attending school (full or part time). Table 10 provides the percentage of patients between 18 and 55 years in these two categories by Network. In calendar year 1998, Network 5 reported the highest percent of

referrals (16.5%) and Network 3 reported the highest percent of patients employed or attending school (40.1%). Appendix S provides additional information on vocational rehabilitation in the Networks.

TABLE 10
VOCATIONAL REHABILITATION BY NETWORK
DECEMBER 31, 1998

Network	% Patients 18-55 Years Referred to Vocational Rehabilitation	Percent of Patients 18-55 Years Employed or Attending School
1	4.0	31.2
2	7.7	29.6
3	11.1	40.1
4	6.5	26.7
5	16.5	27.0
6	10.4	19.7
7	7.4	21.2
8	2.6	19.2
9	3.0	25.5
10	6.3	19.9
11	10.0	26.1
12	7.5	36.0
13	13.8	20.1
14	7.5	23.2
15	12.3	34.5
16	16.1	31.1
17	7.8	24.4
18	8.2	23.9
National Average	8.81	26.6

Source: 1998 Network Annual Reports

■ EDUCATIONAL OPPORTUNITIES

Networks serve as a clearinghouse for educational materials with the purpose of increasing the understanding of End Stage Renal Disease, the care/treatment required, and other related issues. Networks distribute these materials not only to patients and their families, but also to other concerned parties such as dialysis facilities and other renal related organizations. An example of educational materials developed by some Networks include disaster preparedness guides; patient advocacy documents that help patients play a proactive role in improving their health; patient and facility newsletters; information on resolving patient grievances; and vocational rehabilitation information.

Networks also plan and provide support for various educational conferences throughout the year. These conferences benefit both the care providers as well as the patient population. Many Networks provide annual educational conferences and seminars directed toward nephrology nurses and technicians, nephrologists, and social workers. Often the seminars are held in conjunction with the American Nephrology Nurses Association and National Kidney Foundation.

GOAL TWO: IMPROVING DATA REPORTING, RELIABILITY AND VALIDITY BETWEEN ESRD FACILITIES/PROVIDERS, NETWORKS AND HCFA

To accomplish the second goal, Networks utilize both internal and external databases to track various data. Data reporting is an essential function of the Networks. Accurate data collection has a two-fold purpose:

1. Aids the Networks by providing a look at issues facing the regional ESRD population and a check-system to measure facility accuracy and timeliness;
2. Provides the national ESRD data system with accurate data to support quality improvement initiatives, HCFA policy decision and the USRDS research activities.

Each Network supports and maintains its own database to store patient specific information and ESRD related events. On a broad level, these databases maintain demographic data as well as track patient transactions such as changes in modality, facility, transplant status, or death. In this manner, Networks are able to maintain accurate counts of patients within their area.

The information tracked within Network databases is collected from the ESRD provider through the Medical Evidence Report Form (HCFA 2728) and the Death Notification Form (HCFA 2746). Providers are responsible for submitting these documents in an accurate and timely manner. Networks monitor providers based on their data submission practices and are responsible for addressing non-compliance. Other clinical data elements are also retained in their Network database for quality improvement activities.

Networks are also responsible for transmitting these data to HCFA using the ESRD Data Entry and Editing System (EDEES). Each month, Networks must upload all information collected in EDEES to the HCFA database. Table 11 shows the number of forms collected by Networks in 1998.

TABLE 11
DATA FORMS PROCESSED
CALENDAR YEAR 1998

Network	Medical Evidence (HCFA 2728)	Death Notification (HCFA 2746)	Total
1	3,690	2,530	6,220
2	6,414	4,240	10,654
3	3,050	2,924	5,974
4	4,583	2,937	7,520
5	5,705	3,659	9,364
6	6,910	4,333	11,243
7	*	*	9,548
8	4,760	3,294	8,054
9	6,699	4,267	10,966
10	3,871	2,327	6,198
11	6,000	4,000	10,000
12	3,912	2,602	6,514
13	3,986	2,660	9,548
14	6,327	4,038	10,365
15	3,878	2,263	6,141
16	2,265	1,477	3,742
17	4,093	2,661	6,754
18	6,707	4,216	10,923

Source: 1998 Network Annual Reports.
*Network numbers not provided

Recognizing the need to standardize each ESRD Network's data system, HCFA began working with the Networks and Forum of ESRD Networks to accomplish this standardization. In October of 1997, the Southeastern Kidney Council (Network 6) was awarded a 24-month contract to design, develop, and install Standard Information Management System (SIMS). The purpose of the project is to design, develop, purchase and install a standard information management system that supports the ESRD Network Organizations. It will also provide communication and data exchange links among the Networks, HCFA, and other segments of the renal community to support quality improvement activities that relate to the treatment of ESRD. Throughout 1998, Networks began shaping the project through established workgroups to determine core data set elements, security issues and a standardized data dictionary. Two Networks, Network 5 and Network 6, began Alpha testing SIMS in November 1998 with Beta testing expected to begin in June 1999. SIMS has an expected release date of December 1999 (Southeastern Kidney Council 1998 Annual Report).

In building this information infrastructure, the Networks hope to better pursue initiatives to measure and improve the quality of healthcare delivered to the ESRD patient population. The ultimate goal of SIMS is to improve the quality of care delivered by making ESRD data more accessible to dialysis facilities, Networks and the renal community.

GOAL THREE: ESTABLISHING AND IMPROVING PARTNERSHIPS AND COOPERATIVE ACTIVITIES AMONG AND BETWEEN ESRD NETWORKS, PEER REVIEW ORGANIZATIONS (PROS), STATE SURVEY AGENCIES AND ESRD FACILITIES AND PROVIDERS

Networks participate in a number of activities with organizations facilitating cooperation and joint ventures to fulfill this goal. Each Network creates unique partnerships with organizations to help provide better care for the ESRD patient population.

All Networks provide support and leadership to the Forum of ESRD Networks. Network MRB Chairmen and Board members, Executive Directors, and other staff members assist the Forum by volunteering for positions on the Forum Board of Directors as well as on various Forum committees.

The Forum, as a result of the participation of all 18 Networks, has been instrumental in developing and promoting a number of national initiatives that improve partnerships within the Network system. These include the SIMS initiative, the semi-annual meetings of MRB Chairpersons, development of a strategic plan, quarterly conference calls among the Executive Directors, and distribution of clearinghouse materials to all Networks.

The Forum received several contract modifications from HCFA in 1998 to assist in serving the Networks more efficiently. The Forum sponsored a Spring meeting between HCFA representatives and the Networks. The meeting drew representatives from HCFA, Network staff from their Data, Quality and Executive departments as well as many Network Medical Review Board Chairmen to discuss issues impacting the ESRD Networks. The Forum also received a contract modification to print and distribute the 1998 ESRD Core Indicators Data Collection Form as well as to format and distribute the Core Indicators Supplement and Highlight Reports.

In addition to working with the Forum, Networks foster relationships with Peer Review Organizations (PROs). As seen below in Table 12, Networks implemented cooperative studies in conjunction with the PROs in the area of quality improvement during 1998. The projects varied from Network to Network but all projects focused on improving the care received by ESRD patients.

TABLE 12
1998 NETWORK-PRO COLLABORATION PROJECTS

NETWORK	PRO	Topic or Project Name
2	Island Peer Review Organization	Monitoring AV Grafts for Early Detection of Venous Stenosis
5	Delmarva Foundation for Medical Care	Improving the adequacy of hemodialysis
5	West Virginia Medical Institute, Delmarva Foundation for Medical Care, Virginia Health Quality Center	Increasing the influenza vaccination rate
7	Florida Medical Quality Assurance, Inc.	Hepatitis B vaccination
8	Mid-South Foundation for Medical Care	Foot care
11	Michigan PRO North Dakota PRO	Flu vaccination Strategies for Managing the Continuum of Care in the ESRD Patient
13	Louisiana Health Care Review, Inc.	Vascular Access
14	Texas Medical Foundation	Be-Wise Immunize QIP protocol
15	Colorado Foundation for Medical Care	Peritoneal dialysis adequacy
15	Mountain Pacific Quality Health Foundation	Pre-ESRD Care
16	PRO-West	Vascular Access CPMs
17	CMRI, Inc	Hepatitis B vaccination and Immune status among ESRD patients in Northern California

Networks communicate with State Survey Agencies (SSAs) through the exchange of newsletters, annual reports, and other appropriate quality reports. The high degree of communication helps to facilitate the exchange of ideas on issues of quality improvement and patient grievances.

Networks continually communicate and coordinate activities with members of the renal community. In addition, they have fostered strong relationships with advocacy and research organizations. Some of the renal community Networks work with include:

- **AAKP:** American Association of Kidney Patients
- **AKF:** American Kidney Fund
- **ANNA:** American Nephrology Nurses Association
- **ASN:** American Society of Nephrology
- **NKF:** National Kidney Foundation
- **NRAA:** National Renal Administrators Association
- **RPA:** Renal Physicians Association

Other organizations Networks work with include:

- **CDC:** Centers for Disease Control
- **FDA:** Food and Drug Administration
- **NAHQ:** National Association for Healthcare Quality
- **UNOS:** United Network for Organ Sharing
- **USRDS:** United States Renal Data System

Many of the ESRD Network personnel are actively involved on renal community Boards of Directors and committees. For example, several ESRD Network staff work closely with both the National Kidney Foundation (NKF) and the American Association of Kidney Patients (AAKP) to avoid duplication of services to patients within their Network area.

All ESRD Networks collaborate with UNOS to collect transplant data. The Networks' assist UNOS in collecting forms dealing with transplantation which are overdue and UNOS in turn supplies data and reports.

GOAL FOUR: EVALUATING AND RESOLVING PATIENT GRIEVANCES

Networks are responsible for evaluating and resolving patient grievances. Each Network has a formal grievance resolution protocol, approved by HCFA. During 1998, Networks processed 105 formal beneficiary grievances. This represents a small decrease from 1997.

A formal beneficiary grievance is a documented complaint usually alleging that ESRD services did not meet professional levels of care. This type of complaint requires the Network to conduct a formal review of the information and an evaluation of the grievance, which may require the involvement of a Grievance Committee and/or the Medical Review Board.

Grievances come to the Networks in many forms, and from many sources including telephone calls and letters from patients, families, facilities, and patient advocates. Though many of these "complaints" never reach the formal grievance stage, Networks dedicate large amounts of staff time responding to these concerns. It is estimated that ESRD Networks process about 3,000 such patient concerns annually. The relatively small number of formal beneficiary grievances is an indication that Networks address most concerns before they become formal grievances.
Tables 13 displays the number and type of formal written grievances filed in each Network during 1998.

TABLE 13
FORMAL GRIEVANCES PROCESSED
CALENDAR YEAR 1998

Network	# of Grievances
1	0
2	12
3	0
4	1
5	10
6	22
7	10
8	16
9/10	18

Network	# of Grievances
11	0
12	5
13	8
14	10
15	3
16	0
17	2
18	1
Total	118

Source: 1998 Network Annual Reports

As noted, several Networks (1, 3, 11 and 16) had no formal grievance investigations in 1998 while Network 6 processed 22 formal grievances. Table 14 groups grievances into broad categories based on their general type given their description in each Network's Annual Report. The majority of the grievances relate to the patient's relationship to the staff and complaints regarding the staff or dialysis provider. The majority of the complaints lodged by facilities concern the handling of disruptive and abusive patients.

TABLE 14 TYPE OF GRIEVANCE
Treatment Related • Any concern relating to the medical treatment a patient receives at the unit. These may include time of treatment, availability of treatment times, quality of treatment received, etc.
Physical Environment • Any concern relating to the physical atmosphere of the unit. These may include temperature, cleanliness, hazards, etc.
Staff/Provider Related • Any concern including difficulties with provider policies or staff such as professional behavior, competency, adherence to policy, etc.
Disruptive/Abusive Patient • These complaints, lodged by the facility, concern how to handle a patient and/or family that is disruptive, abusive, or non-compliant.
Patient Transfer Related • These complaints relate to the inter-facility patient transfer process.
Transient Dialysis Related • Any complaint concerned with the facility assisting the patient and/or family in identifying a provider for temporary dialysis treatment.

Source: 1998 Network Annual Reports

SANCTION RECOMMENDATIONS

Networks are authorized to propose (to HCFA) sanction recommendations against facilities and to make recommendations for additional facilities in the service area, as they are necessary for each particular Network.

During 1998, only one sanction recommendation was made to HCFA. This sanction involved a facility that the Network felt its practices over time did not meet the standard of care and observed that the standardized mortality rate was consistently higher than the state average. The facility was not closed but was required to follow specific guidelines to monitor and improve deficiencies.

RECOMMENDATIONS FOR ADDITIONAL FACILITIES

There were three Networks recommending additional facilities in their area. These recommendations vary in their objectives which include:

- The need for a Medicare assessment of the costs to operate dialysis centers to include wage adjustments and local regulations to help with shortage of trained personnel.
- The need for HCFA to develop a billing code to accommodate the non-chronic, acute patients who require dialysis for an extended period of time. These patients do not need be hospitalized, but do require dialysis treatment until kidney function returns. Due to billing complications it is difficult to accommodate these patients in the traditional outpatient setting.

- The difficulty of providing ambulance transportation for hemodialysis patients in Skilled Nursing Facilities due to Medicare bundling costs.
- The need to increase transplantation services in one Network.
- The need to evaluate a mechanism for reimbursing acute care facilities adequately for treating patients who cannot be treated in chronic facilities due to behavioral problems.

SUMMARY

This report summarizes highlights of ESRD Network's 1998 activities. The following Internet addresses provide additional information about the ESRD Networks and the ESRD program. All Network web sites can be access through the Forum's home page, www.esrdnetworks.org.

NETWORK WEB ADDRESSES

Network	
1	http://www.networkofnewengland.org
2	http://www.esrdnetworks.org/networks/net2/net2.htm
3	http://www.tarcweb.org
4	http://www.esrdnetworks.org/networks/net4/net4.htm
5	http://www.esrdnet5.org
6	http://www.esrdnetworks.org/networks/net6/net6.htm
7	http://www.esrdnetworks.org/networks/net7/net7.htm
8	http://www.esrdnetworks.org/networks/net8/net8.htm
9/10	http://www.renalnetwork.org
11	http://www.esrdnetworks.org/networks/net11/net11.htm
12	http://www.esrdnetworks.org/networks/net12/net12.htm
13	http://www.esrdnetworks.org/networks/net12/net12.htm
14	http://www.nephron.com/net14.html
15	http://www.esrdnetworks.org/networks/net15/net15.htm
16	http://www.nwrenalnetwork.org
17	http://www.network17.org
18	http://www.esrdnetworks.org/networks/net18/net18.htm
SIMS Project	http://www.simsproject.com

ORGANIZATION WEB ADDRESSES

AHQA	http://www.ahqa.org	Medicare	http://www.medicare.gov
AAKP	http://www.aakp.org	NAHQ	http://www.nahq.org
ANNA	http://anna.inurse.com	NKF	http://www.kidney.org
CDC	http://www.cdc.gov	UNOS	http://www.unos.org
HCFA	http://www.hcfa.gov	USRDS	http://www.usrds.org

A copy of a specific Network Annual Report can be obtained from the Network office. Network addresses and telephone numbers are listed on the inside front cover of this report.

APPENDIX A
1998 INCIDENCE AND PREVALENCE BY DIALYZING NETWORK

Network	Patients New to ESRD in 1998	Patients Dialyzing at 12/31/1998
1	3,469	9,606
2	6,196	18,829
3	3,980	11,394
4	4,698	12,385
5	5,588	15,865
6	6,809	22,450
7	5,182	14,268
8	4,464	14,435
9	6,937	17,351
10	4,215	10,991
11	5,882	15,501
12	3,608	9,533
13	3,622	10,699
14	6,388	19,474
15	3,679	10,056
16	2,184	6,198
17	4,112	11,902
18	6,288	17,908
Total	**87,301**	**248,845**

Source: 1998 Network Annual Reports

APPENDIX B
STATE AND NATIONAL ESRD INCIDENCE RATES
CALENDAR YEAR 1998

Patients' Residence	Initiated ESRD Therapy 1998	General Population (7/1/98)	Incidence Rate Per Million Population
Alabama	1,564	4,351,999	359.38
Alaska	67	614,010	109.12
Arizona	1,580	4,668,631	338.43
Arkansas	734	2,538,303	289.17
California	9,861	32,666,550	301.87
Colorado	761	3,970,971	191.64
Connecticut	948	3,274,096	289.55
Delaware	252	743,603	338.89
District of Columbia	421	523,124	804.78
Florida	5,191	14,915,980	348.02
Georgia	2,567	7,642,207	335.90
Hawaii	457	1,193,001	383.07
Idaho	230	1,228,684	187.19
Illinois	4,395	12,045,326	364.87
Indiana	1,864	5,899,195	315.98
Iowa	666	2,862,447	232.67
Kansas	656	2,629,067	249.52
Kentucky	1,160	3,936,499	294.68
Louisiana	1,928	4,368,967	441.29
Maine	247	1,244,250	198.51
Maryland	2,018	5,134,808	393.00
Massachusetts	1,625	6,147,132	264.35
Michigan	3,131	9,817,242	318.93
Minnesota	1,058	4,725,419	223.90
Mississippi	1,105	2,752,092	401.51
Missouri	1,799	5,438,559	330.79
Montana	158	880,453	179.45
Nebraska	433	1,662,719	260.42
Nevada	459	1,746,898	262.75
New Hampshire	219	1,185,048	184.80
New Jersey	3,003	8,115,011	370.05
New Mexico	466	1,736,931	268.29
New York	6199	18,175,301	341.07
North Carolina	2,712	7,546,439	359.37
North Dakota	127	638,244	198.98
Ohio	3,865	11,209,493	344.80
Oklahoma	987	3,346,713	294.92
Oregon	649	3,281,974	197.75
Pennsylvania	4,321	12,001,451	360.04
Rhode Island	301	988,480	304.51
South Carolina	1,507	3,835,962	392.86
South Dakota	199	738,171	269.59
Tennessee	1,752	5,430,621	322.62
Texas	6,323	19,759,614	320.00
Utah	336	2,099,758	160.02
Vermont	116	590,883	196.32
Virginia	2,319	6,791,345	341.46
Washington	1,075	5,689,263	188.95
West Virginia	612	1,811,156	337.91
Wisconsin	1,343	5,223,500	257.11
Wyoming	74	480,907	153.88

APPENDIX B
STATE AND NATIONAL ESRD INCIDENCE RATES
CALENDAR YEAR 1998

Patients' Residence	Initiated ESRD Therapy 1998	General Population (7/1/98)	Incidence Rate Per Million Population
Unknown US	239		
United States	86,079	270,298,524	318.46
American Samoa	9	62,093	144.94
Guam	73	149,101	489.60
Puerto Rico	1,062	3,860,000	275.13
Saipan	22	66,611	330.28
Virgin Islands	35	118,382	295.65
Unknown	7		
US and Territories	87,287	274,554,711	317.92
Outside US	14		
Total New ESRD	87,301	274,554,711	317.97

Source of Population Census: http://www.census.gov/population/estimates/state/ST9097T1.txt
http://www.census.gov/cgi-bin/ipc/idbsprd

APPENDIX C
Incidence Increase (Decrease) from End Year 1997 and End Year 1998

Patients' Residence	Initiated ESRD Therapy 1997	Initiated ESRD Therapy 1998	% Difference
[redacted]			
Arizona	1,378	1,580	15%
[redacted]			
California	9,094	9,861	8%
Colorado	683	761	11%
Connecticut	946	948	0.00
Delaware	184	252	37%
District of Columbia	378	421	11%
Florida	4,955	5,191	5%
Georgia	2,433	2,567	6%
Hawaii	420	457	9%
Idaho	214	230	7%
Illinois	3,998	4,395	10%
Indiana	1,618	1,864	15%
Iowa	595	666	12%
Kansas	670	656	-2%
Kentucky	1,066	1,160	9%
Louisiana	1,722	1,928	12%
[redacted]			
Maryland	1,810	2,018	11%
Massachusetts	1,592	1,625	2%
Michigan	2,883	3,131	9%
Minnesota	980	1,058	8%
Mississippi	1,063	1,105	4%
Missouri	1,636	1,799	10%
Montana	140	158	13%
Nebraska	401	433	8%
Nevada	406	459	13%
New Hampshire	193	219	13%
New Jersey	2,781	3,033	9%
New Mexico	448	466	4%
New York	5,863	6,199	6%
North Carolina	2,512	2,712	8%
[redacted]			
Ohio	3,483	3,865	11%

APPENDIX C
INCIDENCE INCREASE (DECREASE) FROM END YEAR 1997 AND END YEAR 1998

Patients' Residence	Initiated ESRD Therapy 1997	Initiated ESRD Therapy 1998	% Difference
Oklahoma	901	987	10%
Oregon	618	649	5%
Pennsylvania	3,959	4,321	9%
Rhode Island	267	301	13%
South Carolina	1,399	1,507	8%
South Dakota	194	199	3%
Tennessee	1,729	1,752	1%
Texas	5,794	6,323	9%
Utah	267	336	26%
Vermont	120	116	-3%
Virginia	2,264	2,319	2%
Washington	1,023	1,075	5%
West Virginia	614	612	0.00
Wisconsin	1,212	1,343	11%
Wyoming	69	74	0.07
		74	
Total United States	**79,880**	**86,079**	**8%**
American Samoa	7	9	29%
Guam	7	7	0%
Puerto Rico	974	1,062	9%
Saipan	16	22	38%
Virgin Islands	29	35	17%
Unknown		7	
Total US and Territories	**80,996**	**87,287**	**8%**
Outside US		14	
Total New ESRD	**80,996**	**87,301**	**8%**

Source: 1998 Network Annual Reports

APPENDIX D
INCIDENCE OF DIALYSIS POPULATION BY AGE AND NETWORK
DECEMBER 31, 1998

Network	0-19	20-29	30-39	40-49	50-59	60-69	70-79	≥80	Unk	Total
1	38	79	181	303	496	781	1035	556	0	3,469
2	75	184	390	731	1072	1407	1479	752	0	6,090
3	25	95	235	417	691	973	1043	501	0	3,980
4	57	111	278	492	656	1143	1398	563	0	4,698
5	61	157	409	694	924	1261	1335	529	10	5,380
6	78	247	500	931	1336	1650	1498	567	2	6,809
7	40	116	321	539	773	1126	1474	817	0	5,206
8	57	169	307	602	828	1087	1001	392	0	4,443
9	78	173	464	733	1097	1668	1901	814	6	6,934
10	60	125	287	468	678	929	1139	534	0	4,220
11	77	164	379	730	957	1302	1589	685	0	5,883
12	52	115	243	402	553	826	962	455	0	3,608
13	58	120	263	504	703	885	787	302	0	3,622
14	101	235	475	905	1210	1573	1401	484	4	6,388
15	61	106	264	427	674	877	922	346	1	3,678
16	36	72	171	269	394	495	511	236	0	2,184
17	51	122	255	482	703	968	1016	508	13	4,118
18	74	206	361	680	983	1419	1669	831	0	6,223
Total	1,079	2,596	5,783	10,309	14,728	20,370	22,160	9,872	36	86,933
% Total	1%	3%	7%	12%	17%	23%	25%	11%	0%	

Source: 1998 Network Annual Reports

APPENDIX E
1998 ESRD PREVALENCE OF PATIENTS BY RACE IN NETWORK RECEIVING TREATMENT

Network	Black	White	Asian/ Pacific Islander	Native American	Other	Unknown	Total
1	1,812	7,368	153	31	186	56	9,606
2	7,525	9,161	599	121	1,423	0	18,829
3	3,568	5,296	163	28	2,339	0	11,394
4	4,360	7,754	45	30	170	26	12,385
5	9,462	5,673	245	0	211	274	15,865
6	14,892	6,449	193	348	399	169	22,450
7	5,615	8,304	190	37	122	0	14,268
8	9,136	5,136	73	66	24	0	14,435
9	5,992	10,916	64	73	264	42	17,351
10	4,841	5,504	183	36	421	6	10,991
11	5,033	9,649	224	484	111	0	15,501
12	2,760	6,575	86	105	7	0	9,533
13	5,897	4,228	68	430	76	0	10,699
14	6,160	6,864	260	67	5,936	187	19,474
15	932	7,051	237	1,547	238	51	10,056
16	617	4,858	425	254	44	0	6,198
17	2,170	6,188	3,409	106	0	29	11,902
18	3,505	11,914	2,082	118	289	0	17,908
Total	**94,277**	**128,888**	**8,699**	**3,881**	**12,260**	**840**	**248,845**
%Total	**38%**	**52%**	**3%**	**2%**	**5%**	**0%**	

Source: 1998 ESRD Network Annual Reports. Patient numbers are derived from those patients receiving treatment

APPENDIX F
1998 ESRD INCIDENCE OF PATIENTS BY RACE IN NETWORK RECEIVING TREATMENT

Network	Black	White	Asian/ Pacific Islander	Native American	Other	Unknown	Total
1	483	2,845	44	5	68	24	3,469
2	1,952	3,467	197	25	449	0	6,090
3	1,014	1,854	49	1	1,062	0	3,980
4	1,159	3,414	34	8	65	18	4,698
5	2,613	2,589	70	0	52	56	5,380
6	3,785	2,763	36	49	137	39	6,809
7	1,488	3,600	63	9	46	0	5,206
8	2,270	2,126	21	13	12	1	4,443
9	1,639	5,059	22	49	143	22	6,934
10	1,510	2,385	65	19	234	7	4,220
11	1,340	4,264	71	162	46	0	5,883
12	780	2,726	23	24	55	0	3,608
13	1,654	1,761	19	148	39	1	3,622
14	1,609	2,788	93	23	1,864	11	6,388
15	274	2,838	88	361	97	20	3,678
16	177	1,787	121	80	19	0	2,184
17	622	2,401	1,026	51	0	18	4,118
18	1,039	4,383	663	22	116	0	6,223
Total	**26,956**	**56,837**	**5,088**	**1,104**	**4,504**	**228**	**86,933**
%	31%	65%	6%	1%	5%	0%	

Source: 1998 ESRD Network Annual Reports. Patient numbers are derived from those patients receiving treatment

APPENDIX G
LIST OF PRIMARY CAUSES OF END STAGE RENAL DISEASE

Diabetes
- Type II, adult-onset
- Type I, juvenile type

Glomerulonephritis
- Glomerulonephritis (GN)
- Focal glomerulonephritis
- Membranous nephropathy
- Membranoproliferative GN
- Dense deposit disease
- IgA nephropathy, Berger's disease
- IgM nephropathy
- Rapidly progressive GN
- Goodpasture's Syndrome
- Post infectious GN
- Other proliferative GN

Hypertension/Large Vessel Disease
- Renal disease due to hypertension
- Renal artery stenosis
- Renal artery occlusion
- Cholesterol emboli, renal emboli

Cystic/Hereditary/Congenital Diseases
- Polycystic kidneys, adult type
- Polycystic, infantile
- Medullary cystic disease
- Tuberous sclerosis
- Hereditary nephritis, Alport's syndrome
- Cystinosis
- Primary oxalosis
- Fabry's disease
- Congenital nephrotic syndrome
- Drash syndrome
- Congenital obstructive uropathy
- Renal hypoplasia, dysplasia, oligonephronia
- Prune belly syndrome
- Hereditary/familial nephropathy

Other

Secondary GN/Vasculitis
- Lupus erythematosus
- Henoch-Schonlein syndrome
- Sclerodema
- Hemolytic uremic syndrome
- Polyarteritis
- Wegener's granulomatosis
- Nephropathy due to heroin abuse and related drugs
- Vasculitis and its derivatives
- Secondary GN, other

Interstitial Nephritis/Pyelonehpritis
- Analgesic abuse
- Radiation nephritis
- Lead nephropathy
- Gouty nephropathy
- Nephrolithiasis
- Acquired obstructive uropathy
- Chronic pyelonephritis
- Chronic interstitial nephritis
- Acute interstitial nephritis
- Urolithiasis
- Nephrocalcinsois

Neoplasms/Tumors
- Renal tumor (malignant, benign, or unspecified)
- Urinary tract tumor (malignant, benign, or unspecified)
- Lymphoma of kidneys
- Multiple myeloma
- Light chain nephropathy
- Amyloidosis
- Complication post bone marrow or other transplant

Miscellaneous Conditions
- Sickle cell disease/anemia
- Sickle cell trait and other sickle cell
- Post partum renal failure
- AIDS nephropathy
- Traumatic or surgical loss of kidneys
- Hepatorenal syndrome
- Tubular necrosis
- Other renal disorders
- Etiology uncertain

APPENDIX H
1998 ESRD INCIDENCE BY PRIMARY DIAGNOSIS

Network	Diabetes	Hypertension	Glomerulonephritis	Cystic Kidney Disease	Other Causes	Unknown	Total
1	1,351	805	421	143	719	30	3,469
2	2,437	1,266	640	145	997	605	6,090
3	1,963	1,008	387	97	525	0	3,980
4	1,923	1,152	583	113	920	7	4,698
5	2,243	1,603	639	169	524	202	5,380
6	2,988	1,912	598	185	980	146	6,809
7	1,978	1,633	478	144	757	217	5,206
8	1,872	1,492	374	117	588	0	4,443
9	3,167	1,506	762	165	1,320	14	6,934
10	1,550	1,269	375	87	836	103	4,220
11	2,541	1,502	491	153	940	256	5,883
12	1,561	990	340	191	401	125	3,608
13	1,662	1,115	347	123	271	104	3,622
14	3,233	1,409	637	191	871	47	6,388
15	1,854	639	415	163	427	180	3,678
16	938	419	301	141	297	88	2184
17	1,924	827	585	162	604	16	4,118
18	2,948	1,758	599	131	787	0	6,223
Total	38,133	22,305	8,972	2,620	12,764	2,140	86,933
% of Total	43.86%	25.66%	10.32%	3.01%	14.68%	2.46%	

Source: 1998 Network Annual Reports

APPENDIX I

1998 INCIDENCE OF PATIENTS BY GENDER IN NETWORK RECEIVING TREATMENT

Network	Male	Female	Unknown	Total
1	1,896	1,573	0	3,469
2	3,299	2,791	0	6,090
3	2,192	1,788	0	3,980
4	2,585	2,113	0	4,698
5	2,801	2,579	0	5,380
6	3,317	3,399	93	6,809
7	2,890	2,316	0	5,206
8	2,203	2,240	0	4,443
9	3,564	3,354	16	6,934
10	2,248	1,972	0	4,220
11	3,175	2,708	0	5,883
12	1,953	1,655	0	3,608
13	1,844	1,778	0	3,622
14	3,326	3,062	0	6,388
15	2,028	1,649	1	3,678
16	1,214	970	0	2,184
17	2,214	1,891	13	4,118
18	3,341	2,882	0	6,223
Total	**46,090**	**40,720**	**123**	**86,933**
% Total	**53%**	**47%**	**0%**	

Source: 1998 Network Annual Reports

APPENDIX J
1998 PREVALENCE OF PATIENTS BY GENDER IN NETWORK RECEIVING TREATMENT

Network	Male	Female	Unknown	Total
1	5,134	4,472	0	9,606
2	10,184	8,645	0	18,829
3	6,440	4,954	0	11,394
4	6,639	5,746	0	12,385
5	8,329	7,460	76	15,865
6	10,777	11,308	365	22,450
7	7,774	6,494	0	14,268
8	7,071	7,364	0	14,435
9	9,057	8,277	17	17,351
10	5,748	5,242	1	10,991
11	8,273	7,228	0	15,501
12	4,967	4,566	0	9,533
13	5,456	5,243	0	10,699
14	9,746	9,728	0	19,474
15	5,313	4,738	5	10,056
16	3,375	2,823	0	6,198
17	6,129	5,761	12	11,902
18	9,370	8,538	0	17,908
Total	**129,782**	**118,587**	**476**	**248,845**
% Total	**52%**	**48%**	**0%**	

Source: 1998 Network Annual Reports

APPENDIX K
IN-CENTER DIALYSIS PATIENTS BY NETWORK MODALITY
DECEMBER 31, 1998

NETWORK	Hemodialysis	Peritoneal Dialysis
1	8,138	30
2	16,214	14
3	9,851	1
4	11,099	9
5	13,955	45
6	19,785	0
7	12,489	2
8	12,908	5
9	14,744	30
10	9,788	12
11	13,366	0
12	7,821	0
13	9,368	4
14	17,484	18
15	8,844	2
16	5,052	13
17	10,389	12
18	16,027	13
Total	**217,322**	**210**

Source: 1998 Network Annual Reports

APPENDIX L
HOME DIALYSIS PATIENTS BY NETWORK
DECEMBER 31, 1998

NETWORK	Hemodialysis	CAPD	CCPD	Other PD	Total
1	50	583	707	1	1341
2	145	1,038	781	0	1,964
3	56	657	829	0	1,542
4	59	511	624	0	1,194
5	148	860	810	10	1,828
6	176	1,433	1,141	18	2,768
7	162	508	726	0	1,396
8	124	746	637	10	1,517
9	65	1,636	860	11	2,572
10	65	716	408	2	1,191
11	75	1,350	709	1	2,135
12	136	929	647	0	1,712
13	22	607	420	2	1,051
14	66	796	930	2	1,794
15	62	578	565	1	1,206
16	220	558	340	15	1,133
17	25	685	746	0	1,456
18	17	1,078	837	1	1,933
Total	1,673	15,269	12,717	74	29,733

Source: 1998 Network Annual Reports

APPENDIX M
1997 AND 1998 DIALYSIS MODALITY: IN CENTER

	HEMO			PD		
Network	1997	1998	% Change	1997	1998	% Change
1	7,526	8,138	8%	20	30	50%
2	15,174	16,214	7%	35	14	-60%
3	8,914	9,851	11%	20	1	-95
4	10,291	11,099	8%	44	9	-80%
5	13,108	13,955	6%	59	45	-24%
6	18,161	19,785	9%	5	0	0
7	11,596	12,489	8%	15	2	-87%
8	11,735	12,908	10%	12	5	-58%
9	13,065	14,744	13%	19	30	58%
10	9,096	9,788	8%	18	12	-33%
11	12,128	13,366	10%	0	0	0%
12	7,001	7,821	12%	0	0	0%
13	8,811	9,638	9%	0	4	n/a
14	16,062	17,484	9%	58	18	-69%
15	7,960	8,844	11%	10	2	-80%
16	4,631	5,052	9%	17	13	-24%
17	9,540	10,389	9%	13	12	-8%
18	14,718	16,027	9%	4	13	225%
Total	199,517	217,592	9%	349	210	-40%

Source: 1998 Network Annual Reports

APPENDIX N
1997 and 1998 DIALYSIS MODALITY: SELF-CARE SETTING- HOME

	HEMO			CAPD			CCPD			OTHER PD		
Network	1997	1998	% Change	1997	1998	% Change	1997	1998	% Change	1997	1998	% Change
1	70	50	-29%	691	583	-16%	708	707	0%	0	1	n/a
2	146	145	-1%	1,182	1,038	-12%	763	781	2%	0	0	0
3	64	56	-13%	781	657	-16%	848	829	-2%	0	0	0
4	82	59	-28%	636	511	-20%	597	624	5%	0	0	0
5	152	148	-3%	922	860	-7%	753	810	8%	5	10	100%
6	158	176	11%	1,601	1,433	-10%	1,059	1,141	8%	15	18	20%
7	195	162	-17%	609	508	-17%	666	726	9%	1	0	-100%
8	140	124	-11%	885	746	-16%	545	637	17%	27	10	-63%
9	125	65	-48%	1,725	1,636	-5%	827	860	4%	18	11	-39%
10	100	65	-35%	763	716	-6%	365	408	12%	5	2	-60%
11	89	75	-16%	1,576	1,350	-14%	694	709	2%	2	1	-50%
12	127	136	7%	1,029	929	-10%	667	647	-3%	0	0	0%
13	39	22	-44%	659	607	-8%	428	420	2%	2	2	0%
14	71	66	-7%	868	796	-8%	891	930	4%	5	2	-60%
15	86	62	-28%	558	578	4%	557	565	1%	16	1	-94%
16	272	220	-19%	628	558	-11%	312	340	9%	14	15	7%
17	23	25	9%	738	685	-7%	772	746	-3%	0	0	0
18	20	17	-15%	1,225	1,078	-12%	816	837	3%	0	1	n/a
Total	1,959	1,673	-15%	17,076	15,269	-11%	12,268	12,717	4%	110	74	-33

Source: 1998 Network Annual Reports

APPENDIX O
NUMBER OF RENAL TRANSPLANTS PERFORMED
CALENDAR YEAR 1998

NETWORK	Total Kidney Transplants	Patients Waiting for Kidney Transplants*
1	628	2,112
2	841	3,999
3	314	1,443
4	832	2,580
5	853	3,566
6	788	2,224
7	663	1,265
8	671	2,030
9	972	1,737
10	557	2,157
11	1,375	3,505
12	657	1,126
13	393	1,304
14	954	1,835
15	629	1,237
16	445	907
17	662	1,965
18	978	3,240
Total	13,212	38,232

Source: 1998 Network Annual Reports

* Patients my be placed on more than one transplant center's waiting list, so patients may be counted more than once

APPENDIX P
RENAL TRANSPLANT RECIPIENTS BY DONOR SOURCE
CALENDAR YEAR 1998

NETWORK	Cadaver	Living Related	Living Unrelated	Unknown	Total
1	339	221	68	0	628
2	549	242	50	0	841
3	214	87	13	0	314
4	671	141	19	1	832
5	467	249	137	0	853
6	573	188	27	0	788
7	536	108	19	0	663
8	454	175	42	0	671
9	731	241	0	0	972
10	350	207	0	0	557
11	818	420	137	0	1,375
12	461	157	39	0	657
13	275	98	20	0	393
14	681	228	45	0	954
15	368	188	44	29	629
16	278	134	33	0	445
17	444	167	51	0	662
18	650	247	81	0	978
Total	8,859	3,498	825	30	13,212

Source: 1998 Network Annual Reports

APPENDIX Q
1998 NETWORK QUALITY IMPROVEMENT PROJECTS

TOPIC	NETWORK
ANEMIA	
Cooperative Anemia Project	TransAtlantic Renal Council (3)
A Systems - Based Approach to Quality Improvement	Renal Network of the Upper Midwest, Inc. (11)
HEMODIALYSIS ADEQUACY	
Adequacy of Dialysis	ESRD Network Organization #4
Improving the Adequacy of Hemodialysis	Mid-Atlantic Renal Coalition (5)
Hemodialysis Adequacy	Network 8, Inc.
Hemodialysis Central Venous Catheter	The Renal Network, Inc. (9/10)
Adequacy of Hemodialysis	ESRD Network Organization #13
Improving Adequacy of Hemodialysis in Texas	ESRD Network of Texas, Inc. (14)
Reducing the Rate of Hemodialysis Access Infection	Northwest Renal Network (16)
Improving Adequacy of Hemodialysis in Northern California ESRD Patients	TransPacific Renal Network (17)
PERITONEAL DIALYSIS ADEQUACY	
Improving Peritoneal Dialysis Adequacy Measures	ESRD Network of New York, Inc. (2)
PD Intervention Project	Southeastern Kidney Council, Inc. (6)
Peritoneal Dialysis Adequacy	Network 8, Inc.
Peritoneal Dialysis Prescription Adequacy	The Renal Network, Inc. (9/10)
Peritoneal Dialysis Adequacy	ESRD Network 12
Peritoneal Dialysis Adequacy	Intermountain ESRD Network (15)
Improving Adequacy and Nutrition for Peritoneal Dialysis Patients in Network 17	TransPacific Renal Network (17)
IMMUNIZATIONS	
Texas ESRD Immunization Cooperative Project	ESRD Network of Texas, Inc. (14)

APPENDIX Q
1998 QUALITY IMPROVEMENT PROJECTS

TOPIC	NETWORK
VASCULAR ACCESS	
Increasing the Utilization of Permanent Access in Incident ESRD Patients	ESRD Network of New England, Inc. (1)
Early Detection of Venous Stenosis in AV Grafts to Prevent Thrombosis	ESRD Network of New York (2)
Vascular Access	TransAtlantic Renal Council (3)
Cooperative ESRD Vascular Access Study	ESRD Network of Florida (7)
Vascular Access	ESRD Network 12
Early Detection of Venous Stenosis in AV Grafts to Prevent Thrombosis	ESRD Network Organization #13
Increasing and Maintaing AV Fistula Rates	Southern California Renal Disease Council, Inc. (18)
NEPHROLOGY CARE	
Early Referral to Nephrology Care	ESRD Network Organization #4
Strategies for Managing the Continuum of Care in the ESRD Patient	Renal Network of the Upper Mid-West (11)
HEPATITIS B VACCINATION	
	ESRD Network of Florida (7) Network #12 Southeastern Kidney Council (6) Southern California Renal Disease Council, Inc. (18)
INFLUENZA IMMUNIZATION	
	ESRD Network of New England, Inc. (1) Mid-Atlantic Renal Coalition (5) Southeastern Kidney Council (6) Renal Network of the Upper Mid-West (11) Intermountain ESRD Network (15)

Source: 1998 Network Annual Reports

APPENDIX R
1998 NETWORK SPECIAL STUDY PROJECTS

Network	Special Study
1	Connecticut Bacteremia Project
1	Increasing the Utilization of Permanent Access in Incident ESRD Patients
4	Implementation of the DOQI Guidelines
4	Network 4 Recommended Pediatric Scope of Care Guidelines
5	Increasing Educational Efforts to Promote Living Donor Kidney Transplant
6	Family History Study
6	Racial Variation in Autosomal Dominant Polycystic Kidney Disease
6	Fetal and Early Life Events and the Development of ESRD
7	Home Hemodialysis Training Demonstration Project
7	Customer Contacts and Resolving Grievances
7	Transplant Rate Improvement Project
9/10	Network Core Indicators: 100% Sampling
11	Medical Review Committee Follow-Ups
11	Peritoneal Dialysis Review
15	Network Specific Standard Mortality Ratios

Source: 1998 Network Annual Reports

APPENDIX S
VOCATIONAL REHABILITATION
PATIENTS AGED 18-55 YEARS AS OF DECEMBER 31, 1998

NETWORK	Number of Patients 18-55 Years	Referrals to Vocational Rehabilitation	Patients Employed or Attending School Full or Part time	Facilities Offering Dialysis Shift after 5 pm
1	2,884	116	900	70
2	6,549	505	1,941	119
3	3,897	434	1,564	66
4	3,063	198	818	37
5	5,711	942	1,544	58
6	6,067	629	1,195	31
7	5,123	379	1,085	32
8	4,756	125	911	32
9	6,191	186	1,578	105
10	3,870	243	772	45
11	5,154	517	1,343	63
12	2,867	214	1,032	31
13	4,152	573	834	38
14	8,070	605	1,869	40
15	3,750	461	1,294	47
16	2,389	384	744	51
17	4,337	340	1,058	55
18	6,724	553	1,607	74
Total	**85,554**	**7,404**	**22,089**	**978**

Source: 1998 Network Annual Reports

The CHAIRMAN. Thank you, Dr. Wish.
Now Dr. Kang.

STATEMENT OF JEFFREY L. KANG, M.D., DIRECTOR, OFFICE OF CLINICAL STANDARDS AND QUALITY, HEALTH CARE FINANCING ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Dr. KANG. Good afternoon, Chairman Grassley, Senator Breaux, Senator Wyden, distinguished committee members. Thank you for inviting us to discuss our efforts to improve the quality of care in Medicare's End Stage Renal Disease Program.

I would also like to thank the General Accounting Office and the HHS Inspector General for their assistance in this area and I finally want to thank the other witnesses, Dr. Bay and Mr. Smith, for coming here today to share their experiences and concerns, as well.

As today's testimony has made clear, there is much we need to do to build upon the success we have had in improving the quality of ESRD care. If I can have the first graphic here, the percentage of patients with adequate red blood cells has increased from 46 to 83 percent over the last 5 years.

Next graphic? This is a graphic similar to Dr. Wish's. The percentage of patients receiving adequate dialysis over the same period has increased from 43 percent of patients to 74 percent of patients.

Next graphic? Then finally and most importantly, these improvements in both anemia management and adequacy of dialysis have been associated with a 2 percent reduction in 1-year mortality rates over this similar time period. That means 6,000 lives saved per year on an annual basis.

Despite these measurable successes, we at the Health Care Financing Administration are committed to working with patient groups, ESRD facilities, networks, states, to address outstanding problems and to further improve the quality of care and service that is being delivered. We believe that we can do more by focussing on the patient's entire experience with dialysis and creating a culture of continuous quality improvement throughout the dialysis community.

Some of our efforts we already have in place will help. Perhaps the most important, as Senator Breaux has mentioned, is securing the funding for more surveys. The president's budget in 2001 proposes a tripling of the budget from $2.2 to $6.3 million for surveys. This would allow us to increase the number of facilities surveyed from 15 percent a year to well over 33 percent a year. We look forward to working with this committee on securing that much-needed funding.

Also critical to our efforts to improve responses to beneficiary complaints. The complaint system, as you have heard today, needs to be easier to use and more responsive to patients. It should be more manageable and integrated both into the network process and the survey process. We have already developed a system for network reporting of standardized complaint information in an electronic system and this is the first step toward tracking and being

more responsive. Finally, we are working with the Networks and state surveyors to better integrate their responses to complaints.

We will also work with the Networks and state survey agencies overall to coordinate their efforts. We have asked the Networks to share information and data that they discover to the States and we will be soon asking state survey agencies likewise to share information that they receive from the state survey process to the Networks.

We are in the process of developing new rules to strengthen quality requirements for dialysis centers and also, as Dr. Owen recognized, we are developing new measures and advanced measurements to measure the quality of care in dialysis centers, including patient satisfaction instruments.

We plan to collect these measures on all patients from all providers over the next coming years and then certainly we plan to intend to publish whatever information we have regarding facility-specific performance as soon as we can.

In particular, by the end of this year we will be previewing, similar to our nursing home compare website, another website for dialysis facilities. That will be up by the end of this year and it would include some of the information that we currently have, which is the percentage of patients who have anemia, the anemia has been corrected, the adequacy of dialysis and standardized mortality rates.

We obviously, as new information becomes available, agree with the committee that more information to the public will help in making informed decisions with regard to choosing dialysis facilities.

Finally, with regard to increased payment for out-patient dialysis, in the president's 2001 budget request, as recommended by the Medicare Payment Advisory Committee, he has also proposed to increase the rates another 1.2 percent for the next year. This would actually be a total increase of 3.6 percent over the last 2 years. We look forward to working with the Congress to secure this funding.

Thank you again, Chairman Grassley, for holding this hearing and I am happy to answer any of your questions.

[The prepared statement of Dr. Kang follows:]

Statement of

JEFFREY KANG, M.D., DIRECTOR

OFFICE OF CLINICAL STANDARDS & QUALITY

HEALTH CARE FINANCING ADMINISTRATION

Before the

SENATE SPECIAL

COMMITTEE ON AGING

on the

MEDICARE

END STAGE RENAL DISEASE

PROGRAM

June 26, 2000

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TESTIMONY OF
JEFFREY KANG, M.D., DIRECTOR
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Chairman Grassley, Senator Breaux, distinguished Committee members, thank you for inviting us to discuss our progress in improving the quality of care in Medicare's End Stage Renal Disease (ESRD) program. We would also like to thank the General Accounting Office and HHS Inspector General for their assessments and assistance in this area, as well.

We are working diligently, in partnership with the dialysis community, to improve the quality of care provided to Medicare End Stage Renal Disease beneficiaries, and we have had measurable success. Between 1993 and 1998 the percentage of ESRD patients with adequate red blood cell (hematocrit) levels increased from 46 to 83 percent, while the percentage of patients receiving adequate dialysis increased from 43 to 74 percent. And, between 1990 and 1997, the overall one year mortality rates for dialysis patients declined from 24.9 deaths per 100 patient years to 22.8.

We are committed to working with States and the End Stage Renal Disease Networks to make further improvements and target weak performing dialysis facilities. We are testing more advanced measurements of the quality of care provided in dialysis centers. We are developing new rules to strengthen quality requirements for dialysis centers. And we are developing facility-specific data that will help consumers make informed choices, help facilities identify areas in which they need to make improvements, and help surveyors target oversight efforts.

We also want to decrease the time between surveys of dialysis facilities, from every six years to every three years, so we can better monitor the quality of care. To do so, the President's fiscal 2001 budget would increase funding for surveys from $2.2 million to $6.3 million. And we look forward to working with you to secure this much-needed revenue.

We also want to increase payment for outpatient dialysis, which until this year had not been updated since 1991. For the past several years, the Medicare Payment Advisory Commission (MedPAC) has recommended updating the rates to reflect the increasing acuity of patients and cost of services. The Balanced Budget Refinement Act of 1999 went part of the way by increasing the rates 1.2 percent in 2000 and another 1.2 percent in 2001. The President is proposing to fully comply with MedPAC recommendations and increase the rates another 1.2 percent for 2001. We look forward to working with you to secure this funding, as well.

BACKGROUND

The Medicare statute was amended in 1972 to specifically authorize coverage for individuals with diabetes, hypertension or other diseases that result in severe impairment of kidney function known as ESRD, beginning in 1973. Since then, Medicare has paid for some $126 billion worth of services for a total of more than one million ESRD patients. The number of patients served has grown steadily and there are now over 300,000 Medicare ESRD beneficiaries. The program is projected to pay out $15.3 billion in ESRD-related benefits this year, some $5 billion of which will go to nearly 4,000 dialysis providers, with 58,248 approved outpatient stations providing dialysis treatment.

The Medicare ESRD benefit specifically includes coverage for kidney transplantation. Mortality rates are 50 percent lower for ESRD patients who receive a kidney transplant versus those who remain on dialysis, according to the United States Renal Data System. The 1-year graft survival rate for living donor transplants increased from 88.8 percent in 1988 to 93.9 percent in 1996, according to a recent paper in the New England Journal of Medicine. For cadaveric transplants, the 1-year graft survival rates increased from 75.7 percent in 1988 to 87.7 percent in 1996. Transplantation also eliminates the need to be dialyzed three times per week for three to four hours at a time, and the common adverse side effects of dialysis such as fatigue, loss of appetite, and problems with the vascular access site such as infection, clotting, and stenosis. Medicare has paid for a total of 136,000 kidney transplants since 1973, and expects to cover 8,500 this year.

Congress, in 1978, established the ESRD Network Organizations Program to provide coordination and guidance, and assure effective and efficient administration of the Medicare renal disease benefits. ESRD Network responsibilities include:

- Promoting criteria and standards for quality and appropriateness of care;
- Encouraging the use of treatment settings that are compatible with patients' successful rehabilitation;
- Receiving, evaluating, and resolving grievances involving ESRD patient care and/or services; and
- Establishing a Network Council and Medical Review Board to represent area dialysis facilities.

This program was recodified in 1986 when Congress redefined ESRD Network areas. Funding for the ESRD Networks comes from withholding 50 cents per patient per dialysis treatment from payments to dialysis facilities. There are currently 18 ESRD Network Organization areas, and fiscal 2000 ESRD Network funding is $17 million.

We regularly communicate with and visit ESRD Networks to monitor and assist them in their duties. They submit formal reports to us quarterly, and we conduct annual conferences with the Forum of ESRD Networks to discuss their activities and issues. We now have new contracts with these Networks, which become effective July 1, 2000, that are designed to help us promote a more uniform process for oversight and reporting of Network activities across regions.

The ESRD Network Organizations provide a collegial approach to helping ESRD care providers, with a focus on education to improve quality. State survey agencies also play a critical role in quality assurance and improvement by conducting inspections to verify that minimum quality and performance standards are being met.

Improving Quality

Improving the quality of care delivered to ESRD beneficiaries is a high priority for us. Beginning in 1994, we took a leadership role in developing clinical indicators to assess the quality of care for dialysis patients. Through the ESRD Networks, we collect measurements each year that indicate the quality of clinical care provided on a national sample of dialysis patients. These measures, which focus on issues such as the adequacy of dialysis and anemia management, indicate whether patients are receiving appropriate care.

The data on these measures are detailed in an annual report that we disseminate to all dialysis providers in order to help them identify opportunities for improvement. Using this national sampling approach, we have been able to document improvement every year since 1994 in the number of dialysis patients receiving appropriate care.

We now are working to learn the rate at which each individual dialysis center is providing appropriate care. By next year, we plan to collect these measures on all patients from all providers. This will enable us to assess each facility's care, help each facility address any specific weaknesses it may have, and share findings with the public. We are developing a system for dialysis facilities to collect and report these data electronically, and expect to begin testing this electronic system later this year.

We also are getting ready to begin using 16 additional clinical performance measures, as mandated by the Balanced Budget Act (BBA) of 1997. These measures have been developed and were pilot tested last year by ESRD Networks using a national sample of dialysis patients. They will be collected this year, both on a national sample of patients for quality improvement purposes, and on a all patients from a sample of dialysis facilities, through the electronic reporting system that we are testing.

In another quality improvement initiative, the National Anemia Cooperative Project, our ESRD Networks have worked with dialysis providers to improve the management of anemia in dialysis patients. Its goals were to decrease the proportion of patients with dangerously low hematocrit levels (less than 31 percent), and to educate dialysis providers on how to use quality improvement techniques. The project involved development of tools such as a quality improvement project guide book and an algorithm for determining appropriate steps in anemia treatment. Between 1996, when the project was implemented nationally, and 1998, the percentage of patients with hematocrit levels greater than 30 increased from 72 percent to 83 percent.

Guarding Hemodialyzer Safety

A key area where we want to foster further improvement is in the reuse of hemodialyzers. This long-standing practice is specifically addressed in our current conditions of coverage for dialysis centers, which mandate compliance with comprehensive guidelines issued by the Association for the Advancement of Medical Instrumentation. These extensive guidelines address aspects of safe hemodialyzer reuse, such as personnel training, infection control, and equipment maintenance. The guidelines specifically state that, "A decision to reprocess hemodialyzers should be made by a physician knowledgeable about reprocessing and its medical and economic implications," and they mandate that patients be fully informed about reuse of dialyzers.

Because this is such a critical patient safety issue, we plan to propose that each dialysis facility be required to incorporate its reuse program into its overall quality assurance and performance improvement program. We also believe additional funding for enforcement surveys and for Network quality improvement initiatives would help to ensure the industry remains in compliance with the guidelines.

Strengthening Conditions of Coverage

Revising our conditions of coverage for dialysis centers is a key part of our plans to further strengthen our ability to improve the quality of ESRD care. Dialysis centers must meet these conditions in order to bill Medicare and Medicaid.

We are trying to accomplish several things in the new conditions. We want to:

- Encourage the dialysis industry to work toward continuous quality improvement through systems change;
- Monitor and improve patients' entire experience with dialysis;
- Implement the BBA requirement to monitor the quality of care in dialysis facilities;
- Capitalize on recent improvements in data collection and reporting that we developed in cooperation with the ESRD Networks;
- Incorporate clinical advances created by the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative on adequacy, nutrition, vascular access, anemia, etc.; and
- Incorporate the latest advances in infection control from the Centers for Disease Control.

The proposed conditions would:

- Require facilities to collect and report the performance measures discussed above, and other measures which may include data on patient satisfaction;
- Establish minimum performance standards for clinical outcomes such as adequacy of dialysis, nutritional status, and anemia management, and require facilities that fail to meet these minimum criteria to take corrective actions;
- Hold facilities' governing bodies accountable for developing and monitoring data-driven quality assessment and improvement programs designed to ensure that quality issues are addressed prospectively, rather than waiting for problems to develop and be detected before addressing them; and
- Increase the emphasis on specific health and safety standards, such as water quality and infection control.

We expect to publish these proposed new conditions of coverage next year, and will then accept and consider public comments before issuing a final regulation.

Improving Network and State Surveyor Accountability

We are working to improve the performance and accountability of ESRD Networks and state survey agencies. For ESRD Networks, we want to develop performance-based contracts, which tie contract renewal, as well as bonus payments, to how well the Network does in meeting specific targets. For ESRD Networks, these targets would likely focus on use of standardized performance data to improve the overall clinical performance of dialysis facilities, use of complaints as a quality safeguard, and ensuring that poor performers meet minimum standards of care.

Meanwhile, we have made several improvements to the ESRD survey process. The survey process and manuals have been revised to focus on the critical safety and health areas in a dialysis facility, i.e., infection control, water quality, reuse of hemodialyzers and other dialysis supplies, and the physical environment in the facility. The basic and advanced surveyor training for State agency surveyors has been improved and standardized.

To further improve the State survey process, we are developing facility-specific profiles to help State survey agencies focus their limited budget dollars. These reports will profile dialysis centers by a variety of measures that indicate whether a facility may have quality problems and warrants a closer look. These profiles are being pilot tested in seven states this summer and we hope to make them available nationwide by next year.

We also want to increase on-site oversight of State surveyor activities by exploring the possibility of conducting more observational surveys in which our staff or a contractor accompany State surveyors during their inspections to assess their effectiveness. We also want to increase the effectiveness and efficiency of State surveyors by providing them with more data which they can use to foster quality improvement. We are revising the guidelines that State survey agencies use to reinforce the accountability of dialysis facility medical directors for patient care. We will explore greater use of the Internet to publish survey results. And we will provide more information to the public about State survey agencies.

And, as mentioned above, we want to decrease the time between surveys of dialysis facilities, from every six years to every three years, so we can better monitor the quality of care. To do so, the President's fiscal 2001 budget would increase funding for surveys from $2.2 million to $6.3 million. We believe this would be money well spent, with a direct impact on the quality of patient care

Improving Beneficiary Information

As mentioned above, we are planning to share with the public the information that we will be gathering about the quality of care provided at each dialysis facility. We will do so through a new Internet site that, like our Nursing Home Compare website, will help consumers make informed decisions when seeking care. We plan to preview the site later this year with data we now have available to us, such as the type of treatments offered at each facility, the number of hemodialysis stations, the percentage of patients who receive adequate dialysis, the percentage whose anemia has been corrected, and the actual versus expected patient survival rate. We will add additional information as it becomes available to us and as we ensure that appropriate privacy concerns are addressed.

We also want to increase consumer awareness of the role and activities of ESRD Networks and State survey agencies. We will do so through the new Internet site, a new information packet for patients, and brochures for distribution at dialysis facilities, health fairs, and other sites.

Meanwhile, last year we updated our ESRD beneficiary brochure which stresses the importance of receiving adequate dialysis treatments and what patients can do to improve their adequacy measures. It has been distributed to all dialysis facilities and patients and can be found on our *www.medicare.gov* website.

Improving Responses to Complaints

We are working to improve responses to beneficiary complaints about ESRD facilities. We agree that the eight elements identified by the HHS Inspector General for an effective complaint system -- accessibility, objectivity, investigative capacity, timeliness, responsiveness, enforcement authority and follow-up, improvement orientation, and public accountability -- are essential.

We have a workgroup examining how to ensure that all of these are addressed as we strengthen the complaint resolution process and alternative dispute resolution processes that now exist. Our goal is to make the system easier and more responsive to patients, and more manageable and integrated for ESRD Networks and State survey agencies.

We have already developed a system for Network reporting of standardized complaint information that is the first step toward an electronic system for reporting and tracking responses to complaints. We will develop pilot projects to explore ways in which ESRD Networks and State surveyors can better integrate their responses to complaints, and we will establish guidelines for building a more cooperative relationship between Networks and States. We also want to strengthen procedures for anonymous complaints to address the potential for retaliation against patients.

Expanding Beneficiary Options

To further increase options for ESRD beneficiaries, we are conducting a demonstration project involving Medicare+Choice HMOs. Current law bars ESRD beneficiaries from enrolling in Medicare+Choice plans, although they may remain in one if they develop ESRD after enrollment. As of 1998 there were some 18,500 ESRD beneficiaries in Medicare+Choice plans, and studies show that their dialysis care, access to transplantation, and mortality rates were no different than for fee-for-service beneficiaries.

Our demonstration, being done with three HMOs (Kaiser-Permanente in Southern California, Health Options in South Florida, and Xantus Healthcare), is testing:

- Year-round open enrollment for ESRD beneficiaries;
- Adjusting payment for age, treatment status (dialysis, transplant episode, or functioning graft) and morbidity; and
- Extra benefits uniquely of interest to the ESRD patient.

This test is expected to conclude in September 2001, with independent evaluation due by June 2002. However, since plans do provide comparable care for ESRD beneficiaries, the Administration would support legislation to remove the restriction on enrollment now.

CONCLUSION

We have made substantial improvements in the care provided to Medicare ESRD beneficiaries, and are committed to making further strides. We believe we can do so by focusing on the patient's entire experience with dialysis and creating a culture of continuous quality improvement throughout the dialysis community. Expanding and improving the information available to consumers on the quality of care in dialysis centers should also help to foster renewed attention to providing high quality service that meets beneficiary needs. Strengthening the role of ESRD Networks and State survey agencies, especially by securing funds for more frequent surveys as proposed in the President's budget, is critical. And increasing payments to reflect increasing costs and patient acuity, as the President is proposing, is also essential to ensure high quality. I thank you again for holding this hearing, and I am happy to answer your questions.

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The CHAIRMAN. I am going to direct my first question to you, Dr. Kang, but I want Dr. Owen to listen because I would like to ask his reaction.

In May, the Health Care Financing Administration provided responses to questions from the committee. The letter stated that patients with adequate blood cell levels increased between 1993 and 1998 from 46 percent to 83 percent. In addition, the letter said that the patients receiving adequate dialysis increased from 43 percent to 74 percent.

What exactly is it that prevents all patients from having adequate blood cell levels and adequate dialysis?

Dr. KANG. With regard to dialysis, there is a tradeoff because, as you have heard from previous testimony, patients have to be encouraged to be on the machines as long as possible. I think that this is a matter of education of providers, of facilities and beneficiaries. And I think that since the technology is with us, we are going to continue to work on that and there is no particular reason why we cannot continue to improve the adequacy of dialysis rates and anemia management.

So this is just a matter of continuous quality improvement and the trends continue to show improvement.

The CHAIRMAN. Quality improvement in the procedure or in the education of the patients to stay on the process longer?

Dr. KANG. Well, I do not want to blame the patients because this is a very complicated issue. I think it is patients, facilities, providers in the process, so it is multi-factorial and we need to be working on all angles.

The CHAIRMAN. Now Dr. Owen.

Dr. OWEN. It is actually both. It is patient-specific as well as provider-specific. I am going to start with the providers.

The achievement of the appropriate benchmarks were really generated in the context of the Dialysis Outcomes Quality Initiative by the NKF for anemia, in hemodialysis adequacy by the RPA and then followed by the NKF. That represented the first time that there was a statement of minimum benchmarks.

The reality is that new medical knowledge has got to be disseminated and that dissemination is occurring and that is why you are seeing a secular trend of improvement.

However, addressing your question specifically, will we ever see every patient who has end stage renal disease have their anemia corrected and their hemodialysis dose appropriate? No, and there are medical reasons for that. The medical reason for anemia is that there are processes that keep some patients from responding adequately to erythropoletin and then there are complications associated with dialysis which will cause them to lose blood.

In terms of hemodialysis adequacy, there is the issue of shared decisionmaking and that is the issue of patient choice. There are some patients who just simply say, "Dr. Owen, I don't care what you tell me the consequences of my treatment are; I don't want to stay that length of time" and I respect that decision. I might disagree with it but I respect it and that is shared decisionmaking.

And then last, there are biological variables in there that are a real confounder. There are certain populations of patients where even with the technology that we have for dialysis now, which is

really pretty substantially improved—my mom was on dialysis 20 years ago, so I have lived with this a long time, guys—there are still certain patients, particularly very young, large patients, where even within a 4½ to 5-hour treatment, I cannot give them adequate dialysis. What do I do? Urge them to come back a fourth time a week. In that circumstance, the patients will sometimes say, "Yeah, Dr. Owen, that's fine," and others will say no.

But I agree with you in terms of the context of the question. We certainly should strive. The bar should be set at 100 percent because if it is not, we are never going to achieve the maximum that we would like to achieve.

The CHAIRMAN. Dr. Wish, we had the inspector general tell us that HCFA does not require the collection of a core set of facility-specific clinical performance measures and without such data, how can the network identify poorly performing facilities?

Dr. WISH. Well, each Network has a data collection infrastructure right now that varies and there is going to be a standardization of this infrastructure evolving over the next year or so, which has been called the VISION project. It is an acronym for the Vital Information System for Improvement of Outcomes in Nephrology. That is a standardized data collection system that is going to link every facility with its respective Network so that facility-specific data can be collected periodically from each of the facilities and each facility can be fed back its profile with regional comparatives.

This will have two effects. One is that it will support facility-based quality improvement programs because we presume each facility will want to improve. As this data is publicly released, each facility is going to want to look better and look better in comparison to its competitors. But it will also allow the Networks, which house this data, to target the poor performing facilities for specific intervention activities.

Unfortunately, that data structure is not yet available. It is evolving.

The CHAIRMAN. Dr. Owen, why are dialyzers being reused? Do they need to be reused? And does the reuse have any clinical value or is it simply a cost issue?

Dr. OWEN. I am going to start with your last question to frame the context of the first two that you posed.

Historically, it was of some benefit when the first generation of dialyzers were produced. People used to actually get sick and the patients could appreciate when you hung a new dialyzer. They felt badly. On the other hand, when the dialyzer was reused, it would get coated with proteins, as you heard the doctor comment about, and the patient felt better because the dialyzer was coated with their own proteins.

However, the dialyzer technology has improved, so we now have dialyzers that are much more compatible with the individual in terms of the way they feel and some of the blood tests that we use to show an interaction.

I would say right now, in fairness, that the reason dialyzers are reused is an economic constraint in that obviously if I reuse a dialyzer, I have saved on the cost of introducing a new dialyzer.

The real fancy dialyzers, the real high efficiency dialyzers that remove beta–2 microglobulin that you heard the doctor mention or

that had better improved removal of phosphorus cost substantially more. To get better quality with a dialyzer, you pay more. And as I understand it, and I just do not do dialysis unit economics, the economics are such that to introduce a new very high efficiency biocompatible dialyzer on each occasion, which as I understand it can cost about $40, is a pretty substantial cost of the amount of money that is available as one single pot of money to provide the full course of care for a dialysis patient.

Recognizing that, the RPA said, OK, let's live with dialyzer reuse as a reality but, on the other hand, let's first of all define really specific minimal criteria for how a dialyzer should be introduced back to a patient, which we had done.

Second, we have to recognize the issue of patient safety, which you heard raised in several different contexts here. Many of the same risk factors for patient safety that you heard about in hospitals exist in dialysis units, as well, which is why the RPA is working with the National Patient Safety Foundation to address that.

And third, I hope the dialysis industry continues to evolve to generate a dialyzer that is going to be of relatively lower cost and allow me to give my patient what I think he or she needs and I can give them a new dialyzer each time. I think most of us would prefer to do that.

The CHAIRMAN. Senator Breaux.

Senator BREAUX. I thank the panel very much for your assistance in helping us understand where we are with this industry. What I am getting is a couple of things. No. 1, if you do not inspect them, Dr. Kang, often enough—once every 6 years is too infrequent an inspection program, particularly when you are trying to get it down to three and you see Ohio, one state, going down to one year. So 6 years between inspections—I mean, the whole technology changes; probably a lot sooner than that. So it is almost ludicrous to say we are going to check these facilities once every 6 years. That is not getting the job done and I am happy to hear that HCFA is trying to get more funding to do a better job and more frequent inspections.

The second thing is that when we find a problem exists, we do not have the tools we really need short of decertification and yanking the license. We have to do more inspections and we have to have some penalties that are monetary, I would imagine, that would encourage people to do what is right and what is necessary.

I note that you, on your first page, say that you are developing new rules to strengthen quality requirements for the dialysis centers. What is the timing on this? When can we expect the new rules and basically what are they going to say?

Dr. KANG. This is what is called conditions of coverage and we would propose those regulations for publication in early 2001. In those rules we are interested in much of what the GAO or Inspector General's Office has said, to have stronger protections around patient accountability or facility accountability, strengthen the role of the medical director, mandate the reporting of standardized performance measures to the secretary for public information purposes.

So it is those sorts of things that would be in a proposed regulation to try to——

Senator BREAUX. Of course, the regulations can be wonderful but if we do not have an opportunity to inspect to see if they are being followed, they will really be worthless if we do not do the follow-up, which is very important.

I get from Dr. Bays, who testified on the first panel, that he thought all this, the reporting and everything else, was sort of a joke and he did not really think that it was being handled very well because it is self-reporting, Mr. Bahr and Dr. Owen. I got from Dr. Bays that these people are going to file their own reports on how well they are doing and most of the times they are going to say they are doing pretty well.

Is there a way to improve that? I think he makes a point when he brought that opinion to the committee.

Mr. BAHR. And I think that probably was true. I think more than not, Dr. Wish has pointed out what we are trying to do with the Forum and the networks, sending out specific data. There is data collection that we have to not only report and say, "This is our adequacy for this time period;" specifically they are coming back with data sheets asking you directly, patient X, what are the lab values? How did you derive this? What timeframe? Very specific questions.

Senator BREAUX. What about when something goes wrong in one of the facilities? Is that included on those charts? Or is it just numbers about——

Mr. BAHR. Currently, the data collection, no.

Senator BREAUX. I'm sorry. No?

Mr. BAHR. The data collection, does not include what went wrong at a facility.

Senator BREAUX. So you have a lot of data and numbers on the patients, the blood count and all the other technical things, but if somebody just screws up in the facility, that is not on that sheet, I take it?

Mr. BAHR. No. It is not.

Senator BREAUX. Is that not what Dr. Bays was talking about? He was not so much concerned about the quality of the result; he was just talking about shoddy treatment.

Mr. BAHR. Exactly, and there are specific things, at least in the facilities and in the state we work within and I do think there are different rules per State, but in our State of California you specifically have to report such things as blood loss issues and needle sticks. Our facility asks if you have had extra placement, what is the issue? It is reviewed by our own committee and reported back. So it is looked at and reviewed on a timely fashion.

The other thing I did want to add as far as shoddy treatment, a number of states—California, Ohio—I am trying to think of the other states—New York, I believe—all have gone through certifying the hemodialysis technicians and requiring very stringent training programs to certify that those patient care technicians know what they are doing.

Senator BREAUX. Well, let me ask some questions on that. I think Dr. Bays also said that when he started off, it was basically something that was run by nurses in a dialysis facility. We have

now gone from nurses to technicians and he was even talking about a category that was less than technician, I think.

Is that any concern, Dr. Owen? I mean do you need a nurse? Do you need a doctor? Can you have a technician? What is the standard of treatment that is necessary for someone in a dialysis center from a medical standpoint to be there to supervise it, to know what is happening and what have you?

Dr. OWEN. You need somebody who is trained; you need somebody who is attentive; you need somebody who is compassionate. Do they need to be a doctor? Do they need to be a nurse? Do they need to be a technician? My response to that is no, because patients do it at home.

I use my dad as a paradigm. My dad, the first time he walked into the dialysis unit, fainted. We had to pick him up, shook him off a little bit and then, a year later, he was dialyzing my mom, and my dad was a retired businessman.

So in terms of the degree certification, I would say there is a bit of a disconnect there. What you need is training. You need documentation that that person is trained and knows what they are doing. You need to make certain there is an adequate number of staff to be attentive.

A lot of these patient safety issues that I heard, and those were just—excuse my language, just God-awful stories that I heard, really bothersome—were related, it sounds like, to inattentive staff.

And then last, I heard a lack of compassion there, just people that did not care about the patients that they were caring for. You cannot teach that but you certainly can perhaps select for it a little bit.

Senator BREAUX. I appreciate that. I think that's what Senator Grassley and I are trying to do and the members of the committee, Senator Wyden, is just trying to find out how we can encourage our own government, which is spending $13 billion a year on this, to make sure that people are benefiting from the amount of care that is being given out there. I mean it is a very challenging proposition that we have to supervise these, to regularly inspect them, but I think that it is going to be absolutely necessary that we improve the quality. The new rules hopefully will do that and that is encouraging.

Let me just ask one other question, Dr. Owen. From a technology standpoint, how long has the dialysis been a methodology for treating kidney failure and what is the next step? In 20 years are we still going to have people hooked up to these machines for 8 hours a day?

Dr. OWEN. Boy, I wish our clairvoyant dropped that crystal ball driving over here today.

In terms of your first question, how long has this been around, I will tell you even though we are over 25 years into the program, it has effectively not changed a lot. It is still like an automobile—you know, internal combustion engine, four wheels, looks a little different on the outside.

Same is true with dialysis. It is still a salt and water solution going through a plastic cartridge with the blood going through it.

I think our real promise is in two areas. One is in terms of transplantation. We really need to encourage that and where can you

guys help? You guys can help us in terms of funding some real cutting edge research from NIDDK.

And then also I think we have some real exciting work being done in terms of bioartificial kidneys, where you actually have a combination of an artificial kidney with cells on it that give you the best of both worlds.

Senator BREAUX. I have a staff person in Louisiana that is undergoing a kidney transplant in Oachita on August 7 and the detailed preparation leading up to that is just absolutely incredible and it found his daughter, who is going to be the donor, and I think you are seeing more and more of that now.

Dr. Wish.

Dr. WISH. Yes, can I respond to one of your other questions about the quality of the data? We were also very skeptical as to whether or not the facilities might be gaming the data to make themselves look better. So HCFA actually contracted with my own Network to do a data validation study.

As you may or may not be aware, there are actually two data bases that we have referred to this afternoon. The data base that HCFA uses to do facility-specific profiling and which will be on their website is based on billing data. Each facility has to put in the URR for each patient and the hematocrit for each patient as part of the billing process.

The ESRD Clinical Performance Measures Project, on the other hand, is not facility-specific. It is a random sample of patients from each of the 18 Networks that is used to profile the Networks against each other, as well as to give a composite rate of performance each year with each of the indicators.

HCFA asked our Network, to validate the data by actually going into the facilities and extracting the data from the patients' medical records to see if the data that were being submitted by the facilities for the ESRD Clinical Performance Measures Project were valid. In fact, they were. There was greater than a 97 percent concordance with what was submitted by the facilities in the random sample versus what we found in the patients' records.

Senator BREAUX. What region is that?

Dr. WISH. This is Illinois, Ohio, Indiana and Kentucky.

As far as the billing data are concerned, the concordance were less robust and it was partly due to the methodology. The URR data were actually quite concordant and actually correlated at about 95 percent, but the hematocrit data did not correlate as well and it was because of the methodology of the billing data asking for the last hematocrit of the month and the performance measures data asking for first hematocrit of the month, and that difference in methodology we felt was enough to explain the difference in the concordance, which was only at about 85 percent.

Now, as far as reporting incidents is concerned, this is something that we are working on in terms of this whole patient safety initiative. What we would like to do is establish a patient safety reporting mechanism that is confidential for less than life-threatening or severe types of errors that can be used as repository to analyze system problems and system errors, not unlike what has been done in the Aviation industry.

So you have basically two levels of reporting. Obviously when a plane crashes, everybody knows about it and the FAA investigates in a very public manner; but there are a lot of "near misses" that are recorded in a confidential manner so that there are no sanctions and there is no fear of the reporting process, and those can be analyzed on a systemwide basis to see whether or not there are processes that can be improved to reduce the incidence of errors, and we would like to establish this within the renal community, as well.

The CHAIRMAN. Thank you, Senator Breaux.

Senator Wyden.

Senator WYDEN. Thank you, Mr. Chairman. I want to commend you and Senator Breaux for another important initiative in the aging field. It is such a pleasure to be part of an effort in the U.S. Senate to pursue health issues in a bipartisan kind of way and I congratulate both of you.

Gentlemen, let me start by asking you about the recent analysis that was done in my home State of Oregon with respect to these facilities. What we found in Oregon recently is of our 41 facilities, 39 were surveyed and 11 have what has been termed to be serious deficiencies, some of them life-threatening. So that is a lot of facilities. That means 25 percent have serious problems with respect to a group of patients that we would all acknowledge are very vulnerable.

Now you all represent organizations that work very closely with owners—physicians that in some cases, I gather, may be owners themselves and them, of course, administrators, who are responsible to owners.

My first question for each of you, Mr. Bahr and Mr. Owen, would be what are your organizations doing to crack down on the facilities that seem to be, right now, offering pretty shoddy care to vulnerable patients? Let's begin with you on that, Mr. Bahr.

Mr. BAHR. We have, through our annual and fall and spring conferences, we offer training. We bring in experts. We have had surveyors come in, talk about what they are seeing. Reuse practices—we have worked with AAMI in developing and getting those guidelines out to all the membership. We are constantly providing education to the facilities and saying that this is what needs to be done.

We have worked with HCFA and state agencies on independent and state levels to help survey and facilitate the training of surveyors.

Senator WYDEN. Does that mean you inform the government, Federal and state agencies, about facilities that are problems? I guess——

Mr. BAHR. No, we educate renal administrators.

Senator WYDEN. What I am interested in is what is being done to crack down on the problem facilities because there is no question in my mind that there are good programs and that the majority of them are good. But when you have 11, 25 percent in a state to have serious deficiencies, you have to do more than run some cozy education programs. You have to weed them out and turn it around. Perhaps you could tell me what you are doing to help weed them out besides sending them some information.

Mr. BAHR. We haven't. We have sent, as I said, education material. I do believe that peer review and being part in the competition and not being listed or cited or known for having provided shoddy dialysis treatments is a way to go after poorly performing facilities. I mean I have been in the field for 30 years and I believe that my facilities, have all done a wonderful job and though we have not had any issues, I understand there are real concerns, but we do not have any formal reporting in our system currently.

Senator WYDEN. Dr. Owen.

Dr. OWEN. Certainly, Senator. Unfortunately, dialysis units are not in our purview. The doctors are, however.

What we have done substantive? Banged on a lot of doors, pushing our legislative initiative, which I will remind you of the key features. It tells every dialysis unit that if you want to get your ticket punched so that you can bill Medicare, you have to have a formal organization that is going to address quality assurance and continuous quality improvement.

Second, if you want to get your ticket punched, you are going to have to give unprocessed data to someone else to process that data, to show how good you are or are not doing, every unit and your doctors who are participating in your unit in that care.

Third, we are going to give that data—someone else is going to give that data back to you and there is going to be a checkmark there that is going to show where you are and where your doctors are in comparison to your peers. It is kind of like putting up the names of the guys who have not paid their dues at the country club. Let's embarrass them a little bit. And let's share that information with the consumer, the stakeholder ultimately in all of this.

Fourth, this is going to be done on a routine basis. We do not think once a year is adequate. As a minimum, we suggested twice a year. Tough to hide sins when you have somebody knocking on your door looking at what you are doing and looking at what you are doing on a regular basis.

We have worked closely with Dr. Kang at HCFA. We have worked with Dr. Wish and his predecessor. We have tried to educate our membership by defining what is the best clinical practices. And on a personal level, that is what I do research in. So we have done the best that we can with what we are able to do, sir.

Senator WYDEN. So your sense is that physicians, the best thing you can do to weed out these problem facilities is to support tough Federal and State changes with respect to legislation that would help reverse it?

Dr. OWEN. Tough and fair.

Senator WYDEN. I am going to have a question about physicians and get to you, Mr. Kang, in just a moment.

The other question for you, Mr. Bahr and Mr. Owen, is of the many complaints that we have gotten from families in Oregon, they specifically cite the trend toward more chains, more for-profit chains being in the field being central to the problem that we are seeing.

My question to you is do you both agree with that? And if so, what ought to be done? Should there be additional oversight or additional monitoring of these chains? I would like to hear what your response would be to what the families and the patient advocates

have been saying in the State of Oregon. Let me start with you, Mr. Bahr.

Mr. BAHR. I think that the industry consolidation, is a result somewhat of the funding or the lack thereof. It is tough for an independent provider. I run two facilities for some owners. It is very tough to survive in the field. So there is a push to make that happen.

I have not seen or been witness to any facilities that have changed in our region that have had real quality issues. Are there changes in how they handle the care or procedures? Yes. For patients—it is a very tough thing to be a dialysis patient and to succumb to the decisions and whims of what time you will be at the dialysis facility three times a week. It is a very tough decision. And to upset that, to have any minor changes even, no less real and severe changes, is very dramatic for the patients to deal with. But it has not been my experience in our area that the care has dropped in any of the facilities that have changed hands.

Senator WYDEN. Dr. Owen.

Dr. OWEN. Let me comment on how it has been studied and then offer anecdotal experience. How has it been studied? Garr and Neil Powe's paper, New England Journal of Medicine just about Thanksgiving. I was one of the people who wrote a letter to the editor and was accepted saying I have some real issue with that study.

To remind those of you who are not familiar with it, Dr. Garr reported using a data set that was 7 to 10 years old—often a lot happens in 10 years—that there was a 20 percent higher mortality for patients who were dialyzing at for-profit providers.

It is also noteworthy that a subsequent analysis was done with a much more contemporary data set by the group at the University of Michigan who thought that those numbers were overstated when they used the more contemporary data set and found that if there was a difference, it was about 5 to 6 percent. Now, that is a difference but you are down to a level where it really becomes an issue of how you construct your statistical model. I can make——

Senator WYDEN. Why don't you resolve it as a physician who has expertise in this area? Since we have reports that go in different directions, do you think the families that are calling my office are right in saying that there are additional quality problems when you have these big chains involved? Your compatriot there, Mr. Bahr, says he does not think that there are quality problems associated with chains. What do you think?

Dr. OWEN. That is what I am about to offer now, Senator, is my anecdotal experience. My anecdotal experience, having worked for an independent provider who had four or five dialysis units versus working for a large chain is that actually I saw better care from the chain. Why did I see better care from the chain? Because the chain allowed me to profile my outcomes. I could look at what I did. They had a very sophisticated medical Informatics system so that every quarter I was able to look at my dose of dialysis, my anemia management, my albumin and other intermediate outcomes. I could look at my mortality rate. I could look at my hospitalization rate.

It was like the facility profile that is generated by the University of Michigan on an annual basis except it was timely and it was a pleasure.

Senator WYDEN. Frankly, in theory, that is my assessment, as well, and that is why what the patients' families are saying is so troubling to me. On paper, what you have just described with the additional resources that come about with these larger entities, they would have an opportunity for more sophisticated assessments and for using the research but certainly that is not what we are hearing on the front lines in the State of Oregon and that is why those patient reports are so troubling to me.

Last question I have for you, Dr. Owen, is what do you think physicians, because this is an area where you do have direct involvement, what do you think physicians ought to be doing, other than supporting the legislation that you mentioned, to try to beef up the quality of care in these facilities?

Like in my State we have a quarter of the facilities with serious deficiencies, some of them life-threatening. What is your message to physicians in my State about what they can personally be doing, other than supporting this legislation, to improve quality?

Dr. OWEN. Be good doctors. Be there for their patients in terms of engaging with them on a one-to-one level, doing it often, being attentive to their needs, being responsive, being what they took their oath of medicine for, for available. Sounds corny, but that is the real big issue here.

You should also appreciate, senators, that there is a looming manpower shortage in nephrology. You heard about the 7 percent incidence growth in treatment in the ESRD program. Unfortunately, we do not have an incidence growth of nephrologists of 7 percent. And I am fearful that as we become increasingly manpower constrained and competing tasks arise, not only having to take care of dialysis patients but taking care of dialysis patients in the hospital, taking care of complex hypertension and other renal-related problems, that it is going to get real tough for the profession.

But I think the thing to do is to be available for your patients and be responsive to their needs.

Senator WYDEN. That raises another interesting point because I share your view. There is a personnel crunch coming. What would you get paid by one of these corporate chains if you were just starting out in one of these renal facilities? We are going to have to attract good people. You agree with that; I agree with that.

Dr. OWEN. I would hope we could get good people.

Senator WYDEN. What would they get paid?

Dr. OWEN. That I do not know. As you see, I have a few gray hairs, so it has been a few years since I started out and I do not cut contracts with chains, so I am not the person to address that question.

Senator WYDEN. Mr. Bahr, what do they get paid?

Mr. BAHR. Medical directors?

Senator WYDEN. No, we are talking about somebody who is just starting out, not a medical director.

The CHAIRMAN. A technician, you mean?

Senator WYDEN. Yes, someone who is not a medical director and yes, more of a technician or——

The CHAIRMAN. The hands-on type of person?

Senator WYDEN. An aide, a hands-on staffer, yes.

Mr. BAHR. To attract better——

Senator WYDEN. I am trying to find a way to get the people that Dr. Owen is talking about. And my understanding is that when Dr. Owen says we need people, we need them at every level in these facilities.

Dr. OWEN. Every level.

Senator WYDEN. Which is medical directors, technicians, aides and the like. And one of the reports that I have been getting is that these chains do not pay very well, which is why it is hard to get people in the field.

So could you just sketch out what kind of salaries one might get if one went into this field, at several levels?

Mr. BAHR. Currently I would say, and I do not know on a national level what these salaries are but it would be local, a technician's annual salary would probably be in the $25,000 to $27,000 range. A registered nurse or a charge nurse, their salary range would probably run anywhere from $30,000 to $50,000 a year.

Senator WYDEN. OK. One last question, if I might, for you, Mr. Kang. Your essential thesis has been that quality is starting to go up and your quality standards are working and that folks should feel that the Federal Government is on top of the task. That is not what the people in the State of Oregon are saying. That is not what the health care administrators are saying. That is not what the patients' families are saying. What they are saying is that we have a recipe for disaster on our hands. We have an increasing demand for these services. They are unhappy about the national for-profit chains coming in and buying up the not-for-profit centers. They are concerned about reimbursement. They are concerned about what Dr. Owen talked about, which is that it is difficult to attract people to the field. And they do not share your view that things are improving.

So what are you going to do in my home State, where they do not share your assessment that things are getting better?

Dr. KANG. First of all, Senator Wyden, I am HCFA's Chief Clinical Officer; I am a Physician. I know you were late so——

Senator WYDEN. Right.

Dr. KANG. My thesis was that things are getting better. However, I actually believe that there is plenty of room for improvement and there is much more that the Federal Government can be doing.

We are actually very well aware of what is happening in your State of Oregon and what I would like to actually point out is that what triggered our reviews and our surveys in the State of Oregon was, in fact, lots of complaints coming from the citizens of Oregon and also the fact that ownership had changed.

We do target our surveys based on change of ownership, largely because there is a vulnerability there. So I would just like to point out to you that our national average for surveying ESRD facilities is around 20 percent nationwide; in the State of Oregon we actually surveyed 39 out of 41, as you mentioned, so that is almost 100 percent review within the last year because of these changes.

I think one of the things that we would be very interested in and we are well aware of the life-threatening deficiencies, we obviously are very anxious to work with yourself and members of this committee on intermediate sanctions, which the GAO and the Inspector General talked about, largely because our only sanction right now and enforcement tool is to completely terminate someone from the program. While we are not afraid to do that, I think that there are intermediate sanctions that would be very useful in terms of grabbing facilities' attention.

Senator WYDEN. Can I just ask on that point, Mr. Kang, with respect to these intermediate sanctions, do you need legislation that would give you that power?

Dr. KANG. Yes, we do.

Senator WYDEN. And what would be an example of an intermediate sanction and how would that kick in? I guess what I am concerned about is that if you have a facility with a life-threatening situation, I do not think you have any choice but to move very, very quickly in order to protect the patients. Intermediate sanctions sound, to me, constructive if you are dealing with something that is not at the level of that kind of seriousness we are seeing in the State of Oregon.

So why don't you describe, if you would, what you think intermediate sanctions ought to apply to because to me, when you have life-threatening conditions, we need something considerably more than that.

Dr. KANG. With life-threatening situations, we actually ask for an immediate corrective action plan of that life-threatening situation. Otherwise, they are terminated from the program. So what has happened in the situations in Oregon is that they have made immediate corrective actions.

I think what we are concerned about, though, is that once they have made the immediate corrective action, then the spotlight is off and there can be this yo-yo effect that the General Accounting Office referred to.

I do think that civil monetary penalties really have an effect of keeping one's attention to the task at hand and sticking to the corrective action plan.

So I think that those tools are useful but I want to assure you that if, in fact, a facility is found to have life-threatening—is placing people's lives in jeopardy and they continue to do so, then the Health Care Financing Administration will terminate them from the program immediately.

Senator WYDEN. Well, the message from the State of Oregon is that the Federal Government needs to be a better partner here and that the Federal Government has not moved quickly enough in instances where there are serious deficiencies, which you have correctly described as life-threatening. I have tried to understate what I am hearing from my constituents. These are life-threatening matters and I think the Federal Government needs to be a better partner in terms of working with the States on that matter.

And with respect to further oversight of these facilities after they have been corrected, clearly this is another area we ought to be working on and I hope that you could furnish the committee some additional examples of what you think intermediate sanctions

ought to be because I happen to think that that is an effective approach where you say look, we have a serious problem here. It is not life-threatening but we have a serious problem and we are going to send you a strong message now before we, in effect, boot you out of the program.

I have been trying to watchdog these facilities since the days when I was Director of the Gray Panthers, before I was elected to the House, and I think we have a very serious public health problem on our hands now. The combination of the increased demand and the trend toward for-profit chains, which is not having the effect that Dr. Owen is talking about. Dr. Owen is describing what he would like to see come out of the for-profit chains. He is certainly describing what I would like to see in theory, that those additional resources make it possible for our country to deal with everything from the personnel problem to the research problem and various other issues that relate to the development of public health policy.

I think what we are seeing is something very different and that is we are seeing those big facilities cut corners. We are seeing them cut corners in spite of the fact that we have life-threatening situations and Mr. Kang saying he wants the Federal Government to be more effective.

So there is a lot to do here, folks, and fortunately, we have the chairman, who approaches these issues in a thoughtful and a bipartisan way and Chairman Grassley, again my thanks to you for all your leadership and I look forward to working with you.

The CHAIRMAN. On the point you made about adequacy of research or research generally, we think to some extent what we have done getting ready for this hearing, that there is some just plain necessity of bringing some to conclusions and getting some consensus on what is out there. That does not preclude what you say, that maybe there needs to be some additional research, but we need to get some clarity and consensus on what has already been done. And we are thinking about asking the National Institute of Health to help us with that effort. Thank you very much.

Senator WYDEN. Thank you.

Dr. WISH. Can I make one more comment about the chains, because I have some data?

The CHAIRMAN. Please do.

Dr. WISH. Our Network, which again is in the Midwest—Ohio, Illinois, Indiana and Kentucky—we look at patterns of care. That is our job. And we actually have the data infrastructure in place so that we can collect facility-specific information on all patients three times a year. So we did not want to wait for the VISOIN project to be up and running. We kind of did it on our own.

We looked at patterns of care in Chicago, which is the largest metropolitan area in our Network, and there are three large chains that have a high penetration in Chicago. We looked at the outcomes for anemia management and adequacy of dialysis for those three chains over a year period.

What we found is that there was one chain that was consistently performing at a level higher than the network as a whole; there was one chain that was consistently performing at a level comparable to the Network as a whole; and there was one chain that

was consistently performing all of its facilities at a level below the rest of the Network. So obviously it is not fair to paint all the chains with the same brush.

But what was interesting is that when we contacted the Medical Director of the chain that was having the poorer performance, they were very open to a Network-based intervention. They assembled all of the medical directors from the Chicago facilities in one place at one time so the Network could do an intervention activity with education and giving them tools for quality improvement. And over the next year, that chain brought its level of performance up to that comparable to the rest of the Network.

So you do have some economies of scale when the chain can bring together the people that direct the medical care in all the facilities in one place at one time for a single intervention activity.

The CHAIRMAN. That brings me back to a point that Senator Breaux made and the information that is available. So your view then on information being on the Internet for anybody to have access to, you feel that information is available, that information is accurate, and it would be very beneficial in——

Dr. WISH. That information will be available on a national level. It is not currently available at a national level.

The CHAIRMAN. When would that be?

Dr. WISH. It is hopefully going to be ready, up and going, by mid–2001.

Now there is going to be a website, as Dr. Kang said, at the end of this year that is going to have the URR and hematocrit compliance from the billing data, but the universal data from the Clinical Performance Measures initiative, which is going to be collected on every patient from all facilities, hopefully which will augment the validity of the data that is on the website, will be available, we hope, by mid–2001.

The CHAIRMAN. I have some questions but I want Senator Wyden to——

Senator WYDEN. I will be very brief, Mr. Chairman. I would very much like to see your study, Dr. Wish. And I guess what I would like to see resolved in this is what percentage of patients in these three chains are involved in programs that are seriously deficient. In other words, you described three chains; one of them was above, one of them was at the appropriate level and one was below.

So the question that arises to me, and that is why you have to see the study, is whether or not one third of the patients were in a chain that was offering seriously deficient care. If one third of the patients were in a facility offering seriously deficient care, I think the two of us would agree that is a serious kind of problem. You would want to correct it. I want it corrected because it is considerably higher than even what amounts to the 25 percent in my State.

So if you can get me that survey, I am particularly interested.

Dr. WISH. I would be happy to send you the data. It actually turns out to be about a quarter because there was a quarter of patients in each of the three chains and the other quarter were the independent facilities.

Senator WYDEN. So in your survey——

Dr. WISH. And this is metropolitan Chicago only.

Senator WYDEN. I understand. In your survey in a recent time period, a quarter of the patients in a chain assessment were receiving care that was seriously deficient.

Dr. WISH. That was under the level of the Network as a whole for adequacy and anemia management.

Senator WYDEN. And you would agree with me that that is unacceptable and that is why you stressed over the next year they improved it.

Dr. WISH. Correct.

Senator WYDEN. Well, I would like to see this survey because I think it is pretty clear that with a medically vulnerable population, this country cannot sit around and say we are going to tolerate 25 percent of them, one out of four, in facilities that are seriously deficient and life-threatening. And I see Dr. Owen and Mr. Bahr nodding their heads affirmatively.

Dr. WISH. And the Network did not tolerate it. We went in and we got improvement.

Senator WYDEN. Right, but you got improvement after we did the survey. But then, as Mr. Kang said, we still have an issue with respect to what happens after there has been an improvement after one year and what kind of oversight there is.

Dr. WISH. We continue to get data from every facility three times a year, so we can keep track of that.

Senator WYDEN. I will look forward to seeing that.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

Dr. Wish, I understand that the Networks are collegial in their relationship with providers in their efforts to improve patient care and outcomes. Does this type of relationship work?

Dr. WISH. Yes, we think that it does. It is a peer review kind of paradigm, so we feel that building a nonpunitive environment is important for the facilities to kind of air their dirty laundry so that we can help them. If they fear sanctions, then it is going to be very difficult for us to understand what processes might be flawed so that we can give them interventions that may help to improve those processes. So we feel that collegial relationship is essential for the success of the Networks.

The CHAIRMAN. Dr. Kang, as I am sure you are aware, there are numerous studies about the various quality issues of patient care. We have had a discussion on our staff and it puzzles us why there is no definitive work on quality issues, such as adequacy of dialysis and reuse of dialyzers in this country. Many patients still worry about whether they receive enough time for dialysis.

As the two patients testified today, equally alarming to patients is the reuse of dialyzers. Many patients believe that it is a profit matter for the companies and that the patient quality of life does not matter.

Our committee's research has found numerous medical research studies inside and outside the United States. It appears that the print studies advocate for longer dialysis. Dialyzers are not reused in other industrialized nations.

What do you believe is the reason that research in the United States has not reached any conclusions about these important patient care matters?

Dr. KANG. Chairman Grassley, before I answer that I would like to just take one opportunity on the question that you asked Dr. Wish.

Our approach with regard to survey and certification and Networks is very similar to what the IOM recommended in terms of patient medical errors and patient safety. You actually need two environments. You need the regulatory environment, which is a blaming environment. It is our survey and certification. Then you need the learning environment; that is the Networks. That is the collegial environment. You really do need both.

This goes back to a question for the first panel. It is very similar to the airline industry. In the aviation industry, you have FAA, which is the regulatory, blaming approach, and you actually have NASA, which is the learning, collegial approach. You learn from your mistakes.

So I just wanted to say really for the record that you need both and I would really encourage this committee to support both, really, to improve the care for patients.

In answer to your questions, I think that we are currently actively wrestling with the issue of adequacy of dialysis. And as Dr. Owen mentioned, what this country is wrestling with are the tradeoffs between patient choice and time on the machine, lifestyle issues, et cetera.

I do think that to the extent that we find and the public and doctors begin to realize that the longer you get dialyzed, the more adequate it is and the better your mortality and survival and quality of life is, that over time, this will continue to move as it did in Europe.

With regard to the reuse issue, we actually are actively involved with NIH and the USRDS to look at the reuse issue to try to sort through in follow-up to the study back in 1994 as to what are the issues for reuse, whether we need to be regulating and if so, where we need to be regulating more aggressively.

And then, quite frankly, to the extent that reuse is associated with worse outcomes, there are payment implications, as Senator Breaux has questioned.

But the NIH and USRDS is soon to publish the results of that study. The one thing that I would like to assure you is that we have an agreement with them. To the extent that they find anything untoward early on, that they were actually to report to us so that we could take immediate action. They have not had those findings yet, at least as far as I know, but they are actively looking at the implications of reuse for patient outcomes.

The CHAIRMAN. Is there some academic reason for research to be done and conclusions not reached and we are guessing what those conclusions are going to be? Because I assume that we have had people doing the same research in other industrialized countries and come to conclusions. The way I read it, we have not come to conclusions.

Now maybe you are telling me we have come to conclusions.

Dr. WISH. I do not think we have, as Dr. Owen——

The CHAIRMAN. What is different about the academic environment in the United States that keeps us from coming to those conclusions, as opposed to other industrialized nations?

Dr. KANG. I do not think the other industrialized nations, and maybe Dr. Owen knows more about this, have actually come to conclusions, also. It is just more of a practice style at this point.

The CHAIRMAN. OK. So you get back to a lot of problems in America from one part of the country to the other related to a different style of practice of medicine.

Dr. OWEN. There are substantial differences in practice.

Dr. KANG. What we are very interested in doing is doing what evidence-based medicine would support doing and I want to assure you that to the extent the evidence says reuse is unacceptable, the Health Care Financing Administration would take a strong position that it is unacceptable.

The CHAIRMAN. OK.

Dr. Wish, how are the Networks addressing concerns that patients and dialysis facility staff are reluctant to complain about poor care for fear of retaliation or losing a job?

Dr. WISH. Well, that is a concern. When we get a patient grievance or we get a staff complaint about how a dialysis facility processes may be unsound, what we find is in the vast majority of cases, which we always refer to the medical review board—these are not handled at the staff level at the Network. These always go to a medical review board of peers so that we have all disciplines involved in terms of evaluating the nature of the complaint.

What we find is that in the vast majority of cases, these are communication problems, especially patient grievances. It does not necessarily represent bad care. It just represents the fact that the patient had something done to them that they did not understand, that nobody really explained it to them, that there was a change in their environment that they did not anticipate, and that was the source of the concern and ultimately of the grievance.

And what we find is that by mediating the communication between the facility and the patient, the vast majority of grievances are resolved and there is really no issue in terms of long-term sanctions or fear by the patient that they are going to get inadequate care because of voicing the complaint.

Now, there are situations where we are concerned. There are patients that do file grievances that we feel do represent significant process issues and in those cases what we try to do is keep the patient's identity anonymous to the facility and go into the facility with a site visit to address their processes of care on a hands-on level.

So we actually go through their policy and procedure manuals. We actually observe how dialysis is conducted from the beginning to the end, how the technicians interact with the patients, how the nurses interact with the patients, with special view to what the issues were that the patients did bring to our attention. And if we find that there is a significant deviation from what we feel to be accepted practices, then the facility will be put on record as deficient and they will be required to file a plan of corrective action within 30 days—how the procedures will be corrected. Then a follow-up site visit is done to make sure that the deviation has been corrected. And under these circumstances, the patient's identity is kept anonymous from the facility.

The CHAIRMAN. Mr. Bahr, a little bit along the same line, what do patients or their representatives do if they are dissatisfied with the care that they receive or the services or environment of care that you provide?

Mr. BAHR. One, you have to deal with this in a very sensitive manner. To address a patient while they are on dialysis is inappropriate. We ask to speak to them outside, set up a time, a convenient time, often bringing in family members.

And as Dr. Wish pointed out, more times than not, the issue that has come to our attention that they have finally come to us with is a communication breakdown. Some way or another our team was not communicating with the patient correctly.

So we deal with it outside, bring it back. If they have particular issues with an individual staff member, we may ask for a time-out for both. You know, you will not have this patient care member for a bit. If there were technical problems, that person, when they put that patient back on, will be under direct supervision to observe their technique and ensure what is going on is appropriate and correct.

But more times than not, sir, we have to deal with this outside of the unit. The unit—you have patients right next to patients. You do not need to involve them in that patient's business.

The CHAIRMAN. We had this first panel, Mr. Smith, and so your vice president would not be calling Mr. Smith in the middle of dialysis. That's not good for——

Mr. BAHR. Sir, I am chief cook, bottle-washer, vice president, whatever personnel today. It is a small unit, so I am the vice president.

The CHAIRMAN. The point is still the same.

Mr. BAHR. I understand people wanting to understand what patients' concerns are. I assume that his concerns were voiced at the unit prior to him ever talking to anybody here.

The CHAIRMAN. If you had one of your patients testifying today you would not have called——

Mr. BAHR. I would be nervous.

The CHAIRMAN. But you would not be calling them while they were getting dialysis?

Mr. BAHR. No. I would hope that I knew, because I had had a good communication with them before they got here and they probably would not be here.

I just had one other point.

The CHAIRMAN. Sure.

Mr. BAHR. We talked about longer times on dialysis. In our dialysis unit, our times are increasing, sir. My average length of time for my patients is about 4 hours and 15 minutes actual dialysis treatment time. It is ever increasing.

My population also—I looked at a graph before coming to the meeting today showing the ages. In 1997 the average age of the population was 61.1 years. Mine is 76 due to demographics. It is a different population.

The CHAIRMAN. Dr. Kang, how does HCFA determine that the Networks perform requirements of their contracts? Do you believe that the Networks are performing the job of "improving the quality of patient care"?

Dr. KANG. We are moving toward not only a performance measurement system for each dialysis facility but also for the Networks, we can actually aggregate those measures to also look at network performance.

So at some point when we have the system of performance measurements in place, we plan, in fact, to move the Networks to performance-based contracting, just as we did with the PRO program.

The CHAIRMAN. I might submit some questions for answers in writing. I will review whether or not we got adequate information, but that is the end of my oral questioning, at least.

So I thank you, as well as the first panel, for your testimony. I think has been very helpful in helping us to determine whether the quality of care for dialysis patients is what it ought to be.

I think most importantly, your testimony will help the committee determine how best to approach solutions to the quality of care issues.

I want to bring up again what I said to Senator Wyden, that I think in the process, we have to look for common sense solutions and one of these is bringing some conclusions to the medical research on several of these quality of care issues that we have discussed. Specifically, getting back to adequacy of dialysis, reuse of dialyzers, it appears that it might be advisable to ask the National Institute of Health or some other appropriate body to resolve some of this debate with its research on an expedited basis. I am really surprised that this debate has gone on for so long. The quality of life of too many patients depends on it.

Then we also brought out how oversight is lacking. So the General Accounting Office and Inspector General made that clear. And again it leaves a vulnerable population unprotected. So we will continue to work with HCFA and with the Networks as we strive to improve the quality of care that patients receive.

In addition, we are going to have to further review the recommendations of the General Accounting Office and the HHS Inspector General to determine if legislation is necessary. Part of that relates to some sort of penalty procedures so you do not have to just shut down a facility or not shut them down but take them off of reimbursement, which might be the same. And obviously the issue of more appropriations for enforcement.

We are going to leave the record open for 2 weeks, as I said previously, for additional statements or information. And each of you who had longer statements, your statement in total will be printed in the record, both for your panel and the first panel.

I thank you all very much and the meeting is adjourned.

[Whereupon, at 4:10 p.m., the committee was adjourned.]

APPENDIX

GAO
United States General Accounting Office
Washington, DC 20548

Health, Education, and
Human Services Division

July 10, 2000

The Honorable Charles E. Grassley
Chairman,
Special Committee on Aging
United States Senate

Dear Mr. Chairman:

Enclosed is our reply to your letter of June 27, 2000. As requested, the enclosure provides answers to your follow-up questions regarding our recent testimony before the Committee on Medicare's End Stage Renal Disease Program. If we can be of further assistance in this matter please do not hesitate to call me at 202-512-7250.

Sincerely yours,

Janet Heinrich

Janet Heinrich
Associate Director, Health Financing and
Public Health Issues

Enclosure

Question 1. Your report states that 15% of the inspected facilities in 1999 had deficiencies severe enough that, unless corrected, would warrant terminating their participation in Medicare. How many of these facilities were actually terminated?

Answer: Of the 62 facilities found out of compliance with Medicare conditions of participation in 1999, only one facility left the Medicare program. The facility voluntarily terminated its participation in the Medicare program citing Medicare's low payment level as the reason.

Question 2. What happens to a facility once it corrects its deficiencies? What are the odds that a facility stays in compliance once the threat of termination is lifted?

Answer: Once a facility corrects its deficiencies, it is considered to be in compliance with Medicare's quality-of-care standards. Also, while in the process of correcting its deficiencies, facilities continued to dialyze patients and receive full Medicare payments.

Because of the infrequency with which facilities were inspected, we were unable to establish the odds that a facility will remain compliant with Medicare's conditions of participation. However, we did note that facilities often tended to repeat specific deficiencies found by surveyors. For example, of those facilities with four or more inspections, 38 percent that had deficiencies on their most recent survey were also deficient on at least one of the same requirements on their prior survey. Over half of these facilities had two or more of such repeat deficiencies.

Question 3. Can you explain how a facility can have good clinical outcome scores, but at the same time be identified in on-site surveys as seriously out of compliance with Medicare standards?

Answer. The clinical performance measures are often based on a sample of patients with clinical data that may be several years old. While HCFA is taking steps to collect and analyze clinical outcome data on all patients and improve data timeliness it is unclear the extent to which they would capture all the aspects considered critical to achieving and acceptable level of quality of care. For example, it may be possible for a facility to have good scores for urea reduction and at the same time not have proper controls in place to ensure that patients' dialyzers are cleaned properly or that uncontaminated water is used in the dialysis process. This is why we are recommending that HCFA do more testing before it uses outcome measures as the key factor in selecting facilities to visit for unannounced on-site visits.

Question 4. In your report, you state that "fixed payment rates can create incentives for efficiencies, but they can also be an incentive for underservice. Can you explain what you mean by this and is there evidence that this is occurring?

Answer: The comment on Medicare's fixed payment rate is not meant to criticize the method of payment, but to provide background on the rationale on the need for a strong oversight system to help assure that ESRD patients receive quality services. Medicare pays dialysis facilities a fixed rate to cover a bundle of services, such as laboratory tests, drugs and supplies, that are routinely required for dialysis treatment. This fixed rate is the primary source of facility revenue and has remained essentially unchanged since program inception. While the rate is adjusted to reflect differences in local area wages it is not adjusted for patient case mix or dialysis practice. For example, Medicare makes no additional payments for patients that might require longer dialysis or more frequent weekly sessions.. Therefore, to maximize profits from its dialysis operations a facility has strong incentives to control costs, by 1) becoming more efficient in providing services and, or 2) potentially not providing needed services to all patients.

Studies do show that dialysis facilities have made efficiency gains over time, for example by adopting more technological advanced equipment as well as by consolidating into multi-center companies. Also, productivity gains with staffing have been reported. For example, in 1998 dialysis facilities used about 12 percent fewer staff to administer dialysis than they did in 1993. Facilities increasingly relied on lower-cost personnel to monitor dialysis treatments as well. The extent to which these efficiency gains have resulted in underservice to patients remains unknown.

Question 5. Please describe the other enforcement tools currently available to the HCFA when dealing with an ERSD facility that is out of compliance. How often are these mechanisms used and what is the value of each?

Answer: HCFA has three additional enforcement tools available for facilities that do not comply with Medicare's quality-of-care standards, but they have never been used. Two are of limited value but the third has some potential to provide deterrence to future non-compliance.

1)HCFA has the authority to deny payments for new patients for facilities out of compliance with Medicare's quality of care standards. This enforcement tool is of limited additional value, because, like termination, the law allows facilities to avoid this sanction by returning to compliance. HCFA has not implemented it into regulation.

2)HCFA can also levy financial penalties against facilities that do not participate in ESRD network activities or pursue network quality-of-care goals. Specifically, they can deny payment for new patients, reduce a facilities payment by 20 percent for every 30-day period of non-compliance, or withhold all payments for ESRD services. This authority is also of little practical value, because the law only authorizes its use if the deficiency does not "jeopardize patient health or safety". However, networks

are inclined to refer only facilities with serious deficiencies to HCFA for sanction, but only non-serious deficiencies would be subject to the financial sanctions. As a result, the sanctions are rarely even considered.

3) HCFA can retroactively deny payments for services affected by facilities non-compliance with quality-of-care standards for reusing dialyzers. This authority has never been used because HCFA has not developed agency procedures to implement it. The scope of the sanction is limited in that it applies to non-compliance with reuse standards. Nevertheless, if it is enforced it could provide a strong incentive for compliance, because it can be levied even if a facility corrects its deficiencies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

JUL 10 2000

The Honorable Charles E. Grassley
Chairman, Special Committee on Aging
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

Thank you for your letter of June 27, 2000, posing follow-up questions from your hearing of June 26 on the End Stage Renal Disease (ESRD) Program. This letter will include your original list of questions, followed by our response to those questions.

1) Why has the time between state surveys for ESRD facilities increased? How can this problem be addressed?

The ESRD facilities have no mandatory survey cycle; nursing homes and home health agencies have mandatory survey cycles established by Congress. By statute, States must survey nursing homes approximately once every 12 months and home health agencies once every 36 months. As a result, nursing homes and home health agencies receive funding priority over ESRD facilities. In addition, the Health Care Financing Administration (HCFA) places ESRD facilities under the category of non-long term care providers, which also includes non-accredited hospitals, psychiatric hospitals, ambulatory surgical centers, and hospices. All of these providers compete for the same pool of survey resources. Currently, non-long term care facilities appear tenth on a list of 12 HCFA workload priorities for State agencies. To address the infrequency of ESRD surveys, we recommended that HCFA determine an appropriate minimum cycle for dialysis facilities either through policy, regulatory, or legislative means.

2) In your report, you recommend strengthening the complaint system for both dialysis patients and dialysis facility staff. How does the complaint system currently work and how would you strengthen this system?

Currently, dialysis patients can lodge a complaint with the State survey agency, the Network, or both. Each entity has different authorities, approaches, and expertise. State survey agencies investigate all complaints on site that involve life-threatening situations or possible violations of the Medicare Conditions for Coverage. Their investigations go beyond the episode in question, focusing instead on whether systematic problems make it likely that failures will occur in the future.

Networks receive complaints covering a broader range of issues related to patient care. Network investigations, in accord with HCFA instructions, typically facilitate quick resolution between the complainants and the facilities. To do this, Networks usually identify the complainant to the

dialysis facility. Networks address most problems by working collegially with facilities, whereas the States approach the facilities in a more regulatory manner. Through their board membership, Networks have important clinical expertise in nephrology that gives them substantial ability to assess and follow up complaints regarding the adequacy of the clinical care being provided. Networks have little authority to enforce corrective actions. The States, on the other hand, have enforcement authority for violations of the Medicare Conditions for Coverage, but tend to lack the clinical expertise concerning renal care.

Working single-handedly, neither the States nor the Networks can tap the full potential of a complaint system that effectively addresses quality-of-care concerns. Therefore, we recommend that HCFA work with Networks and State agencies to develop an integrated complaint system that incorporates the following elements: accessibility, objectivity, investigative capacity, timeliness, responsiveness to complainants, enforcement authority and follow-up, improvement orientation, and public accountability. We urged HCFA to convene representatives from the Networks and State survey agencies to identify ways in which these two entities can work together most constructively, drawing on their respective strengths. Secondly, we urged HCFA to conduct pilot efforts through which Networks and State agencies implement a unified complaint system.

We also called upon HCFA to exert national leadership to facilitate the development of a common instrument that dialysis facilities could use to assess patient satisfaction. This could draw upon the instruments that some dialysis corporations have already developed and use for their own internal monitoring efforts. For many patients, an anonymous response to a patient satisfaction survey may serve as a safer vehicle for expressing concern than a formal complaint to a facility, Network, or State agency.

3) Your report shows that HCFA no longer evaluates how well the state survey agencies perform dialysis facility evaluations. Why doesn't HCFA follow-up on dialysis facility surveyors?

In the past HCFA conducted validation surveys through which HCFA staff would review dialysis facilities shortly after a State certification survey. Recently, HCFA eliminated these in favor of periodically observing State surveyors in real time and offering advice and assistance as applicable. HCFA relies on State agencies to assess their own performance and, by working with the HCFA regional offices, to develop and implement their own quality improvement plans. This process is called the State Agency Quality Improvement Program (SAQIP). The program addresses State survey activities generally, and fails to specifically assess dialysis surveys. HCFA decided to move in this direction for a variety of reasons. First, HCFA staff lacks the necessary expertise to evaluate dialysis surveyors. In our interviews with HCFA officials many stated that they do not have the technical knowledge to adequately assess the State surveyors. We were also told by HCFA staff that they do not have the resources available to regularly validate surveys. HCFA staff believe it is more effective to observe surveys because it provides a teaching opportunity.

4) In your report, you recommend that HCFA hold individual dialysis facilities more accountable for the quality of care they provide. How would such a plan of accountability be implemented?

The primary way HCFA can hold individual dialysis facilities more accountable is by collecting and disseminating *facility-specific* performance data and using such data in a balanced fashion, both for improvement and enforcement purposes. Thus far, HCFA has primarily used performance measures for improvement purposes by focusing on national and regional trends. It is time, we believe, to build on this progress by using performance measures as a key mechanism to hold individual facilities more accountable for the care they provide. Performance data can help reviewers ask better, more targeted questions about quality. If a facility's performance on a measure or a cluster of measures has been declining over time, or is consistently less than that of other facilities with a similar patient mix, then it is reasonable to ask why and to do so in a public forum. The answers might well indicate that such a facility is actually a top-quality one, with sound reasons for its statistical ranking. Or, they could indicate that the facility does have problems warranting attention.

We recommended that HCFA, with input from the professional community and from patients and patient advocates, determine a new core set of facility-specific clinical indicators that will be used to help facilities, Networks, State survey agencies, and the public assess the quality of care at a facility. Once an electronic data collection system and data validation procedures are in place, HCFA should generate quarterly, facility-specific reports that compare facilities to their own past performance and to their peers at the State, Network, and national levels for each of the performance indicators in the core set. The data in these reports should be made readily available to all parties: the facilities, the Networks, the State agencies, and through Internet websites (and perhaps even postings in facilities), to the general public. Such data can help facilities gain a better sense of how the facility is performing and can provide the leadership with valuable leverage for initiating change. Networks can use facility-specific performance data to identify outlier facilities that have continued poor performance and to identify best practices. State survey agencies can use performance measures together with other information to help guide the surveyors when they perform surveys or, in cases when the information seems compelling enough, influence when they decide to conduct a survey. Finally and most importantly, the public can use performance data to help make informed decisions and to foster public accountability.

I hope this letter is responsive to your questions. Please feel free to contact me, or your staff may contact Helen Albert, Director for External Affairs at (202) 260-8610 if we can be of any assistance.

Sincerely yours,

George F. Grob
Deputy Inspector General
for Evaluation and Inspections

NATIONAL RENAL ADMINISTRATORS ASSOCIATION

July 5, 2000

Senator Charles E. Grassley
Chairman
Senate Special Committee on Aging
Washington, D.C. 20510-6400

Dear Chairman Grassley:

Thank you for writing with follow up questions to the June 26 hearing on quality of care provided by Medicare's End Stage Renal Disease Program.

In answer to your first question on training programs for dialysis technicians I have enclosed a copy of the draft revised training program the state of California is planning to institute for dialysis technicians later this year. This revised training program is similar to other state technician training programs.

In answer to your second question about effective remedies to improve quality of care, the NRAA believes that if dialysis facilities were surveyed every three years they would more likely be in compliance with HCFA's guidelines on a regular basis. Further, the association would suggest that given the limited resources state surveyors have, that the next three year survey should be relatively brief for those with good previous surveys so that the bulk of funding could be used to target facilities with poor track records. Lastly, the NRAA believes that intermediate sanctions may be another way to create incentives for poorly performing facilities to improve quality of care to their dialysis patients.

Our answer to your third question about the effectiveness of termination with plan of correction, is similar to our answer to the previous question. More frequent surveys in coordination with the ESRD Networks will create the best incentives to ensure quality of care for patients. The NRAA strongly believes that dialysis patient specific profiling by the networks in conjunction with triennial state surveys is the most desirable way to keep dialysis facilities on their toes providing the best care possible to their patients. As the ESRD Networks are the most knowledgeable about quality of care in dialysis facilities, requiring them to monitor, analyze and report back patient specific data to dialysis facilities, in relation to their peers in the state and nation, will incentivize facilities to improve their outcomes. If facilities do not respond to the patient profiling, then the networks should work with the facility to develop a plan of care to improve patient outcomes and monitor the facility's progress in fulfilling the plan of care.

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The association would also like to set the record straight about dialyzer re-use. Currently, approximately eighty percent of freestanding and hospital-based dialysis facilities reprocess dialyzers that are re-used on the same patient. All dialysis facilities must meet the American Association of Medical Instrumentation (AAMI) guidelines on reprocessing dialyzers. The AAMI guidelines are included in the Medicare ESRD Conditions of Coverage and the state surveyors use these standards to determine compliance with reprocessing rules. AAMI updates these guidelines periodically and the latest guidelines become a part of the ESRD Conditions of Coverage by reference.

Further, there was some question as to whether Medicare was paying for new dialyzers when dialysis facilities were actually reprocessing them. The cost of the dialyzer is included in Medicare's composite rate paid to dialysis facilities for each dialysis treatment. As the composite rate has been essentially frozen since 1983 when it was created, except for a $2 decrease in 1986, a $1 increase in 1991, and a 1.2% increase in 2000, it no longer reflects the cost of providing a dialysis treatment. According to MedPAC's March 2000 *Report to the Congress*, three-fourths of dialysis facilities were paid less than their costs for dialysis treatments in 1998. Further, dialysis facilities must submit cost reports to HCFA annually which reflect that the majority of dialysis facilities have been reprocessing dialyzers for over a decade. Therefore, to the extent that costs are taken into consideration by MedPAC and HCFA, the cost of reprocessing dialyzers and the cost of new dialyzers is taken into account in determining what the appropriate composite rate reimbursement should be.

Thank you again for the opportunity to provide further information for the hearing record.

Sincerely,

Terry Bahr

Terry Bahr
President

STATE OF CALIFORNIA

Draft 06/13/00

Chapter 7.7 Certified Hemodialysis Technician Program

Article 1. Definitions.

75600. Agency.

Agency means a private school, organization or individual approved by the Department to provide a continuing education course and a certification training program for hemodialysis technicians.

75602. Clinical Training.

Clinical training means that portion of the orientation program and the certification training program which includes instructions and demonstration of patient care skills relating dialysis treatment by an instructor and a return demonstration of competence in these skills by the trainee.

75605. Continuing Education.

Continuing education means provision of health-related courses for certified hemodialysis technicians by a clinic, unit, agency, public educational institutional or in the facility where the hemodialysis technician is employed.

75607. Core Curriculum.

Core curriculum means a description of each category of study within a program which covers the minimum knowledge and skills required for hemodialysis technicians and builds on their knowledge in a logical and methodical manner.

75610. Gross Negligence.

Gross negligence means the failure of a person to exercise any care, or the exercise of so little care that it is apparent that the person is indifferent to the consequences of his or her conduct and to the welfare of others.

75612. Hour.

Hour means fifty (50) minutes of participation in an organized learning experience. Each hour of classroom theory shall be accepted as one (1) hour of certification training, in-service training or continuing education.

75615. Immediate Supervision.

Immediate supervision means that a supervisor shall be present in the same room in which the person being supervised demonstrates the clinical skills.

75617. Incompetence.

Incompetence means that a certified hemodialysis technician does not possess or fails to exercise that knowledge and/or skill possessed and exercised by a reasonable certified hemodialysis technician under similar circumstances.

75619. In-Service Training Program.

In-service training program means a Department approved program established for hemodialysis technicians and provided by a clinic or unit employer of hemodialysis technicians.

75621. Instructors.

Instructor means: (1) a physician who qualifies as a medical director of the clinic or unit; (2) a registered nurse employed by an agency or public educational institution with a least two years experience and one of which is in the treatment of hemodialysis patients.

75623. Preceptors.

A registered nurse, or licensed vocational nurse employed by the clinic or unit who have at least two years experience in hemodialysis within the last twenty-four (24) months and a current competency skills checklist on file in the clinic or unit may assist in didactic sessions and serve as preceptors for skills within their area of licensure. Certified hemodialysis technician with two years experience may also service as preceptors for task oriented duties within their certification.

75626. Hemodialysis Clinic / Unit.

(a) Clinic means a licensed specialty clinic for the treatment of patients with end-stage renal disease.

(b) Unit means a specialized unit of a licensed clinic or licensed hospital for the treatment of patients with end-stage renal disease.

75628. Public Educational Institution.

Public educational institution means an accredited college, accredited university, a regional occupational center, a high school, or adult education center whose certified hemodialysis technician training programs have been approved by the Department of Health Services, or the Department of Consumer Affairs and offered by the Department of Education.

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75630. Student Performance Standard.

Student performance standard means a standard which is used as a method of measuring trainee learning.

Article 2. Administration.

75633. Administrative Policies and Procedures.

(a) Each clinic, unit, agency or public education institution providing hemodialysis technician training shall develop and implement written administrative and management policies to govern the administration and management of the training program, and the instructors. Such policies shall be reviewed annually and revised as often as the clinic, unit, agency or public educational institution determines necessary. A copy of the policies shall be made available upon request to the Department.

(b) Policies shall include but not be limited to:

(1) Job descriptions detailing qualifications, duties, responsibilities, and limitations for the program director and instructors.

(2) An organizational chart showing the person in charge of the program, the lines of authority, responsibility, communication, staff assignments, and schedules.

(3) The method of monitoring instructors by the individual responsible for the training program.

(4) The ratio of students to instructor(s) for the clinical training, not to exceed a ratio of one (1) instructor to five (5) students.

(5) How student absenteeism and makeup classes will be handled.

(c) Except during training under immediate supervision, no person shall provide services as a hemodialysis technician without being certified.

(d) No clinic, unit, agency or public institution shall make a claim that completion of their program may lead to a student receiving a hemodialysis technician certification unless their program has been approved by the Department.

75635. Director of Staff Development or Instructor.

(a) Each clinic, unit, agency or public educational institution providing hemodialysis technician training shall be responsible for hiring qualified staff and shall submit a resume to the Department reflecting the qualifications of a

Director of Staff Development (DSD) or Instructor who must be approved by the Department. In a clinic or unit, a licensed nurse who meets the qualification in this section may provide the training in place of the DSD when the DSD is absent due to illness or vacation or when the DSD has terminated employment. In the latter instance the clinic or unit must show evidence of recruitment efforts. A copy of the resume must be kept on file at the clinic, unit, agency, or public educational institution. The Department shall be notified within thirty (30) calendar days following the employment of a new Director of Staff Development or Instructor.

(1) Submission of a resume shall be deemed to occur on the date the resume is received by the Department.
(2) A resume shall be considered complete when it clearly addresses all the qualifications required by the Department.

(b) The Department shall inform the facility, agency or public institution within 30 days that it is complete and accepted or that is deficient and what specific information or documentation is required to complete the resume.

(b) Department's maximum time period to approve a resume for an Instructor or Director of Staff Development shall be sixty (60) calendar days, from the receipt of the initial application to the final decision regarding the resume. To prevent delays, the Department may provide telephone approvals whenever possible. Telephone approvals shall be followed by written confirmations.

(c) The clinic or unit, agency, or public educational institution is responsible for assuring that the DSD or Instructor who teaches the certification training program meets the following qualification requirements: a registered nurse with at least 2 years experience and one of which is in the treatment of hemodialysis patient.

75638. Program Flexibility.

(a) All clinics, units, agencies and public education institutions are required to maintain compliance with licensing requirements in Sections 75600 through 75693 These requirements shall not prohibit the use of alternate concepts, methods, procedures, techniques or personnel qualifications or the conducting of pilot projects, provided such exceptions are carried out without reduction in the quality of the hemodialysis technician training program, the quality of patient care in the clinic or unit, or the ability of the certification training program to prepare hemodialysis technicians for certifications. Such exceptions may only be carried out with the prior written approval of the Department which shall provide for the terms and conditions under which the exception is granted. A written request and substantiating evidence supporting the request shall be submitted by the applicant or licensee to the Department.

(b) Submission of a request for program flexibility must be made in the format and on a form developed by the Department. Form, DHS 5000 5/92 is hereby incorporated by reference. Submission of the program flexibility request shall be deemed to occur on the date the request is received by the Department. This form can be obtained by writing to the Department at the address specified in Section 75673.

(c) A request is considered complete when the hemodialysis clinic or unit, agency, or public institution has fully described how it intends to meet the regulatory requirement in an alternate manner.

(d) Any approval of the Department granted under this Section, or a true copy thereof, shall be posted immediately adjacent to the clinic or hospital license.

Article 3. Program Components.

75640. Orientation Program.
(a) An orientation program shall be provided by each clinic or unit. Each clinic must submit for the Department's approval a written plan describing its orientation program. Facilities which already have a written plan approved when these occur. To be considered complete, any new program plan shall include the following.

(b) Experienced hemodialysis technicians, certified and non-certified hemodialysis technicians shall receive eighty (80) hours of documented orientation. The orientation program shall include classroom and clinical instruction, and must be completed within two weeks of employment.

(What of part time employees? 72 hours not 80 hours of orientation if facility operates with 3 (12) hour shifts per week.)

The first eight hours of orientation shall be conducted prior to providing direct patient care. Orientation related to the following facility – specific subjects shall be provided at the facility where the certified or non-certified hemodialysis technician is employed:

(For example)

(a) A tour of the facility, including a description of the patient population, description of the daily routine for patient and demonstration of the use of equipment.
(b) Instruction in the prevention and management of catastrophe and other Unusual occurrences, including but not limited to emergency procedures relating to fire and disaster preparedness.
(c) Introduction to basic patient care, which includes supervised clinical training prior to a patient care assignment.

(The work group needs to determine what items need to be included during this initial period of orientation. Also, is this 80-hour program going to be provided in

addition to the 480-hour certification program suggested for hemodialysis technicians.)? To be included in orientation unit specific policy/procedures. Orientation should be given in addition to the training program.

75643. Certification Training and Competency Evaluation Program.

(a) A certification training shall be conducted either directly by a clinic or unit or through an agreement with another clinic, unit, agency, or public educational institution approved by the Department. All providers of certification training and competency evaluation programs shall meet both state and federal requirements.

(b) When a clinic or unit provides a certification training program through another clinic, unit, agency or public educational institution there shall be a written agreement signed and dated by the authorized representatives of each party. Agencies and public educational institutions must develop the training schedule with the clinic or unit and provide the above record to the clinic or unit. Agencies and public educational institutions which use a clinic or unit as a clinical skills training site for certification training shall keep a record for each student, which includes: the date, the time of the training, and the name of the qualified instructor. The agency and public educational institution providing the training must retain these records for a period of four (4) years starting from the date each class begins. The certification training program records shall be kept available for the Department's inspection for a period of four (4) years from the date the Department approves it. The training records for trainees who have successfully completed the program shall be available for the Department's inspection for period of four (4) years from the date of enrollment. The training records for trainees who have not successfully completed the program will be reviewed to determine the reason for the trainee did not complete the program and whether issues exist which need quality improvement.

(c) A contractor who provided certification training for a clinic or unit by agreement shall be responsible for the program in its entirety. This shall include furnishing the staff to teach theory and supervise the clinical training of the program. Clinics or units shall only contract with a Department approved training programs.

(d) A contractor which provides a certification training for an clinic or unit by agreement shall be responsible for the program in its entirety. This shall include furnishing the staff to teach theory and supervise the clinical training of the program.

(e) A contractor shall maintain evidence that all health professional staff participating in the training program are currently licensed, registered or certified in there area of expertise.

(f) A trainee shall complete the program and the competence evaluation within nine (9) months of the initiation of the certification training program.

(g) A newly hired non-certified hemodialysis technician shall be enrolled in a certification training program within thirty (30) days of the date of employment.

(h) Each clinic, unit, agency or public educational institution shall submit a request for the Department's review and approval thirty (30) days prior to a change in core curriculum content, training hours or contracted services.

(i) The minimum training standards for persons certified as hemodialysis technicians after July 1, 2001 are as follows: A minimum of a 480-hours of training shall be completed with a period of two hundred eighty (280) calendar days. The training shall include not less than 300 hours for Clinical Performance. Training shall include but not to be limited to, instruction in the following subjects:

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75646. Classroom Instruction:

(A) Dialysis Overview.

(1) Principles of Dialysis.
(2) History of Dialysis.
(3) Concepts of fluid and particle dynamics including diffusion, osmosis and ultrafiltration.
(4) Definitions and terminology.
(5) Communications skills.
(6) Medical ethics and professional performance.
(7) Confidentiality of patient medical records and information.
(8) Patient rights and responsibilities.
(9) Multidisciplinary team process.
(10) Quality assurance(QA) and continuous quality improvement (CQI).
   a. Principles of QA/CQI.
   b. Role of the technician in quality assurance activities.
(11) Psychosocial and Financial Issues including dealing with difficult patients.
(12) Renal organizations and resources.

(B) Body Systems Review.
(1) Cardiovascular System.
(2) Renal System Anatomy and Physiology.
(3) Pathology of Renal Failure.
(4) Hemotologic Aspects of Renal Failure.
(5) Fluids, Electrolyte and Acid-Base Balance.

(C) Treatment Modalities.

(D) Renal Diet and Blood Chemistries.

(E) Infectious Diseases.

(1) Basic concepts regarding the science of microorganisms and transmission of infectious diseases.
(2) Blood borne pathogens, hepatitis, and other infectious and communicable diseases.
(3) Prevention and control:
   (a) Standard universal precautions.
   (b) Methods of sterilization.
   (c) Methods of disinfection.
   (d) Isolation techniques.
   (e) Aseptic techniques.

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(F) Dialysis Systems and Equipment.

(1) Fluid delivery systems.
(2) Composition and preparation and monitoring of Dialysate.
(3) Water treatment.
(4) Dialyzers including design and performance characteristics.
(5) Dialyzer re-use.
(6) Electric safety.
(7) Cleaning, disinfection and sterilization for all systems and equipment.

(G) Routine aspects of dialysis care.

(1) Anticoagulation Therapy e.g., Heparin.
(2) Local anesthetics e.g., Lidocaine.
(3) Sodium chloride solutions.
(4) Vital Signs.
(5) Fluid Management calculations.
(6) Patient Monitoring.
(7) Blood pressure, weight change and ultrafiltration.
(8) Monitors for Hemodialysis.
(9) Medical Records/ Charting.
(10) Medication common in dialysis: indications, side effects and interactions of medication commonly prescribed for dialysis patients.
(11) Awareness of outcome and goals for patient care.

(H) Hemodialysis Vascular Access to the Circulation: surgical creation, post-operative care use and observations.

(I) Medical Problems Common During Dialysis.

(J) Complications of Renal Failure.

(K) Special consideration for patients with diabetes, cardiac and respiratory disease; geriatric, pediatric, and new dialysis patients.

(L) Other Modalities e.g., peritoneal dialysis and renal transplantation.

II Clinical Performance.

During the clinical performance section of the training the Hemodialysis Technician will demonstrate competency in all areas of the clinical performance outlined.

(A) Principles of dialysis: understands and applies basic knowledge, theory, and principles behind each procedure consistent with accepted standards.

(B) Dialysis procedures to include:

(1) Infection control and aseptic technique.
(2) Adherence to universal (standard) precautions.
(3) Review of patient care plans and dialysis prescription prior to dialysis therapy.

(4) Vital signs (body weight, blood pressure, pulse, temperature and respiration's); performance and reporting of unusual findings.

(5) Observation and reporting patient condition pre, during and post-dialysis treatment:

(a) Follow plan of action, frequency of checks and appropriate response to changing situations.

(b) Recognize signs and symptoms of hypotenion; administering normal saline, reporting to charge nurse, and rechecking patient vital signs.

(6) Fluid management; calculations of total volume to remove, calculating transmembrane pressure (TMP) when applicable, setting the dialysis machine to achieve prescribed fluid removal, and adjusting fluid management when necessary.

(7) Initiation and termination of dialysis.

(8) Delivering an adequate dialysis treatment according to the written prescription and factors which may result in inadequate treatment.

(9) Glucose monitoring and hemoglobin/hematocrit monitoring.

(10)Obtaining blood specimens for laboratory analysis.

(11)Complications of dialysis. Anticipates, observers, acts appropriately, reports and follows-up on patients complications.

(a Air Embolism.
(b) Hypersensitivity Reaction.

(c) Anaphylactoid Reaction.

(d) Blood and Drug Reactions.

(e)Chest pain.

(f) Convulsions.

(g) Dialyzers; Blood leaks, Clotting, Line disengagement, Recirulation.

(h) Fever.

(i) First Use Syndrome

(j) Hemolysis.

(k) Hypertension.

(l) Idiogenic Osmolar Shift.

(m) Itching and Restlessness.

(n) Leg/Muscle Cramps.

(o) Nausea and Vomiting.

(p) Pyrogen Reaction.

(q) Severe Hypobolemic Shock.

(r) Shortness of Breath.

(s) Sterilant Infusion.

(12) Understands and applies emergency procedures and responses to the complications to hemodialysis treatment, e.g., cardiopulmonary resuscitation.
(13) Patient ancillary care needs, e.g., supplemental oxygen, patient transfer/transport.
(14) External and internal disaster, fire, natural disasters, and emergency preparedness.
(15) Safety, quality control and continuous quality improvement.
(16) Medical records and charting; documents all patient care activities and intervention utilizing appropriate medical-legal guidelines and terminology.

(C) Hemodialysis Equipment and Devices.

(1) Dialyzers models and performance characteristics.
(2) Priming of dialyzers and extracorporeal circuit for patient use; correct dialyzer prescription for a specific patient.
(3) Technical aspects of equipment function and monitoring.
(4) Fluid delivery systems startup and shutdown.
(5) Performance of appropriate safety tests for the presence or absence of sterilants in the fluid delivery system prior to patient use.
(6) Dialysate composition, options indications, complications, monitoring and safety.
(7) Monitoring dialysate prescriptions, conductivity, temperature and flow.
(8) Testing machine monitors and alarms according to facility protocols.
(9) Trouble shooting and response to alarm conditions.
(10) Cleaning, disinfection and sterilization of equipment.

(D) Water Treatment.

(1) Standards used for dialysis Association from the Advancement of Medical Instrumentation (AAMI) Standards and Recommended Practices, Volume 3 Dialysis, current edition.
(2) Systems monitoring.

(3) Performance of appropriate safety tests for the presence of residual sterilants or disinfectants in the water pathway.
(4) Water contaminates and potential complications.
(5) Knowledge and application of emergency interventions.

(E) Reprocessing of Dialyzers.

(1) Understands and applies the principles of reuse.
(2) Safety, quality controls, universal precautions and water treatment.
(3) Labeling of dialyzer with patient name, date reprocessed, reuse number and fiber bundle volume.
(4) Priming of reprocessed dialyzers and extracorporeal circuit for patient use; correct dialyzer for a specific patient.
(5) Performance and significance of appropriate safety tests for the presence of germicides or sterilants for reprocessed dialyzers to assure sterility.

(6) Performance and documentation of safety test for the absence of residual germicides or residual sterilants prior to patient use.
(7) Standards for reuse as described in the American National Standard, Reuse of Hemodialyzers, 1993 Edition, published by the AAMI, or most recent published edition.
(8) Knowledge of potential complications of reuse and application of emergency interventions.

(F) Patient teaching to include: the role of the technician in supporting patient education goals.

(G) Infection control and safety to include:
(1) Basic concepts regarding the science of microorganisms, epidemiology and transmission of infectious diseases.
(2) Risks of nosocomial infections, accidents, and errors in treatment.
(3) Adherence to universal (standard) precautions, aseptic technique, disinfection, sterile technique, isolation technique, and specimen handling.
(4) Risks to employees of blood and chemical exposure.
(5) Knowledge and application of CAL OSHA regulations, and other applicable state, federal and local laws.
(6) Electrical, fire, disaster, environmental safety, and hazardous substances.

(H) Participation in quality assurance (QA), and continuous quality improvement (CQI) activities.

(J) Cannulation of Arteriovenous (AV) Fistulae and Grafts.

(1) Observation, inspection, reporting of patency , infection, and other signs and symptoms of complications,
(2) Needle site preparation; using aseptic technique.

(3) Use and administration of local anesthetics via intradermal injection.
(4) Correct needle placement and prevention of complications.
(5) Knowing when to call for assistance with difficulty in needle placement.
(6) Securing AV fistula needles to prevention dislodgment.
(7) Achieving hemostasis at needle sites following needle removal.
(8) Dressing of needle puncture sites post-dialysis.
(9) Signs and symptoms to report pre, during and post-dailysis.

(K) Administration of normal saline solutions, anticoagulants and local anesthetics:
(1) Safe medication administration practice.
(2) Identifying and double checking the correct label on medication vial prior to use.
(3) Label all syringes with medication content.
(4) Check the patient's order on patient care plan.

(5) Preparation and administration of the correct dose and observing for complications.
(6) Indication for administration.
(7) Dosages, strengths and types.
(8) Potential complications and precautions.
(9) Knowledge of signs and/or symptoms of allergic reactions and /or anaphylaxis.
(10) Correct response to an allergic reaction and or anaphylaxis.
(11) Administration limits.
(12) Information to report and record.
(13) Documentation on patient records; drug, dose, route of administration, time and signature.

75650. During clinical training and demonstration of skills, there shall be no more then five (5) trainees assigned to each agency or public institution at any time.

75653. Preceptor Staffing Ratio: In a clinical care setting the ratio of preceptors to trainee shall not exceed I to 1, when ~~responsible for~~ engaged in the provision of direct patient care.

75656. Reciprocity.

(a) An individual who attended training and obtained a hemodialysis technician certificate.out-of-state, and is not Bonent certified must become certified by the Department before he or she can work as a Certified Hemodialysis Technician in California. The individual must submit to the Department a copy of their certificate of training and the didactic curriculum. Only original documents and transcripts from out of state will be accepted by the Department for equivalency consideration. If the certification training program completed meets the

regulatory requirements, the Department will issue the individual a hemodialysis technician certificate within thirty (30) of the date of the application.. If the Department determines that the training program completed does not meet the same criteria for training outlined herein, the individual must take classes in those areas required by these regulations to be certified. Following the completion of the required classes, the individual shall submit to the Department a document from the training program verifying that he or she has successfully completed the required classes. The Department will then issue the individual a certificate.

(b) When employed the newly certified individual will be required to complete a competency skills check list. The clinic or unit shall assess individual's competency to provide quality patient care before assigning the individual to direct patient care. If the individual is not found to be competent to provide patient care; the individual shall be required to obtain additional instruction in the areas required by these regulations. Once the required instruction has been completed the clinic or unit will conduct a follow-up competency assessment. The clinic or unit may not assign the individual to patient care until he or she has been found to be competent to provide patient care.

75659. New Employee.

A new employee with California CHT shall not be assigned to provide direct patient care until the competency assessment has been completed. A registered nurse who is qualified as an instructor shall be responsible for a written evaluation of each clinical skill demonstrated by the employee and shall determine the individual's competency and ability to provide patient care. The written evaluation shall be retained in the employee's personnel file.

75662. Trainee Evaluation.
Each trainee shall be evaluated on a bi-monthly ~~weekly~~ basis during the training program to ascertain the trainee's progress.

75665. Competency Test:
(a) A facility, agency, public institution providing a hemodialysis technician certification training program shall develop a competency test, which complies with the minimum training standards.
(b) A hemodialysis technician shall successfully complete:
(1) a written examination to validate knowledge and skills and
(2) a skills checklist to determine clinical competency.

75667. Certified hemodialysis technicians shall complete a competency test and skills checklist at least annually.

75670. Qualifications.

A clinic or unit shall require that each prospective trainees for a hemodialysis technician training program have the following qualifications / education:
(a) high school diploma or graduate equivalent degree (GED).,to include
(b) communication skills
(c) fluent in English to include comprehension, reading, writing, and speaking
(d) current certification in cardiopulmonary resuscitation (CPR)

75673. Issuance of Certificates.

(a) The Director of Staff Development or Instructor shall notify the Department in writing of those individuals who have completed the certification training program and have successfully passed examinations testing the knowledge and skills related to the training outlined herein. Those who do not pass the examination may be given two more opportunities to take the examination and pass, Notification of those who passed or failed shall be sent no later than ten (10) working days following the examinations. Certification of hemodialysis technicians issued by the Department shall be valid for four years.

(b) No part-time or full-time hemodialysis technician shall be employed as hemodialysis technician by a facility beyond ten (10) months unless he or she is certified.

(c) Every person applying for, holding or to whom a certificate is issued, shall file his or her present mailing address with the Department and shall notify the Department of an change therein. Applicants shall notify the Department in writing or by telephone. The application and subsequent correspondence shall be mailed to the same address:

Department of Health Services
Licensing and Certification
Nurse Assistant Certification Section
714/744 P Street
P.O. Box 942732
Sacramento, CA 94234-7320

(d) Starting from the date the Department receives the application for the certificate, the Department shall inform the applicant within 30 days whether the application is complete or whether it is deficient. If it is deficient the Department shall inform the applicant what specific areas need to be changed to what information needs to be added.

(e) The Department shall make a decision whether or not to issue a certificate within 90 days from the date the Department receives a completed application.

75676. For renewal of unexpired Certificates after January 1, 1996 a hemodialysis technicians shall submit a certification renewal application, an application fee and verification of the required in-service or continuing education training every four (4) years.

(a) Submission of an application for renewal shall be deemed to occur on the date the application is received by the Department.
(1) Starting from the date the Department receives an application for a renewed certificate the applicant shall be informed within thirty (30) whether the application is complete and accepted for filing or that the application is deficient and what specific information is needed.
(2) An application is considered complete when the correct fee is received and the accompanying documentation verifies completion of required thirty (30) hours of in-service or continuing education training in dialysis care of general health as required within the four (4) year renewal period.

75679. Fees.

(a) Each individual shall submit a fee for the issuance and renewal of certificates, and replacement of certificates.
(1) The application for certification fee shall be fifty dollars ($50.00).
(2) The renewal fee shall be fifty dollars ($50.00).
(3) The duplicate fee for lost certificates shall be five dollars ($5.00)
(b) Payment by mail for the required fee shall be by personal check, cashiers check, certified check or money order.

Article 4. Continuing Education and In-Service Training

75682. Provider Identification Training Number.

The Department shall issue a provider identification training number to all existing hemodialysis clinics and units who have an hemodialysis technician training program.

75685. In-service Training Program. Each clinic or unit shall have an ongoing in-service program planned and conducted for the development and improvement of necessary skills and knowledge for the hemodialysis technician staff. Each program shall include, but not be limited to:

(1) Prevention and control of infections.
(2) Fire prevention and safety.
(3) Cardiopulmonary resuscitation.

(4) Internal and external disaster plans.
(5) Accident prevention and safety measures.
(6) All newly developed policies and procedures.

75688. In-service Training and Continuing Education Sources.
A hemodialysis technician may obtain the in-service training or continuing required from one of the following sources:

(a) Health-related courses offered by accredited post secondary institutions.
(b) Health-related courses offered by the continuing education providers approved by the California Board of Registered Nursing.
(c) Health-related courses offered b recognized health associations if the department determines the courses to be acceptable.
(d) Health-related, employer-sponsored in-service training or continuing education programs.

75690. In-Service Training Program and Continuing Education Course Record of Attendance.

(a) The clinic, unit, agency, public educational institution shall provide each certified hemodialysis technician with a record of the in-service training program or continuing education course he or she has completed. The record shall include:
(1) The individual's name and hemodialysis technician certification number.
(2) Title of the program.
(3) The date and hours attended.
(4) The name, address and telephone number of the organization or individual providing the training.
(5) The name, professional title and signature of the Director of Staff Development or Instructor.
(6) The provider identification number issued by the Department.
(7) The following statement: "This record shall be retained by the certified hemodialysis technician for a period of 4 years starting from the date of enrollment.
(b)The orientation program in clinic or unit and the certification training program shall not be claimed by the hemodialysis technician as in-service or continuing education credit.

(c) Credit shall not be claimed for partial completion of in-service or continuing education by the certified hemodialysis technician.

(d) Each participating facility, agency, or public educational institution shall retain in-service or continuing education class records. The records shall include the name and title of presenter, date of presentation, title of subject presented, description of content and the signatures of those attending. The records shall be

retained for a period of four (4) years from the date each class starts, and shall be kept available for Department review.

Article 5. Adverse Actions and Corrective Remedies

75693. Disciplinary Actions and Appeals.

(a) The Department shall take disciplinary action against certified hemodialysis technician in accordance with the specifications in section 1247.66 of the Business and Professions Code.
(b) The Department may deny, suspend or revoke the certification of a hemodialysis technician if it finds that the individual is not in compliance with the provisions of section 1247.66 the Business and Professions Code or any regulations adopted by the Department to administer this article.
(c) Proceedings to deny, suspend, or revoke a certification under this article shall be conducted with Section 100117 of the Health and Safety Code.
(d) At least twenty (20) business days prior to the effective date of the action, the Department shall mail the certified hemodialysis technician written notice of the proposed action. The Department shall send this notice by certified mail to the most recent address on record and shall indicate the reasons for action, and shall include a copy of the charges and material upon which the action is based and an explanation of the right to respond verbally or in writing to a Department representative at an informal hearing. Persons convicted in a court of law are not eligible for the informal hearing process. The informal hearing shall be held at the location designated by the Department. The hemodialysis technician must submit a request for an informal hearing within fifteen (15) business days of receipt of the notice of the effective date of an action to suspend or revoke his or her certificate. The Department shall conduct the informal within five (5) business days of receipt of a request for a hearing.
(e) Any certified hemodialysis technician may forego the informal hearing process and proceed directly to a formal administrative hearing by writing to the Department's Hemodialysis Technician Certification section within twenty (20) calendar days of receipt of the Department's notice of adverse action.

(f) The Department must issue a written decision to the individual by certified mail within five (5) business days after close of the informal hearing. The decision must notify the individual of his or her right to an appeal pursuant to chapter 5 (commencing with section 11500) of part 1 of division 3 of title 2 of the Government Code if the individuals dissatisfied with the decision. The Aide and Tech Certification Section at the address provided in section 75673 within twenty (20) business days of the decision.

FORUM OF END STAGE RENAL DISEASE NETWORKS

July 10, 2000

Senator Charles E. Grassley
Chairman
Senate Special Committee on Aging
G31 Dirksen Senate Office Building
Washington, DC 20510

Dear Senator Grassley:

The Forum of ESRD Networks is pleased to provide the following responses to the questions you posed in your June 27, 2000 letter:

1.) How are the Networks addressing concerns that patient and dialysis facility staff are reluctant to complain about poor care for fear of retaliation or losing their jobs? Most, if not all, Networks allow a patient who has submitted a grievance to remain anonymous (to the facility and to other involved agencies, if any) as long as possible and to identify the patient with the grievance only when authorized by him/her to do so. Many Networks have a statement of Patients' Rights and Responsibilities that is mailed to every new patient which outlines the grievance procedure and which specifies that the patient has a right to confidentiality when filing a grievance with the Network. Patient names are never included when a grievance is reported to HCFA or a state survey agency. Many patient grievances are really comfort and/or communication issues that do not violate standards of care or pose a threat to the patient's health. In such cases, many Networks will attempt, with the patient's consent regarding identification, to arbitrate the dispute to reach a resolution that is satisfactory to the patient. Network interventions in response to a grievance may vary from education of facility staff to a site visit with requirements for a corrective action plan. In the latter cases, Networks will follow-up to assure that the corrective action plan has been implemented by the facility and will reinvestigate if additional concerns are noted. Networks are process and systems focused, so their emphasis is on improving the processes and the culture of the facility, not only to resolve the stated grievance and satisfy the grievant, but also to improve the care for all patients at the facility. The Networks are sensitive to the issue of fear of retaliation, and are prepared to investigate any patient allegations of retaliation or threat of retaliation. However, such allegations are very rare.

Employee fear of retaliation for "whistle blowing" to a Network regarding substandard patient care practices is a concern, but is not an issue which the Networks have the authority to investigate or apply sanctions. The Forum response to the OIG report recommended that this issue be addressed with a clearly defined system for responding to such threats.

2.) How do Networks work with state survey agencies to ensure that facilities are providing quality care to their patients?

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The collaboration between the Networks and the state survey agencies was a focus of both the GAO and OIG reports and offers considerable opportunities for improvement. There is substantial variation among the fifty state survey agencies in how they collaborate with their respective ESRD Network. Since there is no national directive on how these entities should work together, the relationships vary from a formal interactive relationship (as the OIG report described in Texas) to no relationship at all. Surveyor turnover can be a significant barrier to ongoing cooperation. Some Networks assist in providing ESRD training to surveyors. A complaint or grievance to a Network about a facility that involves a potential violation of the conditions of participation is referred to the respective state survey agency. In such cases, Network staff may accompany surveyors on a site visit to the involved facility if Network resource limitations allow. More often, technical assistance to the state surveyors is provided by telephone. Many Networks provide their educational materials to state surveyors and invite state surveyors to attend their educational conferences (usually at reduced cost). Profile reports provided to facilities by the Networks are not released to state survey agencies because this would undermine the sanction-free quality improvement Network-facility paradigm, and because release of these data to the state survey agencies would place the data in the public domain. State survey agencies are generally aware of the kinds of profile reports that the Networks provide to facilities and the agencies can request these reports from the facilities themselves.

HCFA has recently drafted a policy memorandum that would strengthen the sharing of information between Networks and state survey agencies. In their current contracts, the Networks are required to share information with state survey agencies regarding noncompliant and/or uncooperative providers, provide technical assistance to state surveyors in the investigation of quality of care issues, and share information necessary for the state survey agencies to carry out their legislative or regulatory responsibilities. Although state survey agencies are obligated to share information and support Networks in their oversight responsibilities for ESRD facilities, the nature and extent of this information sharing and support was not specified. HCFA has requested that state survey agencies send copies of Statements of Deficiencies (HCFA form 2567) to Networks following facility surveys and that in occurrences that immediately impact patients' welfare the state survey agencies should notify the Network in advance of sending the form 2567. This will allow the Network to collaborate, as resources allow, with the state survey agency and the affected facility in developing process improvements and providing ongoing monitoring of progress.

3.) GAO has told us that facilities with violations avoid termination with simply a plan of action to address their deficiencies. Does the Forum or the individual Networks do anything to follow up with these facilities?
In the past, since the state survey agencies were not required to share the Statement of Deficiency reports with the Networks, such information exchange was quite variable, and few Networks were informed of facility deficiencies. In cases where the Networks are informed of facility deficiencies, which should become routine under the proposed HCFA policy memorandum, Network interventions are limited to quality of care issues (as opposed to governance and documentation issues over which state surveyors also have authority). Such interventions would be process and systems oriented (quality improvement) as opposed to a band-aid approach merely to correct a deficiency (quality assurance). It is ultimately the responsibility of the state survey agencies to follow-up on deficiencies and to determine the effectiveness of the corrective action plan because only the state survey agencies and not the Networks can impose sanctions if the facility's response is inadequate.

The Forum appreciates the opportunity to assist your committee with its investigation of the quality of care provided by Medicare's End Stage Renal Disease Program. The Forum and ESRD Networks are committed to promoting the process improvements at the facility and system level that will lead to an improvement in the quality and quantity of life for Medicare ESRD beneficiaries. The Forum applauds the committee's work in this investigation, and we hope it will result in greater funding for the infrastructure to provide quality oversight not just to protect patients, but also to make their lives better and longer.

Sincerely yours,

Jay Wish, MD

Jay Wish, MD, President

FORUM OF END STAGE RENAL DISEASE NETWORKS

July 24, 2000

Cecil Swamidoss
Senate Special Committee on Aging
G31 Dirksen Senate Office Building
Washington, DC 20510

Dear Mr. Swamidoss:

As you might recall, during the questioning following my testimony on June 26, I mentioned that my ESRD Network (Network 9/10) had done an analysis of the patient outcomes in three dialysis chains in the Chicago area. One chain had outcomes that were comparable to the Network average, one had outcomes that were better than the Network average, and one had outcomes that were worse than the Network average. Network 9/10 targeted the poor performing chain for an intervention activity that included education of the Medical Directors and administrative leadership regarding quality improvement tools and practice guidelines for adequacy of dialysis and treatment of anemia. This was followed by an improvement in the outcomes in the targeted chain which demonstrated decreased variability and approached the Network average. Senator Wyden requested a report of these data, which I am forwarding to you in the attachment to this e-mail. I wish to acknowledge the effort by the staff of Network 9/10 in preparing this report in what I hope was a timely manner. I trust you will distribute the report to Senator Wyden and the other members of the Special Committee on Aging. If you or anyone on the Committee has any questions regarding this report, please do not hesitate to contact me by return e-mail. Thank you.

Sincerely,

Jay Wish, MD

Jay Wish, MD
President
Forum of ESRD Networks

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THE RENAL NETWORK, INC.

PATIENT OUTCOME IMPROVEMENTS SHOWN IN DIALYSIS CORPORATE CHAIN FACILITIES IN END-STAGE RENAL DISEASE NETWORKS 9 AND 10

BACKGROUND

The Renal Network, Inc. is the contractor for End-Stage Renal Disease (ESRD) Networks 9 and 10. The Network contract with HCFA is defined by the statement of work, which specifies activities in quality improvement, data collection, analysis, and community outreach for the states of Illinois, Indiana, Kentucky and Ohio.

The Renal Network, Inc. is governed by a Board of Trustees (BOT) and has three standing committees: a Network Coordinating Council (NCC) that consists of one member from each Medicare-approved ESRD, a Medical Review Board (MRB) and a Patient Leadership Committee (PLC). Memberships on the Board of Trustees and all standing committees include renal professionals, dialysis patients and public members.

The Renal Network, Inc. collects dialysis patient information from Medicare-approved ESRD providers. Patient information is aggregated into various data profiles and displayed with comparisons to geographical locations, i.e. dialysis facility, health service areas (HSA), state, network region and corporation. In the 1980s, states were divided into health service areas, a convention that accounted for numbers of ESRD patients and utilization of services in geographical areas. The ESRD Networks and local state health departments used the HSA information for Certificate of Need (CON) applications. The Renal Network, Inc. analyses these data profiles and targets providers for quality improvement and community outreach.

Quality improvement activities on dialysis adequacy and anemia management are under the direction of the Medical Review Board. The MRB reviews adequacy and anemia data several times each year. In 1996, the Network collected urea reduction ratio (URR) and hematocrit values on all ESRD patients in the Network area during the fourth quarter of the year. This data established a baseline from which comparisons could be made and the MRB agreed to collect all clinical performance measures data on all ESRD patients in the Network 9/10 area during the fourth quarter of every year. In 1997, the MRB provided facility feedback reports to each dialysis facility and provided regional educational workshops targeting dialysis providers in each state. In 1998, the MRB targeted low-performing health service areas and began to provide physician-specific feedback reports to renal physicians. [1,2,3]

In January 1999, the MRB further analyzed the data by corporate chain in a large metropolitan area based on the results of a health services area analysis. The data revealed a statistical difference in the outcomes among chains and the MRB designed a targeted corporate-wide intervention with the low-performing chain (Chain 3). The intervention included meetings with chain physicians, education on renal clinical practice guidelines and Network, state, corporate chain, and facility data comparison.

The other corporations reviewed in this analysis (Chains 1 and 2) received routine data feedback reports and were offered regional and network educational workshop opportunities, however, no targeted Medical Review Board intervention was conducted.

METHODS

1. Subjects and Facilities

Facility samples consisted of three corporate chain chronic hemodialysis facilities in a large metropolitan health service area. All patients on chronic hemodialysis in October, November and December 1997-1999 were included.

2. Data Collection

As part of a 1997, 1998 and 1999 quality improvement activity of Networks 9 and 10, all facilities reported the first monthly hematocrit and measured pre/post blood urea nitrogen (BUN) for October, November, and December for each patient. Pre/post BUN measurements were used to calculate a urea reduction ratio: ((pre BUN-post BUN)/ pre BUN) x 100.

Monthly individual patient measurements were averaged and the average value was used for the quality indicator criteria.

3. Statistical Analysis

Analysis was done comparing three corporate chains. Two quality indicators were used: the percent of patients meeting an average urea reduction ratio (URR) equal or greater than 65% and the percent of patients meeting an average hematocrit equal or greater than 31 volume percent (vol%). Ninety-five percent confidence intervals were calculated for each facility and the facility's upper confidence interval value was compared to the Network rate.

RESULTS

Thirty-two chronic hemodialysis facilities in the three corporate chain facilities reported URR and hematocrit data for approximately 15,000 patients (Tables 1 and 2). Four corporate facilities are included in the 4th quarter 1997 and 1998 sample but did not provide patients samples for the 4th quarter 1999 period.

1. Hemodialysis Adequacy: URR Results

In Networks 9 and 10 the percent of patients with an average URR equal or greater than 65% increased in each year, 1997 through 1999 and were calculated as 71%, 76% and 79%, respectively.

Fourth quarter Chain 1 facility URR rates ranged from 54%-85% in 1997, 63%-85% in 1998, and 69-92% in 1999. The rate range variation between Chain 1 facilities reduced from 31% to 23%. Eighteen percent of Chain 1 facilities (2 out of 11) had statistically different (lower) rates from the Network rate in the fourth quarter 1997. Nine percent of Chain 1 facilities (1 out of 11) had statistically different rates from the network rate in the fourth quarter 1998 and no facilities were statistically different from the network rate in the fourth quarter 1999 (Figure 1).

Fourth quarter Chain 2 facility URR rates ranged from 62%-98% in 1997, 69%-88% in 1998, and 67-95% in 1999. The range variation between Chain 2 facilities reduced from 36% to 28%. No Chain 2 facilities had rates statistically different (lower) from the network rate in the fourth quarter 1997. Seven percent of Chain 2 facilities (1 out of 14) had statistically different rates from the Network rate in the fourth quarter 1998 and 21% (3 out of 14 facilities) were statistically different from the Network rate in the fourth quarter 1999 (Figure 2).

Fourth quarter Chain 3 facility URR rates ranged from 32%-79% in 1997, 48%-86% in 1998, and 57-93% in 1999. The range variation between Chain 2 facilities reduced from 47% to 36%. Forty-seven percent of Chain 3 facilities (8 out of 17) had statistically different (lower) rates from the Network rate in the fourth quarter 1997. Fifty-nine percent of Chain 3 facilities (10 out of 17) had statistically different rates from the Network rate in the fourth quarter 1998 and 41% of its facilities (7 out of 17) had statistically different rates from the Network rate in the fourth quarter 1999 (Figure 3).

The comparison of corporate chain data shows overall increases in the percent of patients meeting the URR criteria. Facility rate comparisons show statistical increases between fourth quarter 1997 and 1999 in six Chain 3 facilities.

2. Anemia Management: Hematocrit Results

In Networks 9 and 10 the percent of patients with an average hematocrit (Hct) equal or greater than 31vol% increased in each year from 1997 through 1999 and were calculated at 72%, 79% and 85%, respectively.

Fourth quarter Chain 1 facility Hct rates ranged from 44%-87% in 1997, 51%-93% in 1998, and 69-95% in 1999. The range variation between Chain 1 facilities reduced from 43% to 26%. Forty-five percent of Chain 1 facilities (5 out of 11) had statistically different (lower) rates from the network rate in the fourth quarter 1997. Twenty-seven percent of Chain 1 facilities (3 out of 11) had statistically different rates from the Network rate in the fourth quarter 1998 and 50% of its facilities (5 out of 10) were statistically different from the Network rate in the fourth quarter 1999 (Figure 4).

Fourth quarter Chain 2 facility Hct rates ranged from 72%-92% in 1997, 72%-91% in 1998, and 77-93% in 1999. The range variation between Chain 2 facilities reduced from 20% to 16%. No Chain 2 facilities had statistically different rates from the Network rate in the fourth quarter 1997 and 1998. Twenty-seven percent of Chain 2 facilities (3 out of 11) had statistically different rates from the Network rate in the fourth quarter 1999 (Figure 5).

Fourth quarter Chain 3 facility Hct rates ranged from 34%-76% in 1997, 53%-85% in 1998, and 68-97% in 1999. The range variation between Chain 3 facilities reduced from 42% to 29%. Fifty-nine percent of Chain 3 facilities (10 out of 17) had statistically different (lower) rates from the Network rate in the fourth quarter 1997. Fifty-nine percent of Chain 3 facilities (10 out of 17) had statistically different rates from Network rate in the fourth quarter 1998 and 35% of its facilities (6 out of 17) were statistically different rates from the Network rate in the fourth quarter 1999 (Figure 6).

The comparison of corporate chain data shows overall increases in the percent of patients meeting the hematocrit criteria. Facility rate comparisons show statistical increases between 4th quarter 1997 and 1999 in six Chain 3 facilities (Figures 4, 5 and 6).

Variation between facility rates in each of the chains decreased from 1997 to 1999. For URR, Chain 3 had the largest decrease, 36% versus 11% in Chain 2 and 8% in Chain 1. For hematocrit, Chain 1 had the largest decrease, 17% versus 13% in Chain 3 and 4% in Chain 2.

DISCUSSION

The baseline data demonstrated significant variation among providers with regards to clinical outcomes, which is a commonly observed function of process variation and case-mix. Unexpected, however, was the stratification among dialysis chains with regards to clinical outcomes. This presented both a challenge and an opportunity for The Renal Network, Inc. to develop an intervention strategy that would exploit the single corporate affiliation of a number of underperforming facilities (Chain 3) with a program customized to their organization and culture, while continuing to promote the application of quality improvement principles at all facilities. The follow-up data reflect the success of that strategy to accelerate the rate of outcomes improvement in Chain 3 such that the outcomes of the chain are approaching the Network average, which is also improving. The lower than average baseline performance by a majority of facilities in a single chain is more than a coincidence, and reinforces the link between process and outcome. What changed between 1997 and 1999 in Chain 3 to account for the improvement in outcomes was not the case-mix nor technological advancements. By providing the tools for process improvement (facility-specific profiles, care paths and clinical algorithms, and an incentive for a culture change at the corporate level), The Renal Network, Inc. had a major impact on the outcomes of over 1500 patients. The results of this project confirm the principles of continuous quality improvement (CQI):

- CQI is directed at improving outcomes as well as decreasing variation.

- The availability of facility specific data is essential for targeting quality improvement interventions. Nephrology peer review strongly influences process change. Combining data with knowledgeable peer review, patient outcomes improve.

- The bar moves for all providers. Network target hematocrit rates increased 13% between fourth quarter 1997 and 1999. Chain 3 facilities had to increase at a faster rate to meet the comparison criteria.

REFERENCES

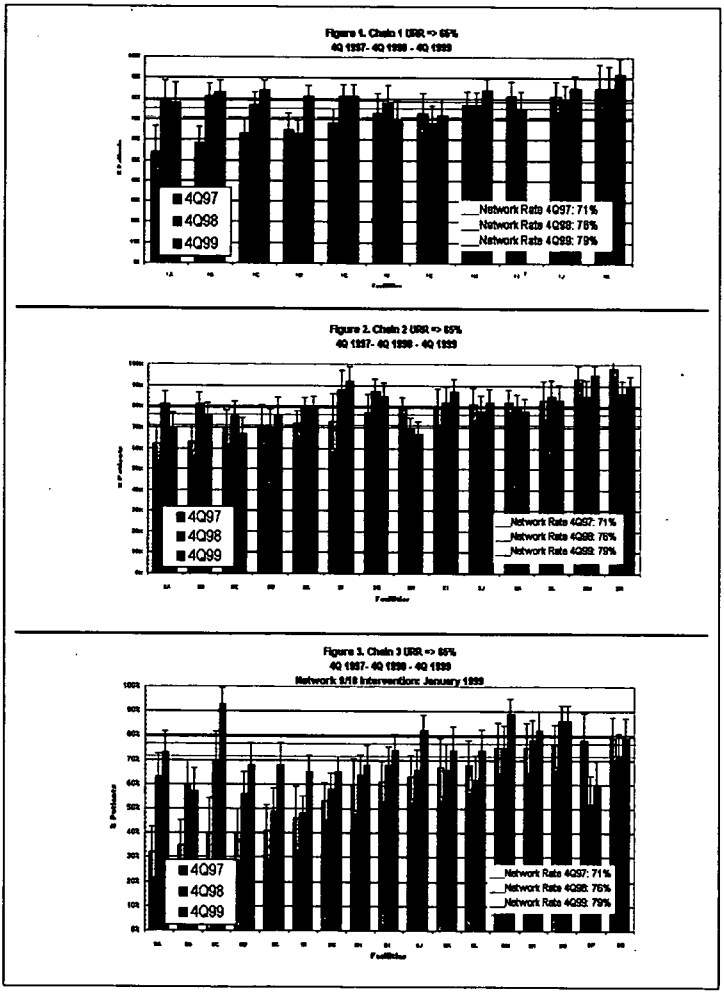
1. 1997 Annual Statistical Report for End-Stage Renal Disease Networks 9&10, The Renal Network, Inc., Indianapolis, IN., 1998.
2. 1998 Annual Statistical Report for End-Stage Renal Disease Networks 9&10, The Renal Network, Inc., Indianapolis, IN., 1999.
3. 1999 Annual Statistical Report for End-Stage Renal Disease Networks 9&10, The Renal Network, Inc., Indianapolis, IN., 2000.

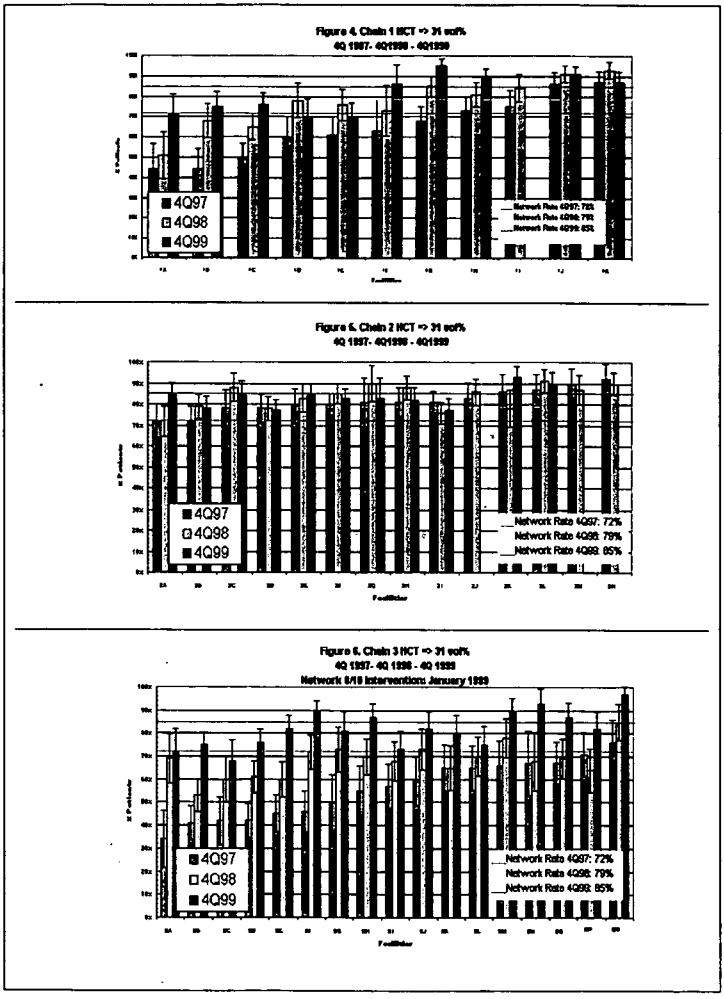
Table 1. Number of facilities and patients in corporate chain and Network 9 and 10 samples for URR measurements for fourth quarter 1997, 1998, and 1999.

Year	Chain 1 # fac/ #pats	Chain 2 # fac/ #pats	Chain 3 # fac/ #pats	Network 9 and 10 # fac/ #pats
1997	11/1238	14/1518	17/1429	311/22312
1998	11/1436	14/1919	17/1877	326/25701
1999	10/1359	14/2085	17/1964	348/27337

Table 2. Number of facilities and patients in corporate chain and Network 9 and 10 samples for Hematocrit measurements for fourth quarter 1997, 1998, and 1999.

Year	Chain 1 # fac/ #pats	Chain 2 # fac/ #pats	Chain 3 # fac/ #pats	Network 9 and 10 # fac/ #pats
1997	11/1263	14/1565	17/1646	311/22923
1998	11/1482	14/1935	17/1917	326/25618
1999	10/1372	11/1704	17/2009	348/26905


4Q97
4Q98
4Q99
Network Rate 4Q97: 71%
Network Rate 4Q98: 76%
Network Rate 4Q99: 79%


4Q97
4Q98
4Q99
Network Rate 4Q97: 72%
Network Rate 4Q98: 79%
Network Rate 4Q99: 85%
4Q97
4Q98
4Q99
Network Rate 4Q97: 72%
Network Rate 4Q98: 79%
Network Rate 4Q99: 85%
4Q97
4Q98
4Q99
Network Rate 4Q97: 72%
Network Rate 4Q98: 79%
Network Rate 4Q99: 85%

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administrati

7500 SECURITY BOULEVARI
BALTIMORE MD 21244-1850

The Honorable Charles E. Grassley
United States Senate
Washington, D.C. 20510-6400

JUL 25 2000

Dear Senator Grassley:

This is in response to your June 27, 2000 request for answers to questions that you were unable to ask during the June 26, 2000 hearing on the End Stage Renal Disease Program. Below please find my answers to your specific questions.

1Q. **HCFA's May 2000 letter to the Committee discusses how it is "working aggressively with (poor performing) facilities to improve their care." How do you identify "poor performing facilities," and how are you improving them?**

1A. In our survey and certification program, we have recognized the need for clear, defensible data to assist the States in their decision-making about identifying facilities for inspection. Therefore, we have used a data model to describe each dialysis facility in the country. We combine the data elements into a composite score, which reflects standardized mortality rates, adequacy of dialysis, and adequacy of anemia management. Our empirical model suggests that facilities with higher mortality, inadequate dialysis, and inadequate anemia management are more likely to have deficiencies than facilities with low mortality, good dialysis, and good anemia management. We currently are pilot testing the use of this composite score in our survey process to see if it helps us to adequately identify poor performers. At the end of this year, based on our evaluation of the pilot project, we expect to use the data nationally to help us identify facilities that are more likely than others to have deficiencies, and therefore ought to be inspected. After selecting facilities to inspect, State surveyors will conduct surveys to determine if a facility is in compliance with Medicare standards.

Meanwhile, we have been working to improve these poor performing facilities by providing them with detailed clinical data gathered from a national sample of dialysis patients. Using this national sampling approach, we have documented improvement every year in the number of dialysis patients achieving the benchmarks for these clinical indicators since 1994. In addition, the ESRD Networks investigate any complaints made against ESRD facilities. If they find complaints are valid, the Network will work with the facility until conditions are improved.

2Q. **The HHS-Inspector General tells us that the majority of ESRD patients are unlikely to complain much about their care. Clearly, they are a very vulnerable population that relies everyday on the dialysis care they receive. What guidelines does HCFA have to provide a confidential setting where patients can raise concerns and have those concerns satisfactorily addressed?**

2A. We have guidelines in place at a number of levels to protect patient confidentiality and address patient concerns.

In the survey and certification process, the States follow the guidance of a State Operations Manual (SOM). This manual describes each step in the processing of a complaint from receipt to closeout, and indicates it is not necessary to obtain the complainant's name during collection of information about a potential problem if the complainant requests anonymity. Additionally, when visiting a facility to investigate a complaint, the State Agency does not divulge the complainant's identity. The State Agency is responsible for notifying the complainant that the complaint is being investigated, and also for taking "appropriate precautions to protect the complainant's anonymity and privacy."

Additionally, ESRD Networks must follow our national policy as described in the Draft ESRD Network Organizations Manual. Each Network is responsible for having a procedure to receive, evaluate, and resolve grievances involving patient care. Recognizing the vulnerability of ESRD patients, Networks are able to receive and act on anonymous complaints as well as verbal complaints. Currently, we have a workgroup completing a revised Network grievance process that is designed to be responsive to beneficiaries (in time and results) and user friendly for Networks and patients. In addition, the Network contract calls for the Networks to assume a proactive role in the prevention, facilitation, and resolution of difficult patient/facility situations, including the implementation of educational programs that will assist facility staff in handling difficult situations.

3Q. **Why are staff training guidelines generally voluntary? As Mr. Smith on our first panel stated, Arizona has stricter requirements for manicurists than for dialysis technicians. What is HCFA doing to address this problem?**

3A. Medicare has a consistent policy of respecting State control and oversight of health professionals by deferring to State licensing laws to regulate health professional practice. The Congress left this licensure function to States, and Medicare recognizes the scope of practice for which States license health care professionals.

We are aware that several States (e.g., California, Oregon, Texas, Ohio, and Virginia) have regulations to require licensing, credentialing, and/or certification tests for dialysis technicians. However, State requirements are uneven and applied through a variety of methodologies. For example, some States require examinations prepared by the State Department of Health or certification examinations administered by national organizations such as the Board of Nephrology Examiners Nursing Technology. Other national organizations such as the National Association of Nephrology Technicians/Technologists publish

comprehensive manuals and study guides used by many dialysis facilities to train their technicians.

There are federal requirements in the current ESRD conditions of coverage mandating that:

- all facility staff be qualified to perform assigned duties and responsibilities;
- all applicable federal, State and local professional requirements must be met; and,
- trainees must work under direct supervision of qualified professionals.

In addition, the ESRD conditions of coverage specify that all personnel in the facility must participate (not voluntarily participate) in educational programs (i.e., orientation, in-service, and infection control training). The federal regulations further specify that the medical director must ensure that nurses and technicians have adequate training in dialysis techniques. Additionally, there are very prescriptive curriculum requirements for reuse technicians, developed by the Association for the Advancement of Medical Instrumentation, which are incorporated by reference into the ESRD conditions of coverage.

We are drafting new, comprehensive conditions of coverage for renal dialysis facilities. In this process we will review and evaluate existing federal personnel requirements relative to all dialysis facility staff, including dialysis technicians. We will evaluate current State requirements, beneficiary complaints, patients' health and safety needs, current clinical practices by the dialysis industry, and the potential costs and benefits resulting from new federal requirements for dialysis technicians. Dialysis technician competency is an important issue that we will consider carefully as we develop the new conditions of coverage.

4Q. Both the GAO and IG reports criticize HCFA's oversight of ESRD facilities. How do you respond to the criticism?

4A. Our efforts to improve performance of the dialysis facilities have had measurable success. For example, between 1994 and 1998 the percentage of ESRD patients with adequate hematocrit (red blood cell) levels increased from 55 to 83 percent. Additionally, in the same time period, the percentage of patients receiving adequate dialysis increased from 49 to 74 percent. We also know from the U.S. Renal Data System, a joint HCFA and National Institutes of Health project, that the one year mortality rates for dialysis patients decreased from 24.9 deaths per 100 patient years in 1990 to 22.8 in 1997.

These improvements are due in part to the leadership role we assumed, beginning in 1994, to develop clinical indicators that assess the quality of care for dialysis patients. This effort is now known as the Clinical Performance Measures Project.

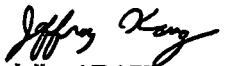
Through the ESRD Networks, we collect clinical indicators on a national sample of dialysis patients in the areas of adequacy of dialysis, anemia management, and serum albumin (a protein in the blood that is an indicator of the patient's overall health). These data are collected, analyzed, and described annually in a detailed report, the *ESRD Clinical Performance Measures Project Annual Report*. This report is distributed to all dialysis providers for their use in identifying opportunities for improvement. Using this national sampling approach, we have documented improvement every year in the number of dialysis patients achieving the benchmarks for these clinical indicators since 1994.

We also have undertaken steps to begin collecting facility-specific data. A provision in the Balanced Budget Act of 1997 required us to measure and report the quality of renal dialysis services; and so in 1998 we directed the development of 16 clinical performance measures that we are collecting from a sample of facilities this year. The 16 clinical measures are similar to those of what was formerly the Core Indicators Project, with the addition of measures for evaluating vascular access (the point of access to the dialysis patient's blood stream). In 1999, this work was merged with the Core Indicators Project to form the ESRD Clinical Performance Measures Project mentioned above. This project is part of a larger ESRD Core Data Set that is under development. Through the ESRD Core Data Set, we are striving to determine and report accurate, meaningful facility-specific performance measures that will allow comparisons across dialysis centers and will ultimately increase facility accountability and patient choice. Facility-specific data profiles have been developed for the use of State Survey Agencies.

Despite our progress in improving the quality of care, there continues to be weak performing dialysis facilities. However, the Networks and States are working aggressively with these dialysis facilities to improve their care. Additionally, the proposed rule on new conditions of coverage for dialysis facilities, which we intend to publish in 2001, will strengthen requirements for these facilities. And the President's FY 2001 budget asked Congress to increase the funding level for surveys of ESRD facilities from $2.2 million to $6.3 million. By increasing the funding level, Congress would enable us to decrease the time between surveys from every six years to every three years and increase the number of surveys from 956 to 1,847 in FY 2001.

I hope you find this information helpful. If you require further information, please let me know.

Sincerely,



Jeffrey L. Kang, MD, MPH
Director
Office of Clinical Standards and Quality

Statement of Rep. Pete Stark (D-CA)
to
The Senate Special Committee on Aging

The Need to Improve Quality in the ESRD Program

Chairman Grassley, I commend you for holding this important hearing. I have had a long interest in the Medicare End Stage Renal (ESRD) Disease Program, and have introduced a number of bills relating to improving the outcomes and the quality of care for patients in the Medicare program. Unfortunately there has been little action on most of these proposals.

The ESRD networks, in association with the renal community are trying to improve quality in dialysis centers, with some success. We know from the U.S. Renal Data System, a joint HCFA-NIH project, that one year mortality rates for dialysis patients decreased from 24.9 deaths per 100 patient years in 1990 to 22.8 in 1997. Using information obtained from the ESRD Clinical Performance Measures (CPM) Project, we also know that between 1993 and 1998, the percentage of ESRD patients with adequate red blood cell (hematocrit) levels increased from 46 to 83 percent while the percentage of patients receiving adequate dialysis increased from 43 to 74 percent. Despite this progress, there continue to be weak performing dialysis facilities, endangering renal patients.

My staff reviewed data from the ESRD CPM project regarding these same dialysis and blood level parameters, recorded over the same time period. They ranked networks in order, by percent of patients achieving the desired standards. These are only preliminary findings and probably do not reach statistical significance but do suggest that some Networks could be doing a better job in assuring that weaker performing dialysis centers improve. There is a stratification of some Networks, (No.10, 13 and 2) into the lowest one-third consistently and another (No. 11) nearly so. Others (No. 14,15,16) are always found in the top

third. This certainly suggests that some networks may reliably be doing their tasks better and some a consistently poor job.

It is not just Networks that may fall into a consistent pattern of poor or medicore quality (while others seem to achieve a tradition of excellence). Earlier this year, I reviewed Network #3's rating of dialysis facilities. There seemed to be a pattern of consistently poor quality among a number of centers. (See attached).

Poor centers are killing people, Mr. Chairman. It should be the duty of a Network to aggressively seek out the worst performing centers in a region and work with them to improve. If there are no extenuating circumstances–an unusually difficult-to-treat patient mix, and the dialysis center does not improve after assistance from the Network, it should be terminated from the program and not permitted to "terminate" patients. Medicare already has the authority to end poor performers. It is time that the threat was made a reality by a sound system of review and CQI.

The Renal Physicians Association's proposals make great sense to me, and I hope that we could enact legislation to provide a system of ESRD CQI and give the Networks more authority to coordinate quality improvements and provide data to the public on quality and outcomes, center by center.

Although I believe we can continue to employ the ESRD Networks for quality oversight, there are obviously opportunities to improve their quality management. HCFA should require that Networks collect facility-specific clinical performance measures, in order to allow Networks (and States) to identify poor facility performance. Outcomes data should be compared between Networks as well as providers, and appropriate results made available to patients. Not only should minimum levels of performance be established and monitored, but improvement above these benchmarks encouraged using continuous quality improvement techniques for <u>both</u> Networks and providers.

While HCFA receives regular information from Networks, it provides little in the way of reference points, evaluation and

comparisons, and only minimal feedback to them. HCFA should hold Networks accountable for how well their facilities carry out their responsibilities by developing a performance-based system for evaluating them and by increasing public disclosure of information about them.

Again, I thank you for holding this hearing and I hope to work with all of you to ensure that all ESRD Medicare beneficiaries across the country receive the best possible care.

COMMITTEE ON WAYS AND MEANS

U.S. HOUSE OF REPRESENTATIVES
WASHINGTON, DC 20515

SUBCOMMITTEE ON HEALTH

March 13, 2000

The Honorable Nancy Ann DeParle
Administrator
Health Care Financing Administration
Washington, DC 20201

Dear Nancy Ann:

The ESRD Networks are supposed to help improve quality in dialysis centers.

One of my staff tracked one Network's data on dialysis centers across a 2.75 year period.

Too many Centers are **consistently** poor. It can be fairly said that people are dying needlessly in some of these Centers.

1. What do we do about this?

2. What do the other Networks look like? Can HCFA give me this data, or would it be helpful to ask the GAO to do it? Please let me know.

Sincerely,

Pete Stark
Member of Congress

ESRD Facility Status Report On Hemodialysis Adequacy

# of Facility	Quality Markers (Facility caseloads above 11%)	(Facility caseloads above 11%)
	URR<=60%	Hemoglobin <10 gm
	(Number of quarters the facility appears out of compliance)	
25	6 out of 11	7 out of 11
27	9 out of 11	10 out of 11
29	7 out of 11	6 out of 11
30	6 out of 11	6 out of 11
39	6 out of 11	6 out of 11
61	9 out of 11	6 out of 11
62	8 out of 11	6 out of 11
64	8 out of 11	4 out of 11
65	10 out of 11	8 out of 11
67	8 out of 11	6 out of 11
70	6 out of 11	6 out of 11
71	8 out of 11	6 out of 11
78	9 out of 11	6 out of 11
80	10 out of 11	6 out of 11
84	5 out of 11	9 out of 11
85	9 out of 11	9 out of 11
94	7 out of 11	5 out of 11
113	6 out of 11	6 out of 11

New Jersey units coded 1-61, Puerto Rico 62-83, Virgin Islands 84-85, and various from 86 to end.

Special Committee on Aging
Hearing on End Stage Renal Disease
Written Statement of Brent Smith
June 26, 2000

June 6, 2000

Lauren Fuller
Senate Special Committee on Aging
G-31 / Dirksen Center Office Building
Washington D.C. 20510

Lauren;

Before I begin this dissertation I must express my gratitude on behalf of the many, many dialysis patients both present and future, to you and your colleagues for undertaking such an arduous task. Investigating an industry long overdue for investigation, especially one that undermines ever effort to do so, must be difficult at best.

Regarding our phone conversation last week and subsequent discussion of and requested assessment of the industry providing dialysis prescription care and fulfillment in Arizona.

Without hesitation, and putting forth no personal malice towards any one person, specific dialysis unit or purporting any personal agenda, I submit to you simply this; the dialysis industry from a patient's point of view, has proven itself worthy of every investigative effort. Substantive accountability is seriously lacking throughout the system of providers, their administrators, staff and support personnel. It is the intention of this statement, and contents there of, to address specific issues of concern in general tone with a supportive incident appendix to follow.

A patient myself since 1973, I have witnessed the gradual decline in competency of those given the responsibility of our care. This trend continues and worsens each year as providing companies focus on bottom line management and not patient care. The origin of this downward spiral, in my opinion, is the deregulation of the industry in the early 1980's. And make no mistake, what once *was* a provider of medical service is *now* an industry. Dialysis became a "for profit" entity at that time.

Quality of care, as attributable to that event, has declined in direct proportion to the rise in profitability, revenues, and the sustained growth of providers. The term "quality of care" is dangerously subjective. For the sake of your investigation, the major discrepancy in definition confronting dialysis today falls stoically between the perception of care being offered by the providers and the actual care being experienced by the patients. All is not as portrayed by the providing companies. (Appendix A)

Absolute clarity requires the quality of care issue be categorized into five major components. Others may see this differently. The first component is: adequacy of the dialysis treatment. The second, though patients by a large majority would rank it first, is: the competency of the patient care technician. The third, following closely is: knowledgeable and disciplined nursing staff. The fourth, though just as important as the first three, is: facility and technology (machines) condition. The fifth and final component: procedural and financial accountability, may apply in part to the previous four components.

Adequacy of treatment
Competency of patient care technicians
Knowledgeable and disciplined nursing staff
Facility and technology (machines) condition
Procedural and Financial accountability

Each elemental component listed encompass a general area of concern for patients. Using the list as a guide I will attempt to simplify (only as I see them) the complex problems now facing the dialysis patient community as a whole. It is my sincere belief this method will demonstrate how intricately dependent the components are.

As you know, I contend that being around dialysis for so many years, on and off, has been a blessing and a curse as well. It is my hope the content and context of the following will explain why.

Adequacy of treatment

No other area of the dialysis circle has been more researched, more discussed, more debated, and now more shamelessly exhibited that this component. NKF-Dialysis Outcome Quality Initiative (DOQI), the National Kidney Foundation's initiative launched in 1997, issued a wide range of new guidelines for dialysis treatments. The 114 results based guidelines were an attempt to lower the unacceptably high death rate of dialysis patients in the United States.

From the National Kidney Foundation's press release: (October 1, 1997)

Quoting Dr. Garabed Eknoyan, president of NKF -

"Patients' survival and well being depend on our ability to convince all parties - the government, the medical profession and the patients themselves - that we all have a role to play in bringing better care to everyone on dialysis."

Dr. Nathan Levin, co-chair -

"Nearly one-fourth of the patients on dialysis in the U.S. die each year. That figure is needlessly high and avoidable. Implentation of these new guidelines should lower the death rate and provide a better quality of life for patients with kidney disease."

End quotes.

I am sure DOQI will help a few patients here and there. Those who have doctors or have had doctors in the past not attending to their care to the degree necessary. And I am also sure that a tremendous amount of time and energy was spent compiling the data and writing the 114 new guidelines. Not one guideline by the way, addresses the qualifications, mandatory training, experience, capabilities of patient care technicians.

In shortened form, DOQI requires a minimum dose of dialysis and a requirement that the results of that prescripted dose be measured at least once a month. The document mandates nothing, demands little, and only recommends minimum standards. Which also, by doing so, sets artificial maximum standards as well.

For anemia, something that most patients endure, the guidelines call for proper and early evaluation. A hematocrit (the amount of red blood cells in the blood) of 33 to 36% is recommended as the target range. The recommendations also include a strategy implementation that provides sufficient amounts of iron and epogen to achieve the target.

Other recommendations include access placement and care.

One more quote from Dr. Levin -

"The guidelines give patients important specific information to actively participate in decisions regarding their own health care. No longer will they have to simply receive treatment — with guidelines as support, they can insist on better quality care."

Most patients, to their disadvantage, show little interest, if any, in learning about their disease. Seminars and classes are offered to patients, and have been, through various organizations. Most at little if any cost. However, a large portion of the dialysis population depend on others for transportation to and from treatments. It is often difficult if not impossible to find rides to any of the classes. Other members of the community are employed full time and can not attend classes offered during the day. Evening classes conflict their treatments.

DOQI

The DOQI initiative was completely funded by Amgen, the sole manufacturer and supplier of Epogen to the dialysis industry and the largest biotechnology company in the world. The struggle with hematocrit and anemia has plagued the patient community for decades.

The target guidelines used to be 30 -33%. Educated patients have been complaining for years about the lower target ranges, formulation and procedural computations. (How it was decided if your dose increased or stopped all together) We were told repeatedly that the target levels were recommended by Amgen, the manufacturer, not to be exceeded because of the clotting risk.

The old method required the dose be completely stopped once a patient attained a hematocrit of 33%. It was statistically impossible for a patient to maintain an average measure within the target range. The new target range 33 - 36%, as I understand it, is a rolling average with a patients dose reduced by percentages, not stopped completely when the patient surpasses a hematocrit above 36%. This is not new information. The higher hematocrit was always possible. Imagine if you will, all the patients through the years who may have felt better. (Appendix B)

As a patient, I am grateful for this guideline. I have been challenging the old one for years. It is way overdue. However, one concern I do have is this; it seems the only guideline to truly increase the cost of a dialysis run to HCFA is the increase of epogen expense in order to meet the recommended guidelines. I believe this will coincidentally (?) increase the sales levels and revenues of Amgen, the sole manufacturer/supplier of epogen. They also financially sponsored DOQI entirely.

I have one question regarding the DOQI research as a whole. How does an industry spend millions of dollars, conduct countless hours of research, bring all the "experts" of the industry together and conclude that the minimum acceptable results of a dialysis prescripted run are exactly, more or less, what they have been all along? The recommended results purported by DOQI are the same targets any good doctor would have been expecting to see in his patient anyway. It seems the industry is now recommending guidelines they SHOULD have been attaining in the first place.

The attempt will accomplish little if anything at the patient care level. Achieving the target results recommended can be easily accomplished through normal, medically adequate, and carefully monitored dialysis treatments in conjucntion with the patient's own diligent adherence to dietary and fluid restrictions.

The press release seems to be in conflict with regards to the reuse (reprocessing of dializers) issue. They recommend continued use of the practice yet, at a later point, refer to the higher mortality rate in facilities where reuse of dializers is common procedure. Does this imply that DOQI recommends the acceptance of the higher mortality rate among patients of reuse facilities? Could financial constraints and priority dictate and contribute too the conflict?

Again, DOQI provides for and sets little if any guideline or recommendation for the training, minimum required education, and prerequisite medical experience of patient care technicians.

Competency of Patient Care Technicians

This component is the most controversial. Descriptions and requirements of just what is or what makes a tech "competent" fall to subjective perception. It is here in this issue the greatest discrepancy is found. As a patient, it is difficult to script the tremendous differences in what a dialysis technician was before deregulation and what they have become in the eighteen or so years after.

In the year I started dialysis, 1973, the dialysis technicians were, by large margin, nurses. Not the average nurse, but graduates in the top percentages of their class. We had bio-medics returning from Viet Nam. Even a few interns would participate for a year or so to get the experience. Every technician had a college degree. Every technician had previous medical exposure. It was an elite, enviable profession. Today, a high school diploma is the minimum required education level. If that. Absolutely NO previous medical experience is required.

The new patient care technicians are put through a general, superficial eight week training period and assigned to the floor with supervision. The present process is absolutely unsatisfactory and exposes the patient to critically dangerous situations.

The lack of training and prerequisite medical experience are not the only concerns involved. More importantly to some, the labor pool from which new technicians are drawn is not dissimilar to that which supply employees to fast food chains, grocery stores and large discount stores. The compensation packages and benefits offered the new personnel allows for little else.

I have witnessed countless examples of poorly trained patient care technicians, whose background fits this description, demonstrating a complete inability to learn or retain information. By making the same procedural mistake or miscalculation repeatedly, the conclusions are accurate and clear. There are exceptions, but those technicians tend to be those who have worked in the industry for well over fifteen to twenty years.

To summarize: in place of the nurses, college graduates, interns, and bio-medics, we have inexperienced high school graduates with no medical exposure. A training program which offers little resemblance to actual real world substance and degree, leaves today's patient care technicians lacking in every critical criteria required to provide for safe, accurate, antiseptic, procedurally guided dialysis treatments. The patients are truly at risk.

The dialysis procedure, the initiation of and removal from the machine, the inherent dangerous exposures, the stringent antiseptic requirements demanded by the

procedure itself, have NOT changed. Only the quality and ability of those administering the care have.

In Nephrology News & Views, December 1999 issue, an article titled Seeing Dialysis Technicians as Nephrology Practitioners in the 21st Century, Russell Dimmitt, CHT and Belinda Bethea, CHT write;

The future of NANT (National Association of Nephrology Technicians/ Technologists) is promoting throughout all facilities and boundries in this coming year (2000) the importance of providing quality service to the ESRD patients through standardized training. What are the benefits to the renal care staff? Technicians will:

- ***Come with the tools of education and theory.***
- ***Know patient signs and symptoms of high and low blood pressure changes during treatment.***
- ***Know the why's and how's of a patient having a pyrogenic reaction.***
- ***Know the dialysis machine***
- ***Foster positive attitudes***

Technicians should understand all aspects of chronic renal failure and it's treatment, including the patient and machine. Standardized curriculum and certification is crucial in providing increased awareness and knowledge of ESRD patients.

The outgoing president (Mr. Dimmitt) of NANT, and the incoming president (Ms. Bethea) certainly must be aware that this encapsulation and it's content bare little resemblence to the actuality of dialysis care provided in the country. Are we as patients to believe that this organization, which attempts to set the standards for the patient care technician position, is offering (only now) this proclamation of intended care for the New Century? What happened to the past twenty-five years? Are they intimating that the ESRD patient may have received improper, inadequate treatment initiated by poorly trained unqualified staff over the past decades?

If PCT's are to understand all aspects of chronic renal failure and it's treatment, the labor pool of potential applicants, present training, minimum educational requirements, and absence of prerequisite medical experience in sum are at best, impossible to correlate into the above dictated practice. As of this writing, only six states have licensing or mandated certification statutes in place. In my state, Arizona, we license manicurists and NOT patient care technicians.

Quoting Mr. Martin V. Hudson, former Chief of Dialysis Operations at Palo Alto VA Medical Center :

Some believe that 400/600 hours of training is enough for the PCT; that equates to 10 to 12 weeks. At the dialysis facility where I trained and later became

supervisor of a ten- member technical staff, the introductory training to dialysis therapy was six months! Clinical, as well as non-clinical issues were taught in equal amounts. The finished product was a soundly prepared practioner. But time and circumstances have changed, and most definately, in my view, not for the present and future good of our practice. This does not bode well for positive patient outcomes.

Excerpts from article How Can We "Standardize" Technician Training? Nephrology New & Views; November 1999

An exemplary example of training deficiency among patient care technicians is found in the following summary of an experience I endured.

At one point I suffered an extended period of appetite loss, weight loss, and over all lethargy caused predominately by depression. The condition due, in part, to personal and work related issues. Prior to each dialysis treatment, then as now, the patient is assessed and asked directly about his appetite. Responding in similar fashion at each treatment with "poor" and I'm not eating," this dialogue continued for close to four months.

My dialysis prescription calls for a potassium bath of 1. The bath values vary from 1 to 4, measuring the amount of potssium in the bath and the level of possible exchange and removal. The lower the bath level, the lower the potassium outcomes. My potassium bath level remained constant while my ingestion of foods (any food) containing potassium declined.

Monthly lab results showed clear evidence of steady decline in potassium levels for three consecutive months. The fourth week into the fourth month, the potassium level carried in my blood fell to a point below the 3.5 minimum level required to live. During the third hour of a four hour treatment, I suffered cardiac arrest. After seventeen minutes the paramedics were able to revive me successfully. Emergency Room records show a potassium level of 2.9 at arrival and admittance. Discharge Summary records ventricular fibrillatory arrest, secondary to hypokalemia. (low potassium)

The patient care technicians lacked the training to correlate the lack of appetite and weight loss with the low potassium bath. The seriousness of the problem and possible results were never addressed to the staff dietician or any of the charge nurse staff. The event was completely preventable.

Knowledgeable and disciplined nursing staff

The practicing dialysis nurse is bound by two of the most diametrically opposed forces found in todays provider facility. A nurse's desire to provide safe, adequate, and compassionate care to the patients versus the ability to provide such care under the considerable constraints found in most facilities with regards to the demands of bottom line management.

Medical administrators (nurses) and full charge nurses in each facility may or may not have a lengthy employement history and or experience in the dialysis field. The large majority of them do. However many of the floor nurses today are not as experienced. Some seem to lack even the most basic, remedial knowledge and understanding of the dialysis machine, it's processes, related outcomes, and result-driven changes in settings. Only general, generic information is offered with specific subject matter inquiries directed to the patient's primary physician or nephrologist.

It is understood that the patient's doctor writes the presciption for dialysis and that the prescription itself is referred to and used as a guide by the attending nurse. However, a patient may, in some instances, require suttle changes be made on a treatment by treatment basis in an attempt to improve their result and outcome. Nurses should be qualified to answer questions pertaining to potential outcomes and risks associated with the patients request. Many are not.

The nursing staff in any present dialysis facility face arduous, contradictory and complex issues on a dailiy basis. The average facility today is understaffed. Finding and keeping competent employees is difficult and frustrating at best. Personnel are constantly overworked. Twelve hour shifts plus happen frequently. The staff in general (with exception), is undertrained to begin with. Undertrained nurses cannot supplant or support overworked, undertrained patient care technicians.

Sitting in a patients chair for four hours, three times per week, exposes the cognizant patient to the results of the situation described above. First and foremost, patient care technicians, as well as floor nurses NOT PAYING ATTENTION. This is the biggest contention most patients have. All, if not most, patient concerns are rooted in this issue.

High infiltration percentages, miscalculated settings, wrong dializers, machines set up incompletely, heparin not initiated or clamped after initiation, these are just a few incidents that occur repeatedly. The staff usually attributes these lapses in procedure or judgement to human error. Human error occurs by chance. Pure chance dictates a one in five (20%) opportunity of occurance. Anything above that is negligence.

Facility and Technology (machines) & conditions

In the facility where I dialyze most machines are over seven years old. Newer, more efficient machines are always being produced. For relevancy, compare the advances in the personal computer industry the past seven years. This industry refuses to introduce, on a industry wide basis, maximum standards for length of operation, critical component replacement, and hours of operation for the equipment being used. Each unit maintains and replaces equipment as they see fit. With the emphasis so solidly focused on the bottom line, equipment is hardly ever replaced with new, upgraded and technologically advanced models. Most units have one equipment maintenance worker. If he or she continually calibrates all the equipment to her own standards and beliefs, uses his or her own methodology, the equipment usually will be calibrated wrong, exposing patients to undo risk. Most of which they are never told about. All can not or will not be detected.

Facility maintenance and upkeep varies form unit to unit. I am unaware of any mandated requirements for this area. Most units however, seem to forget that they are MEDICAL FACILITIES. Some units I have been in were filthy. Others needed an exterminator. In general I would say most units do attempt to keep the facility looking presentable. But, since they are rarely if ever inspected, what incentive do they have to maintain it as a medical facilty should be maintained?

On any given day, techs routinely mishandle critical components of the patient's care apparatus. Dialyzers are thrown into containers, not placed. I've seen dialyzers dropped hard to floor and hit directly on end, and then placed into cabinets for future use. This despite procedural requirements to the contrary. Gloves, gauze, and other components of the treatment are consistantly exposed to patient care technician's uncleaned hands, sink spilliage, and periferal contaminents. Procedural conditions do exist, they are just not adhered to, or they are adhered to at the whim of the technicians.

Dialysis companies usually have their own code of ethics. But those companies many times handle large number of patients while consistently being understaffed. Therefore any code of ethics is easily ignored. This definition of ethics with reagrd to patient treatments falls into constant compliancy question when the definition of "clean" as required by Medicare for all gloves and medical supplies. Storage of such items is most often out in the open, uncovered. Boxes of gloves placed and stored near sinks, risking contamination from water spillage.

x

Procedural and Financial Accountability

The dialysis providing industry is the only entity that I am aware of where the consumer, the patient, has little if any avenue of financial recourse or control of the disbursement of funds used to pay for the expense of their treatment. The treatment and it's peripheral or direct procedural activities can start, endure, and end at the unit's dispersion with the patient (again the consumer) having absolutely NO CONUMER RIGHTS.

Complaints to the individual unit's management go unanswered at worst. At best, the patient is led to believe the management is concerned and will attend to the issue. Mostly, they pacify the patient, tell them what they want to hear, and turn away from the issue. (Appendix C)

A patient does have the right to forward the complaint or issue to the End Stage Renal Disease Network. The usual path of information flows back to the unit. Even if the complaint is offered, tended anonymously, it is irrelevant. It is not difficult for the unit's management to discover who the complaintant is. Therefor most patients do not offer a complaint. Fear of sure retribution, in even the most subliminal way, prevents them from it.

Full financial accountability to the consumer and their agents, HCFA and Medicare, is nonexistent. A unit, their nurses, technicians, and additional staff can administer the treatment and conduct themselves in any manor, with the patient being the recipient of the activity and results thereof, and yet still get reimbursed for the treatment in full. even if a patient's treatment is cut short by a significant margin due to unit or human error, the treatment is submitted and paid for in full.

The providers often claim that the patient's care would be better if the patient would make the effort to educate themselves about their care and treatment. Yet, even as late as last week, I have encountered another patient who, while actively seeking to educate themselves as the providers suggest, continually get rejected at the attempt. In point of fact and actuallity, the providers would rather keep the patients uneducated and submissive. Controlling the patient population is much easier when their treatments keep them barely alive, and little on site education if any, is offered.

Closing Statement

In closing, I say to you simply this; through the entirety of my dialysis experience I have shunned the classification as and avoided the label of "dialysis patient." And the stereotyping that went with it.Yet today I appear before you, in a public forum, as a dialysis patient. The subject matter being discussed is that important.

Patients can and do lead productive, purposeful lives. It has become however, an ever increasing burden to do so. Monitoring a patient care technician's ability and intention every treatment week after week is a tremendously stressful undertaking. Enduring the limits and inadequacies of the present system compound the tolerable symptoms of treatment into intolerable, unjustifiable, and inexusably frustrating experiences.

My purpose today in appearing before this committee was to present the life of a dialysis patient to you. It is my life and that of many others. We live it every day. You can not possibly understand it unless you are a dialysis patient yourself. I sincerely hope you or a loved one will never experience it, but I do, with dignity and all do respect, implore you to do something about it.

Thank you, on behalf of all dialysis patients,

Brent Smith

Appendix A

As testimony given at this hearing will attest, accurate, truthful, comprehensive records keeping within the industry is relegated to the lowest of priority. Especially those records meant to assess the quality of training, ability of staff, and patient care technician errors in judgement, skill, or attentiveness to detail.

The "Incident Report" record, the report procedurally used to summarize an event or issue with regard to patient care and mistakes given thereof, are rarely if ever written. I was unable to attain a copy of the incident report written at the time of my death experience refrenced in earlier testimony. When approached for a copy of the report the nurse responded that the report " if written" was their property and not part of my accessable medical records.

This type of incident is never documented correctly (without prejudice given the staff member or unit) and upper management receives little if any supporting evidence to the contrary.

No incentives exist within the industry to keep accurate records of mistakes, human errors, faulty equipment incidents, etc. Exactly the opposite incentives do exist. The main one being the threat of litigation. This lack of documentation leads upper management into a false sense of what is real, in turn a false sense of security. When patients do file complaints, most are never recorded, except possibly by a patient's written communication, and most take upper management by complete surprise.

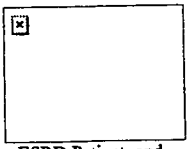
Even the entity ESRD (End Stage Renal Disease) has come under fire. ESRD, established in 1978 to provide an oversight program. Two of their stated goals are to ensure quality of care for dialysis patients through continuous examination and evaluation of practice and to ensure patient satisfaction and good quality of life. (see page three of four — **Can we Count on Federal Center for Patient Safety to Represent Patient Interests.** *

* Taken from Colorado Healthsite:

To Err is Human: Building a Better Health Care System
by the Institute of Medicine, National Academy of Medicine

National Academy Press, Advance Copy, Copyright 1999

As reviewed by Sandra McCray, J.D., Executive Director of Colorado Healthsite, ESRD Patient, and Transplant Recipient



To Err is Human: Building a Better Health Care System

by the Institute of Medicine, National Academy of Medicine
National Academy Press, Advance Copy. Copyright 1999.

Reviewed by Sandra McCray, J.D., Executive Director of Colorado HealthSite, ESRD Patient, and Transplant Recipient

This report by the Institute of Medicine represents a major step forward in the recognition and documentation of medical errors in the U.S. medical system. With surprising candor, the committee gives us frightening anecdotes and alarming statistics.

Evidence of the Problem

Anecdotes that are far too common:

- **The knowledgeable health reporter for the Boston Globe, Betsy Lehman, died from an overdose during chemotherapy. Willie King had the wrong leg amputated. Ben Kolb was eight years old when he died during "minor" surgery due to a drug mix-up.**

Here are the statistics, which are based on data from hospitals:

- **...at least 44,000 Americans die each year as a result of medical errors. ...the number may be as high as 98,000. More people die in a given year as a result of medical errors than from motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516).**

The Tip of the Iceberg

According to the committee:

- These figures offer only a very modest estimate of the magnitude of the problem since hospital patients represent only a small proportion of the total population at risk, which includes all patients undergoing some sort of medical treatment.

The Most Common Errors

The most common categories of medical errors are:

- Diagnostic - including error or delay in diagnosis, failure to employ appropriate tests, use of outmoded tests or therapies, failure to act on results of monitoring or testing.
- Treatment - including error in the performance of an operation, procedure, or test; error in administering the treatment; error in the dose or method of using a drug; avoidable delay in treatment or in responding to an abnormal test; inappropriate (not indicated) care.
- Preventative - failure to provide preventative treatment, inadequate monitoring or follow-up of treatment.

Medication errors are particularly common and are preventable. Inappropriate prescribing is an important factor in accounting for medication errors. Here are some examples of inappropriate prescribing:

- physicians do not routinely screen for potential drug interactions, even when medication history information is readily available,
- pharmacists dispense the wrong drug or wrong strength,
- physicians prescribe inappropriate drugs for nearly a quarter of all older patients,
- hospitals order and/or administer the wrong medications

The Goal of the Report

The Committee describes the purpose of the report as follows:

"...to break the cycle of inaction. The status quo is not acceptable and cannot be tolerated any longer. Despite the cost pressures, liability constraints, resistance to change and other seemingly insurmountable barriers, it is simply not acceptable for patients to be harmed by the same health care system that is supposed to offer healing and comfort."

The overall goal of the authors is patient safety, which the committee defines as freedom from accidental injury resulting from medical treatment.

Recommendations

Given the magnitude of the problem, all of us should look carefully at the recommendations of the committee and ask whether these recommendations are likely to meet the goal set by the committee. The recommendations are built on the following premise:

- The committee asserts that a major force for improving patient safety is the intrinsic motivation of health care providers, shaped by professional ethics, norms and expectations. ... Factors in the external environment include availability of knowledge and tools to import safety, strong and visible professional leadership, legislative and regulatory initiatives.... Factors inside health care organizations include strong leadership for safety, an organizational culture that encourages recognition and learning from errors, and an effective patient safety program.

Here are some of the specific recommendations of the committee:

1. Congress should create a Center for Patient Safety

2. A nationwide mandatory reporting system should be established that provides for the collection of standardized information ... about adverse events that result in death or serious harm.
3. The development of voluntary reporting should be encouraged.
4. Health care organizations should focus greater attention on patient safety.
5. Performance standards and expectations for health professionals should focus greater attention on patient safety.
6. The FDA should increase attention to the safe use of drugs.
7. Health care organizations and the professionals affiliated with them should make improved patient safety a declared and serious aim.

What is Missing Here?

My first thought on reading these recommendations was: isn't patient welfare already the primary objective of health care organizations, professionals, and the FDA? If not, what are the primary goals of these organizations and professionals?

I was also startled to find that the report, which has as its goal patient safety, was virtually devoid of recommendations that include patient education, direct patient representation, regional patient committees with power to review and offer public critiques of the actions of the proposed Center for Health Care Policy and Research. In fact, I could find only one reference to the role of patients in the report.

What recourse will pateints have except expensive litigation in an unreasonably delayed judicial system?

Can we Count on the Federal Center for Patient Safety to Represent Patient Interests?

One way to begin to answer this important question is to look at existing federal health care oversight organizations. One of us has direct personal experience with one such organization - the End-Stage Renal Disease Network (ESRD). This program was established in 1978 to provide an oversight system. The Network initiated a quality assurance program in 1991. Two of the stated goals of the program are to ensure quality of care for dialysis patients through continuous examination and evaluation of practice and to ensure patient satisfaction and good quality of life. Indeed the ESRD Network system states clearly that patients are the ultimate benefactors of the ESRD Network Program . We can evaluate the success or failure of the program in two ways - through patient anecdotes and through scientific studies.

I was for several years a patient member of the Medical Review Board of one of the ESRD networks. During that time, on numerous occasions I voiced my concern about the poor quality of care in some of the dialysis units in the network. I watched the members of the Board fail to take meaningful action even in the face of known substandard practice. I heard physician members of the Board find self-serving reasons why they shouldn't take action. I heard them claim that they couldn't make expensive changes to effect better care because the reimbursement from Medicare was too low. I wondered how these physicians could cope with their own disregard for their patients' health. Finally, having been unable to bring about any change for better quality of care for dialysis patients and unwilling to sit on a Board that did not give its highest priority to patient safety, I resigned in 1999.

Another way to determine the success of the ESRD network program is to look at scientific studies of dialysis in the U.S. since the initiation of the ESRD quality assurance program in 1991.

A brief look at the **CHS Reports on Kidney Dialysis** demonstrates the many serious problems with dialysis morbidity and mortality in the U.S. as compared with other industrialized nations. Here is how two physicians, writing a **review article on Dialysis in the US** in the *The New England Journal of Medicine* recently summed up the problems:

- The yearly mortality among patients being treated with dialysis is nearly 25%,
- Deaths are due mainly to cardiovascular diseases and infections,
- Hypertension is a major risk factor for cardiovascular disease,
- The administration of erythropoietin may worsen blood pressure in about 25% of patients,
- Malnutrition is estimated to be present in about 50% of patients with ESRD and is associated with increased morbidity and mortality,
- **The rates of death among dialysis patients in the US are 25 to 50% higher than those in Japan and Europe.**

This is some of the shocking evidence that the federal ESRD Network program has failed to deliver quality of care for US dialysis patients. The ESRD Network program is physician-run and mandates secrecy of quality of care data. Patients are largely defenseless.

What Patients Need

It is time to give up models such as the ESRD Network program and develop programs that include public release of quality of care data, patient education, direct patient representation, regional patient committees with power to review and offer public critiques of the actions of the proposed Center for Health Care Policy and Research. A serious patient safety program should also require dialysis units and hospitals to release data on their patient safety record in a form that patients can understand.

It would be unthinkable for our government to hide the existence of airplane crashes, along with the reasons for the crash. Yet, that is what is happening now with medical errors. Once this information is released on a continuous basis, patients will have the tools and information they need to protect the quality of their care.

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Appendix B

The following article *The Making and Selling of a Star Drug*, written by Merrill Goozner, appeared in the Chicago Tirbune, Monday, May 24, 1999.

The content of the article describes in detail how a patient's health is being dictated by the corporate lobbiest and driven by corporate profit.

THE MAKING AND SELLING OF A STAR DRUG

By Merrill Goozner, Washington Bureau.
Published: Monday, May 24, 1999
Section: NEWS
Page: 1

The most expensive drug in the federal government's medicine chest is called Epogen--a synthetic version of one of the body's most vital proteins.

Epogen performs what it was designed to do in spectacular fashion, helping dialysis patients fend off anemia and stay more active.

Just as spectacularly, it has propelled its manufacturer, California-based Amgen Inc., to the front ranks of the pharmaceutical industry's biotech wing.

This side effect wasn't a miracle. Instead, Epogen's success is the inevitable by-product of a Medicare system that has failed to control costs and a company that knew how to play the game, whether that meant paying for high-powered lobbying or for influential research.

How Epogen went from its development in a University of Chicago laboratory to a blockbuster drug sheds light on the high-stakes maneuvers of the pharmaceutical industry and on a costly reimbursement system that is underwritten by taxpayers.

The tab for Epogen, with 80 percent being picked up by the government, has more than tripled during the 1990s and now exceeds $800 million, according to government records.

The story of Epogen also is an important one for the nation's policymakers and health-care officials as the government contemplates using Medicare to pay for an array of prescription drugs.

Although there are legitimate concerns about how changes in government policies might create hardships for dialysis patients, the debate over Epogen has effectively been framed by the one participant with the most to gain and a big budget to get its way: Amgen.

The company spends $1.5 million a year to lobby in Washington. And when its Epogen profits were threatened, it turned to some of the capital's heaviest hitters: the former chairman of the Republican National Committee, former Sen. Bob Dole and Sen. Arlen Specter.

Amgen argues that government efforts to curb spending on Epogen were not in the best interest of patients and that taking more of their drug would make dialysis patients healthier. Amgen's long-term agenda could double, and perhaps triple, the use of the drug.

Nearly 40 percent of Amgen's total revenue comes from sales of Epogen to government-funded dialysis clinics, according to the company's Securities and Exchange Commission filings. Last year, Amgen's pretax profit margin was 32 percent of sales, compared with a 19 percent industry average. Amgen is now the biggest biotechnology company in the world.

As Amgen's profits suggest, efforts to control spending on Epogen have failed consistently. The government has the power to rein in Epogen's costs in several ways: For instance, it could unilaterally reduce the price it pays per unit of the drug; it could cap patient dosages, which

have been pushed steadily higher despite ongoing debate over the health and cost benefits; and it could order changes in the way the drug is administered. It has done nothing.

A star drug is born

The protein erythropoietin (EPO), secreted into the blood by the kidneys, was first identified at the University of Chicago by molecular biologist Eugene Goldwasser in 1977 after two decades of government-funded research.

EPO signals the bone marrow to produce red blood cells, which transport oxygen around the body. When the blood's red cell count declines--a routine, daily function--the kidneys automatically secrete EPO to restore the count.

Failing kidneys do not produce enough EPO, leading to anemia. In the early 1980s, the biotech industry realized that whoever developed a synthesized version of EPO would tap into the huge market among the nation's steadily growing dialysis population, which is now 220,000.

Amgen, based in Thousand Oaks, Calif., won the race to the patent house, although it had to go through protracted litigation to win exclusive rights to manufacture its artificial version of EPO, which it called Epogen. The company also has exclusive rights to sell to the dialysis market.

Before the Food and Drug Administration approved Epogen in 1989, some dialysis patients needed blood transfusions to combat severe anemia, but the transfusions have side effects, including mood swings and energy depletion. Epogen was meant to be a substitute for transfusions and is administered intravenously during dialysis

sessions.

Many dialysis patients, 90 percent of whom receive Epogen, are living much better lives because of the drug.

"This product has eliminated the need for 10 percent of blood transfusions in this country," said Amgen's chief Washington lobbyist, Peter Teeley, who was ambassador to Canada under President George Bush. "It reduces hospitalizations."

But exactly how much Epogen is necessary and safe for dialysis patients seeking to maintain a normal lifestyle remains the subject of intense debate.

The standard that helps determine Epogen dosages is a dialysis patient's red blood cell count, or hematocrit. The hematocrit for healthy men and women ranges from 38 to 42.

But humans can lead active lives with red blood cell counts well below that range. For instance, dialysis patient Robert Monroe is happy with a hematocrit between 30 and 33. During a dialysis session in Baltimore's not-for-profit Parkview Clinic, he proudly pointed out that he can still climb the stairs to his apartment and ride his bicycle to visit friends.

"Sometimes I wake up and I don't have much energy," he said. "But most of the time I feel OK."

The FDA's original approval for Epogen had recommended that doctors keep patients in the 30 to 33 range, which became standard practice in the field. But, for the last several years, Amgen and some researchers have argued that the government should support a hematocrit in the range of 33 to 36.

Studies have shown that higher hematocrits, into the upper 30s, make patients feel better, with more energy and greater mental alertness.

But other research questions whether these lifestyle benefits are worth the cost. Higher hematocrit requires a significantly higher dosage of Epogen, ultimately affecting the government's bottom line, Amgen's profits and the lives of thousands of dialysis patients.

"It's far from proven that hematocrits of 33 to 36 are better than 30 to 33, and it is certainly very costly," said Dr. James Kaufman of the Boston Veterans Administration hospital.

Dr. Allan Collins, a physician at Nephrology Analytical Services at the University of Minnesota, also questioned whether the benefits are worth the cost of raising hematocrits.

"Raising people with hematocrits already in the mid-30s higher would take three times as much EPO and have very small benefits at best," Collins said. "That's not responsible health-care policy. It would be much better if the renal community focused on those patients with hematocrits below 30 who have very serious other diseases."

Most patients on dialysis have debilitating diseases like hypertension, heart disease, diabetes and drug abuse, the main causes of kidney failure. Nearly 20 percent of patients die annually. Although that is down from the 25 percent death rate recorded earlier this decade, many physicians in the field argue that lowering the mortality rate further requires better treatment of patients' underlying diseases.

"Focusing on hematocrits oversimplifies,"

said John Sadler, who has been treating patients with kidney failure since the 1960s and now runs Baltimore's Independent Dialysis Foundation. "People have to learn how to cope properly with long-term chronic diseases."

Proponents of the higher dosages of Epogen to achieve higher hematocrits in dialysis patients usually can boil down their argument to a simple question:

"Why shouldn't dialysis patients have the same hematocrit as everyone else?" asked Allen Nissenson, a researcher at UCLA and president of the Renal Physicians Association.

Nissenson's research is partially funded by Amgen, and he sits on Amgen's medical advisory board.

The debate over hematocrits not only is complicated by questions of cost and effectiveness; it also is clouded by Amgen's role as an underwriter of research.

But Nissenson and other researchers in the field say that the money they take from pharmaceutical companies does not sway their work.

The National Kidney Foundation--a patient advocacy group--conducted one of the most sweeping reviews of the evolving medical literature, resulting in a comprehensive set of guidelines in 1997 aimed at reducing the death rate among U.S. dialysis patients. The final report notes that the research project was funded entirely by Amgen.

While not all the foundation's conclusions of the report were favorable to Amgen, one key finding bolstered the need for higher hematocrits--and, thus, for higher dosages of Epogen. The foundation

recommended raising hematocrits into the 33 to 36 range.

Success, but at what cost?

Using a strategy common among pharmaceutical companies but little noticed by the public, Amgen turned to an aggressive behind-the-scenes marketing program to boost Epogen's profile.

Amgen sought to get the word out on the possible benefits of higher hematocrits, setting its sights on the physicians and nurses working in the nation's 2,747 outpatient dialysis clinics.

Many doctors listened, and began administering more Epogen.

In 1994, dialysis patients with hematocrits above 36, which Medicare only reimbursed if a physician prescribed that higher level, constituted just 7 percent of those on dialysis, according to government officials at the Health Care Financing Administration (HCFA), which oversees Medicare. By 1997, that total had reached 15 percent and some parts of the country had reached 30 percent.

Government expenditures for Epogen also soared. Average annual patient costs for Epogen rose to $5,000 to $6,000 a year in 1997, up from $2,000 to $3,000 a year in 1993, because of increased dosages.

It was about this time, with the Medicare bill for Epogen rising to $668 million in 1997 from $446 million in 1993, that HCFA decided that it was time to do something about Epogen expenditures. Including patient co-payments, Amgen received $847 million through the Medicare program in 1997. Based on figures in Amgen's annual report, that figure grew again in 1998.

HCFA published a new rule in August 1997 that said clinics would not be paid for the last month's dosage of Epogen if a patient's hematocrit went over a three-month average of 36.5. The agency also eliminated the ability of physicians to make exceptions to its hematocrit guidelines.

The policy worked. During the next few months, the average patient's hematocrit stopped rising and government expenditures on the drug leveled off, according to HCFA data.

Amgen, clinic operators and physician groups asked HCFA to rescind the rule, claiming that doctors might withhold Epogen as patients neared the top of the desirable range.

HCFA refused. Amgen then hired outside lobbyists to press its case on Capitol Hill.

Among them were Haley Barbour, the former chairman of the Republican National Committee, and C. Boyden Gray, a former high official in the Bush administration. Later, the Amgen added former Senate Majority Leader Dole, now at the high-powered Washington lobbying firm of Verner Lipfert Bernhard McPherson & Hand, to its list of lobbyists.

The lobbying appeared to pay off.

Last year, Specter, a Republican senator from Pennsylvania whose state is home to many pharmaceutical companies, and who, according to Federal Election Commission records, received $7,000 from Amgen's PAC during his latest re-election run, took up the issue at a hearing of his Health and Human Services Subcommittee of the Senate Appropriations Committee, which determines HCFA's budget.

Specter angrily demanded that HCFA rescind the controversial rule. HCFA complied the next day.

"No company came to me," Specter told Bloomberg News at the time. "There have been a lot of complaints . . . from people who are suffering."

Specter declined to comment for this report.

The Amgen-led lobby, once in motion, did not stop with mere repeal of the rule. A week after the hearing, Specter convened a meeting in his office between HCFA chief Nancy-Ann DeParle, David Goodkin, who is Amgen's chief medical officer, and several leading academic researchers, including Nissenson.

DeParle, who is not a physician and was relatively new to her post, brought along no medical advisers of her own to counter the company presentation on the necessity of higher hematocrits, according to Nissenson.

"It was outrageous," said one government official who was present, but did not wish to be identified. "Amgen's doctors turned it into a sales meeting."

DeParle declined to be interviewed for this article.

Last June, HCFA issued another new rule. This time, it raised the allowable hematocrit level to 37.5, the highest ever. And if a patient happens to go over that limit, the last month's payment wouldn't be withheld. It would simply trigger a "post-payment review."

Epogen sales, after two relatively flat quarters when the restrictions were in place, began rising dramatically and finished up 19 percent for the year. Last

November, company officials told Wall Street analysts to expect continued strong growth in sales of the drug.

The price game

At the same time that the HCFA rule had the effect of limiting Epogen sales by putting a cap on its medical use, the HCFA had in hand a report by its own inspector general recommending a decrease in the price paid clinics for Epogen to $9 per 1,000 units, from $10.

The move would immediately save the government $94 million a year, and patients, who must make a co-payment for each administration, $24 million a year, the November 1997 report said.

The National Renal Administrators Association, which represents the clinic operators, blasted the report as "ridiculous."

"Providing that drug costs money for nurses, syringes, keeping it refrigerated," said Gwen Gampel, the group's chief Washington lobbyist. "Take that into account and they're not making much money on this drug."

But industry filings with the Securities and Exchange Commission suggest otherwise. National Medical Care, which has 550 clinics and treats 23 percent of the U.S. dialysis population, says Epogen sales "materially contribute to operating earnings" because Amgen gives the company "significant price protection and volume discounts."

The Clinton administration included the price reduction in its 1999 budget. Amgen hired Dole and Verner Lipfert Bernhard McPherson & Hand to press legislators. The price stayed at $10 per 1,000 units.

But it doesn't require an act of Congress to lower the price of Epogen. HCFA could do it on its own but refuses because the White House would prefer Congress to do it. When money is saved legislatively, it can be spent on other programs. If saved administratively, it is returned to the Treasury under current budget cap rules.

President Clinton again included the price reduction in his new budget submitted to Congress in February. Democratic staffers give it little chance of passage.

There are still other ways to reduce the cost of EPO.

The government could revamp its entire dialysis reimbursement system, some experts in the field say. Medicare could pay a basic rate for dialysis treatment that would include all drugs and testing, which would encourage a more cost-effective use of drugs like Epogen.

Another potential strategy involves the method of administering the drug.

The same National Kidney Foundation guidelines that called for higher hematocrits also called on doctors to give patients Epogen with a shot rather than intravenously, because that could substantially cut dosages--and government payments for the drug.

"Studies have indicated that EPO requirements are, on average, about 15 percent to 50 percent less (with) subcutaneous than with intravenous dosing," the guidelines said.

"Is it appropriate to introduce some discomfort for cost savings? I'd say yes given what the U.S. spends on its dialysis program," said Dr. Kaufman of the Boston VA Hospital, which conducted

one of the studies.

But Amgen is opposed to the change. "It would be a dramatic step to get involved in the medical process," said Goodkin, Amgen's chief medical officer. "Some people say (the shot) is very painful. This should be left to the doctor and the patient."

It also would be very painful to the company.

In the office of Amgen's chief lobbyist in Washington, late in 1998, a chalkboard diagram showed that company sales would fall 30 percent if clinics began to administer Epogen through injections rather than intravenously.

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Appendix C

This letter was written for and submitted at a meeting between the Unit Manager, her superior, and myself, in 1994. It is important simply because it demostrates the manner in which patient complaints are dealt with. This letter *was* posted to my record and I was told at the time, referred to and addressed at a staff meeting. It was then summarily dismissed and never discussed again. Even though the superior present, with out hesitation, agreed with it's content completely.

It is now six years later, and the same issues remain.

Accompanying the letter are the results of a small survey I issued to a few patients and one biotechnician. I asked them to respond to this question: What are the five most important issues in the dialysis industry today. Their answers can be found following the letter.

Expectations of your Patient

Always remember your patient is not here by choice. Their journey to your facility is the result of a devastating trauma. For most, the path to your door has been fraught with painful medical procedures, long hospital stays, grievous changes in diet, and a frightening prognosis for the future.

You *choose* to work at this facility. It is your *job*. With it comes the responsibility and accountability of the position.

Every job inherently has difficult tasks to perform. As well as personal interface with patients who, under other circumstances would exhibit different behavior than they sometimes demonstrate under the trying conditions of dialysis.

It is imperative to remember that the interaction between the facility and the patient remains a buyer/seller arrangement. The patient is still and always will be a client. A customer to be treated as such. The dialysis facility and it's employees offer a professional, medical service. The dialysis patient is the end user of that service.

As a standing business entity your facility demand of its patients certain criteria of protocol and behavior. These policies and procedures have been initiated to act as a control mechanism, establish guidelines of address, and to attain compliance with standard medical dictates of the industry.

The patients are asked to familiarize themselves with the required regulations and prospective treatment programs. Acceptance is considered to be a formality.

This mandatory list of acceptable behavior and compliance, broken to its simplest component, reflects the facility's expectations of those who choose to use their facility for treatment.

The failure or weakness of this process lies in the answer to one question. What does the patient expect from the facility? From the health care provider he or she has chosen? Perhaps this aspect of the treatment program has never thoroughly been explored. If not, it is time to do so.

Accordingly, the following are the expectations of a patient.

First and foremost, I am a human being. Know that and keep it ever present as you prepare for my treatment. What you expect for yourself, expect for me.

Second, study my previous run sheets. Be prepared. If something listed is unclear, clarify it. Do not guess. Do not assume. If some piece of required information is missing, ask about it. Verify it. Anything less is unacceptable.

Third, be aware of any blood work that needs to drawn prior, during or after my run. The information attained from the sample may be vital to a doctor's next course of action or treatment decision. It must be timely submitted. Preventable delays cause prolonged suffering of one type or another.

Fourth, my access is my life line. Do not attempt to facilitate the run if you are not confident with your ability to do so. If I as a patient do not feel comfortable with your experience and capability, I am protecting my access, not degrading your ego. If I suggest or demand certain procedures be followed or sights be used, I DO KNOW BETTER. It is my body. It is my right. You would do the same.

Fifth, when initiating a treatment, do not allow distractions. Do not attempt to hold a conversation with another technician. Do not attempt to answer a question from another patient. Focus on my access, especially when you have the needle in your hand. Or are about to remove one. Any unintentional tug or errant movement of the bloodline causes an immediate reaction at the needle sight. Please pay attention to what you are doing at all times. The preservation of my access is at stake.

Sixth, during the treatment, chart my progress more often than the half hour BP check. Do not assume that everything is proceeding well all the time. Dialysis remains an arterial access medical procedure. The risks of such have not improved over the years. The machines have technically improved, the human side has not. Be responsible for your patient. Chance occurrences do not watch the clock.

Seventh, when discontinuing the run, pay attention to me and only me. Patients differ on take-off procedures. Again, remember that any movement of the bloodlines has an immediate affect at the needle sight. DO NOT RUSH. Artificially forcing the saline back through the return line by squeezing the saline bag is unacceptable. It puts undo stress on my access. Do not argue, just don't do it.

Eighth, follow ALL policies and procedures with regards to keeping the access sight clean and sterile no matter how trivial they seem to you. They are not trivial to an educated patient. If I ask you to change gloves, change gloves. No looks, no stares, no questions. It's not your access.

Ninth, leave your personal life and it's moods at the door. If I can do it, so can you. The responsibility of the position you have chosen dictates you do so. As a patient, I do not

expect you to endure any demands that are not part of the process. I do expect you as a Patient Care Technician to fulfill your obligation of completing my treatment to the best of your abilities under the guidelines set fourth to do so. You expect as much as a consumer. I, as a patient, expect and will accept nothing less.

Patient's response (Jason)

1.Patient Care Technician competency.

2. Patient Care Tech training, or lack thereof.

3. Patient education as to patient rights

4. Lack of continual education provided to or taken by Pateint Care Technicians.

5. Lack of understanding by most Patient Care Technicians as to how dialysis truly affects patient health and strength.

Patient's Family (Husband & Wife)
(Chris Draper)
as wriiten:

My wife is a relatively new dialysis patient, less than a year since her first hook-up. In our limited experience with dialysis units we have a couple of concerns that could potentially be addressed through legislation.

In a conversation I had with a Dialysis tech she said that she was going to go back to school to become a dental hygienist. She indicated that she could work less hours and make much more money. I think this points to fundamental error in the paradigm of the tech's job. These tech's literally hold the life of our loved ones in their hands evrey visit. And yet, another job has a better reward system. What is it about these two jobs that allow such a disparity in pay?

All patients in dialysis are in crisis and need special and individual attention by the Techs. How can you compare that with what a hygienist does?

The hygienist has to go through much more schooling than a dialysis tech. I believe this to be the fault of the industry. The Techs are given just enough training to do specific tasks. The rest is learned on-the-job. My understanding is that when dialysis ub\nits were starting out, the "techs" were mostly emergency room nurses. Now days the training is significantly less than that. I'm not suggesting that techs need that much training and experience, though patients would certainly benefit, the expenses to that would be prohibitive. But, there must be some middle ground.

In the unit where we go to, there are roughly three time slots on Monday-Wednsday-Friday. Somebody must be in attendance from about 6:00 AM to 9:30 PM. Ancedotally, I would say Dialysis techs must have a worse work schedule than a hygienst. That should also be reflected in the pay scales. If the job were more lucrative, hence attractive, then units would not have as much trouble filling later shifts.

So, what I believe needs to happen, 1) the Techs need to be better compensated. 2) The techs need to be better educated. How can this be mandated/ Perhaps through a more rigorous certification process. This should probably include periodical additional training as a requirement for continuing certification.

I have one other concern, and I really don't know how to approach a mandated solution to this. I have noticed as occasional lapse in clean techniques. I realize that units do not require the same level as say an OR. But, we are dealing with invaions into people's blood streams. and, there is potentially hazardous blood being split in the ordinary order of these procedures. The incidences I have noticed are not frequent, bit if I, an un-trained person has noticed some, what is actually occring? maybe this could be included in the continuing education I referred to above.

Thank You,
Chris Draper

The last response, from a biotechnician with twenty years plus experience, follows on the next page.

5 Concerns About the Future of Dialysis

1. **Training of professionals – technicians, nurses, administrators.** Dialysis is a highly specialized, highly technical branch of medicine. At the present time, technicians make the majority of dialysis center personnel. In most centers, they have virtually no background requirements and receive a minimum of training. Initiatives are underway in several states to set standards, but uniformity is unlikely. Technician training is usually done by registered nurses. Their skills are vital to providing a safe treatment for the patient. However dialysis is not like other medical treatments. It has features that are more like an industrial process. Nurses are not normally trained in the chemistry and physics of water purification, fluid dynamics, or electronics needed to process hundreds of gallons of blood and thousands of gallons of water daily. Most fatal accidents in dialysis occur in this realm although it is often given short shrift by managers and educators. Likewise dialysis administrators need to be able to measure costs and benefits with regard to safety and efficiency.
2. **Inspection of equipment and technical procedures.** Medicare inspectors need to be technically aware. Inspections are vital to patient safety. They provide a monetary incentive for industry compliance to safe practices. However, most inspectors focus on nursing aspects such as charting, aseptic technique, etc. Water purification equipment, delivery systems and maintenance practices are almost never inspected.
3. **Reuse of dialyzers.** Since the implementation of prospective reimbursement in 1984, the reuse of supposedly disposable dialyzers has become the norm. The practice is supported by a great deal of self-serving industry research that purports to prove that it is "safe" or even beneficial, although not recommended by most manufacturers. It is likely responsible for a great deal of unreported death and morbidity among patients.
4. **Development of new techniques.** Daily dialysis, wearable kidneys, and many other promising techniques are not being developed under the present system. There has not been a really innovative breakthrough in treatment since the advent of continuous peritoneal dialysis in the early 1980's.
5. **Home dialysis.** The ultimate objective of dialysis research should be to make it so simple that the patient could carry out the procedures at home without the assistance of an expensive staff and facility. We should encourage the development of home dialysis.

United States General Accounting Office

GAO

Report to the Special Committee on Aging, U.S. Senate

June 2000

MEDICARE QUALITY OF CARE

Oversight of Kidney Dialysis Facilities Needs Improvement

GAO/HEHS-00-114

Contents

Abbreviations

ESRD	end-stage renal disease
HCFA	Health Care Financing Administration
NIH	National Institutes of Health
OSCAR	On-Line Survey, Certification, and Reporting
USRDS	United States Renal Data System

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Accountability * Integrity * Reliability

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

Health, Education, and
Human Services Division

B-284615

June 23, 2000

The Honorable Charles E. Grassley
Chairman
The Honorable John B. Breaux
Ranking Minority Member
Special Committee on Aging
United States Senate

More than 288,000 people suffering from kidney failure depend on Medicare to cover the cost of the life-sustaining kidney dialysis treatments they receive several times each week. These end-stage renal disease (ESRD) beneficiaries are among Medicare's sickest and most vulnerable patients, costing Medicare about $10 billion in 1998. Dialysis is a technically complicated process, and mistakes or poor procedures can cause patients serious injury or even death. The quality of care that these Medicare beneficiaries receive at some of the nation's 3,817 dialysis facilities is in dispute. On the positive side, death and hospitalization rates related to dialysis appear to have declined over time. But at the same time, concerns have been raised about reduced staffing levels at ESRD facilities and the greater use of potentially less skilled technicians rather than nursing personnel to administer dialysis treatments.

The Health Care Financing Administration (HCFA), the agency that administers Medicare, is responsible for overseeing adherence to its quality-of-care standards and promoting quality improvement among ESRD facilities. HCFA pays state agencies to perform on-site inspections of these facilities and contracts with 18 organizations, called ESRD networks, to gather data about dialysis treatments and conduct activities to improve the quality of care patients receive. You asked us to evaluate HCFA's processes to ensure that ESRD facilities meet quality-of-care standards. We focused our work on determining (1) the extent to which on-site inspections of dialysis facilities are performed and problems are identified, (2) whether an effective process exists to ensure that dialysis facilities correct problems, and (3) what steps are being taken to use available monitoring resources as effectively as possible.

Our report is based in part on analysis of information from national databases compiled by HCFA, state survey agencies, and ESRD networks. For a more in-depth review of actual monitoring and enforcement

activities, we focused on work being done by state agencies in California, New Jersey, Texas, Oregon, and Washington, and at the four HCFA regional offices and the four ESRD networks that oversee dialysis facilities in those states. We conducted our work between November 1999 and May 2000 in accordance with generally accepted government auditing standards. Appendix I contains a more detailed explanation of our scope and methodology.

Results in Brief

Over the past 7 years, the number of HCFA-funded inspections of dialysis facilities has declined significantly. These unannounced inspections, commonly called surveys, which are HCFA's primary tool for ensuring that facilities meet standards protecting patients' health and safety, were conducted at only 11 percent of the dialysis facilities eligible for recertification in 1999, compared with 52 percent in 1993. When such surveys were conducted, they showed that noncompliance is a problem. For example, in 1999, 15 percent of the surveyed facilities had deficiencies severe enough, if uncorrected, to warrant terminating their participation in Medicare. To enable more frequent surveys, HCFA has requested a threefold increase in funding for on-site inspections in its budget request for fiscal year 2001. This funding level would support a survey of all dialysis facilities every 3 years.

While increasing on-site surveys will likely encourage more facilities to improve conditions, the enforcement system provides little assurance that corrections will be sustained. Essentially, HCFA's only current enforcement tool is to terminate a facility from the Medicare program if it does not correct its deficiencies. The threat of termination brings nearly all facilities into compliance for a while, but they do not necessarily stay that way. In every state we visited, we found instances in which facilities that had corrected their problems were found to have serious problems shortly afterward. The Congress has authorized HCFA to use other enforcement tools, such as the denial of payment for Medicare services, but HCFA maintains that this authority would have limited effectiveness and applicability. For example, HCFA has not taken steps to use denial of payments because, like termination from the program, this sanction could be applied only if the facility failed to return to compliance.

HCFA is planning to use clinical and outcome data (such as patient death rates) more extensively in deciding which facilities to survey and monitor more closely. Although the information HCFA intends to use may help in that regard, it has limitations as well. These data are designed to give a

picture of the care being provided to ESRD patients generally, but they are often not current, detailed, or reliable enough to detect specific facilities that are providing substandard services. For example, we found instances in which facilities had above-average clinical outcome scores but were found to have serious deficiencies during on-site surveys. HCFA's ESRD networks already collect considerable facility-specific information, such as patient complaints, that is more timely, but they do not necessarily share it with state survey agencies. One state where such sharing had occurred showed positive results.

To give facilities a greater incentive to remain in compliance, we suggest that the Congress consider strengthening HCFA's authority to impose monetary penalties on dialysis facilities that have the most severe or repeated serious deficiencies. We are also recommending that HCFA strengthen its systems for targeting on-site surveys and make use of additional available enforcement tools.

Background

Kidney Dialysis Services

The Medicare program covers dialysis services for patients suffering from ESRD, the stage of kidney impairment that is considered irreversible and requires either regular dialysis treatments or a kidney transplant to maintain life. Kidney failure can result not only directly from kidney disease but also indirectly from other diseases, such as diabetes and hypertension. Dialysis is a technically complicated process that is individualized to accommodate each patient's needs. There are two general modes of dialysis treatment: hemodialysis and peritoneal dialysis, both of which can be performed at a dialysis facility or at home. During hemodialysis, the patient's blood is filtered through a dialysis machine that withdraws fluid and toxic materials before returning cleansed blood to the patient. In peritoneal dialysis, the removal of fluid and toxic materials takes place within the abdominal cavity by means of cleansing fluid and drainage. The vast majority of ESRD patients (86 percent) receive hemodialysis. Generally, an ESRD patient has three dialysis sessions per week, lasting 3 to 4 hours each, usually provided on an outpatient basis.

Program Has Grown Dramatically

Almost all dialysis patients, regardless of their age, are Medicare-eligible, making Medicare the main payer of dialysis services. Total expenditures for

the Medicare ESRD program, authorized in 1972, have grown steadily from $229 million in 1974 to over $11.4 billion in 1998. A major reason for the increase in program costs is the dramatic rise in enrollment: total enrollment for those beneficiaries requiring dialysis or transplants has risen from approximately 16,000 in 1974 to over 360,000 in 1998. The increase in enrollment has been fueled by expansion of the criteria that determine who is an acceptable candidate for dialysis. For example, physicians are recommending dialysis for older patients—the number of patients in the ESRD program who are 65 or older increased from 5 percent in 1973 to 50 percent in 1997. In addition, the program is admitting more patients with hypertension and severe diabetes (see app. II for additional information on the changing demographics of dialysis patients). The number of dialysis facilities has grown in step with the growth in the number of dialysis patients. Since 1993, the number of facilities has increased at an average rate of 6 percent annually, reaching 3,817 participating facilities in 1999.

Medicare payments, which are based primarily on a fixed rate per treatment, have essentially remained unchanged since program inception. For facilities that aim to maximize profits, such fixed payment rates can create incentives for efficiencies, but they can also be an incentive for underservice. This movement toward greater efficiencies has spurred considerable industry consolidation into for-profit facilities and chain providers. The Medicare Payment Advisory Commission reported that in 1997, 68 percent of the non-hospital-based facilities were for-profit. And three-quarters of all for-profit dialysis facilities were affiliated with a chain. In 1998, dialysis facilities used about 12 percent fewer staff to administer dialysis than in 1993. Furthermore, they increasingly rely on lower-cost technicians rather than nursing personnel to monitor dialysis treatments.

HCFA Relies on State Agencies and ESRD Networks for Oversight

HCFA has established a set of quality-of-care standards, called "conditions of participation," that dialysis facilities are required to meet before they can receive Medicare payments. The conditions of participation are regulatory standards, first established in 1976, designed to ensure that dialysis facilities are capable of furnishing quality care in a safe environment. There are 11 conditions of participation covering areas such as the physical environment of the facility, the adequacy of patient care plans, and the management of the facility (see app. III for a more detailed description of the 11 conditions of participation).

Oversight of the program falls primarily on state survey agencies and ESRD networks working under contract with HCFA. Each plays a separate oversight role. State survey agencies—generally state departments of health—are responsible for verifying that dialysis facilities comply with conditions of participation. They do so primarily through unannounced site surveys of dialysis facilities. These agencies, which have expertise in health and safety issues, are frequently responsible for surveying other types of health care facilities that require certification for participation in the Medicare program, including nursing homes and home health agencies. No statutory requirements exist for the frequency of state surveys of dialysis facilities; rather, the frequency is determined mainly by the funding available. For fiscal year 2000, state agencies are expected to receive about $2 million for survey and certification of dialysis facilities.

State agencies, with HCFA's concurrence, determine whether problems identified during a survey are serious enough to warrant finding a facility out of compliance with a condition of participation. If a facility is found to be out of compliance and the deficiencies are not corrected—generally within 90 days—the facility is subject to termination from the Medicare program. If deficiencies are so severe that they put patients' health and safety in immediate jeopardy, the facility has only 23 days to make corrections (this is called the "fast track" for termination). To determine whether deficiencies have been adequately addressed, the agency conducts another on-site survey. If the facility is still out of compliance, the state agency refers the facility to HCFA, which is responsible for prescribing and reviewing additional corrective actions and, if these additional steps are insufficient, proceeding with the termination process. If deficiencies are corrected or plans for correction are developed at any time during this process, the process to terminate is stopped.

ESRD networks are organizations that contract with HCFA to help ensure effective and efficient administration of the ESRD program and improve program performance. The 18 networks are funded through a fifty-cent charge on each Medicare dialysis treatment, which for fiscal year 2001 is expected to total about $18 million. ESRD networks have medical staff with experience in dialysis, and their boards of directors and medical review boards are composed of dialysis facility representatives, physicians, and dialysis patients. As a result, they tend to have more clinical expertise specifically on dialysis than do state survey agencies.

In contrast to state agencies, which check for adherence to conditions of participation, the networks are responsible for quality improvement, which focuses on improving the clinical outcomes of dialysis facilities. Network activities include identifying and collecting data on key clinical indicators and furnishing individual facilities with regional performance data on clinical indicators so a facility can compare its performance with that of other facilities. The networks also provide technical support to help facilities improve their performance on the key indicators. In the aggregate, these indicators show that the quality of dialysis care nationwide has been improving. As evidence, HCFA's 1999 data report cited first-year patient death rates, which, after adjustments for some patient conditions, declined from more than 30 per 100 patient years in 1986 to slightly more than 21 in 1996.[1] The data also showed that in 1997, 72 percent of the sampled patients received adequate dialysis as measured by urea reduction, an increase from 59 percent in 1995. The use of clinical outcome data has evolved from a tool to assess the overall quality of dialysis services at the patient level to being considered by HCFA as a method to assess the quality of services at individual facilities.

In addition, networks conduct specific quality improvement projects with dialysis facilities, handle grievances regarding patient care, and assist patients in finding dialysis providers. Networks also conduct on-site inspections at facilities to assess procedures and assist facilities in improving the quality of care they provide. To participate in Medicare, facilities must cooperate with network data collection efforts and quality improvement projects.

Oversight of state survey agencies is coordinated by HCFA's Center for Medicaid and State Operations in its central office and its 10 regional offices. Oversight of the 18 ESRD networks and their activities is coordinated by HCFA's Office of Clinical Standards and Quality and regional offices in Boston, Dallas, Kansas City, and Seattle.

[1]National Institutes of Health (NIH), United States Renal Data System (USRDS), *USRDS 1999 Annual Data Report* (Bethesda, Md.: NIH, Apr. 1999), p. 76.

On-Site Monitoring Program Surveys a Limited Number of Dialysis Facilities

On-site inspections by state survey agencies are HCFA's primary oversight tool to ensure that ESRD facilities meet Medicare conditions of participation. An effective monitoring program should ensure that deficiencies are identified and corrected at surveyed facilities and that facilities are surveyed often and with enough randomness to give facilities an incentive to remain in compliance with standards. However, the number of recertification surveys performed each year is decreasing and has reached the point that only a small fraction of the facilities are surveyed. This is a matter for concern because we found ample evidence that serious health and safety problems exist in a number of dialysis facilities. Recognizing that dwindling surveys presents a serious risk to effective monitoring, HCFA has requested a nearly threefold increase in funding for ESRD surveys in its 2001 budget.

Most Facilities Go Many Years Between Surveys

Inspections are required (1) when a facility begins to participate in Medicare, (2) when a facility changes or expands services, such as starting a dialyzer reuse program,[2] and (3) when a facility relocates. Aside from these requirements, there is no provision in law or regulation that sets a maximum period between surveys. Rather, the interval between a facility's initial survey and subsequent recertification surveys depends on HCFA's survey goals; indications that additional surveys are needed because of a complaint or a grievance; and the extent of the survey resources made available through HCFA's contract payments to the states and through other funding sources, such as state appropriations. Generally, states determine which facilities to survey with only limited input from HCFA or ESRD networks. State agency officials told us that they use criteria such as the date of the last survey and the volume and type of complaints received to set their survey agendas.

Since 1993, the number of HCFA-funded dialysis facility surveys has declined substantially. At the same time, the number of new facilities entering the program annually has increased. These new facilities—each requiring a survey—along with a decrease in funding from HCFA, have led to a substantial drop in the percentage of existing facilities surveyed (see table 1). In 1993, 52 percent of facilities in the program prior to 1993

[2]A dialyzer is a filter that is used to clean waste material from the patient's blood. Dialyzers can be used multiple times on the same patient if dialysis facilities establish procedures—that comply with Medicare standards—to clean and disinfect dialyzers after each use.

received a recertification survey. By 1999, only 11 percent of the facilities subject to a recertification survey were resurveyed. At the current survey rate, once a dialysis facility receives its initial certification survey, it is not likely to be resurveyed for about 9 years. Currently, 772 active dialysis facilities have not been resurveyed in the last 5 years.

Table 1: Number and Percentage of Dialysis Facilities Resurveyed, 1993–99

Year of survey	Total number of facilities participating in Medicare	Total number of facilities that could be resurveyed (existing facilities only—excludes new facilities)	Total number of facilities resurveyed	Percentage resurveyed
1993	2,559	2,334	1,216	52
1994	2,741	2,517	727	29
1995	3,000	2,697	389	14
1996	3,209	2,942	476	16
1997	3,448	3,148	469	15
1998	3,659	3,370	398	12
1999	3,817	3,589	409	11

Note: Our analysis starts with 1993 because it represents the point where the downward trend in resurvey activity starts. In addition, data from prior years are less complete and likely understate the true level of survey activity. Nevertheless, the prior-year data show that the number of existing facilities resurveyed in prior years was comparable to 1993 levels.

Source: GAO analysis based on data from HCFA.

Percentage of Surveyed Facilities With Condition-of-Participation Deficiencies Is Rising

The infrequency of surveys makes it impossible to determine the exact extent to which dialysis facilities are currently in compliance with the conditions of participation. However, data indicate that the percentage of inspected facilities found to be out of compliance has increased significantly during the 1990s. In 1993, 6 percent of facilities surveyed were cited for a condition-of-participation deficiency; that number rose to 15 percent in 1999.[3] In two states we visited, state survey officials have conducted more frequent on-site inspections. They were able to do this either by reallocating survey resources from other types of health care facilities, like rural health clinics, to dialysis facilities or by using additional funding from their state governments to fulfill their role in state dialysis

[3]These data are based on our analysis of recertification surveys only.

facility licensing laws. In these states, inspectors found facilities out of compliance at high rates.

- *Oregon.* During a 20-month period from June 1998 to March 2000, Oregon's state agency conducted 41 surveys spread across the state's 39 dialysis facilities.[4] Eleven facilities (26 percent) were found to be out of compliance with the Medicare conditions of participation. Had the state not stepped up its efforts, it would have taken 4 to 10 years to identify these seriously deficient facilities.[5]
- *Texas.* The passage of a state dialysis licensing requirement in 1996 led to a dramatic increase in the number of dialysis facility surveys in Texas. In 1996, in order to license the facilities, the agency surveyed all 244 in the state and found that 33 (14 percent) were out of compliance with Medicare conditions of participation, compared with a national average at the time of about 9 percent.

The five conditions of participation most commonly cited as deficient accounted for 75 percent of all deficiencies reported during 1993 through 1999. Table 2 lists these conditions of participation as well as describes examples of the potential for harm resulting from these deficiencies.

[4]These inspections included initial surveys, recertification surveys, and surveys required before the facility can initiate a dialyzer reuse program.

[5]Both the minimum and maximum estimates assume that the state would survey 10 percent of its facilities each year (the HCFA goal at the time). The minimum estimate assumes that the 11 out-of-compliance facilities were surveyed first, and the maximum estimate assumes they were surveyed last.

Table 2: Top Five Conditions of Participation Identified as Deficient and Their Potential Adverse Effects, 1993–99

Percentage of total deficiencies, 1993-99	Condition of participation	Example of potential adverse effects of noncompliance
23	The facility's governing body should adopt and enforce written rules and regulations, including operational rules and patient care policies, to safeguard the health and safety of patients.	Certain procedures are associated with dialysis for which failure to follow established protocols could result in serious injury. For instance, inadequate medication delivery system policies and procedures can lead to medication errors and adverse drug events that increase a patient's risk of complications or death.
19	The facility's physical environment should be functional, sanitary, safe, and comfortable for patients, staff, and the public.	Deficient equipment could lead to life-threatening complications. For instance, if a dialysis pump is not inspected and calibrated properly, the patient may experience blood loss, receive an air bubble, or sustain other serious injury during dialysis.
13	The reuse of hemodialyzers and supplies should occur only in facilities that meet certification standards.	Deficient reuse practices can expose patients to chemical or infectious hazards by means of direct introduction into their circulatory systems. ESRD patients are more susceptible to infection, and close attention to infection control is a critical prevention measure.
12	The long-term program and patient care plans should show that a professional, multidisciplinary health care team developed a written long-term-care plan to ensure each patient receives individualized care and the appropriate type of dialysis treatment.	Deficient patient care planning can result in ineffective treatment. For instance, an inadequate patient care plan could fail to identify and refer a patient who is eligible for kidney transplant. Or the care plan could fail to include monitoring alerts for patients with cardiac conditions such as arrhythmia, which can be a life-threatening complication during dialysis.
9	The director of the renal dialysis facility should be a Board-certified physician and trained in the care of ESRD patients. The director, among other things, is also responsible for ensuring the proper training of staff.	If dialysis staffs are not properly trained, they cannot be expected to respond quickly and effectively to the range of complications that can arise during dialysis treatment.

Source: GAO analysis of HCFA data.

HCFA Is Seeking Funding for More Surveys

In its 2001 budget submission to the Congress, HCFA requested a nearly threefold increase in the funding for dialysis facility surveys—from $2.2 million in fiscal year 2000 to $6.3 million in 2001. This increase, according to HCFA, will ensure that ESRD facilities are surveyed at least every 3 years. HCFA is seeking this additional funding in response to the declining survey frequency and the rising number of deficiencies identified, as well as information from states regarding complaints about dialysis facilities. Nationwide, complaints to state survey agencies rose 22 percent from 1998 to 1999. As a case in point, the Oregon Department of Health received just 2 complaints in 1997, 6 in 1998, and 19 in 1999.

Enforcement Process Gives Facilities Little Incentive to Sustain Compliance

Even if the frequency of state on-site inspections increases, HCFA's enforcement actions against noncomplying facilities provide little incentive for facilities to make more than temporary improvements. The effectiveness of HCFA's enforcement of condition-of-participation requirements is limited because HCFA relies on termination from Medicare—or, in reality, the threat of termination—as its sole enforcement tool. To escape termination from the program, facilities almost always bring themselves back into compliance, but they face minimal consequences if they again slip out of compliance. For a variety of reasons, HCFA has not developed or used other sanctions that would give facilities more of an incentive to maintain compliance with conditions of participation.[6] In combination with the decreasing frequency of state surveys, these factors severely limit HCFA's ability to promote long-term compliance.

Threat of Termination Brings Facilities Into Compliance but Does Not Necessarily Keep Them There

HCFA uses the threat of termination as its primary enforcement tool. When state agencies identify problems that are sufficiently serious to put the facility out of compliance with a condition of participation, they begin a process, through HCFA, by which the facility either corrects its deficiencies or is terminated from the Medicare program. Before a facility can be terminated, it has an opportunity to correct its deficiencies or develop an acceptable plan of correction. Actions and plans may include establishing new procedures and policies, documenting and clarifying roles and responsibilities of facility staff and managers, recruiting qualified staff, and conducting in-service training of personnel. Once the state agency determines, normally by a revisit, that the deficiency has been corrected and has reasonable assurance that it will not recur, the termination process is stopped.

[6]We use the term "sanctions" in this report to refer to all of the penalties available for noncompliance, including denial of Medicare payments and termination from the Medicare program.

In practice, facilities nearly always correct such deficiencies and are rarely terminated. For example, 481 of the surveys conducted since 1993 resulted in at least one condition-of-participation deficiency,[7] but only three facilities have been terminated for not correcting a deficiency.[8] According to HCFA officials, the goal of the monitoring and enforcement program is to bring problem facilities back into compliance with conditions of participation, not to punish them. They stated that the threat of termination from Medicare is an effective method to bring about compliance.

Although the threat of termination is effective in bringing a facility into compliance, it provides little assurance that a facility, once recertified, will not immediately slip out of compliance again. For one thing, while facilities are correcting their deficiencies, they are allowed to continue to receive full Medicare payments, and they do not have to reimburse Medicare for payments they received when the services and care they provided were not at the level required for payment. Moreover, if they slip out of compliance again and face termination, they can avoid it by returning to compliance during the grace period.

The length of time between surveys makes it difficult to determine how quickly and how often facilities fall out of compliance. However, analysis of the survey deficiency database suggests a pattern of repeated deficiencies. For example, of facilities with four or more surveys,[9] 38 percent of those that had deficiencies on their most recent survey were also deficient on at least one of the same requirements on their last prior survey. More than half of them had two or more such repeat deficiencies.

In some situations, termination is not used even when a facility fails to take appropriate corrective action after the termination process has begun. State, network, and HCFA officials told us that termination is not always an option because it could create serious access problems for patients using that particular facility. In fact, to avoid such access problems, throughout the termination and corrective action process—which can last 90 days or

[7]This figure includes both recertification surveys and complaint surveys.

[8]One additional facility voluntarily withdrew from Medicare because of the threat of termination. While HCFA's deficiency data identified 12 facilities involuntarily terminated, we excluded those terminations that were not linked with a facility's failure to correct condition-of-participation deficiencies.

[9]Only a facility's four most recent surveys are included in HCFA's survey database.

more—noncomplying facilities continue to receive Medicare payments and may continue to accept new Medicare patients.

During our state visits, we also identified cases in which facilities returned to compliance only to be found out of compliance again a short time later. Three examples follow.

- *Washington.* On March 24, 1999, a facility was cited for noncompliance with such requirements as following physician orders, following anemia management protocols, and following up on adverse incidents at the facility. The state accepted a corrective action plan on July 21. However, on October 13, a lengthy complaint was filed alleging that the same types of deficiencies found during the survey were still occurring and that the facility's management was not correcting the problems. The complaint also included a long list of incidents that allegedly occurred over a 6-month period, including the months the facility was reported to be taking corrective actions. Many of the allegations and incidents in the complaint were substantiated during the state investigation, including problems that were also cited on the prior survey: for example, not writing reports for serious incidents, such as medication errors, in which patients did not receive prescribed medication and in which other patients received medications that had not been prescribed for them. During this same investigation, the state found poor patient care practices, such as leaving a patient on a bedpan throughout the 3-hour dialysis treatment, causing blisters. Overall, the deficiencies found were so severe that they posed immediate jeopardy to patient health and safety, and the facility was placed on a fast track to termination. The facility again took corrective actions that were acceptable to the state and HCFA, and at the time of our work, continued to dialyze Medicare patients.

- *New Jersey.* A facility's initial certification survey on February 26, 1996, found numerous deficiencies, including having untrained personnel responsible for water treatment, not testing chloramine levels of water daily, not having a quality assurance plan, and poor patient care planning. After developing an acceptable plan of correction, the facility was certified to operate six dialysis stations, treating 35 patients. Over the next 18 months, the ESRD network conducted several on-site visits at the facility and each time found serious and continuing problems. For example, patients were placed at serious risk because dialysate (the fluid used to extract toxins from the blood) was prepared using untreated water. Furthermore, the facility's treated water, dialysate, and dialysis machines had bacterial contamination that exceeded acceptable levels.[10] In 1998, the state agency resurveyed the facility and found the problems identified by the network as well as the same deficiencies found earlier by the state. In response, the facility again developed an acceptable plan for corrections. Since then, the facility has continued to treat Medicare patients and has not been resurveyed in more than 2 years.
- *Texas.* A facility cycled in and out of compliance over a 9-year period while developing numerous plans of correction at the direction of both the state and the ESRD network. On many occasions, the deficiencies were so severe they put the health and safety of the facility's 227 patients in immediate jeopardy. For example, the facility had repeated problems regarding providing adequate levels of dialysis, managing patient anemia, and planning patient care. In 1999 HCFA put the facility on a fast track to termination, citing such deficiencies as not providing care necessary to address patients' medical needs, not complying with physicians' orders, lack of physician planning of and supervision over patient care, and not following up on adverse incidents. It took more than 4 months and two revisits from the state before the facility came back into compliance. However, when the state conducted a survey 4 months later, the facility was again out of compliance. At the time of our review, state agency officials were exploring enforcement options under state licensing authority.

[10]Federal surveyors from the HCFA regional office accompanied the network surveyors on one of the facility visits and observed many of these problems.

Other Enforcement Tools Are Not Being Used

Termination is one of several enforcement tools available to HCFA, but it is the only one in use (see table 3). HCFA maintains that the other tools have varying limitations that have prevented them from being used as effective alternatives. The following sections discuss each enforcement tool for dialysis facilities and the limitations that might be affecting its use.

Table 3: Overview of Enforcement Tools Available to HCFA

Type of noncompliance	Enforcement tool	Extent used	Concerns or limitations
Failure to comply with Medicare conditions of participation for dialysis facilities	Termination from the Medicare program	Invoked when a facility is not in compliance with a condition of participation	Successful in bringing facilities back into compliance, but not necessarily at keeping them in compliance
	Denial of payment for new Medicare patients	Not implemented into regulation by HCFA	Like termination, facilities can avoid this sanction by returning to compliance
Failure to follow industry standards and practices for reusing hemodialyzers	Retroactive denial of payments for services provided when the facility was out of compliance	Not implemented into HCFA procedures	HCFA maintains that applying this sanction would be cumbersome
Failure to participate in ESRD network quality-of-care initiatives, or to pursue quality-of-care goals	Termination from the Medicare program	Never levied against a facility	Only option available if the deficiency is serious
	Denial of payment for new patients admitted after the effective date of the sanction	Never levied against a facility	Limited applicability—can be used only for nonserious deficiencies
	Reduction of a facility's payment rate by 20 percent for each 30-day period that the facility continues to not participate or pursue goals after being directed to do so	Never levied against a facility	Limited applicability—can be used only for nonserious deficiencies
	Withholding all payments, without interest, for all ESRD services	Never levied against a facility	Limited applicability—can be used only for nonserious deficiencies

Denial of Payment for New Medicare Patients

In 1987 the Congress gave HCFA the authority to develop regulations allowing the agency to deny Medicare payments for new patients at facilities that are not in compliance with the conditions of participation. At that time, the Congress noted that HCFA may be reluctant to use termination, even in cases of serious deficiencies, but that persuasion or technical assistance alone may not be sufficient to bring facilities into compliance. However, HCFA has not promulgated regulations for denying

payments. HCFA officials told us that denying payments would offer no advantages over termination because, under the law, facilities can avoid the penalty by returning to compliance within the grace period. In that sense, denial of payments would operate the same as termination—it would occur only if the facility did not comply.

Retroactive Denial of Payment for Improper Dialyzer Reuse

The Congress provided HCFA additional and broader authority to address facilities not complying with standards and requirements for reprocessing and reusing dialyzers. Compliance with accepted standards is important to prevent the weakened immune systems of dialysis patients from being exposed to microbial contamination and dangerous levels of the germicide used to clean the dialyzers. HCFA was authorized to impose sanctions retroactively when a facility failed to follow industry guidelines on appropriate reuse procedures, even if the facility had corrected its deficient practices. Unlike termination, this tool also can be used for deficiencies that are not considered severe enough to constitute a violation of the applicable condition of participation. HCFA has not incorporated this authority into its procedures, believing that it would be too cumbersome to do so. HCFA officials explained that it is administratively difficult to use this sanction because it is hard to identify which specific dialysis treatments are actually affected by a facility's deficient process for reusing dialyzers.

We disagree that this authority would necessarily be cumbersome to implement—at least not in all instances. Many of the important reuse standards relate to processes and procedures that affect almost all patients in a facility. As a result, if a deficiency is cited that affects all or most of a facility's patients, determining which payments should be denied may not be as difficult as HCFA assumes. Our state-level reviews showed instances in which such conditions applied. That is, many of the deficiencies affected all patients that were dialyzed during the period examined, and surveyors were able to identify specific days of noncompliance. Payments made for services provided during the period of the deficiency would thus be subject to recoupment under current regulations, requiring relatively little effort on the part of claims processing contractors to establish the appropriate amounts.

Penalties for Noncompliance With ESRD Network Activities or Initiatives

HCFA has several financial sanctions at its disposal if facilities do not cooperate with ESRD network activities or pursue the network's quality goals and initiatives. After providing notice to chronically deficient facilities, HCFA can deny payment for new patients, reduce payments for services provided, or withhold payments altogether. However, the law only

authorizes use of these financial sanctions if the deficiency does not "jeopardize patient health and safety." This, in practice, creates an enforcement paradox. Networks are inclined to refer only facilities with serious deficiencies to HCFA for sanction, but only the nonserious deficiencies would be subject to the financial sanction. For serious deficiencies, termination is the only sanction available.

In practice, the networks try to educate, provide technical assistance, require corrective action plans and progress reports, and generally use more collegial means to change the behavior of noncomplying facilities. Since 1993, only two facilities nationwide have been recommended for alternative sanctions by ESRD networks.[11] Each involved a situation in which the network determined that patient health and safety were being jeopardized because of a lack of fundamental processes and systems, but the facility did not respond to the network's efforts to address the problems. In both cases, HCFA did not proceed with sanctions but instead relied on surveys to document problems and on the threat of termination to bring about needed changes.

Enforcement Tools Available for Dialysis Facilities Are More Limited Than Those Available for Nursing Homes

HCFA does not have the same tools to create strong incentives for ESRD facilities to maintain compliance that it does for nursing homes. In 1987, largely in response to studies showing that many nursing homes tended to cycle in and out of compliance with standards, the Congress authorized HCFA to levy civil monetary penalties of up to $10,000 per day on homes that do not meet Medicare requirements of participation. The Congress intended these penalties to create a strong incentive to maintain compliance. In July 1995 HCFA established in regulation that nursing homes are subject to these financial sanctions on the basis of the severity of their deficiencies and can also face financial sanctions if they have repeated serious deficiencies. These latter penalties can be levied without allowing a grace period to correct the deficiencies, and they can be applied even if a nursing home corrects the deficiencies. In our previous review of

[11]Two other facilities voluntarily withdrew from Medicare before HCFA could consider network recommendations. In one case, a facility failed to improve and sustain improvement in removing an adequate amount of contaminants from patients' blood. After considerable monitoring and various approaches to improving the facility's performance over an 8-month period, the network recommended that HCFA impose an alternative sanction. Although the facility withdrew from Medicare before the recommendation could be considered, the HCFA project officer stated that because the issues involved patient health and safety, HCFA could not pursue alternative sanctions.

enforcement of nursing home standards, we reported that while administrative problems with appeals had not yet been resolved, civil monetary penalties may provide a strong deterrence to severe or sustained noncompliance.[12]

Steps Under Way to Target Survey Resources Have Limitations

HCFA has been working on a pilot project that will use available facility-specific data to help state surveyors select facilities for review. While this idea has merit, for such a screening process to be effective, the data must be more timely and reliable than what HCFA currently has at its disposal. Moreover, the extent to which outcome measures, which would be included, would accurately predict the presence of serious health and safety deficiencies that would be identified through on-site inspections is unclear. In contrast, opportunities exist to better target resources through improved communication between the ESRD networks and state survey agencies. Thus far, HCFA's efforts to facilitate the exchange of information between networks and survey agencies have been inconsistent.

HCFA Is Pilot Testing Data Profiles of Individual Facilities to Help Target Surveys

In May 2000, as part of a pilot project, HCFA sent individual dialysis facility profiles created using available facility-specific data to the seven state survey agencies participating in the pilot. These profiles are designed to help state agencies determine which facilities to select for on-site inspections. The information focuses on the adequacy of dialysis provided, the frequency of some dialysis-associated complications and diseases, and the types of practices used by the facilities in administering dialysis and reusing dialyzers. This information comes from a number of sources. Part of it is data currently used to prepare annual reports on renal care, such as standardized mortality and hospitalization rates. HCFA obtains other data through claims for payment that facilities file with intermediaries. These claims include information on the adequacy of dialysis treatments (the urea-reduction ratio) and an assessment of anemia in patients (hematocrit). HCFA is also using data on patient infections collected by the Centers for Disease Control and Prevention.

HCFA plans to collect feedback from the seven pilot states in the fall of 2000 and to begin training surveyors in the use of the profiles in early 2001.

[12]*Nursing Homes: Additional Steps Needed to Strengthen Enforcement of Federal Quality Standards* (GAO/HEHS-99-46, Mar. 18, 1999).

The evaluation of the pilot project is scheduled to be completed in early 2001, but at the time of our review, the evaluation plan and criteria had not been set.

Available Information Reflects Problems in Capturing Conditions at Individual Facilities

Because the facility profile project is now being tested, we did not comprehensively evaluate it. However, we did identify several issues that need to be considered before the data are used to significantly influence the survey selection process. The major concern is whether the data are a strong predictor of noncompliance with Medicare standards. In the states we visited, we found cases in which facilities had good clinical outcome scores but were identified in on-site surveys as seriously out of compliance with Medicare standards. For instance, during a complaint investigation, state surveyors and network quality assurance staff found serious, life-threatening deficiencies, such as a lack of knowledge of basic medical and dialysis practices like anemia management, infection control, and water purity. However, when network officials reviewed the facility's clinical outcomes, the facility had better-than-average scores.

Available Data Are Neither Timely nor Necessarily Reliable

Whether the data come from Medicare claims or through collection by ESRD networks, the process by which HCFA collects and aggregates data on ESRD patients and services takes time. Much of the data for the facility-specific profiles is at least 2 years old. For example, the facility profiles for the year 2000 report hospitalization and mortality data from 1996 through 1998. The Centers for Disease Control and Prevention surveillance data included in these profiles were collected through a 1997 survey. The screening tool proposed in the HCFA pilot would thus reflect conditions at the facility that were at least 2 years old. It is reasonable to assume that, given the dynamic nature of the industry, such a screen would not reflect current conditions.

Although clinical outcome measures, such as hematocrit levels and the urea-reduction ratio, are generally accepted as good measures of dialysis service quality, the assessment of the reliability of the measures reported to fiscal intermediaries yielded mixed results. For example, an initial internal study found differences between the clinical measures facilities reported to fiscal intermediaries and the information collected by ESRD networks. Preliminary results of a later HCFA study found the two data sets to be more closely correlated. A primary concern that remains is the lack of assurance that a single set of procedures to collect, store, assay, and report laboratory values is being followed consistently.

Predictive Power of Outcome Measures Is Unclear

Another significant issue involved in using clinical outcome data in conjunction with the facility selection process is whether outcome measures are a reasonable predictor of a facility's level of compliance with Medicare standards. Although a limited analysis found outcome measures can have a predictive power,[13] there is disagreement on the extent to which outcome measures currently available to HCFA are strong predictors of compliance with Medicare standards. Moreover, concerns exist that using outcome measures to inform the survey selection process may complicate the process of collecting accurate data.

For example, clinical outcome measures like urea-reduction ratios were designed to estimate the extent to which health care providers conformed with clinical practice guidelines, and not necessarily to reflect the extent to which facilities complied with important condition-of-participation standards. As a result, ESRD network and state agency staff told us that dialysis providers could have clinical outcome scores within the average range for the region and still have serious deficiencies, often in such critical areas as water purity, staff competence, and infection control.

The experience of the Texas network shows the difficulty of using outcome measures as the key tool to predict which facilities do not comply with Medicare conditions of participation. The network compared clinical outcome data with the results of state surveys for 179 facilities for 1996.[14] An analysis of the data found that using outcome measures would have been an improvement over the random chance that selected facilities would have condition-of-participation deficiencies. However, network officials cited methodological difficulties that, in their view, would have limited the usefulness of these results for targeting surveys. For example, clinical outcome data are not current enough and would not have been available in the same year as the surveys. Network officials also pointed out that the data did not account for the severity of the deficiencies, in that some facilities with the most severe noncompliance problems had acceptable outcome measures. As a result of these and other concerns, the network's medical review board reported that its analysis was inconclusive

[13]Robert Wolfe, *Facility Statistics, Patient Care and Science: A Re-evaluation of Network 14 State Surveyor Data*, a presentation to the HCFA Dialysis Facility-Specific Reporting Workgroup, Aug./Sept. 1999.

[14]ESRD Network 14 Medical Review Board, *Position Paper on the Use of Outcomes Data for Survey Selection Purposes* (Dallas, Tx.: June 2, 2000).

about the merits of using clinical outcome data as a controlling factor in targeting state survey resources.

Over time, the process of using clinical performance measures to score facilities and then conduct surveys on the basis of these scores could, in itself, complicate efforts to improve the accuracy of the facility-reported data. In the long term, the use of facility-specific data to inform the regulatory oversight process creates an incentive for facilities to report data that indicate acceptable performance whether they are providing an acceptable level of service or not. HCFA quality assurance specialists reported in 1999 that clinical performance data were to be used primarily for population-based quality improvement rather than for evaluating facilities' care of specific patients or compliance with quality assurance standards. The report noted considerable concern that, if inappropriately used (particularly by regulators), the clinical performance measures could potentially have a deleterious effect on the care of dialysis patients, presumably by creating incentives for facilities to "game the reporting system."[15] Such incentives are particularly problematic with the ESRD program because currently most of the data are self-reported. Verification of the data is limited to a review for transcription errors.

Lack of Communication Has Hindered Monitoring Effectiveness

By building stronger cooperation between ESRD networks and state survey agencies, HCFA has an opportunity to improve the quality of facility-specific performance data used in selecting facilities to survey. ESRD networks collect a variety of data from individual dialysis facilities and in some cases have facility performance information that is available on a real-time basis, rather than after a lag of several years. However, HCFA has not consistently encouraged this coordination, and, in some cases, through conflicting policy interpretations, has actually impeded it. As a result, the level of coordination and information sharing varies dramatically across the nation, and in most cases little of it takes place.

HCFA has not been clear on the type of relationship and coordination it expects between networks and states. HCFA's current policy is that networks may readily share facility-specific information with state survey agencies to aid in the certification process. This stance reinforces HCFA contract requirements with networks from prior years, in which networks

[15]PRO-West, *Developing Clinical Performance Measures for the Care of Patients With End Stage Renal Disease*, final report to HCFA (Seattle, Wash.: PRO-West, Jan. 1999).

were instructed to achieve a working relationship with state agencies and HCFA regional offices that would assist each in improving the quality of care provided to ESRD patients. Activities the networks are to undertake with state agencies include sharing information and data reports, communicating on patient quality-of-care issues, providing facility-specific data to the state agency, and working to support their survey activities.

HCFA regional offices that oversee network and survey agency activities have not applied this policy consistently. In fact, most HCFA regional offices restrict networks from sharing facility-specific information and support ESRD networks when they deny requests by state survey agencies for such information, saying that federal confidentiality restrictions prohibit this sort of exchange. In contrast, with the knowledge of the HCFA regional office, the ESRD network in Texas began providing facility-specific information to the Texas Department of Health after the state passed a licensure law for dialysis facilities in 1996. More recently, in early 2000, some HCFA regional offices have begun efforts to facilitate the communication and exchange of information, including facility-specific performance information, between ESRD networks and state agencies.

By sharing information and knowledge, ESRD networks and state agencies can effect a more complete picture of ESRD facilities. Each has different information and knowledge about a facility that together provide a more accurate overall assessment of the quality of care a facility provides. ESRD networks work solely with ESRD facilities; have information on the clinical aspects of the care in facilities; and also may be more aware of staffing and management changes, patient complaints, and the results of network quality improvement initiatives, which can have a major impact on the quality of care provided. In contrast, networks do not have detailed information about facilities' systems and processes that are key to quality of care, such as the quality of water used, infection control procedures, reprocessing of dialyzers, and care planning. This type of information can be provided by state survey agencies.

Conclusions

Oversight of ESRD facilities needs improvement. While many facilities may be conscientiously and consistently providing quality care, some do not, and current oversight efforts are not enough to find and correct the problems in a timely manner. HCFA's request for a threefold budget increase for inspecting ESRD facilities is a sign that the agency realizes additional oversight is necessary.

While increasing the number of inspections should help improve oversight, other things can be done as well. One is to put some teeth into the enforcement process. Currently, when condition-of-participation violations are found, even on a recurring basis, ESRD facilities essentially face no actual penalty as long as they correct any problems identified. Part of the reason is that HCFA has chosen not to exercise its authority to levy certain sanctions. HCFA has not instituted procedures to deny Medicare payments for dialysis if a facility does not meet dialyzer reuse standards. However, in practice, other sanctions now available to HCFA have little application because either they are restricted to less serious deficiencies or, in the case of more serious deficiencies, facilities can take corrective action, even temporarily, and avoid them altogether.

One way to give facilities more of an incentive to stay in compliance is to have available the kinds of monetary penalties that can be used when nursing homes are found to have severe or repeated serious deficiencies. For example, HCFA can fine nursing homes, and the fines are not forgiven when the facility corrects its problems. We have previously reported that such penalties can give nursing homes a strong incentive to remain in compliance with Medicare standards. Making such financial penalties more applicable to ESRD facilities would require action by the Congress.

Another way to strengthen oversight is for state agencies and the ESRD networks to share information on complaints and known quality-of-care problems at specific facilities. Doing so would help target inspection resources where they are most needed. HCFA's efforts to use available outcome data for targeting its survey efforts may also eventually help in this regard, but more testing and evaluation are needed to ensure that the data used are sufficient to predict noncompliance with Medicare quality standards.

Recommendations to HCFA

We recommend that the Administrator of HCFA take the following actions to strengthen oversight of ESRD facilities:

- Develop procedures on how and when to use HCFA's existing authority to impose partial or complete payment reductions for ESRD facilities that do not meet Medicare quality standards for dialyzer reuse.
- Establish procedures to facilitate better and more routine cooperation and information sharing between ESRD networks and state survey agencies, particularly in targeting facilities for on-site surveys.

- Evaluate the results of HCFA's project for using clinical outcome data to select facilities for on-site review before it recommends that states use such data as a key factor in the selection process. A central component of the evaluation should be determining the extent to which the data are sufficient to predict which facilities have a higher likelihood of not complying with Medicare's conditions of participation.

Matter for Congressional Consideration

To improve ESRD facilities' incentives to maintain compliance with Medicare's conditions of participation, the Congress should consider authorizing HCFA to assess monetary penalties on ESRD facilities like those it is authorized to assess on nursing homes that have severe or repeated serious deficiencies.

Agency Comments

In commenting on the report, HCFA agreed with the report's findings and expressed overall agreement with its recommendations. HCFA cited a number of steps it intends to take or that are already under way to address our recommendations. HCFA also pointed to a variety of patient outcome measures over the last several years as evidence of improved overall quality of ESRD treatment. While these data are encouraging about nationwide quality, they do not mean that particular facilities are not problematic. This is evidenced by the fact that the number of facilities found to be out of compliance with Medicare conditions of participation increased from 6 percent in 1993 to 15 percent in 1999.

Regarding the recommendation about sanctions for inappropriate dialyzer reuse, HCFA stated that it would develop necessary regulations and procedures to implement such sanctions. In response to our recommendation to facilitate cooperation among state agencies and ESRD networks, HCFA stated that it is now taking steps to clearly delineate responsibilities of state survey agencies and ESRD networks that would encourage cooperative information-sharing to help identify poor-performing facilities.

Regarding our recommendation to evaluate whether outcome data are an appropriate means of selecting facilities for on-site surveys, HCFA stated that this process is already under way. HCFA cited an analysis of recent data on facilities in Texas that indicated a strong relationship between state survey results and outcome measures. We have included information in the report about this analysis. However, we believe additional testing and

evaluation are needed before outcome measures are used as a significant factor in selecting ESRD facilities for survey. HCFA stated its intention to continue studying this issue.

HCFA did not specifically comment on our suggestion that the Congress consider authorizing it to assess monetary penalties on ESRD facilities similar to those authorized for nursing homes. However, HCFA did state that it was pursuing a legislative strategy to consolidate and clarify current alternative or intermediate sanctions and possibly establish new authorities across all provider types.

HCFA also provided detailed technical comments, which we incorporated in the report where appropriate. HCFA's comments are in appendix IV.

As agreed with your offices, we will make no further distribution of this report until 4 days after its issue date. At that time, we will send copies to the appropriate authorizing committees; the Honorable Nancy-Ann Min DeParle, Administrator of HCFA; and interested congressional committees. We will also make copies available to other interested parties.

Please contact me at (202) 512-7119 if you have any questions about this report. Major contributors included Margaret Buddeke, Timothy Bushfield, and Mark Ulanowicz, under the direction of Frank Pasquier.

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Appendix I

Scope and Methodology

In order to evaluate the procedures and processes employed by HCFA, state survey agencies, and ESRD networks to monitor dialysis facilities, we interviewed (1) HCFA officials at its central office and four regional offices; (2) state survey officials in California, New Jersey, Texas, Oregon, and Washington; (3) ESRD network officials in five networks; and (4) officials from the Network Forum, which is the organization that represents all of the ESRD networks. We also collected data on the policies and procedures used by HCFA, state survey agencies, and ESRD networks to monitor dialysis facilities. We judgmentally selected these five states because they appeared to be typical based on available data on clinical outcome measures for each ESRD network and HCFA data on the number of condition-of-participation deficiencies. We also considered other factors, such as networks with larger states and more surveys, networks in which innovative monitoring practices were being employed, and networks with a mix of geographic oversight responsibility (networks with small geographic areas, large geographic areas, and multistate coverage). Within each network we selected and visited state survey agencies in the largest states. We reviewed and obtained documentation on facility surveys from HCFA and state agencies and clinical performance data collected by ESRD networks. We also analyzed data on the results of state surveys and the clinical outcomes of dialysis treatments from national databases.

To determine the extent to which on-site inspections of dialysis facilities are done to ensure compliance with Medicare quality standards, we analyzed HCFA's nationwide database of health care facility inspection results—the On-Line Survey, Certification, and Reporting (OSCAR) system. This data system records state survey results in a standard format. We analyzed data to identify the level of survey activity over time and to determine the extent that survey resources are spent on recertification surveys or initial surveys. We analyzed the frequency of citation of condition-of-participation deficiencies, which, unless corrected, are severe enough to warrant a facility's termination from the Medicare program. Determinations of such deficiencies are made by state agencies and receive HCFA's concurrence. Although we did not thoroughly assess the reliability of the database for the purpose of analyzing the frequency of recertification surveys, HCFA officials generally recognize it to be reliable for this purpose. However, the extent to which the data provide a consistent measure of quality of care across states is unknown. To make such a determination would require a review of the consistency of state survey processes nationally, which was beyond the scope of our work.

To determine the effectiveness of the processes used to ensure that facilities correct identified deficiencies, we reviewed the procedures used by state agencies and networks to require corrective actions and to evaluate whether facilities return to compliance. To gain more insight into the effectiveness of HCFA's procedures to ensure sustained compliance with quality-of-care standards, we looked particularly at the cases in which state agencies and/or ESRD networks knew about facilities that had serious and recurring problems. We reviewed the enforcement tools HCFA has available to address noncompliant facilities and assessed the extent to which these tools are utilized. We also analyzed HCFA data to identify the number of facilities that were terminated from the program.

In assessing HCFA's efforts to improve the targeting of facilities to inspect and monitor, we focused on HCFA's ongoing pilot project to profile facilities using a variety of facility-specific data. Because this project is in process and no strong indicators currently exist that identify facilities with quality-of-care problems, it is difficult to assess the overall effectiveness of this approach as a tool to identify noncompliant facilities. Instead, we assessed the limitations of the data that HCFA is planning to use to target facilities for on-site inspections. To this end, we reviewed the data HCFA plans to use and discussed data reliability issues with ESRD networks, HCFA researchers, noted renal care researchers, and the peer review organization that has contracted with HCFA to develop the pilot program. In addition, we discussed with state survey agency, ESRD network, and HCFA officials the extent to which state agencies and ESRD networks share information and coordinate their oversight activities.

Appendix II

Comparison of New ESRD Patients by Age and Primary Diagnosis, 1989, 1993, and 1997

	1989		1993		1997	
	Patients	Percentage of total	Patients	Percentage of total	Patients	Percentage of total
Age						
Under 15	430	1.0	475	0.8	583	0.7
15-24	1,309	3.0	1,337	2.3	1,373	1.7
25-34	3,435	7.8	3,652	6.2	3,833	4.8
35-44	4,649	10.6	5,840	10.0	7,080	9.0
45-54	5,850	13.3	7,846	13.4	10,936	13.8
55-64	9,100	20.8	11,383	19.4	15,317	19.4
65-74	11,978	27.3	16,964	28.9	22,056	27.9
75 or older	7,090	16.2	11,127	19.0	17,924	22.7
Total	**43,841**	**100**	**58,624**	**100**	**79,102**	**100**
Primary diagnosis						
Diabetes	14,404	32.9	21,319	36.4	33,096	41.8
Hypertension	12,786	29.2	17,333	29.6	20,066	25.4
Glomerulonephritis	5,863	13.4	6,439	11.0	7,390	9.3
Cystic kidney	1,307	3.0	1,624	2.8	1,772	2.2
Other urologic	772	1.8	888	1.5	1,388	1.8
Other cause	4,453	10.2	5,400	9.2	8,284	10.5
Unknown cause	2,209	5.0	2,621	4.5	2,920	3.7
Missing cause	2,047	4.7	3,000	5.1	4,186	5.3
Total	**43,841**	**100.0**	**58,624**	**100.0**	**79,102**	**100.0**

Source: National Institutes of Health (NIH), United States Renal Data System, *USRDS 1999 Annual Data Report* (Bethesda, Md.: NIH, Apr. 1999); and HCFA.

Appendix III

Medicare Conditions of Participation for Dialysis Facilities

Condition of participation	Number of standards and requirements	Description
Compliance with federal, state, and local laws and regulations	4	The facility and personnel employed by the facility must be licensed as required by federal, state, or local laws. This includes compliance with all public safety laws and requirements.
Governing body and management	70	The facility must be under the control of an identifiable body that adopts and enforces rules and regulations, including operational rules and patient care policies to safeguard the health and safety of individuals.
Patient long-term-care program and patient care plan	20	A professional, multidisciplinary health care team and the patient must develop a written long-term-care plan to ensure each patient receives the appropriate type of dialysis and care. Patient care plans, which have shorter time lines, must be personalized for each patient to address their specific medical, psychological, social, and functional needs. Both plans are to be regularly reviewed and updated to respond to changing patient needs.
Patients' rights and responsibilities	12	Dialysis facilities must have written policies describing the rights of the patients in order to ensure patients are fully informed about the services available, their medical condition, whether the facility reuses dialysis supplies, and whether the patient is a candidate for transplantation and home dialysis.
Medical records	21	Patient medical records must be maintained to document patient assessments, diagnosis, and treatment, and medical and nursing histories.
Physical environment	29	Dialysis services are to be provided in a setting that is functional, sanitary, safe, and comfortable for patients, staff, and the public.
Reuse of hemodialyzers and other dialysis supplies	92	Facilities that reuse hemodialyzers and other dialysis supplies must follow established protocols and standards to ensure patient and staff safety.
Affiliation agreement or arrangement	4	Agreements between dialysis facilities and inpatient dialysis centers must be in writing to ensure inpatient care and other hospital services are promptly available to dialysis patients.
Director of renal dialysis facility	6	Dialysis treatments must be under the general supervision of a qualified director, who is responsible for planning, organizing, conducting, and directing professional services.
Staff of a renal dialysis facility or center	6	Properly trained and qualified personnel must be present in adequate numbers to meet the needs of patients, including needs arising in emergencies
Minimal service requirements	27	Dialysis facilities must provide dialysis services as well as laboratory, social, and dietetic services needed to address ESRD patient needs.

Appendix IV

Comments From the Health Care Financing Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

DATE: JUN 5 2000

TO: Janet Heinrich , Associate Director
Health Financing and Public Health Issues
General Accounting Office

FROM: Nancy-Ann Min DeParle
Administrator

SUBJECT: General Accounting Office (GAO) Draft Report: "Medicare Quality of Care: Oversight of Kidney Dialysis Facilities Needs Improvement," (GAO/HEHS-00-114)

We appreciate the opportunity to review the GAO inspection of the monitoring of dialysis facilities for compliance with federal regulations and actions taken to correct deficiencies when they are identified. The Health Care Financing Administration (HCFA) agrees with the report's findings and will take appropriate additional steps to further improve the oversight and quality of care in dialysis facilities participating in the Medicare program.

Overall, HCFA agrees with your recommendations. Our efforts to improve performance of the dialysis facilities have had some measurable success. For example, between 1994 and 1998 the percentage of ESRD patients with adequate hematocrit (red blood cell) levels increased from 55 to 83 percent. Additionally, in the same time period, the percentage of patients receiving adequate dialysis increased from 49 to 74 percent. We also know from the U.S. Renal Data System, a joint HCFA and National Institutes of Health project, the overall one year mortality rates for dialysis patients decreased from 24.9 deaths per 100 patient years in 1990 to 22.8 in 1997.

These improvements are due in part to the leadership role HCFA took beginning in 1994 to develop clinical indicators that assess the quality of care for dialysis patients. This effort is now known as the Clinical Performance Measures Project (formerly the National/Network ESRD Core Indicators Project). HCFA, through the ESRD networks, collects clinical indicators on a national sample of dialysis patients in the areas of adequacy of dialysis, anemia management, and serum albumin (a protein in the blood that is an indicator of the patient's overall health). These data are collected, analyzed and described annually in a detailed report, the *ESRD Clinical Performance Measures Project Annual Report*. This report is distributed to all dialysis providers for their use in identifying opportunities for improvement. Using this national sampling approach, we have documented improvement every year in the number of dialysis patients achieving the benchmarks for these clinical indicators since 1994.

Page 2 - Janet Heinrich

We have also undertaken steps to begin collecting facility-specific data. In 1998, HCFA directed the development of 16 clinical performance measures that we are collecting from a sample of facilities this year. This effort was initiated to implement a provision in the Balanced Budget Act of 1997 that requires HCFA to measure and report the quality of renal dialysis services. The 16 clinical measures are similar to those of the Core Indicators Project described above, with the addition of measures for evaluating vascular access (the point of access to the dialysis patient's blood stream). In 1999 this work was merged with the Core Indicators Project and the combined project is known as the ESRD Clinical Performance Measures (CPM) Project. The CPM Project is part of a larger ESRD Core Data Set that is under development. Through the ESRD Core Data Set, we are striving to determine and report accurate, meaningful facility-specific performance measures that will allow comparisons across dialysis centers and will ultimately increase facility accountability and patient choice.

Facility-specific data profiles have been developed for the use of State Survey Agencies in targeting their surveys and this tool is currently being piloted in 7 States. These reports will be only one of several diagnostic tools to determine which facilities to survey. Other tools will include complaints, past inspection behavior, change of ownership, and ESRD Network information. Once the pilot project has been completed, we will evaluate the effectiveness and efficiency of these reports.

Despite our progress in improving the quality of care, there continue to be weak performing dialysis facilities. However, the Networks and States are working aggressively with these dialysis facilities to improve their care. We also intend to publish in early 2001 a proposed rule on new Conditions for Coverage for dialysis facilities that will strengthen requirements. In addition, the President's FY 2001 budget would increase the funding level for surveys of ESRD facilities from $2.2 million to $6.3 million. This funding level would allow us to decrease the time between surveys from every six years to every three years and increase the number of surveys from 956 to 1,847 in FY 2001.

Attached are our comments on the specific recommendations in the report. We look forward to working closely with GAO on these issues in the future.

Comments of the Health Care Financing Administration on the General Accounting Office (GAO) Draft Report "Medicare Quality of Care: Oversight of Kidney Dialysis Facilities Needs Improvement"

GAO Recommendation 1

Develop procedures on how and when to use its existing authority to impose partial or complete payment reductions for ESRD facilities that do not meet Medicare quality standards for dialyzer re-use.

We concur with the recommendation. The GAO report suggests that implementing an additional sanction, partial or complete payment reductions for ESRD facilities that do not meet standards for dialyzer re-use, is appropriate in certain situations. We agree that development of alternative sanctions to apply to ESRD facility that do not meet Medicare quality standards for dialyzer re-use would be useful. We will develop an Notice of Proposed Rule Making (NPRM) and procedures to implement these sanctions as well as other sanctions which may be included in the NPRM.

In addition, HCFA is also pursuing a legislative strategy to consolidate and clarify current alternative or intermediate sanctions, and possibly establish new authorities across all certified provider-types.

GAO Recommendation 2

Establish procedures to facilitate better and more routine cooperation and information sharing between ESRD Networks and State survey agencies, particularly in targeting facilities for on-site surveys.

HCFA agrees that certain facility-specific data held by the ESRD Networks should be shared with the State survey agencies. To this end, HCFA is currently working with the Office of General Counsel to resolve issues stemming from section 1160 of the Social Security Act that deals with "Prohibition Against Disclosure of Information" by Networks. Once these issues are resolved, we will expect and require a higher degree of information sharing between the State agencies and the ESRD Networks.

We are now taking steps, in response to an earlier recommendation by the Inspector General, DHHS, to clearly delineate the responsibilities of the State agencies and the ESRD Networks. While the State agencies will continue to perform their traditional role of carrying out unannounced Federal inspections of ESRD facilities, and ESRD Networks will continue to perform their traditional role of improving the quality of care delivered by ESRD suppliers by engaging in performance improvement projects with ESRD facilities, we would encourage any cooperative information sharing to facilitate the identification of poor performing facilities.

HCFA will also establish specific guidelines for coordinating, monitoring and reporting to build a more cooperative relationship between States and Networks, especially in the area of sharing expertise to further protect ESRD patients. HCFA has established a State Agency Information Workgroup that includes State survey agency representatives and ESRD Network representatives, as well as technical, clinical, and scientific experts in data base management and clinical nephrology. This workgroup is identifying data elements from current data bases that will be helpful to State survey agencies in selecting facilities for surveys and in structuring surveys. In structuring the survey process, data will be used to understand a facility's potential strengths, to identify potential problems, to increase the efficiency of the survey, and to increase the effectiveness of the survey.

In addition, as funding permits, we plan to convene forums in which, HCFA, Network and State officials can discuss ways to partner to ensure the sharing of information and promote quality care for ESRD patients.

GAO Recommendation 3

Evaluate its project for using clinical outcome data to select facilities for on-site review before it uses such data as a key factor in the selection process. A trial component of the evaluation should be a determination of the extent to which the data are sufficient to predict which facilities have a higher likelihood of not complying with Medicare's conditions of participation.

We concur with the recommendation and note that this process is already underway. HCFA is currently managing an ESRD facility-specific data project under contract with the Colorado Foundation for Medical Care. That project is being pilot tested in 7 States (i.e., Alabama, Georgia, Massachusetts, Montana, North Carolina, North Dakota, and Oklahoma). This HCFA project will have both a quantitative and qualitative evaluation component.

HCFA is interested in the relationships and predictive value of facility-based data profiles. Of particular interest is the relationship of surveyor results with mortality rates and practice patterns at the facility level. Based on recent data from Texas, the University of Michigan showed that mortality is strongly related to both dose of dialysis and to hematocrit levels. The same data showed a strong relationship of State surveyor results with mortality and practice patterns.

Mortality has been shown to be associated with several facility-level practice patterns, including the dose of dialysis (both Kt/V and URR). The earliest report was a United States Renal Data System (USRDS) abstract at the American Society of Nephrology (ASN) Annual Meeting in 1995. McClellan (1996) reported similar results in a regional study. The University of Michigan completed analyses of HCFA's URR and mortality data, showing that the relationship of higher dose to lower mortality is still important at the facility level. These reports fit well with the other sources, such as the Dialysis Outcomes Quality Initiative (DOQI) guidelines and the recommendations of the HCFA ESRD Clinical Performance Measures Project. The University of Michigan has used information in the facility-specific reports to quantify for clinicians how many deaths at their facilities are attributable to low dialysis dose.

HCFA recognizes that mortality statistics exhibit substantial random variation, especially for small facilities. Despite this random variation, the University of Michigan has evaluated a classification rule for identification of "high mortality" facilities defined as having a statistically significant elevation of mortality risk by more than 20 percent above the national norms. Calculations show that this classification scheme has error rates of about 10 percent (90 percent accuracy) for the mix of facility sizes in the United States, with lower error rates for larger facilities. Both false positives and false negative rates are at about the 10 percent level.

Furthermore, the HCFA project to use data reports will be only one of several diagnostic tools to determine which facilities to survey. Other tools will include complaints, past inspection behavior, change of ownership, and Network information.

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Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

External Quality Review of Dialysis Facilities

Two Promising Approaches

JUNE GIBBS BROWN
Inspector General

JUNE 2000
OEI-01-99-00051

EXECUTIVE SUMMARY

PURPOSE

To describe two promising approaches to hold dialysis facilities more fully accountable for their quality of care.

BACKGROUND

Importance of External Quality Review

Case files, performance data, and marketplace realities underscore the importance of external quality review for dialysis facilities. Case files reveal numerous instances of poor care. In one instance we found that a patient received a drug overdose that resulted in prolonged bleeding and subsequent hospitalization. Performance data collected from dialysis facilities reveal that a substantial portion of patients do not achieve the outcomes recommended by clinical practice guidelines. Similarly, scientific studies suggest widespread variations in the quality of care patients receive. Of particular note is one that revealed higher mortality rates at facilities providing lower doses of dialysis. Finally, marketplace pressures triggered by growth, consolidation, competition, and concerns about cost have caused service disruptions that can and have jeopardized patient care.

External Review Bodies

The Health Care Financing Administration (HCFA) relies upon two major entities to conduct such external reviews: the End-Stage Renal Disease (ESRD) Networks established under the Social Security Act and the State survey agencies. HCFA contracts with the 18 Network organizations, which are governed primarily by renal professionals associated with facilities in the Network's region, to perform multiple functions, mostly oriented around collegial efforts to promote improvements in the quality of care, and to respond to complaints lodged by patients, facility staff, or others. HCFA funds the State agencies, typically within departments of public health, to perform a more regulatory role: to conduct on-site Medicare certification surveys of facilities and to investigate complaints, both in accordance with Medicare Conditions for Coverage for dialysis facilities.

Our Companion Report

In our companion report, *External Quality Review of Dialysis Facilities: A Call for Greater Accountability*, we identified major shortcomings in the external quality review system upon which HCFA relies. We indicated that it was overly collegial in nature, that it reflected little collaboration between the Networks and the State agencies, and that in many respects it lacked accountability. One of our major recommendations to HCFA was

to hold dialysis facilities more fully accountable for the quality of care they provide. We elaborated on steps that could be taken toward that end by (1) revising the Medicare Conditions for Coverage, (2) using facility-specific performance measures both to help facilities improve the quality of care and to ensure that they meet minimum standards, (3) enhancing the role of Medicare certification surveys conducted by the State agencies, and (4) facilitating the development of publicly accountable mechanisms for identifying medical injuries.

This Report

During the course of our inquiry into the external review system, we learned of two initiatives that are particularly instructive to how facilities can be held more fully accountable. One was a State-initiated effort intended to revitalize the on-site survey process through issuing tougher standards, conducting more frequent surveys, and developing close collaboration between the State survey agency and the Network. The other was a Network-initiated effort to develop *facility-specific* performance measures and to apply them in ways that both foster improvement for all facilities and target corrective interventions for poorly performing facilities. Because these initiatives are so pertinent to our recommendations, we devote this report to describing them.

INITIATIVES

Initiative 1. Collaborative enforcement of more stringent State standards.

In 1995, in the aftermath of an outbreak of hepatitis B in a Houston dialysis facility, the Texas legislature passed a law calling for the licensure of all dialysis facilities in the State. This in itself was a step that many States had previously taken. What distinguished the Texas action was that it involved developing more rigorous standards, close collaboration of the Texas Network and the State survey agency, and additional State funding.

Additional minimum standards. The Texas Department of Health (the State survey agency), with input from the Texas Network's medical review board, established minimum standards for facilities that exceed the Medicare Conditions for Coverage. The standards call for facilities to report adverse events, maintain minimum staffing ratios, and provide formal training to all technicians.

Required reporting on a set of performance measures. Texas licensure law requires facilities to report annually on a set of clinical performance measures. The Network and the State agency both review the performance measures.

More frequent on-site surveys. In the first year of operation (1996/97), the State surveyed all 237 dialysis facilities in the State. In each of the subsequent two years, it has surveyed about one-half of all facilities. By contrast, only about 17 percent of dialysis facilities in the country received a Medicare survey in 1998.

Ongoing and pervasive Network-State agency collaboration. The Network medical review board serves as a source of clinical expertise that contributes to the State agency's enforcement efforts. It advises on how the State should address problems concerning clinical outcomes that the surveyors come across during their site visits. It helps monitor facilities put on corrective action plans by the State.

Initiative 2. Use of facility-specific performance measures

The Renal Network, covering Indiana, Kentucky, Ohio, and Illinois, uses facility-specific performance data in a balanced fashion: to foster improvements in the overall level of care as well as to identify poor performers for further review. This Network, which has the largest number of patients of the 18 Networks, conducts this initiative without additional Federal funds.

Electronic data system. The Network developed software to track patients and their care. Facilities use the software to submit data electronically to the Network on multiple clinical performance measures, throughout the year on all dialysis patients.

Facility-specific and physician-specific report cards. The Network disseminates confidential, facility-specific performance reports three times a year to all facilities in its region. The report compares the performance of an individual facility to its own past performance as well as to its peers. The Network also disseminates confidential physician-specific reports three times a year to all physicians, which compares their performance to their peers.

Targeted interventions of poor performers. The Network analyzes the facility-specific performance data to identify particular facilities as well as corporate entities in need of interventions.

CONCLUSION

Better collaboration between State survey agencies and Networks and better use of facility-specific performance measures are two important paths to improve the oversight of dialysis facilities. These two initiatives demonstrate what can be accomplished given innovative leadership and adequate resources. In both cases, the Networks play central roles promoting continuous quality improvement *and* enforcing minimum standards of care. Although we did not evaluate the results achieved by each, we find both initiatives to be promising enough in their conception and early implementation to warrant careful consideration by other Networks and States, and by HCFA, as it seeks to develop effective mechanisms for holding facilities more fully accountable for the quality of care they provide.

COMMENTS

Within the Department of Health and Human Services, we received comments from HCFA. We also solicited and received comments from the following external parties: the Forum of End Stage Renal Disease Networks, the Association of Health Facility Survey Agencies, and the American Association of Kidney Patients. We include the detailed text of all these comments and our responses to them in the our report, *External Quality Review of Dialysis Facilities: A Call for Greater Accountability* (OEI-01-99-00050).

TABLE OF CONTENTS

INTRODUCTION

PURPOSE

To describe two promising approaches to hold dialysis facilities more fully accountable for their quality of care.

BACKGROUND

Importance of External Quality Review

About 3,200 dialysis facilities provide ongoing, life-sustaining dialysis treatments to about 230,000 patients. Many of these patients are suffering from other complicated diseases such as diabetes and hypertension, and nearly all of them are Medicare beneficiaries. To foster improved care and minimize risks to patients, dialysis facilities conduct their own internal monitoring efforts. External review provides a vital additional safeguard.

Case files, performance data, and marketplace realities underscore the importance of external review. Case files reveal numerous instances of poor care. In one instance we found that a patient received a drug overdose that resulted in prolonged bleeding and subsequent hospitalization. Performance data collected from dialysis facilities reveal that a substantial portion of patients do not achieve the outcomes recommended by clinical practice guidelines. Similarly, scientific studies suggest widespread variations in the quality of care patients receive. Of particular note is one that revealed higher mortality rates at facilities providing lower doses of dialysis. Finally, marketplace pressures triggered by growth, consolidation, competition, and concerns about cost have caused service disruptions that can and have jeopardized patient care. (See our companion report, *External Quality Review of Dialysis Facilities: A Call for Greater Accountability.)*

HCFA's Oversight through Networks and State survey agencies

The Health Care Financing Administration (HCFA) is responsible for ensuring that all beneficiaries who undergo dialysis treatment receive proper care in dialysis facilities. HCFA contracts with two groups, the End-Stage Renal Disease (ESRD) Networks[1] and the State survey agencies, to oversee the quality of care that dialysis facilities provide. HCFA requires the 18 regional Networks to collect data from facilities, conduct annual quality improvement projects, and evaluate and resolve complaints. HCFA contracts with the State agencies, typically within departments of public health, to conduct on-site Medicare certification surveys of facilities and to investigate complaints, both in accordance with Medicare Conditions for Coverage for dialysis facilities.

Medicare Coverage of ESRD

In 1972, Medicare began providing coverage to individuals with ESRD, or permanent kidney failure, making it the only entitlement criteria for Medicare based solely on a disease category.[2] Medicare covers all treatment methods for patients: hemodialysis, peritoneal dialysis, and renal transplants. Patients receiving hemodialysis, the most common method, typically receive treatment in outpatient facilities three times a week. Peritoneal patients typically perform daily treatments at home and rely on outpatient facilities for ongoing support. (See Primer on Dialysis.)

Our Inquiry

In our companion report, *External Quality Review of Dialysis Facilities: A Call for Greater Accountability*, we identified major shortcomings in the external quality review system that HCFA relies upon. We indicated that it was overly collegial in nature, that it reflected little collaboration between the Networks and the State agencies, and that in many respects it lacked accountability. One of our major recommendations to HCFA was to hold dialysis facilities more fully accountable for the quality of care they provide. We elaborated on steps that could be taken toward that end by (1) revising the Medicare Conditions for Coverage, (2) using facility-specific performance measures both to help facilities improve the quality of care and to ensure that they meet minimum standards, (3) enhancing the role of Medicare certification survey conducted by the State agencies, and (4) facilitating the development of publicly accountable mechanisms for identifying medical injuries.

During the course of our inquiry into the external review system, we learned of two initiatives that are particularly instructive to how facilities can be held more fully accountable. One was a State-initiated effort intended to revitalize the on-site survey process through issuing tougher standards, conducting more frequent surveys, and developing close collaboration between the State survey agency and the Network. The other was a Network-initiated effort to develop *facility-specific* performance measures and to apply them in ways that both foster improvement for all facilities and target corrective interventions for poorly performing facilities. Because these initiatives are so pertinent to our recommendations, we devote this report to explain them further.

The promising approaches presented here appear to have wider applicability, although we recognize that what works well in one part of the country may not necessarily work well elsewhere. We also recognize that our highlighting of these two approaches does not necessarily mean that other important initiatives are not taking place. In fact, in our companion report we reference a number of such initiatives.

Our understanding of the two promising approaches addressed in this report draws on site visits, interviews with State surveyors, Network staff, HCFA personnel, and renal professionals, and a review of relevant documents.

We conducted this study in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

PRIMER ON DIALYSIS

TYPES OF TREATMENT

Dialysis is the process of removing toxins from the body by diffusion across a semipermeable membrane, thereby compensating for kidney failure. There are two types of dialysis:

Hemodialysis. Removal of toxins directly from the patient's blood stream, requiring direct access to the bloodstream. The patient's blood is cycled through an artificial kidney, an external machine, that removes the toxins and excess fluids from the blood. The artificial kidney machine uses a semipermeable membrane, called a hemodialyzer, to filter out the toxins from the blood.

Peritoneal dialysis. Utilizes the patient's natural peritoneal membrane, located in the abdominal cavity, to remove toxins and excess fluids.

COMMONLY USED PERFORMANCE MEASURES

Adequacy. Refers to the amount of toxins, such as urea and creatinine, removed from the body during dialysis.

- **Urea reduction ratio (URR) and Kt/V.** Two measures used to measure adequacy in hemodialysis patients based on the removal of urea. The URR is a function of the amount of urea removed during dialysis, as determined by the pre- and post-dialysis blood urea nitrogen levels. The Kt/V is a function of the amount of urea removed multiplied by the time on dialysis, divided by the volume of urea distribution, or approximately the amount of water in the body. The National Kidney Foundation's Dialysis Outcomes Quality Initiative (DOQI) practice guidelines recommend a Kt/V of at least 1.2, or an average URR of at least 65 percent for the minimum delivered dose of hemodialysis.
- **Creatinine clearance and Kt/V_{urea}.** Two measures used to measure adequacy in peritoneal patients. Creatine clearance measures the removal of creatine and Kt/V_{urea} measures the removal of urea. DOQI recommends a weekly dose of continuous ambulatory peritoneal dialysis of at least 2.0 per week and a creatine clearance of at least 60L/week/1.73 m^2.

Anemia management. Anemia, or inadequate red blood cells, is a common concern among dialysis patients.

- **Hematocrit and hemoglobin.** Two measures of the severity of anemia. Hematocrit measures the ratio of red blood cells to the plasma volume, and hemoglobin measures the amount of a specific protein in red blood cells that carries oxygen. DOQI recommends a target range of 33 percent to 36 percent for hematocrit and between 11 g/dL to 12 g/dL for hemoglobin.
- **Ferritin level and transferrin saturation (TSAT).** Two measures used to monitor the level of iron. Ferritin is a measure of the level of iron stored within the body and TSAT is a measure of iron immediately available to produce red blood cells. DOQI recommends a ferritin level of $\geq$100 ng/mL and a TSAT $\geq$20 percent.

Vascular access. The point of direct access to the blood stream for hemodialysis. There are three types:

- **Catheter.** A tube is placed in a blood vessel, primarily used for temporary access to the blood stream.
- **Native arteriovenous fistula.** A patient's own artery and vein are joined surgically to allow arterial blood to flow through a vein, usually placed in the forearm and takes several weeks to mature. DOQI guidelines recommend that primary fistulas be placed in at least 50 percent of new patients.
- **Synthetic arteriovenous graft.** A synthetic blood vessel is used to surgically join the patient's artery and vein, usually placed in the forearm and takes several weeks to mature.

Nutrition. Inadequate nutrition is a common concern among dialysis patients.

- **Serum albumin level.** A measure of the level of proteins in the blood.

INITIATIVES

Initiative 1. Collaborative enforcement of more stringent State standards.

Through its licensure program, the Texas Department of Health has increased its regulatory presence by requiring facilities to meet standards that exceed Medicare's and by enforcing them through frequent on-site surveys. The program has also established a formal working relationship between the Department (the State survey agency) and the End-Stage Renal Network of Texas, Inc. (Network #14). This collaboration is facilitated in part by the fact that the Network covers only the State of Texas, whereas most other Networks cover several States.

History of the Texas licensure program

The Texas initiative to license dialysis facilities grew out of concerns for patient safety precipitated by several well- publicized events. In 1994, 14 patients contracted hepatitis B in a Houston dialysis facility that failed to take the appropriate precautions to prevent the spread of infectious diseases. As a result, the city of Houston's Health Department alerted the State agency. Upon its investigation, the State found the facility out of compliance with several Medicare Conditions for Coverage related to infection control and it placed the facility on a 23-day Medicare termination track. Shortly thereafter another complaint investigation at the same facility identified continuing problems with infection control and the facility was placed on a second 23-day termination track. The facility received no monetary or administrative penalty such as exclusion from the Medicare program for the harm it caused patients. The lack of any substantiative corrective action led concerns about the ability of the Federal oversight system to protect patients from harm in dialysis facilities.

Thus, the State legislature in 1995 enacted a law requiring all dialysis facilities to be licensed in order to operate in the State.[3] The legislation established a formal relationship between the Department of Health and the Network's medical review board, which comprises local renal professionals with clinical expertise as well as patient representatives.[4]

The State legislature established licensing fees for 250 dialysis facilities in the State. Facilities pay an initial licensing fee of $2,000 and an annual licensing fee that ranges from $1,500 - $2,500 depending on the number of dialysis treatments at the facility. Licensure fees are not directly funneled to the program. Fees go into the State general fund and program funding is appropriated every two years. Recently, due to budget cuts to the Department of Health as a whole, the future operations of the program may be reduced.[5]

Texas standards for dialysis facilities

The Texas Department of Health, with input from the Network's medical review board and the renal community, developed and implemented minimum standards for dialysis facilities. The licensure standards are similar to the Medicare Conditions for Coverage but also include additional standards. One of the more significant standards under Texas licensure is the requirement for facilities to conduct their own internal quality assurance programs led by the facility's governing body. This program must include data analysis and implementation of their own improvement plans. Other Texas standards that exceed Medicare Conditions include annual reporting on a set of standardized performance measures, required staffing ratios, required training of technicians, and specific requirements for water treatment.

Another important licensure standard is the requirement to report adverse events. Facilities must report all events involving a patient death or hospitalization, conversions of staff or patients to hepatitis B+ status, fire, or a natural disaster. These reports must be submitted within 10 working days to the Department of Health. The State surveyors review the reports and, if warranted, conduct a survey. Since the program began, the greatest majority of adverse events reported have been those involving a hospitalization. (See table 1.)

Table 1. Dialysis Facility Accident Reports

Occurrence	1996-1997	1997-1998	1998-1999*
Death	32	28	6
Hospitalization	275	565	543
Conversions to hepatitis B+	10 patients	6 patients 1 staff**	14 patients
Fire	1	1	3

* As of June 18, 1999
** Staff found to be hepatitis B+ at hire
Source: 1999 ESRD Facility Annual Report, Texas Department of Health

Network-State collaboration around on-site surveys

The Department of Health enforces its minimum standards for dialysis facilities primarily through unannounced on-site surveys. With its additional funds from licensure fees, Texas is able to conduct surveys more frequently than the national average. In the first year of the program, the State surveyed all of its approximately 250 facilities. Subsequently, the State has surveyed about half of all facilities annually.[6] By contrast in 1998, only 17 percent of existing facilities nationwide received a Medicare survey. (See our companion study entitled *External Quality Review of Dialysis Facilities: A Call for Greater Accountability.*) Also due to additional funds, Texas has been able to maintain surveyors that specialize in surveying dialysis facilities.

A unique aspect of the Texas survey process is the involvement of the Network's medical review board. When a surveyor identifies a facility problem that is related or potentially related to negative patient outcomes, it refers the facility to the medical review board for review. The medical review board reviews a short, blinded narrative prepared by the surveyor indicating the reason for the referral, comparative data on the facility's performance, and the facility's history. Based on its review, the medical review board makes recommendations to the State for the appropriate corrective action plan the State should impose. The State made 33 referrals to the Network in the first year of the program, 11 in the second year, and 21 in the third year. (See figure 1.)

Figure 1. Examples of survey deficiencies that led the State to refer a facility to the Network's medical review board.

Facility failure to:

- assess patient status before beginning treatment
- train and supervise dialysis technicians
- monitor patients during treatment
- provide adequate dialysis
- provide effective treatment of anemia
- ensure water is safe for dialysis
- provide a sanitary environment for dialysis
- provide adequate infection control practices
- provide sufficient qualified staff

The State usually agrees with the Network's recommendations and informs the facility of the corrective action(s) the State is requiring the facility to take.[7] The State can require a facility to develop and implement one of three levels of corrective action plans. A level one corrective action plan involves little monitoring by the State and none by the Network. Level two and level three plans involve more monitoring that can include the appointment of an on-site monitor or manager, subject to the approval of the State and the medical review board. In addition, the State can take enforcement actions against a facility that range from fines to revoking licenses.

Once the State requires a facility to develop and implement a corrective action plan, the medical review board continues to play an important role. The medical review board, at the request of the facility, can provide important technical assistance on corrective action plans. For more serious problems the medical review board and the State jointly monitor the facility for up to 6 months. During this time, the medical review board and the State review key facility documents, including policies, educational programs for staff, practice audits, and quality improvement meetings.

If the State requires the facility to appoint a monitor, the medical review board and the State receive regular updates directly from him or her. When the medical review board determines that the facility has made sufficient progress towards correcting the problem, it recommends to the State that the facility be released from its monitoring requirements. The medical review board can also recommends follow-up surveys. The State reviews the medical review board's recommendation and makes the final decision.

Additional collaboration sometimes occurs in complaint investigations when the State finds it needs some additional clinical expertise. The State may consult the Network when it receives a complaint that requires the expertise of the medical review board such as complaints involving questionable medical practice and patient behavior. The State surveyors may consult with the Network staff or its medical review board prior to going on-site and sometimes invite Network staff or medical review board members to assist on the actual survey depending on the complexity of the issue. Once the surveyors perform a complaint survey, the process is similar to the one described above for any survey process. In addition, the Network can refer complaints to the State, which most other Networks routinely do as well.

The renal professionals we interviewed in Texas felt that an increase in on-site surveys and the collaboration between the State and the Network in monitoring facilities has resulted in greater accountability of facilities. Surveyors and renal professionals agreed the frequent surveys help enforce minimum standards. Surveyors also indicated that they now have greater credibility when they are on-site because they are backed by the Network's medical review board that has clinical expertise. As a result, the State surveyors are able to more easily cite facilities for quality of care problems. Facility staff also reported that surveys now are more valuable and substantive due to the new standards.

Network-State collaboration around standardized performance measures

Another major aspect of the Texas licensure program involves the sharing of standardized performance measures between the State and the Network — a practice that rarely occurs in other States. Beginning in 1997, the State contracted with the Network to collect a core set of performance measures on a sample of 30 patients at each facility from the last quarter of 1996. Under its contract with the State, the Network collects data on the adequacy of dialysis (urea reduction ratio and Kt/V), the management of anemia (hematocrit level), and the rate of peritonitis episodes (a bacterial infection that commonly afflicts patients undergoing peritoneal dialysis). The Network also collects on its own patient demographic information and mortality data. Facilities report the data to the Network either by filling out paper forms or by saving the data on a computer diskette for electronic transmission. Most facilities use the paper method.

The Network uses the data it collects on behalf of the State to produce annual facility-specific reports called *Quality of Care Indicator Reports*. These reports compare a facility's performance to itself over time and to other facilities in the State on each performance measure required by the State. In addition, national comparative data and clinical guidelines are included where available. The Network uses the additional data it collects on its own to produce annual facility-specific reports entitled, *Facility Trends and Profiles*. These reports compare a facility's mortality rate and patient demographic to other facilities in the State. The Network disseminates both reports to the individual facilities and to the State. The facility-specific reports are not released to the public; the data are protected under the licensure law. However, some aggregate information is

available to the public. The Network also uses the data to identify future quality improvement activities.

Surveyors use both reports as they conduct surveys. Prior to going on site, surveyors review a facility's reports to note areas that warrant further probing. While on site, surveyors carefully walk through the reports with the head nursing staff and explain how to interpret the information. Also, surveyors probe areas of poor performance. If a facility cannot provide an adequate explanation for its poor performance, surveyors will discuss possible improvement activities. Because licensure standards require facilities to conduct their own quality assurance program, surveyors will cite a facility if they determine that the facility was not making efforts to conduct its own internal monitoring of the performance measures and take corrective action as needed.

Texas licensure also requires the Network's medical review board to review the facility-specific reports annually and to refer poor performers to the State. To meet this task, the medical review board developed criteria to identify facilities for a referral. For 1999, the medical review board used the following criteria: (1) any two indicators that were one standard deviation below the State mean, (2) any one indicator that was two standard deviations below the State mean, or (3) any statistically significant, high 3-year aggregate standard mortality rate. Facilities referred by the Network receive a high priority for a survey.[8] The Network referred 39 facilities in 1999, 31 facilities in 1998, and 47 facilities in 1997.

Network staff and medical review board members stated that the data were helpful for their quality improvement activities. Without a licensure law requiring facilities to report and ensuring confidentiality, as well as providing additional funding, the Network felt it would be difficult for them to collect and analyze facility-specific data of this scale. Facility staff we spoke with found the facility-specific report helpful for internal quality improvement activities. Facilities also reported that without the Network data many would not have comparative information on their performance. The performance data suggest that improvements have been made. The percent of patients receiving adequate dialysis, as measured by a urea reduction ratio >65 percent, has increased from 77.5 percent in 1996 to 84 percent in 1997.[9]

Initiative 2. Use of facility-specific performance measures.

The Renal Network, Inc. collects and uses facility-specific performance data involving all patients at all facilities in its region. It uses these data in a balanced fashion: to foster improvements in the overall level of care as well as to identify poor performers for further review.

The Renal Network is a consolidation of two Networks. In 1996, HCFA awarded the Tri-State Renal Network (#9) covering the State of Indiana, Kentucky, and Ohio the contract for Network #10 covering the State of Illinois to become The Renal Network, Inc. (#9/10). The Network covers over 390 facilities that serve an estimated 28,000 patients. Based on the number of patients undergoing treatment in the Network, it is the largest of the 18 Networks. The Network has not received additional funds from HCFA to perform this project.[10]

Collecting performance measures

The Network collects performance measures from facilities on all their patients. The selected performance measures cover the following treatment areas: adequacy of dialysis, anemia management, and nutrition. The Network collects the measures at various times throughout the year depending on the measure itself and the treatment modality of the patient. The Network also routinely collects and updates patient demographic and medical history information, such as a patient's physician, type of vascular access, progress towards a transplant, and mortality. The Network's patient-specific data provides greater analytical possibilities. On facilities themselves, the Network collects key descriptive information such as location, number of shifts, chain affiliation, and names of key personnel. (See figure 2.)

Figure 2. Performance Measures Collected by The Renal Network

For all hemodialysis patients for five months each year, the Network collects: urea reduction ratio, Kt/V, hematocrit, ferritin levels, transferrin saturation, and type of vascular access, serum albumin.

For all peritoneal patients on six months each year, the Network collects: Kt/V, serum creatinine, hemoglobin, ferritin levels, transferrin saturation, blood pressure, and serum albumin.

For all patients the Network updates monthly: date of birth, sex, race, date of first dialysis, primary diagnosis, co-morbidities, insurer, physician, type of dialysis, transplant status, and mortality data.

To facilitate the collection of performance measures, the Network developed, and has since revised, a software program for facilities to enter and electronically submit their data to the Network on a computer diskette. The Network downloads the data from the diskettes into its own database for analysis. This type of electronic submission greatly reduces the costs and errors associated with data entry and allows for more timely

analysis. The data are only about three months old when the Network feeds it back to facilities.

Using performance measures to improve the quality of care

Facility-specific reports. Since 1996, the Network has created and disseminated facility-specific performance reports to all facilities. Facilities receive their own individual *Clinical Performance Measures Feedback Report* three times a year. (See appendix A.) The Network's report is similar in format to HCFA's national reports on the quality of care in dialysis facilities. However, HCFA's report makes comparisons of performance measures at the Network level only and does not provide any information on the performance of individual facilities.[11] In contrast, the Network's reports compare an individual facility to its own past performance and to other facilities in its region, State, and Network on each performance measure.[12] The *Clinical Performance Measures Feedback Report* also contains the number of patients, mean, and standard deviation for each measure. In addition, the report contains a comparison of a facility's patient demographics compared to the region, State, and Network to help address case mix issues.

The facility's administrator, medical director, and all attending physicians receive a copy of the report. The Network does not routinely share these reports with the State survey agencies. However, some State surveyors review a facility's reports when on site. The Network also does not share the facility-specific reports with the public. Instead, it releases reports to the public presenting aggregate trends at the State and Network level.

Since 1991, the Network also has disseminated the *Patient Demographic Report*. This annual report compares a facility's patient population to its State and Network and provides an analysis of facility-specific mortality rates. These reports also are not routinely shared with the State and are not disclosed to the public.

The Network's data suggest that the percentage of hemodialysis patients with adequate dialysis, as measured by a urea reduction ratio of >65 percent, has increased from 71 percent in 4th quarter 1997 to 76 percent in 4th quarter 1998. Network data also suggest that anemia management has improved as measured by higher patient hematocrit levels. The percentage of hemodialysis patients with a hematocrit >31 percent has increased from 72 to 79 percent over the same time period.[13] The nurses and technicians we interviewed indicated that the facility-specific reports are the most important activity the Network performs. Without the Network data, nurses stated they would have no idea how their facility's performance compared to others in the area. These reports were a motivator for improvement, according to these nurses. The nurses also stated that the benefits of having the reports outweighed the burden on the facility to report the data.

Physician-specific reports. The Renal Network is the only Network that provides physician-specific reports. In 1997, the Network created a *Physician Activity Sheet*, that compares the performance of individual physicians to their peers at the facility, State, and

Network level and to clinical guidelines on the performance measures collected by the Network. (See appendix B.) The Network disseminates the physician reports three times a year. Only individual physicians receive their report unless a physician group requests to have an aggregate analysis of its physicians. Physicians are provided the opportunity to verify the patients assigned to them.

The Network's analysis suggests that physician-specific reports have been influential in improving the quality of care. A recent Network survey showed that 55 percent of physicians use the reports for internal quality improvement activities and over 40 percent review them as part of dialysis facility meetings and/or to assess their overall patient population. Another Network analysis showed that even as the patient/physician ratio has increased from 45.9 to 51.4 between 1997 and 1998, physician performance has improved. Between 1997 and 1998 the percentage of patients with Kt/V $\geq$1.2 increased from 77 percent to 80 percent and the percentage of patients with hematocrits $\geq$31 increased from 71 to 77. The Network concluded that these physician report cards have helped fostered improvements by encouraging physicians to better follow clinical guidelines.[14]

Identifying topics for improvement activities. The Network also conducts additional analyses of the performance measures to identify trends. This helps the Network choose topic areas for future improvement activities that will have the greatest impact on improving quality. The Network is flexible in the types of analyses it performs. It tries to incorporate suggestions from the renal community as well as address timely issues. In the past, the Network has conducted special analyses looking at the comparative performance of facilities located in metropolitan regions as well as looking at the comparative performance of facilities after new patients have been excluded.

Using performance measures to identify poor performers

Facility profiling tool to identify poor performers. In order to help identify poor performers, the Network's medical review board is developing a new system that profiles facilities based on their performance in several categories. The profiling tool uses the following categories: complaints, data compliance, mortality, hospitalization, the use of catheters, facility-specific core indicators, and participation in Network projects. Each category captures a different method of evaluating the quality of care provided at the facility. This tool is based on the notions that quality of care cannot always be captured by one or even several performance measures, and a facility that provides poor clinical care is probably performing poorly on administrative duties as well, which are easier to measure.

A facility receives a *hit* for poor performance or non-compliance in each of the categories based on the criteria determined by the medical review board. For example, if a facility's urea reduction ratio is two standard deviations below the Network average, it would receive one hit. Each hit is multiplied by a weight that is attributed based on its correlation to the quality of care in the facility. For instance, a hit for a mortality rate is

multiplied by greater weight than a hit for data compliance. The hit multiplied by the weight equals the number of points the facility receives. The total sum of a facility's points determines its overall score. In theory, the higher the score, the poorer the performance of the facility.

The Network plots the final scores of all facilities and identifies facilities in the highest decile. The Network performs a pattern analysis on the highest tenth decile to determine any common factors that might help in conducting interventions, such as whether they are all in the same metropolitan area. Once this analysis is complete, the Board determines how to proceed with the poor performers. Interventions are specific to the problems and facilities involved and can range from off-site assistance to on-site focused reviews.

The Network recently intervened with a facility identified through this profiling system. In this instance, the Network convened an interdisciplinary team to conduct a formal site visit of the facility using a protocol developed by the Network. Prior to going on site, the group reviewed a sample of patient medical records. While on site, the team conducted interviews of the nursing and technical staff, the facility administrator, the medical director, and several patients. Based on its findings, the Network required the facility to develop and implement an improvement plan, subject to the medical review board's approval, and to submit monthly documentation of its progress. Since that time, the Network has been on site to help the facility implement its plan and has seen signs of improvement. The team plans to revisit the facility six months after its initial site visit to verify its progress.

Comparative analysis to identify a corporate chain for intervention. Another method the Network uses to identify poor performer is comparative analyses. The Network reviews the comparative reports it sends to facilities and performs additional analyses as necessary to identify facilities that are lagging behind. Recently, the Network analyzed the comparative performance of facilities by chain affiliation. The analysis showed that one of the three largest corporations in a metropolitan area was lagging significantly behind the others on several performance measures. Due to resource constraints, it was impossible for the Network to work with each individual facility; instead, it intervened at the corporate level. The Network shared the data with the regional corporate leaders and they agreed to convene their medical directors together for a formal session with the Network. At this session, the Network presented its analysis and provided the medical directors with information on how to improve the quality of care at their facilities. The Network has since seen an improvement in the chain's performance. The Network indicated to us that without the quantitative evidence it would have been difficult to get the attention and subsequent support of the corporation for quality improvement activities.

CONCLUSION

Better collaboration between State survey agencies and Networks and better use of facility-specific standardized performance data are two keys to improving the oversight of dialysis facilities. In our companion report, *External Quality Review of Dialysis Facilities: A Call for Greater Accountability*, we set forth recommendations calling for national reforms in these directions. In this report, we focused on two local initiatives that provide models for such reforms and that warrant careful consideration in that context.

The Texas initiative occurred because the State legislature became concerned about the adequacy of dialysis care after some highly publicized reports of poor care. The legislature's interventions led to a significant change in the thrust of external oversight conducted on dialysis facilities in the State. It shifted what was a highly collegial approach to oversight to one that was more balanced between collegial and regulatory approaches. It also brought clarity to the relationship between the Network and State by establishing clear operational parameters. The infusion of State funds and the establishment of new standards for facilities were all keys to its success.

The Renal Network's initiative occurred because its staff and board members sought, with some sense of urgency, to use performance data to hold facilities more accountable for their performance. By collecting a broad range of facility-specific measures from 100 percent of the patients at those facilities, it set a foundation for using performance data as a rigorous tool for oversight. It emphasized the use of such data to improve overall professional care processes and outcomes, but also showed a readiness to use them to target and correct poorly performing facilities. This effort also illustrates the potential that such data can have in profiling the performance of individual physicians.

These two initiatives demonstrate what Networks and States can accomplish given innovative leadership and adequate resources. In both cases, the Networks play central roles promoting continuous quality improvement *and* enforcing minimum standards of care. Although we did not evaluate the results achieved by each, we find both initiatives to be promising enough in their conception and early implementation to warrant careful consideration by other Networks and States, and by HCFA, as HCFA seeks to develop effective mechanisms for holding facilities more fully accountable for the quality of care they provide.

APPENDIX A

An Excerpt from a Facility-Specific Report

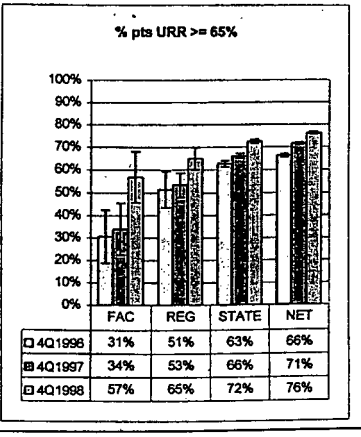
The following are highlights of the information provided in The Renal Network's *Clinical Performance Measures Feedback Report* for in-center hemodialysis patients for 4th quarter 1998. The complete report also contains information on Kt/V, hematocrit, hemoglobin, Epoetin dosage, ferritin levels, transferrin saturation, and serum albumin.

Patient Demographics

	Fac	Reg	State	Net
# Patients	79	376	10,364	26,545
SEX				
Men	62%	57%	53%	52%
Women	38%	43%	47%	47%
RACE				
Amer Indian	0%	1%	0%	0%
Asian	1%	2%	1%	1%
Black	28%	24%	45%	40%
White	71%	66%	48%	56%
Other	0%	7%	5%	3%
AGE				
< 18	0%	1%	0%	0%
18 - 44	22%	16%	17%	16%
45 - 64	43%	33%	36%	35%
65 +	35%	49%	46%	47%
DIAGNOSIS				
Diabetes	41%	41%	35%	38%
Hypertension	34%	26%	36%	29%
GN	6%	12%	11%	13%
Other	16%	21%	18%	19%
Unknown	3%	1%	1%	0%

Urea Reduction Ratio

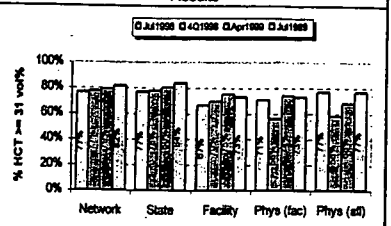
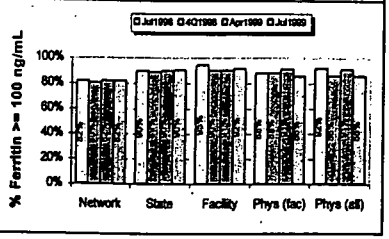
	Fac	Reg	State	Nat
# Patients	74	368	10,044	25,701
Mean	65.06	66.90	68.45	69.29
Std Dev	9.17	7.90	8.46	7.92
# pts 4Q1997	*65*	*332*	*8,950*	*22,312*



APPENDIX B

An Excerpt from a Physician-Specific Report

The following are highlights of the information provided in The Renal Network's *Physician Activity Report* for in-center, hemodialysis patients for November 1999. The complete report also contains information on urea reduction ratio, Kt/V, transferrin saturation, and serum albumin.

Measurement	Description	Results
Treatment of Anemia: Hematocrit (HCT) vol% Your % pts meeting the criteria during July 1999 is 0.19 std dev below the Network rate	**Pt values this fac:** # values 22 Mean 32.07 Std Dev 3.91 **Pt values all facs:** # values 30 Mean 32.88 Std Dev 4.25	
Treatment of Anemia Ferritin Levels (ng/mL) Your % pts meeting the criteria during July 1999 is 0.22 std dev above the Network rate	**Pt values this fac:** # values 21 Mean 712.71 Std Dev 723.33 % < 100 14% **Pt values all facs:** # values 29 Mean 660.14 Std Dev 648.34 % < 100 14%	

APPENDIX C

ENDNOTES

1. The ESRD Networks, established in 1976, are HCFA's main contractors for monitoring dialysis facilities. The main mission of the Networks as set out in the Statute is to ensure "effective and efficient administration of the benefits" provided under the ESRD program. Section 1881(c) of the Social Security Act.

2. In order to qualify, individuals must be fully insured under Social Security or be a dependent of someone who is. In 1996, about 8 percent of individuals with ESRD who needed treatment did not qualify for Medicare coverage. U.S. House of Representatives, Committee on Ways and Means, *1998 Green Book*, (Washington, DC: Government Printing Office), 162.

3. Texas Health and Safety Code, Chapter 251, End-Stage Renal Disease Facilities. In 1996, the department implemented the final rules and standards of the program; these were subsequently revised in 1999.

4. Health Facility Licensing Division, Title 25 Texas Administrative Code, Chapter 117 End-Stage Renal Disease Facilities Licensing Rules, effective April 11, 1999.

5. Due to current budget constraints, the Texas Department of Health reduced the number of full-time surveyors. This reduction in staff will likely have an impact on the frequency of surveys.

6. In the first year, (9/1/96 to 10/30/97) the State surveyed all 237 facilities. In the second year (11/1/97 to 9/1/98) the State conducted about 109 surveys and in the third year (9/1/98 to 8/30/99) the State conducted about 137 surveys.

7. The State and Network each maintain their independent authorities. If the State disagrees with the medical review board's recommendation it can take its own course of action. Similarly, the Network can require facilities under its own authority to develop and implement corrective action plans if it disagrees with the State.

8. The current priority list for State surveys is as follows: (1) complaints, (2) initial surveys, (3) expansions -- facilities adding additional dialysis stations, (4) facilities referred to the Network's medical review board the previous year, (5) referrals from the medical review board based on the performance data, (6) facilities chosen by surveyors, and (7) routine resurveys -- facilities that have gone the longest without a survey.

9. *1998 Quality of Care Indicators Report*, Texas Department of Health ESRD Licensing Program, July 1998, p 4.

APPENDIX C

10. Under statute Networks are supposed to receive 50 cents per dialysis treatment in their region to fund their activities. Social Security Act 1881(b).

11. HCFA does not collect a large enough sample to analyze the data at the facility level.

12. "Region" for this report is defined as a health service region.

13. The Renal Network's, Inc., *1998 Annual Report.*

14. Emil P. Paganini et. al., "Physician Activity Reporting: Is it Worthwhile?" *American Society of Nephrology 1999 Program Abstracts On-line from 32nd Annual Meeting,* http://www.asn-online.coni/ accessed November 23, 1999.

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Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

External Quality Review of Dialysis Facilities

A Call For Greater Accountability

JUNE GIBBS BROWN
Inspector General

JUNE 2000
OEI-01-99-00050

EXECUTIVE SUMMARY

PURPOSE

To assess external mechanisms the Health Care Financing Administration relies upon to monitor the quality of care provided by dialysis facilities to Medicare beneficiaries with end-stage renal disease.

BACKGROUND

Importance of External Quality Review

Case files, performance data, and marketplace realities underscore the importance of external quality review of dialysis facilities. Case files reveal numerous instances of poor care. In one instance, we found that a patient received a drug overdose that resulted in prolonged bleeding and subsequent hospitalization. Performance data collected from dialysis facilities reveal that a substantial portion of patients do not achieve the outcomes recommended by clinical practice guidelines. Similarly, scientific studies suggest variation in the quality of care patients receive. Of particular note is one that revealed higher mortality rates at facilities providing lower doses of dialysis. Finally, marketplace pressures triggered by growth, consolidation, competition, and concerns about containing costs have caused service disruptions that can and have jeopardized patient care.

External Review Bodies

The Health Care Financing Administration (HCFA) relies upon two major entities to conduct external reviews of dialysis facilities: the End-Stage Renal Disease (ESRD) Networks established under the Social Security Act and the State survey agencies. HCFA contracts with the 18 Network organizations, which are governed primarily by renal professionals associated with facilities in the Network's region, to perform multiple functions, mostly oriented around collegial efforts to promote improvement in the quality of care and to respond to complaints lodged by patients, staff, and others. HCFA funds the State agencies, typically within departments of public health, to perform a more regulatory role: to conduct Medicare certification surveys of facilities and to investigate complaints, both in accordance with the Medicare Conditions for Coverage for dialysis facilities.

This Inquiry

In our inquiry, we relied on a rich variety of data sources. We reviewed and analyzed HCFA's database on State survey agencies; conducted a survey of all 18 Networks;

visited 5 Networks; held extensive telephone discussions with representatives of another 8; reviewed the complaint logs of 9 Networks; observed a State survey of a dialysis facility; interviewed staff at 5 State survey agencies; interviewed many stakeholders representing national organizations; and reviewed Federal documents and pertinent literature.

FINDINGS

The major strength of the external oversight system is the use of standardized performance measures to encourage improvements in the quality of care.

- HCFA-generated data show measurable improvements in clinical outcomes at the national and regional levels.
- Network quality improvement projects show improvements at the regional level and, in some cases, at the facility level.

Yet, that system of oversight falls short in several respects.

Standardized performance measures are rarely used to hold individual facilities accountable.

- HCFA does not require the collection of a core set of facility-specific clinical performance measures.
- Without such a set, Networks and States have limited means of identifying poorly performing facilities.
- A few Networks do collect facility-specific performance measures, but have limited authority to use them to correct poor performance.
- Networks and State agencies rarely share facility-specific data with one another.
- Facility-specific performance measures are not publicly disclosed.

The complaint systems serve as unreliable means for identifying and resolving quality-of-care concerns.

- Both patients and staff tend to be reluctant to lodge complaints because of concerns about the possible consequences for them.
- States and Networks conduct few investigations of complaints concerning the quality of care. In 1998, State survey agencies conducted about 250 on-site investigations; the Networks, about 35.

- States and Networks rarely conduct joint complaint investigations or share information on their own investigations.

Medicare certification surveys play a limited role in ensuring dialysis facilities meet minimum standards.

- The elapsed time between Medicare certification surveys conducted by the State survey agencies is increasing. In 1995, 20 percent of all facilities were not surveyed within 3 years; by 1998, that increased to 44 percent.

- Medicare Conditions for Coverage for dialysis facilities provide an inadequate foundation for accountability.

- State survey agencies have difficulty maintaining the expertise of surveyors, largely due to the infrequency of surveys.

Medical injuries are not systematically monitored. HCFA does not require the Networks, the State agencies, or facilities to identify and analyze medical injuries attributable to the care provided to the patient as opposed to the patient's underlying condition.

HCFA does little to hold the Networks and State survey agencies accountable for their effectiveness.

Minimal assessment of Networks' performance. Although HCFA receives regular information from Networks, it provides little substantive evaluation and feedback to them. HCFA does not hold Networks accountable for how facilities fare on performance measures.

Minimal assessment of State survey agencies' performance. HCFA has few means to evaluate the content or quality of the surveys the State agencies conduct on behalf of Medicare. HCFA no longer validates surveys and rarely observes surveys in action.

Minimal public disclosure. HCFA, the Networks, and the States disclose little information to the public on actions taken to protect dialysis patients.

RECOMMENDATIONS

Our review indicates that the external review system carried out on HCFA's behalf by the Networks and the State agencies has major shortcomings. It is imbalanced, in that it stresses improving overall quality more than enforcing minimum requirements that protect patients from harm. It is fragmented, in that Networks and State agencies rarely coordinate their efforts. And it lacks sufficient accountability on the part of the Networks, the State agencies, and, most of all, the facilities.

As HCFA provides leadership to address these shortcomings, we suggest that it (1) steer external oversight of the quality of dialysis facilities so that it reflects a balance between collegial and regulatory modes of oversight, and (2) foster greater collaboration between the Networks and State survey agencies. Specifically, we offer the following recommendations.

RECOMMENDATION 1. HCFA should hold individual dialysis facilities more fully accountable for the quality of care they provide.

- Revise the Medicare Conditions for Coverage for dialysis facilities so that they serve as a more effective foundation for accountability.
- Use facility-specific standardized performance measures to encourage facilities to improve the quality of care and to help ensure facilities meet minimum standards. Regularly issue reports incorporating comparative performance data and make them available to the facilities, the Networks, the State agencies, and the public.
- Strengthen the complaint system for dialysis patients and staff. Work with Networks and State agencies to develop an integrated complaint system that incorporates the following elements: accessibility, objectivity, investigative capacity, timeliness, responsiveness to complainants, enforcement authority and follow-up, improvement orientation, and public accountability.
- Enhance the role of Medicare on-site certification surveys by determining an appropriate minimum cycle for conducting the surveys and conduct pilot tests to determine the potential of Network and State joint initial certification visits of dialysis facilities.
- Facilitate the development of publicly accountable means for identifying serious medical injuries and analyzing their causes. Work with the Networks to establish pilot projects.

RECOMMENDATION 2. HCFA should hold the Networks and State survey agencies more fully accountable for their performance in overseeing the quality of care provided by dialysis facilities.

- Issue policy guidance delineating the distinctive roles of the Networks and State survey agencies and providing direction on how they should collaborate.
- Foster greater accountability of the Networks by developing a performance-based system for evaluating them and by increasing public disclosure of information on them.
- Foster greater accountability of the State survey agencies by establishing better means for assessing State surveys and by increasing public disclosure of information on the extent, nature, and results of the surveys.

COMMENTS ON THE DRAFT REPORT

We received written comments on the draft report from the Health Care Financing Administration, the Forum of End Stage Renal Disease Networks (the Forum), the Association of Health Facility Survey Agencies (AHFSA), and the American Association of Kidney Patients (AAKP). Overall, the reports received wide support. In the body of the report we summarize the major comments and offer our responses. Based on the comments, we changed one recommendation and made several technical changes.

HCFA's Comments

HCFA largely agreed with our recommendations. In response, HCFA offered a detailed action plan that addresses each of our recommendations. The plan demonstrates HCFA's commitment to publicly releasing facility-specific performance data, revising the complaint process, increasing on-site surveys, holding Networks more accountable for performance of their facilities, and assessing the performance of State surveys agencies. HCFA did take issue with our recommendation calling for Networks and State agencies to conduct joint surveys for initial certification visits.

HCFA's action plan is a positive step toward implementing our recommendations and we urge HCFA to give it a high priority. In response to HCFA's concern about joint surveys, we changed our prior recommendation from one requiring such surveys to one urging that they be conducted on a pilot basis.

External Organizations' Comments

The external organizations supported the majority of findings and recommendations but also raised some concerns. The Forum expressed concern that some of our recommendations, especially the public release of facility-specific performance data , threaten patient confidentiality and undermine the collegial nature of the Networks. AHFSA expressed concern about the lack of funding for State survey agencies and AAKP urged that funding for strengthening oversight not come at the cost of patient activities.

We recognize patient confidentiality is critical, but we believe that mechanisms can be devised to ensure patient confidentiality. We want to emphasize that the Networks should not only take a collegial approach with facilities, but also must be willing to take more regulatory actions when warranted or to inform others, such as the State, that can take such actions. Finally, we recognize the significance of the concerns about funding. We address AHFSA concerns about the funding for State agencies by calling for HCFA to determine an appropriate minimum cycle for conducting surveys and we underscore AAKP's point that funding for oversight activities should not jeopardize patient care.

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INTRODUCTION

PURPOSE

To assess external mechanisms the Health Care Financing Administration relies upon to monitor the quality of care provided by dialysis facilities to Medicare beneficiaries with end-stage renal disease.

BACKGROUND

About 3,200 dialysis facilities provide ongoing, life-sustaining dialysis treatments to about 230,000 patients with end-stage renal disease, or permanent kidney failure. Many of these patients are suffering from other complicated diseases such as diabetes and hypertension, and nearly all of them are Medicare beneficiaries. To foster improved care and minimize risks to patients, dialysis facilities conduct their own internal monitoring efforts. External review provides an additional safeguard.

External Review Bodies

The Health Care Financing Administration (HCFA) has the primary responsibility of ensuring beneficiaries receive appropriate care in dialysis facilities. To carry out the bulk of the oversight activities for dialysis facilities, HCFA relies upon two entities, End-Stage Renal Disease (ESRD) Networks and State survey agencies.

ESRD Networks. The 18 regional Networks are HCFA's main contractors for monitoring dialysis facilities, as they are the only entities created for and entirely devoted to the ESRD program. Federal statute requires Networks to assure the "effective and efficient administration of the benefits" provided under the ESRD program.[1] Network staff, typically 7 to 10 people, work closely with their board membership made up of local renal professionals. HCFA requires the Networks to conduct at least one HCFA-approved quality improvement project a year, to collect HCFA forms from facilities, and to resolve patient complaints. Networks also assist and educate facilities on issues related to quality improvement.

State Survey Agencies. HCFA relies upon State survey agencies, typically within departments of public health, to conduct Federal certification surveys and investigate complaints, both in accordance with the Medicare Conditions for Coverage. The Conditions for Coverage dictate the obligations of facilities under the Medicare program and are used by State surveyors to certify facilities.[2] Some State agencies have additional functions under their own State licensure program.[3]

External Quality Review Framework

We have identified four key elements that can be applied to any external quality review system for health care facilities. This framework is meant to be used by purchasers, such as Medicare, to ensure that dialysis facilities provide quality care, and by consumers, such as ESRD beneficiaries, concerned about the quality of care they receive in their facility. Each element in the framework provides a different perspective on the quality of care. For a comprehensive and effective external quality review system, all components need to be adequately addressed. Throughout our inquiry we relied on this framework to assess the overall effectiveness of the external review system for dialysis facilities.

Table 1. External Quality Review Framework for Dialysis Facilities

Element	Description
Use of standardized performance measures	Standardized performance measures allow purchasers, consumers, and overseers to compare the performance of facilities or physicians. The comparison can examine a single facility over time or one facility against another. Such measures can be used for quality improvement activities and to enforce minimum standards.
Response to complaints	Complaints can come from patients, staff, and other interested parties. They can be of a particular instance of care or about broader matters concerning a facility's performance. The response to complaints can range from an off-site follow-up to an on-site investigation. The process can trigger corrective actions and system improvements.
On-site surveys	On-site surveys can be either announced or unannounced. Surveyors observe the conditions of the facility and equipment and interview patients and staff. The process can trigger corrective actions and system improvements.
Response to medical injuries	Medical injuries are adverse events attributable to medical management and unrelated to the patient's illness or underlying condition. The response to such events can range from minimal to thorough and can trigger corrective actions and system improvements.

Medicare Coverage of ESRD

In 1972, Medicare began providing coverage to individuals with ESRD making it the only entitlement criteria for Medicare based solely on a disease category.[4] Medicare covers all treatment methods for patients: hemodialysis, peritoneal dialysis, and renal transplants. Patients receiving hemodialysis, the most common method, typically receive treatment in outpatient facilities three times a week. Peritoneal patients typically perform daily treatments at home and rely on outpatient facilities for ongoing support. (See Primer on Dialysis.) Medicare covers dialysis services performed by hospital-based and free-standing facilities. Hospital-based facilities are financially and organizationally integrated with a hospital whereas free-standing facilities are not.[5]

Our Inquiry

Our report focuses on the two main entities the Federal Government relies upon to oversee dialysis facilities: the State survey agencies and the Networks. We did not evaluate the activities of any one Network or State, rather, we assessed if the activities of the Networks and States overall create an effective external review system for dialysis facilities. Also, we did not evaluate the adequacy of the Medicare on-site survey process. This report is one of two from our overall inquiry. Our companion report, *External Quality Review of Dialysis Facilities: Two Promising Approaches*, presents two innovative initiatives used to monitor facilities.

We surveyed all 18 Networks, reviewed their annual reports for 1997 and 1998, and reviewed their responses to complainants for 1998. With eight Networks we held telephone interviews and reviewed their complaint logs for 1998. We also visited an additional five Networks. Over the course of these visits we spoke with patients, Network staff, and renal professionals (e.g., administrators, nephrologists, social workers, dieticians, nurses, and technicians.) We also analyzed data on the frequency of Medicare surveys, interviewed staff at 5 State survey agencies, and observed a survey in a dialysis facility.

Throughout our inquiry we interviewed HCFA personnel, including the project officers for the Networks. We also spoke with several renal professional organizations and patient advocacy groups. Finally, we conducted a review of scientific literature and Federal documents. (See appendix A.)

In the next section, we provide a brief overview underscoring why external quality review is so important as a patient protection mechanism. Then we present our findings and recommendations.

We conducted this study in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

PRIMER ON DIALYSIS

TYPES OF TREATMENT

Dialysis is the process of removing toxins from the body by diffusion across a semipermeable membrane, thereby compensating for kidney failure. There are two types of dialysis:

Hemodialysis. Removal of toxins directly from the patient's blood stream, requiring direct access to the bloodstream. The patient's blood is cycled through an artificial kidney, an external machine, that removes the toxins and excess fluids from the blood. The artificial kidney machine uses a semipermeable membrane, called a hemodialyzer, to filter out the toxins from the blood.

Peritoneal dialysis. Utilizes the patient's natural peritoneal membrane, located in the abdominal cavity, to remove toxins and excess fluids.

COMMONLY USED PERFORMANCE MEASURES

Adequacy. Refers to the amount of toxins, such as urea and creatinine, removed from the body during dialysis.

- **Urea reduction ratio (URR) and Kt/V.** Two measures used to measure adequacy in hemodialysis patients based on the removal of urea. The URR is a function of the amount of urea removed during dialysis, as determined by the pre- and post-dialysis blood urea nitrogen levels. The Kt/V is a function of the amount of urea removed multiplied by the time on dialysis, divided by the volume of urea distribution, or approximately the amount of water in the body. The National Kidney Foundation's Dialysis Outcomes Quality Initiative (DOQI) practice guidelines recommend a Kt/V of at least 1.2, or an average URR of at least 65 percent for the minimum delivered dose of hemodialysis.
- **Creatinine clearance and Kt/V_{urea}.** Two measures used to measure adequacy in peritoneal patients. Creatine clearance measures the removal of creatine and Kt/V_{urea} measures the removal of urea. DOQI recommends a weekly dose of continuous ambulatory peritoneal dialysis of at least 2.0 per week and a creatine clearance of at least 60L/week/1.73 m^2.

Anemia management. Anemia, or inadequate red blood cells, is a common concern among dialysis patients.

- **Hematocrit and hemoglobin.** Two measures of the severity of anemia. Hematocrit measures the ratio of red blood cells to the plasma volume, and hemoglobin measures the amount of a specific protein in red blood cells that carries oxygen. DOQI recommends a target range of 33 percent to 36 percent for hematocrit and between 11 g/dL to 12 g/dL for hemoglobin.
- **Ferritin level and transferrin saturation (TSAT).** Two measures used to monitor the level of iron. Ferritin is a measure of the level of iron stored within the body and TSAT is a measure of iron immediately available to produce red blood cells. DOQI recommends a ferritin level of $\geq$100 ng/mL and a TSAT $\geq$20 percent.

Vascular access. The point of direct access to the blood stream for hemodialysis. There are three types:

- **Catheter.** A tube is placed in a blood vessel, primarily used for temporary access to the blood stream.
- **Native arteriovenous fistula.** A patient's own artery and vein are joined surgically to allow arterial blood to flow through a vein, usually placed in the forearm and takes several weeks to mature. DOQI guidelines recommend that primary fistulas be placed in at least 50 percent of new patients.
- **Synthetic arteriovenous graft.** A synthetic blood vessel is used to surgically join the patient's artery and vein, usually placed in the forearm and takes several weeks to mature.

Nutrition. Inadequate nutrition is a common concern among dialysis patients.

- **Serum albumin level.** A measure of the level of proteins in the blood.

THE IMPORTANCE OF EXTERNAL REVIEW

Many dialysis facilities and corporations conduct their own internal quality monitoring and improvement projects. However, in order to protect patient safety, it is essential that an external oversight system exists to provide objectivity and public accountability that internal quality reviews lack. Below we present four key factors that underscore the need for external oversight in dialysis facilities.

Instances of Poor Care

Although dialysis treatment and patient outcomes have improved since the ESRD program began, much can and has gone wrong in facilities. Several well-publicized events in the media and in letters from patient advocates have documented cases of patient harm and have questioned the systems in place to protect patients.[6] In the course of our review of documents we came across several examples where patients were put at risk due to inappropriate treatment. In our review of documents from the States and Networks we learned of cases where a patient received another patient's hemodialyzer, putting him at risk for blood-borne diseases; a patient in cardiac arrest was put at risk as facility staff searched for a misplaced code cart; a patient was exposed to a toxic disinfectant through his bloodstream when hooked up to a reused hemodialyzer that had not been rinsed properly;[7] a patient received a drug overdose that resulted in prolonged bleeding and subsequent hospitalization; several patients received blood transfusions when a facility ran out of the appropriate medicine to treat anemia; and a patient's infected catheter was not removed in time, causing the patient to die of infection.

Vulnerable Patient Population

Dialysis patients are a vulnerable patient population that is growing. Many dialysis patients are elderly and suffering from other complicated illnesses such as diabetes and hypertension. Overall, the ESRD population is growing at a rate of 7 percent a year and for some of the more vulnerable types of patients, the growth rate is even higher.[8] More importantly, dialysis patients depend on regular dialysis treatments for survival. In the words of one physician, dialysis is "intermittent, ambulatory life support."

Variation in the Quality of Care

HCFA's data indicate that a significant portion of dialysis patients fail to meet clinical practice guidelines developed by the National Kidney Foundation Dialysis Outcomes Quality Initiative. For the last quarter of 1998, 20 percent of a national sample of hemodialysis patients did not meet the guidelines' recommendation for the minimum dose of dialysis as measured by the Kt/V ratio.[9] For the same period, 41 percent of hemodialysis patients failed to achieve a hemoglobin level that met or exceeded the target range recommended by the guidelines.[10]

Scientific literature also suggests variation in the quality of care dialysis patients receive. Several studies have shown that mortality rates vary significantly among facilities, even after adjusting for patient characteristics such as age and diabetes.[11] Other studies have shown variation at the patient and facility level in the delivered dose of dialysis.[12] One recent study found that higher mortality rates at facilities were associated with lower delivered doses of dialysis, after adjusting for patient characteristics.[13] This same study also found that free-standing facilities, as opposed to hospital-based facilities, and lower amounts of physician supervision were associated with increased mortality rates. Another study found that patients treated in for-profit versus non-profit facilities had a 20 percent higher mortality rate and 26 percent lower rate of enrollment on a waiting list for a kidney transplant.[14] The investigators of this study concluded, "Greater oversight or competing incentives to improve quality may be necessary to ensure that cost containment is not so extensive that it affects patient outcomes adversely."[15]

Marketplace Pressures

The dialysis industry has grown significantly in recent years. The number of dialysis patients grew from about 160,000 in 1992 to 230,000 in 1997, the number of dialysis facilities increased from about 2,000 to over 3,000 — averaging about 200 new facilities each year.[16] Most of this increase in facilities occurred among free-standing as opposed to the more traditional hospital-based facilities that receive an additional layer of oversight as part of the hospital. About 78 percent of dialysis patients receive treatment in free-standing facilities.[17] Moreover, through a series of mergers and acquisitions, there has been increased consolidation in the ownership of the facilities. About 54 percent of dialysis patients receive treatment in facilities owned by one of three multi-national for-profit corporations.[18]

Along with growth and consolidation, the dialysis treatment environment is characterized by at least three other increasingly prominent forces: (1) increased competition for patients, (2) heightened concerns to contain costs,[19] and (3) increased difficulty in finding and retaining experienced nurses and technicians in an increasingly competitive marketplace. Individually and cumulatively, these forces have caused service disruptions that can and have jeopardized patient care.

FINDINGS

The major strength of the external oversight system is the use of standardized performance measures to encourage improvements in the quality of care.

HCFA's performance data show improvements.

HCFA's Clinical Performance Measures Project collects a set of performance measures annually on a national sample of dialysis patients.[20] HCFA disseminates data to facilities that show national trends and Network variation. These data can serve as a stimulus for facilities to examine their own performance and to assess how it can be improved. The data show consistent improvements nationwide in patient outcomes since the project began in 1994. The percentage of patients achieving a mean urea reduction ratio ≥65 percent has increased from 43 percent in 1993 to 74 percent in 1998. Similarly, the percentage of patients achieving a mean hematocrit >30 percent has increased from 46 percent in 1993 to 83 percent in 1998.[21] Even though these data are not facility-specific, Networks have drawn on these performance data to assess the overall performance of facilities in their region and to identify topics for regional quality improvement activities.

Networks' performance data also show improvements.

Networks through quality improvement projects and ongoing initiatives, collect performance data from facilities to help stimulate improvements. For example, one Network quality improvement project resulted in a 20 percent increase in the number of patients receiving the hepatitis B vaccine.[22] Another Network project helped decrease the percentage of patients with inadequate peritoneal dialysis from 31 percent to 20 percent.[23] Several Networks have shown similar improvements by collecting and disseminating regularly a set of facility-specific measures; one Network even disseminates physician-specific reports.[24]

Yet, the current system of oversight falls short in several respects.

Standardized performance data are rarely used to hold individual facilities accountable.

No requirement to collect a core set of facility-specific performance measures. Several entities, including HCFA, collect facility-specific performance data. (See appendix B.) However, these measures are housed across several databases, collected using different methodologies, and designed for different purposes. Networks have some access to these measures. States have almost no access. HCFA has not

established a facility-specific core data set that all facilities must report to one central location directly under HCFA's control. The closest that HCFA has come is the Clinical Performance Measures Project, but it is not facility-specific. On their own a few Networks collect facility-specific data, but this effort is limited to the facilities in their region.

The two main barriers reported by Networks to collecting facility-specific data are limited resources and no HCFA requirement. Networks are funded through statute. Statute requires that 50 cents of the composite rate facilities receive for each treatment goes towards the Networks.[25] Networks are not appropriated funds. Many Networks may not have the resources to collect and analyze additional data. Also, without a HCFA requirement, Networks do not think facilities will submit facility-specific data regularly.

Difficulty identifying poor performers. Without a national facility-specific core data set, most Networks and States are left with limited means of assessing the performance of individual facilities within their regions. In the few instances where Networks collect their own set of facility-specific data, they are left without comparable national data. Facility-specific data are necessary to identify facilities that are well below the regional mean or the accepted standard of care. Few Networks take full advantage of existing facility-specific data that they have access to and few Networks have a formal process for identifying outliers. HCFA does not require Networks to establish quantitative criteria to identify poor performers using existing facility-specific data. Networks complain that existing facility-specific data are limited, because they are too old, inaccurate, and not designed for performance assessment.

Limited Network authority to correct poor performers. Networks lack the authority to impose sanctions directly on facilities. In the cases where facilities are not cooperative or fail to make improvements, Networks must rely on either HCFA or the State survey agencies to take enforcement actions. Networks either can recommend to HCFA that it sanction a facility, or Networks can recommend to a State survey agency that it conduct a review of a facility. However, we found that some Networks are reluctant to make recommendations to HCFA or the State survey agencies for several reasons.[26] First, problems identified by the Networks may not fall directly under the Conditions for Coverage that HCFA and the States must rely upon when sanctioning a facility. Second, HCFA and the States are limited in the types of enforcement actions they can take.[27] Finally, Networks reported cases where HCFA and the States did not adequately follow-up with the Networks recommendations, leaving some Networks to conclude that referrals are futile.[28]

Instead Networks typically seek to work with the facility collegially to correct the problem. Such efforts are likely to involve a meeting with key staff to discuss the facility's performance data and brainstorm about potential causes and solutions. In some cases, the Network will ask a facility to prepare a corrective action plan and will then

monitor adherence to that plan. Networks reported that, in most instances, this approach is successful.

Little sharing of data between Networks and State survey agencies. The Networks, as we noted, tend to have little facility-specific data to share. But even in cases where they have such data, they are not inclined to share it with the State agencies. In response to our survey of Networks, only 3 of the 18 reported that they routinely share facility-specific data with the States.

We identified two major barriers to Networks sharing data with the States. First, Networks fall under confidentiality laws that exempt them from Federal disclosure laws.[29] As such, Networks are reluctant to share data with the States because of concerns about eventual public disclosure. Second, Networks are concerned about the States using the data to take punitive actions. Networks officials fear that if the data are used in this way they will undermine their quality improvement efforts and their trusting relationships with facilities.

With respect to State agencies, information they collect as a result of their surveys of dialysis facilities could be useful to the Networks. But, even though much of this is public information, it does not tend to be shared with the Networks on a regular or timely basis.

Minimal public disclosure. Currently, neither HCFA nor the Networks make any facility-specific performance measures readily available to the public. HCFA does disclose facility-specific cost reports on its website, but this information requires some manipulation before it can provide useful performance data.[30] Networks, as we have previously mentioned, are exempt from public disclosure by statute. HCFA and others do disclose to the public data aggregated at the Network and national level, and in some cases, at the State level. Networks are especially reluctant to release facility-specific data to the public for fear of misinterpretation and of undermining internal quality improvement efforts. Most States will disclose survey results upon request.

The complaint systems serve as unreliable means for identifying and resolving quality-of-care concerns.

Throughout this report we use the term complaints generically to include concerns brought forth by patients, staff, or other individuals.

Barriers to lodging complaints. Two basic barriers inhibit patient complaints about the quality of care. First, dialysis patients find it difficult to complain about an individual or facility providing treatment that their lives depend upon. Network officials, other renal professionals, and patient representatives stressed that fear of retribution deters patients from complaining. The second major barrier is limited patient information and understanding about the technical aspects of their care. For example, a previous Office of Inspector General study found that although 73 percent of all patients reported

knowing there was a recommended level of adequate dialysis, only 36 percent could correctly identify the urea reduction ratio or the Kt/V as the test used to measure adequacy.[31]

In many respects, the staff in dialysis facilities are in the best position to lodge complaints about continuing problems with the quality of care in a facility. But as we were often reminded, staff also face significant deterrents to lodging complaints; such actions could put their jobs at risk and brand them as a trouble-makers, thereby jeopardizing future employment in the field.

Network officials are aware of and often sympathetic to these barriers. But, in general, their policies and practices make the barriers even more imposing. First, they tend to discourage confidential complaints by stopping investigations short if complainants are unwilling to allow their name to be disclosed to the facility in question. Networks reported that it is difficult for them to investigate complaints fully without disclosing the complainants name to the facility. (Neither Networks nor States will release a complainant's name without consent.) Second, about half of the Networks require grievances to be in writing, before they take any action, unless it involves a life-threatening situation even though HCFA policy states that it is not necessary.[32] Finally, Networks, and even more so the States, conduct little outreach to inform, let alone encourage, patients or staff to use the complaint system. The information that the Networks provide tends to be limited to posters sent to facilities and information packets sent to new patients. We found little evidence that Networks or States convey to patients that the complaint system is an important safeguard.

Limited investigations. HCFA looks to the State survey agencies to investigate complaints that involve life-threatening situations or possible violations of the Medicare Conditions for Coverage. The States conduct investigations on site that focus on the specific Medicare Conditions for which compliance is in question. If State surveyors believe it is warranted, they can extend the complaint investigation into a complete Medicare certification survey. Although HCFA has established complaints investigations as a top priority for States, the number of complaint investigations States conduct each year is minimal.[33] In 1997 and 1998, when about 230,000 dialysis patients received treatment under the auspices of about 3,200 dialysis facilities, we found that the States conducted only about 260 complaint investigations each year.

HCFA looks to the Networks to play a broader and a more front-line role in responding to complaints. Networks receive complaints covering a wide range of issues related to patient care and sometimes refer complaints to the States involving life-threatening situations or possible violations of the Medicare Conditions.[34] States also receive complaints directly.

Little national information is available on how many and what kind of complaints the Networks handle.[35] In an effort to gain some understanding of Network complaints, we conducted our own analysis of nine Network complaint logs for 1998. We found that

these nine Networks combined received over 700 complaints. However, the majority of these complaints did not involve quality-of-care concerns. About 45 percent were actually requests for information and 13 percent involved concerns expressed (typically by staff) about disruptive patients. Of all the complaints, 25 percent concerned service quality (e.g. temperature of facility, waiting times, friendliness of the staff) and 15 percent technical quality (e.g., clinical care, adequacy of equipment).[36]

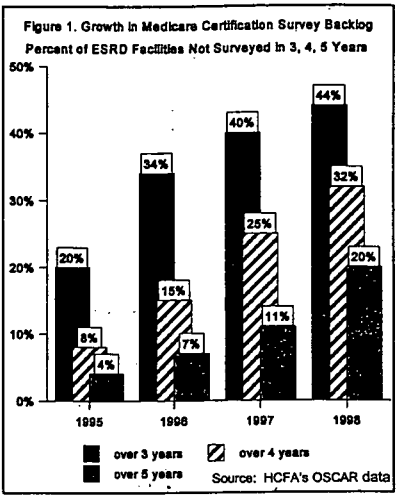
In response to our survey, the 18 Networks reported that they investigated 170 complaints in 1998, only 34 of which involved a site visit. Most Networks encompass many States and have limited resources for in-depth complaint investigations. Network investigations, in accord with HCFA instructions, typically facilitate quick resolution between the complainants and the facilities. Networks address most problems by working collegially with facilities. We also found that Networks rarely conduct (or have the resources to conduct) pattern analyses to identify trends in complaints with the intent of identifying and correcting systematic problems.

Fragmented process for responding to complaints. Working single-handedly, neither the States nor the Networks can tap the full potential of a complaint system that effectively addresses quality-of-care concerns. Through their board membership, Networks have important clinical expertise in nephrology that gives them substantial ability to assess and follow up complaints regarding the adequacy of the clinical care being provided. But the Networks have little authority to enforce corrective actions. The States, on the other hand, have enforcement authority for violations of the Medicare Conditions for Coverage, but tend to lack the clinical expertise concerning renal care. Little coordination occurs between States and Network. The Networks do refer to the State agencies complaints which concern the Medicare Conditions. We found that in 1998 each Network referred, on average, three complaints to the States. But, the Networks report that the State agencies do not routinely inform them of the results of complaint investigations or even whether they conducted an investigation. Similarly, Networks themselves do not tend to be any more forthcoming in informing the States of their own investigations. In the same vein, Networks and State agencies seldom undertake combined investigations in response to complaints about the quality of care.[37]

Medicare certification surveys play a limited role in ensuring facilities meet minimum standards.

HCFA relies solely upon the State survey agencies to conduct on-site certification surveys to ensure a facility's compliance with the Medicare Conditions for Coverage.[38] States conduct an initial survey of all newly established facilities to ensure that they meet minimum standards. Thereafter, States conduct recertification surveys to ensure ongoing compliance. Both surveys, particulary the recertification surveys, provide an opportunity to examine the actual day-to-day practices of the facility. Some of the major components of a dialysis facility survey include: examining the reuse of hemodialyzers and water treatment areas, interviewing patients and staff, observing personnel, and reviewing patient medical records and personnel files.

The elapsed time between Medicare surveys is increasing. In 1995, 20 percent of ESRD facilities had not been surveyed in the past three years.[39] By the end of 1998, that number had grown substantially to 44 percent of facilities not receiving a survey in the past three years. (See figure 2.) Ten percent of facilities had not been surveyed in 6 years or more by the end of 1998. The average elapsed time between surveys had doubled between 1994 and 1998, from once every 1.7 years in to once every 3.4 years[40] In fact, during 1998, States surveyed only 17 percent of facilities. This is a dramatic decrease compared to 1993 when over 50 percent of facilities received a survey.[41]



A major reason for the decline in ESRD surveys is competing budget demands.[42] Nursing homes and home health agencies both have mandatory survey cycles established by Congress.[43] As a result, nursing homes and home health agencies receive funding priority over ESRD facilities, which lack such a mandate. In addition, ESRD facilities are included under the category of non-long term care providers, which also includes non-accredited hospitals, psychiatric hospitals, ambulatory surgical centers, and hospices. All of these providers compete for the same pool of resources allocated by HCFA. Currently, non-long term care facilities appear tenth on a list of 12 HCFA workload priorities for State agencies.[44]

Medicare Conditions for Coverage for dialysis facilities provide an inadequate foundation for accountability. Established in 1976, the Conditions fail to reflect major changes in the delivery of dialysis services, in the organizational auspices of dialysis facilities, and in the concepts of quality oversight and quality improvement. During our inquiry, the following emerged as particularly notable shortcomings:

- ***The facility governing body is insufficiently accountable for the quality of care facilities provide.*** The Conditions do not explicitly hold the governing body accountable for overall patient care and outcomes.[45] In practice, responsibility is often diffused among administrators and distant parent corporations. At times, this makes it difficult for the Networks and State survey agencies to get timely information and sustained attention to corrective actions.

- ***The medical director has limited authority and as such is inadequately accountable for the quality of care.*** Medical directors and Network officials often stressed to us that medical directors tend to exert little influence over the day-to-day care offered in dialysis facilities and have little authority to do so. They are particularly frustrated when attending nephrologists do not engage in quality improvement efforts or address situations where medical directors thought patients were receiving inadequate care. These are serious limitations addressed only indirectly in the existing Medicare Conditions.[46]

- ***Facilities are not required to report electronically on standardized performance measures determined by HCFA.*** The limited capacity of some facilities to provide electronic submission of data has inhibited Network initiatives to collect facility-specific data. Under HCFA's plans for collecting and using clinical performance data in the years ahead, it will be essential for facilities to meet standard specifications for electronic reporting.

- ***Facilities are not required to conduct their own quality improvement program.*** The Medicare Conditions only require facilities to monitor specific events and do not explicitly require facilities to continually improve care and/or to identify trends in care. Without such a mandate, and in facility settings where the pressures of providing adequate day-to-day care are considerable, it is often difficult to devote much attention to deliberative efforts that would identify improvement needs, to collect and analyze data concerning those needs, and then to determine and monitor changes in facility practices.

- ***Facilities are not required to monitor patient satisfaction.*** Patient satisfaction is an important, often overlooked dimension of quality. The Medicare Conditions do not require facilities to routinely monitor patient satisfaction. Some Networks have taken the initiative to develop and encourage the use of patient satisfaction surveys. Similarly some dialysis facilities and corporations have developed patient satisfaction surveys.

State survey agencies have difficultly maintaining the expertise of surveyors. Facility, Network, and State agency staff view the Medicare surveys as an important part of external oversight. However, they raise concerns about the skills of the surveyors. They stressed that dialysis surveys are highly technical, requiring knowledge not only of water treatment processes but also of the complexities of dialysis treatment. As dialysis surveys become less frequent, surveyors are increasingly hard pressed to maintain their familiarity with dialysis facilities, let alone keep pace with technological advances.

HCFA does require all surveyors to attend a basic training course specific to dialysis facilities before they can conduct dialysis surveys.[47] HCFA also provides advanced training courses regularly.[48] However, lessons learned in these courses may be forgotten if surveyors do not have the opportunity to use these skills regularly.

Medical injuries are not systematically monitored.

Medical injuries are attributable to the care provided to the patient, not to the patient's underlying conditions. Such injuries can happen even in the best of health care facilities.[49] Some dialysis corporations may have internal systems for addressing medical injuries, but, if they do, little is known about their scope and effectiveness. Some States have adverse event reporting requirements, but they appear to be of little overall consequence to dialysis facilities.[50] Facilities that are associated with hospitals accredited by the Joint Commission for Accreditation of Healthcare Organizations are subject to the Commission's "Sentinel Event" program for reporting adverse events, but as we have shown in a prior report, this system is still in an early stage of development.[51] HCFA lacks any requirement that facilities establish their own, internal systems for identifying and analyzing adverse events or that they report such events to Networks or States.[52]

HCFA Does Little to Hold Networks and State Survey Agencies Accountable for Their Effectiveness.

Minimal assessment of Networks' performance.

Project officers in four regional offices are HCFA's main operational contacts with the Networks. These project officers receive considerable information from the Networks. They get regular updates on the quality improvement projects that Networks are mandated to conduct. They conduct periodic site visits, receive quarterly reports providing detailed updates on the Networks' activities, and receive annual reports with a comprehensive summary of the year's activities.

However, this regular flow of information results in little substantive evaluation and feedback on the effectiveness of the Networks. How effective are the Networks in using standardized performance data to foster overall improvement across facilities and, in particular, in poorly performing facilities? How successful are they in operating a complaint system that is accessible, fair, and responsive to complainants? We found few signs of probing, independent assessments of these and other such basic questions. Nor does HCFA call for the Networks themselves to address such evaluative questions in more than a passing way.

HCFA's most formal mechanism for evaluating the Networks is the year-end evaluation questionnaire that the project officers complete and send to the central office. This is a three-page form that poses 13 performance-related questions, and in each case, calls for the project officer to indicate "satisfactory," "unsatisfactory," or "comments attached."[53] In our review of the completed questionnaires for all 18 Networks in 1998, we found that in the total inventory of 234 questions, all but 2 were checked satisfactory.[54]

Further HCFA does not hold the Networks accountable for how the facilities in their regions fare on HCFA's Clinical Performance Measures Project. There are notable differences from Network to Network. For example, across all 18 Network regions, the percentage of hemodialysis patients with a Kt/V ≥1.2 ranged from 74 percent to 87 percent for the last quarter of 1998. Similarly, the percentage of hemodialysis patients with hemoglobin levels >10 gm/dL ranged from 72 to 85 percent among the Networks.[55] In this context, it is important to note that HCFA gives the Networks little discretion to undertake a range of quality improvement activities targeted to the distinctive needs of their region. Instead, HCFA requires them to conduct formal quality improvement projects that can take years to complete and that must follow a prescribed format.

Minimal assessment of State survey agencies' performance.

HCFA's assessment of the performance of the State survey agencies is even less exacting than that for the Networks. In the past, HCFA would conduct validation surveys, through which HCFA staff would review dialysis facilities shortly after a State certification survey.[56] Recently, HCFA eliminated these in favor of periodically observing State surveyors' performance and offering advice and assistance as applicable. While the latter approach has potential and may well involve some useful informal assessment and feedback to the State surveyors, we found no evidence of substantive evaluation and feedback to the States on such key matters as the effectiveness of the surveys, the skill of the surveyors, and the adequacy of collaboration with the Networks.

HCFA relies on State agencies to assess their own performance and, by working with the HCFA regional offices, to develop and implement their own quality improvement plans. This process is called the State Agency Quality Improvement Program (SAQIP). The program addresses State survey activities generally, and fails to specifically assess dialysis surveys. The summary report that HCFA issues on SAQIP activities provides few meaningful insights into the challenges or successes of any one State.[57]

Minimal public disclosure.

HCFA offers no readily accessible public information (e.g, on the Internet) on any Network or State actions taken by either Networks or States to protect the public. All Networks have websites, but they vary significantly in the amount and type of information that they post. None publishes any information on complaints received and investigated at a particular facility or on any corrective actions pending against a particular facility. Similarly, little information is readily available on the performance of States. Survey results are available only upon request and are difficult to interpret. Results are not routinely posted on the Internet or in facilities.

RECOMMENDATIONS

The 230,000 patients receiving life-sustaining dialysis treatments rely upon the professionalism of their caregivers and the internal monitoring efforts of their facilities to provide high quality care and minimize risks. Yet, documented variations in the quality of dialysis care and reported incidents of poor care reinforce the need for an external quality review system to serve as a safety valve for patients.

As we have indicated, the quality oversight system carried out on HCFA's behalf by the Networks and State agencies has major shortcomings. It is imbalanced, in that it stresses improving overall quality more than enforcing minimum requirements that protect patients from harm. It is fragmented, in that Networks and State agencies rarely coordinate their efforts to foster patient protections. And, fundamentally, it lacks sufficient accountability on the part of the Networks, the State agencies, and, most of all, the facilities themselves.

HCFA should exert leadership to address these shortcomings. In this section, we present two guiding principles and two recommendations that address how HCFA can provide this leadership. In doing so, we stress that while HCFA has authority and leverage, it must approach the Networks and State agencies as partners who contribute to and share a commitment to high-quality dialysis care. We also stress that external oversight must be conducted in ways that minimize the regulatory burden on dialysis facilities and seek to complement the facilities' own internal quality review efforts. In some cases HCFA has already undertaken initiatives that move in the directions we call for.

We present our recommendations in the context of the current oversight system in which HCFA relies upon the Networks and State survey agencies. We believe that this system has the potential to provide effective oversight. Yet, we recognize and suggest that HCFA take into account that a system for private accreditation of dialysis facilities, if held properly accountable, can be a valuable complement — particularly because it can readily adapt state-of-the art standards that respond to changes in dialysis delivery and evaluation methodology.[58]

In making our recommendations, we must stress that our focus is on the external quality oversight of dialysis facilities and not on the Medicare payment policies concerning dialysis treatment. We note that because in the course of our interviews and in the professional literature many parties have expressed concern that the fragmented nature of the payment system and the current rate of reimbursement for dialysis treatment are themselves factors that may adversely effect the quality of dialysis care. We offer no such evidence in this report, but recognize that they are factors warranting attention, as has been pointed out by the Institute of Medicine and the Medicare Payment Advisory Commission.[59]

Finally, we recognize that our findings and recommendations suggest a sense of urgency in improving the quality oversight of dialysis facilities. At the same time, we recognize that in an environment of limited resources and competing priorities, all the actions we call for cannot readily be taken. We present them as a blueprint for actions that can be carried out over a reasonable period of time.

GUIDING PRINCIPLE 1. HCFA should steer external oversight of the quality of dialysis facilities so that it reflects a balance between collegial and regulatory modes of oversight.

In our work on external quality oversight of various kinds of health care providers, we have found it helpful to consider oversight efforts in terms of a continuum, characterized by a collegial approach on one side and a regulatory approach on the other. External reviewers in the collegial mode focus on educating and improving performance; those in a regulatory mode focus on investigating and enforcing of minimum requirements. In the continuum below, we present the major characteristics we associate with each mode.

Figure 2. A Continuum of External Review

Collegial Mode (Educate and Elevate)	Regulatory Mode (Investigate and Enforce)
Cooperative	Challenging
Flexible	Rigid
Foster Process Improvements	Enforce Minimums
Guidance	Directive
Trusting	Skeptical
Professional Accountability	Public Accountability
Confidentiality	Public Disclosure
Systems Focus	Outlier Focus
Improve Patient Outcomes	Minimize Preventable Harm

Both approaches have value and ardent supporters. But, as the National Roundtable on Health Care Quality and others have found, neither approach is backed with sufficient data to warrant concentrating on one at the expense of the other.[60] A credible system of external review must, therefore, reflect a reasonable balance between the two.

In the current system of oversight, the State agencies clearly operate on the regulatory side of the continuum. They are public bodies that as HCFA's agents perform on-site surveys that can serve as the basis for regulatory actions. But as we have shown, the

frequency of those surveys has declined markedly, resulting in only 17 percent of all dialysis facilities being surveyed in 1998.

In contrast to the State agencies, the Networks function on the collegial side of the continuum. They are governed primarily by physicians who are associated with individual facilities, who have expertise on dialysis treatments that State agency representatives lack, and who stress education and improvement objectives. As we have shown, their collegial orientation, which can often be effective, is apparent in how they use standardized performance data and respond to complaints. Some Networks do reflect a greater readiness to take a more challenging approach to facilities, but their limited authorities, resources, and mandate from HCFA preclude them from moving very far in this direction. In working with the Networks, HCFA in recent years has reinforced their collegial role, viewing them increasingly as functioning in a penalty free environment, while the State agencies serve as the regulators.

The Networks have much to offer in using collegial approaches to foster improvements in the quality of care. Given their greater expertise on dialysis matters and their closer relationships with dialysis facilities, it would seem to be desirable for HCFA to look to them to tilt toward the collegial end of the continuum. But it is not feasible for a Federal oversight entity not to have some clear requirements for enforcing minimum standards of performance. HCFA, we believe, should exert a steering role that, over time, achieves a reasonable balance between the two approaches to oversight. In our recommendations, we offer specific suggestions on how that can be done.

GUIDING PRINCIPLE 2. HCFA should steer the external oversight of dialysis facilities so that Networks and State survey agencies collaborate more effectively.

As we have shown, the Networks and State agencies operate in two separate realms and rarely interact. Given the crucial and often interrelated roles that both play as HCFA's agents, it is vital that HCFA provide direction that facilitates better collaboration. Through a clear delineation of their mutual roles, specific operational mandates, support for demonstration efforts, sharing of information about promising approaches, and perhaps other ways, HCFA can steer the efforts of the Networks and State agencies in ways that foster more frequent and effective collaboration. The joint efforts taking place in Texas illustrate some of the potential that exists. (See our companion report, *External Quality Review of Dialysis Facilities: Two Promising Approaches.*)

RECOMMENDATION 1. HCFA should hold individual dialysis facilities more fully accountable for the quality of care.

1a. HCFA should revise the Medicare Conditions for Coverage for dialysis facilities so that they serve as a more effective foundation for accountability.

The current Conditions are close to a quarter century old.[61] It is time for HCFA to update and reinforce them as a tool for holding dialysis facilities accountable for the quality of care they provide. A number of years ago, HCFA proposed a set of revisions that reflected some progress in this direction. But that effort stalled. We recommend that HCFA revise the current Conditions so that, at a minimum, they:

- ***Strengthen the accountability of the dialysis facility governing body.*** The governing body should be held clearly accountable for the overall quality outcomes provided by the facility.[62] Moreover, since most dialysis facilities are now part of national or multi-national corporations, the governing bodies should ensure that authoritative representatives are readily available to respond to queries and/or visits by State survey agencies or Networks.[63]

- ***Reinforce the accountability of the dialysis facility medical director for patient care.*** While the governing body of the facility is the basic source of accountability, the medical director should clearly be empowered as the on-site agent most directly responsible for the quality of care being delivered. In this capacity, the medical director should clearly have the authority to develop and monitor quality improvement efforts, to serve as an educational resource for medical and nursing staff, and, where individual care staff are not performing adequately, to bring that to the attention of the facility's designated governing authority.[64]

- ***Require facilities to report electronically on standardized performance measures determined by HCFA.*** HCFA must make clear a facility's obligation to report facility-specific patient outcome data to a designated entity or entities on a national set of performance measures.[65] As HCFA continues to focus more on performance measures, facilities must submit their data electronically in order to make this task feasible and allow for timely analysis and dissemination of the data.

- ***Require dialysis facilities to conduct their own quality improvement program.*** An internal quality improvement program serves as a valuable complement to network-wide or national improvement efforts. It is a mechanism for addressing the distinctive needs of a facility and of fostering a culture of continuous improvement.[66]

- ***Require dialysis facilities to establish internal systems for identifying and analyzing the causes of medical injuries and medical errors.*** Injuries associated with patient care will happen from time to time and a facility must be alert to spotting them and learning from them. Such internal systems help protect patients from harm.

- ***Require dialysis facilities to monitor patient satisfaction.*** Over the past 25 years, patients have come to play an increasingly important role in their own health care, and techniques of assessing patient satisfaction have become increasingly sophisticated. Given that, it is reasonable to expect dialysis facilities to integrate patient satisfaction as an element in their own quality improvement efforts. Moreover, an ongoing mechanism for monitoring patient satisfaction can serve can serve as a way of surfacing patient concerns that complaint systems do not.[67]

1b. HCFA should use facility-specific performance measures to encourage facilities to improve the quality of care and to help ensure facilities meet minimum standards.

We recommend that HCFA move in the direction of collecting and disseminating *facility-specific* performance data and of using such data in a balanced fashion — for both improvement and enforcement purposes. HCFA has made progress in developing and using performance measures that provide the basis for assessing the quality of dialysis care. But, thus far, HCFA has focused on using performance measures almost completely for improvement purposes by focusing on national and regional trends. It is time, we believe, to build on this progress by using performance measures as a key mechanism for holding individual facilities more accountable for the care they provide.

Identify a core set of performance indicators to collect regularly on all patients from facilities. HCFA, with input from the professional community and from patients and patient advocates, should determine a core set of clinical indicators that will be used to help facilities, Networks, State survey agencies, and the public assess the quality of care at a facility while ensuring patient confidentiality. Once established, this core data set should be continually examined and revised so that it includes the most pertinent, reliable measures. HCFA has already implemented core data sets for other providers, such as nursing homes and home health agencies, which serve vulnerable patient populations. It is time to do the same for dialysis facilities. In the interest of accuracy and timeliness, HCFA should develop a system that collects the performance data on a regular basis directly from patient's medical records. At a minimum HCFA should collect these measures annually and work towards quarterly reporting.

HCFA has already begun to take significant steps toward the goal of facility-specific data. Namely, HCFA has invested in an extensive computer infrastructure for electronically linking facilities, Networks, and HCFA together. This system will make a data collection of this size more feasible.[68] HCFA has also created the National ESRD Core Data Set Initiative to begin to develop a core data set for dialysis facilities.

Already, HCFA has funded the creation of three facility-specific reports. One facility-specific report is to be used by Networks and the facilities for quality improvement purposes.[69] HCFA has also developed two other facility-specific reports that will contain performance data, one for State survey agencies and one for consumers.[70] These three reports rely largely on HCFA billing data for clinical indicators such as urea reduction ratios, hematocrit levels, and patient mortality.

Disseminate comparative facility-specific reports to facilities, Networks, State survey agencies, and the public containing all the performance indicators in the core set. Once HCFA has a data collection system in place, it should generate quarterly, facility-specific reports that compare facilities to their own past performance and to their peers at the State, Network, and national levels for each of the performance indicators in the core set. Where possible, HCFA should account for case mix differences among facilities. At a minimum, this should include patient demographic information. Eventually, HCFA should generate similar reports at the physician level.

The data in these reports should be made readily available to all parties: the facilities, the Networks, the State agencies, and, through Internet websites (and perhaps even postings in facilities), the general public. Such an effort will require HCFA to ensure patient confidentiality and may call for statutory changes. As we previously mentioned, HCFA already has an effort underway to develop a core data set, the National ESRD Core Data Set Initiative. However, HCFA has not yet determined specifically how this data set will be used by all the various parties.

Figure 3. The core set of facility-specific performance measures should be available to:

- **facilities** to support internal quality improvement activities,
- **Networks** to support regional quality improvement activities and to identify outliers for further review,
- **State survey agencies** to help guide and inform the survey process, and
- **the public** to foster public accountability.

We also recognize the sensitivities associated with such widespread release of this information. The data, many note, can be misleading. For instance, some patients may not choose to have optimum dialysis treatments because they wish to spend less time on dialysis. To help foster the responsible use of the performance data, we suggest that all quarterly performance reports include a prominent statement up front noting the limitations of the data and emphasizing that performance data are *indicators*, not absolute markers of quality.

At the core, the performance data can help reviewers ask better, more targeted questions about quality. If a facility's performance on a measure or a cluster of measures has been declining over time or is consistently less than that of other facilities with a similar patient mix, then it is reasonable to ask why and to do so in a public forum. The answers

might well indicate that such a facility is actually a top-quality one, with sound reasons for its statistical ranking. Or, they could indicate that the facility does have problems warranting attention.

- ***Facilities.*** Perhaps the most compelling reason for distributing facility-specific standardized performance data is to spur internal improvements by the facilities themselves. Such data can help leadership in the facilities gain a better sense of how the facility is performing and can provide the leadership with valuable leverage for initiating change. This would appear particularly true in competitive markets.

- ***Networks.*** Once equipped with facility-specific performance data, Networks will have a valuable additional tool to guide their external oversight of facilities. HCFA should require that Networks use these data for both improvement and enforcement purposes. It should look to the Networks to take the lead in identifying best practices, conducting educational and technical assistance efforts, and other initiatives that foster continuous improvement in the quality of care provided at dialysis facilities. At the same time, HCFA should look to the Networks to work with outlier facilities that have continued poor performance that cannot be explained by extenuating circumstances. HCFA should also make clear that this may well call for imposing corrective actions, or perhaps, referrals to the State survey agencies or HCFA itself.

- ***State survey agencies.*** The professional renal community is concerned about the potential use of performance data to trigger State surveys. Their concern centers around the credibility of such information in identifying problem facilities and in the use of performance data for regulatory as opposed to improvement purposes. We recognize the danger of drawing upon performance data too literally as an alarm-call for a regulatory-focused State survey. Yet, we see no basis for not regularly sharing such data with the State surveyors. Together with other information that the State may have on a facility, it can help guide the surveyors when they do survey a facility or, in cases when the information seems compelling enough, influence when they decide to conduct a survey.[71]

- ***The public.*** With the rapid advances taking place in information and medical technology, patients and consumers, in general, are becoming increasingly active partners in their own health care.[72] Even though many dialysis patients may not be inclined to draw on facility performance data, many of them and many family members, surely would be interested in such data. Moreover, the influence of public release would likely contribute to how seriously facilities respond to the data. HCFA has moved in this direction in providing data on the performance of nursing homes and managed care organizations.[73] It should do the same for dialysis facilities. HCFA's posture toward performance data should be that if they are worth collecting, they are worth disclosing.

1c. HCFA should strengthen the complaint system for dialysis patients and staff.

Work with the Networks and the State survey agencies to establish an effective complaint system. On the basis of this inquiry and our prior inquiries of external quality oversight of health care providers, we have developed a template for an effective complaint system. Below, we identify and explain the eight key elements of that template. We present it here as a frame of reference for the kind of system that HCFA should seek to establish in the dialysis field.

Table 2. Template for an Effective Complaint System

Element	Description
Accessibility	Makes efforts to inform potential users of the system and is easy to use.
Objectivity	Respects the rights of all parties involved. Conducts unbiased investigations.
Investigative Capacity	Has access to clinical expertise and has sufficient resources and authority to thoroughly review and evaluate complaints, including the ability to go on-site whenever necessary.
Timeliness	Complaint investigations conclude within a reasonable time frame.
Responsiveness to Complainants	Complainants receive substantive information about the process and any resulting actions.
Enforcement Authority and Follow-up	Has the authority to hold facilities and individuals accountable when complaints are substantiated. Follows up with appropriate corrective actions.
Improvement Orientation	Uses complaints to help identify opportunities for improvement and prevention.
Public Accountability	Facility-specific complaint information is available to the public so that they can be aware of any disciplinary actions or any past problems at a particular facility.

Conduct pilot projects to test ways in which the Networks and the State survey agencies could work together to create an integrated complaint system. Given the fragmented nature of the current complaint systems, we recognize that even at best it is likely to take some time to develop a system that as a whole reflects the characteristics of the above template. Thus, we urge HCFA first to convene representatives from the Networks and State survey agencies to identify ways in which these two entities can work together most constructively, drawing on their respective strengths. Secondly, we urge HCFA to conduct pilot efforts through which Networks and State agencies implement a unified complaint system based on our template. The results of such pilots could help guide the efforts of other Networks and States and, over time, could provide the basis for explicit expectations incorporated in HCFA contracts with both the Networks and States.

Develop a common instrument that facilities and others could use to assess patient satisfaction. For many patients, an anonymous response to a patient satisfaction survey may serve as a safer vehicle for expressing concern than a formal complaint to a facility, Network, or State agency. We have already called for HCFA to revise the Medicare Conditions for Coverage so that facilities are required to conduct their own assessments of patient satisfaction. Given the importance of this kind of effort, we also call upon HCFA to exert national leadership to facilitate the development of a common instrument that dialysis facilities could use to assess patient satisfaction. This could draw upon the instruments that some dialysis corporations have already developed and use for their own internal monitoring efforts. HCFA could make such an instrument available to facilities for their own use. HCFA could also test such an instrument on a national, Network, or even facility-specific basis. Recently, the Medicare Payment Advisory Commission made a similar recommendation.[74]

1d. HCFA should enhance the role of Medicare on-site certification surveys.

Determine an appropriate minimum cycle for conducting Medicare certification surveys of dialysis facilities. Routine on-site surveys of dialysis facilities are important to help ensure that facilities comply with minimum standards outlined in the Medicare Conditions for Coverage.[75] But, as we have shown, the elapsed time between the State surveys has been growing, with the result that close to half of all facilities have not been surveyed within a 3-year period. As a result, surveyors have difficulty maintaining their skills.[76] By contrast, nursing homes and home health agencies, which also serve vulnerable populations, are surveyed according to a congressionally mandated cycle. By determining an appropriate minimum cycle for dialysis facilities, HCFA will increase the attention that dialysis quality issues receive and will enable surveyors to better maintain their competencies.

Conduct pilot tests to determine the potential of Network and State joint initial certification visits of dialysis facilities. All new facilities must undergo an initial certification visit by the State survey agency. We suggest that this initial review presents a major opportunity for State agencies and Networks to bring together their respective strengths and ensure that the facilities have in place the necessary elements to provide top-quality dialysis care. We recognize that at the time of initial reviews few patients are receiving treatment at the facility and therefore major problems rarely are uncovered. We think that initial reviews provide an opportunity for the Networks and States to work together cooperatively without the pressures associated with a for-cause investigation. Such a joint effort would get the two entities more accustomed to working together and could therefore have residual benefits for their other oversight functions.

1e. HCFA should facilitate the development of publicly accountable means for identifying serious medical injuries and analyzing their causes.

We have already recommended that HCFA require facilities to develop their own, internal mechanisms for addressing medical injuries and medical errors. It is essential,

we believe, for this internal safeguard to be complemented with an external, publicly accountable means for addressing adverse events resulting in death or serious harm while ensuring patient confidentiality. The Institute of Medicine recently called for a mandatory national system for reporting of such adverse events in hospitals and other health care facilities.[77] Given that dialysis treatments are paid for primarily by Medicare funds, and that HCFA has the major responsibility for the external quality oversight of the facilities, dialysis facilities are an ideal candidate for testing this kind of reporting system. The system should provide for the analysis of adverse events and for any necessary corrective actions at the facilities involved. It should also involve the maintenance and regular analysis of a data base of such events in order to identify injury-prevention strategies that could be shared across facilities.

In particular, we suggest that HCFA work with the Networks to establish pilot efforts to conduct such monitoring. Those pilots should test ways to identify major adverse events occurring in dialysis facilities that trigger subsequent analyses that shed light on (1) the causes of the events in those facilities and (2) the broader prevention strategies that can be taken across facilities. In any such pilot effort, HCFA should require that collaborative arrangements be made with the State survey agencies.[78]

RECOMMENDATION 2. HCFA should hold the Networks and State survey agencies more fully accountable for their performance in overseeing the quality of care provided by dialysis facilities.

The Networks are private, federally funded contractors accountable to HCFA for their performance. The State survey agencies are public bodies accountable to their States' governors and legislatures, but also to HCFA for the services they are providing on behalf of Medicare beneficiaries. If HCFA is to hold the facilities more accountable as we called for in the prior recommendations and if it is to continue to rely upon the Networks and State agencies as its main agents toward that end, then it must also find ways to hold those agents more accountable. Below, we set forth specific actions HCFA can take.

2a. HCFA should issue policy guidance delineating the distinctive roles of the Networks and State survey agencies in quality oversight and providing direction on how they should collaborate.

HCFA should clearly state that the Networks serve as its primary agents in fostering continuous quality improvement in the care provided to dialysis patients, but yet must also support enforcement efforts. Similarly, it would be helpful for HCFA to clearly state that the State survey agencies serve as HCFA's primary agents in enforcing compliance with the Medicare Conditions for Coverage, but also must support improvement opportunities. With the two entities having a mutual appreciation of these distinctions, the stage is more effectively set for effective joint efforts — for a more effective oversight process that marries the clinical expertise of the Networks with the

regulatory powers of the State agencies. HCFA can convey this in two ways. For Networks, their contracts, particularly in the section explaining HCFA's Health Care Quality Improvement Program, would seem to be a particularly appropriate vehicle. For the State agencies, the annual budget call letter would appear to be the most appropriate forum.

We recognize that there are significant barriers to achieving collaboration between the Networks and the States. As we have already mentioned, Networks and States take markedly different approaches to oversight. Also limited resources make it difficult for the States and the Networks to have face-to-face meetings. This may be even more difficult for the Networks because most Networks cover multi-state regions. Finally, HCFA needs to address the issue of confidentiality and if necessary request statutory changes so that the Networks and the States can disclose information to one another and to the public.

HCFA should also target, for both the Networks and State agencies, particular spheres of activity in which collaborative arrangements are not only desirable, but also necessary. HCFA should go beyond the general statements on coordination, as now appear in the Network contracts, and offer firm direction. HCFA should then hold both parties accountable for adhering to that direction. At a minimum, the Networks and State agencies should be held accountable for collaboration in the following four areas:

- ***Sharing facility-specific data.*** Such data are important vehicles for facility self-improvement. But they also can be useful (if not necessarily determinative) in informing State on-site surveys.

- ***Sharing State survey results.*** Similarly, results of the State surveys can be helpful to the Networks as they carry out their quality improvement efforts and as they address specific complaints involving individual facilities.

- ***Working together in addressing complaints.*** To help protect patients, the Networks, and State agencies should agree on when to make referrals to one another involving complaints. The pilot efforts we called for earlier can be helpful here.

- ***Consulting one another on areas of expertise.*** States and Networks both need to be valued for their perspective and expertise. Networks could help surveyors target facilities for surveys and help monitor and correct deficiencies involving the quality of care. Similarly, States could help Networks enforce minimums and identify regional trends. To make sure this occurs, HCFA should establish guidelines for when Networks and States should solicit the advice or assistance of the other.

One way in which HCFA can facilitate collaboration between the Networks and States is to convene forums in which HCFA, Network, and State officials come together to discuss the approaches to collaboration, the barriers that inhibit them, and actions that might be taken to overcome such barriers. The forums could also provide a good venue

to showcase promising approaches to collaboration that some Networks and States have already undertaken.

2b. HCFA should foster greater accountability of the Networks.

Develop, with input from the Networks, a system for performance-based evaluations of the Networks. This system would have to be established from the ground up since no such system is in place now. The current evaluations of Network are rudimentary, more of an accounting of activities than an evaluation of performance. We call for a reinvention of this entire approach in a way that minimizes routine annual reporting burdens and maximizes opportunities for substantive assessment and continuous improvement.

We suggest that, at least at the start, this reinventing effort focus on two central questions:

- ***How effectively are Networks drawing on standardized performance data to improve the overall clinical performance of facilities in their region and to ensure that poor performers meet minimum standards of care?*** Given the development of increasingly sophisticated clinical performance measures for facilities, it is reasonable to use them as key references in assessing the Networks' own performance. HCFA has moved in this direction with the Medicare Peer Review Program. It would appear to be timely to do the same for Networks.

- ***How effectively are Networks using a complaint system as a quality-of-care safeguard?*** The template we developed offers eight specific elements that can be examined to help answer this question.

As HCFA puts in place a performance-based evaluation system, it should give the Networks increased flexibility in how they use their resources. Such flexibility should enable Networks to develop improvement projects, intervention strategies, educational efforts, and other initiatives that are most pertinent to their region. The aim should be to find reasonable ways of holding Networks more accountable for results that make a difference in patient care while giving them added discretion in tailoring their efforts to the needs and characteristics of their regions. Providing Networks with the added flexibility we call for need not preclude developing a nationwide quality improvement project that all Networks participate in, if the rationale for that effort were sufficiently compelling.

Increase public disclosure of information on the Networks. As HCFA proceeds in developing an evaluation system as we call for above, it should also develop a core set of information on Network activities and performance that would be readily available to the public, preferably on the Internet — either on HCFA's own web site or on the Networks' web sites or posted in facilities. Such disclosure can be particularly important in helping the media, advocates, patients, and other interested parties

understand how Networks use performance data to improve dialysis care and of how they handle complaints. In the process, it reinforces the point that publicly-funded Networks are accountable to the general public as well as to HCFA.

2c. HCFA should foster greater accountability of the State survey agencies.

Establish a means to periodically assess the State surveys. One way HCFA could better assess the State surveyors is to observe more State surveys. This provides HCFA with the opportunity to provide direct feedback to surveyors and can be more instructive and timely than validation surveys. However, because of the technical nature of these surveys, it may be difficult for HCFA personnel to develop and maintain the expertise to constructively assess State surveys. In this regard, HCFA should consider developing a small group of contracted, experienced dialysis surveyors that it could draw upon to periodically observe State surveys as well as to investigate complaints as needed. For years, HCFA has relied upon a panel of contracted psychiatric surveyors to survey psychiatric hospitals. A similar mechanism could be used for the oversight of dialysis facilities.

Increase public disclosure of information on the State survey agencies. Disclosing information about the activities and performance of the State survey agencies is just as important as for the Networks. Particularly relevant would be information on the number of surveys conducted, the specific facilities surveyed, the type of deficiencies found, and the corrective actions taken. As with the Networks, HCFA could post this and other pertinent information on its own website or call for the States to post it on their own or even post it within the facilities as is the case for nursing homes.[79]

COMMENTS ON THE DRAFT REPORT

We received comments on the two draft reports from HCFA and three additional outside parties: the Forum of the End Stage Renal Disease Networks, the Association of Health Facility Survey Agencies, and the American Association of Kidney Patients. Based on the comments we changed one recommendation and made several technical changes to the report. We include the complete text of the comments in appendix C. Below we summarize the comments and, in italics, we offer our responses.

HCFA Comments

HCFA generally supported our findings and recommendations and responded by submitting a detailed action plan. The action plan outlines HCFA's commitment to collect and disclose facility-specific performance data, increase on-site surveys, revise the Conditions for Coverage, strengthen the complaint process, and explore ways to implement a system to monitor adverse events. HCFA indicated that it intends to establish minimum performance standards for some clinical outcomes. HCFA did take issue with our recommendation to require joint Network-State initial certification surveys of facilities. HCFA also expressed concerns with assessing patient satisfaction, given a likely low response rate.

We find HCFA's detailed action plan to be a positive step toward strengthening the system of oversight for dialysis facilities. We caution HCFA not to include specific performance measures or minimum thresholds within the Conditions for Coverage. This will prevent timely updates as scientific knowledge advances. We believe that measures with minimum thresholds would be more aptly laid out in provider agreements with facilities. With regards to HCFA's concern about joint Network-State surveys, we revised the recommendation to state that HCFA should first conduct pilot tests to determine the effectiveness of this approach rather than requiring it. We recognize the shortcomings of such an approach, but we maintain that initial certification surveys offer a less threatening environment compared to a for-cause survey. Thus, Networks and States may find it easier to work together. We also think initial certification surveys are a good opportunity for the facility to meet both the Networks and the States before a problem arises. We encourage HCFA to move forward with assessing patient satisfaction even given the likelihood of low response rate. Finally, we want to further stress that HCFA release any and all facility-specific data that it collects to the public.

Forum of the End Stage Renal Disease Networks Comments

The Forum agreed with the majority of our findings but expressed concerns over several of our recommendations. The Network took issue with our finding that Networks rarely target poor performing facilities. It emphasized that Networks and States approach such facilities in different ways and both approaches are valuable. It cautioned against

specifying outcome targets in the Conditions for Coverage. The Forum raised concerns that efforts to monitor adverse events, patient satisfaction, and the public release of performance data may undermine the collegial role of the Networks. It suggested that initial certification surveys may not provide the best opportunity for joint Network and State surveys and suggested instead joint surveys of poor performers. It also took issue with our recommendation for developing a performance-based evaluation mechanism for the Network without a similar requirement for the States. Finally, it pointed out the Networks' role in monitoring transplant centers was not addressed.

We recognize that some Networks are targeting poor performing facilities, but our evidence shows that many Networks are not and that many do not have reliable facility-specific data to identify such facilities. We want to reiterate that the Networks and States both have responsibilities to ensure minimums and to improve the overall performance. It is not feasible at this time for the Networks to work exclusively in a non-punitive manner. We believe that the Texas example presented in our second report demonstrates that Networks and States can work in both realms, each with their respective emphases. We agree that joint Network-State surveys of poor performers may be valuable and may be an option that HCFA would want to test along with joint initial certification surveys. Given the emphasis of the Networks on quality improvement and the States' emphasis on enforcing minimums, we think that it is feasible to hold the Networks accountable for improving the performance of their facilities. We call for States to be held accountable for their role in enforcing minimums. Finally, we agree that the oversight of renal transplant centers is important, but that issue was beyond the scope of this inquiry.

Association of Health Facility Survey Agencies Comments

The Association of Health Facility Survey Agencies (AHFSA) agreed with the majority of our findings and recommendations, but indicated that we failed to provide any discussion of funding issues. Specifically, it called for additional funding for States to conduct more surveys. AHFSA also offered several additional recommendations that provide more operational approaches to our recommendations. It supported the notion of greater collaboration between the Networks and the States, the public release of facility-specific outcome data, and called for the Conditions for Coverage to require reporting of adverse events to the States.

We acknowledge in the report that competing budget demands is a major reason for the lack of surveys and recognize that many of recommendations will require additional funds. We address the concern about funding of the State agencies by calling for HCFA to determine an appropriate minimum cycle for conducting surveys. HCFA itself addressed this issue in its comments by noting that the President's Budget for FY 2001 calls for a substantial increase in funding for ESRD surveys. However, our recommendations require more than just additional funding — they also require strong leadership on the part of HCFA.

American Association of Kidney Patients Comments

The American Association of Kidney Patients (AAKP) strongly agreed with our recommendations and believed that our recommendations could result in better care for patients. AAKP pointed out its own concerns with the variability among Networks and States. It believes that the greater accountability we call for will lead to more consistent performance across Networks and States. AAKP also highlighted HCFA's current efforts underway to release performance data publicly and asked us to ensure that funding to implement our recommendations does not come at the cost of funding patient activities.

We are pleased to receive such strong support from AAKP which represents the patients that we aim to protect. In our report we acknowledge HCFA's effort to release performance data to the public and we believe it is a step in the right direction. Furthermore, we underscore AKKP's point that funding for oversight activities should not jeopardize patient care.

APPENDIX A

Methodology

HCFA

We interviewed HCFA officials responsible for the ESRD program at both the Central Office and the four lead ESRD regional offices (Boston, Kansas City, Dallas, and Seattle.) This included all the project officers for the Networks and HCFA officials involved with the State survey and certification programs. We gathered information on how HCFA evaluates the Networks and State agencies, their perceptions on the strengths and weaknesses of the program, and any recommendations they had for improving the oversight of dialysis facilities.

ESRD Networks

We conducted a mail survey of all 18 Networks to gather information on the types of performance data Networks use and collect, on how they handle complaints and adverse events, and how often they conduct on-site surveys. All 18 Networks responded. In addition to our survey, we received and analyzed the following documents from all the Networks: 1997 annual reports, 1998 annual reports, and 1998 responses to complainants.

We selected nine Networks to participate in telephone interviews. We chose at least two Networks from each of the four lead HCFA regions. Network staff and board members participated in the interviews, which covered topics related to the oversight of facilities such as quality improvement projects and other sources of performance data, complaint procedures and trends, and their relationships with HCFA and State agencies. We also selected two Networks for site visits lasting several days. These visits included interviews with staff, board members, patients, and renal professionals. While on-site we examined their complaint files. Three additional Networks received site visits that involved discussions with Network leadership about oversight in general.

State Survey Agencies

In order to gain information on the State agencies we analyzed HCFA's On-line Survey, Certification and Reporting System (OSCAR) to determine the frequency with which State agencies conduct Medicare certification and complaint surveys of ESRD facilities which includes both transplant facilities and dialysis facilities. We pulled two data sets from the system: one in May 1999 and one in August 1999. We analyzed these data sets using SAS and Excel software programs. In addition, we interviewed five State survey agencies. We also observed a dialysis facility survey.

APPENDIX A

Stakeholder Interviews

We interviewed several representative of organizations involved with dialysis issues. These organizations included professional groups, consumer groups, Federal agencies, and Federal contractors.

Literature Review

Throughout our evaluation, we reviewed various documents including statutes and regulations, Federal agency documents, policy reports, media articles, and scientific journal articles.

APPENDIX B

Major Sources of Clinical Performance Data for ESRD

Below we highlight several of the major sources of performance data for dialysis facilities.

HCFA's Clinical Performance Measures Project. Since 1994, with the help of the Networks and facilities, HCFA has collected a set of measures on a national sample of patients. In 1999, the set included 16 measures such as urea reduction ratio, Kt/V, hematocrit, hemoglobin, and type of vascular access. Facilities abstract the measures from patient medical records and Networks validate a sample of the data. HCFA disseminates aggregate measures at the national and Network level to the renal community and the public. The sample does not allow facility-specific analysis.

Medicare Billing and Enrollment Data. HCFA claim and administrative forms are a rich source of information on patients and facilities, such as patient hematocrit levels, urea reduction ratios, and mortality. Since 1996, HCFA has used this data to generate confidential facility-specific reports on anemia management for its National Anemia Cooperative Project. A few Networks reported using the anemia data to monitor facility performance and to identify facilities in need of interventions. HCFA currently uses these data to generate various facility-specific reports for facilities, Networks, States, and the public.

United States Renal Data System. Funded by the National Institutes of Health and partially funded by HCFA, this database compiles numerous data sources on renal patients, most of which come from Medicare billing data. Each year, an annual data report is disseminated to the public that provides trend information at the Network and national level. Previously, the USRDS generated confidential, facility-specific standardized ratios for mortality, hospitalization, and transplantation for facilities, which have been helpful in identifying regional problems in the quality of care. These reports are now being generated by HCFA. Most Networks reported that they use the USRDS methodology, or one based on it, to calculate their own standardized mortality ratios for facilities. A few Networks reported that they use the facility-specific ratios generated by USRDS to identify poor performers.

National Surveillance of Dialysis Associated Disease. This voluntary survey, started in the early 1970s by the Centers for Disease Control and Prevention, monitors infectious disease rates, such as hepatitis B, within facilities. It also collects facility-specific information on vaccination rates, vascular access, staffing ratios, and reuse of hemodialyzers. The data are disseminated to the public showing trends at the Network and national level. Every Network, except one, reported that they use these data to help determine future topic areas for quality improvement projects, to provide baseline data,

and/or to identify poor performers. These data are not readily available to the public or the States.

Network Databases. Networks maintain their own databases that vary from Network to Network. Some of the elements Networks collect on their own and some they obtain from the databases listed above. A few Networks disseminate confidential facility-specific reports to facilities. Network data is not regularly available to HCFA, States, or the public.

APPENDIX C

Comments

In this appendix we include the full text of comments of the parties that responded to our two draft reports. We present them in the following order:

- HCFA
- Forum of the End Stage Renal Disease Networks
- Association of Health Facility Survey Agencies
- American Association of Kidney Patients

APPENDIX C

DEPARTMENT OF HEALTH & HUMAN SERVICES — Health Care Financing Administration

DATE:

TO: June Gibbs Brown
Inspector General

FROM: Nancy-Ann Min DeParle
Administrator, Health Care Financing Administration

SUBJECT: Office of Inspector General (OIG) Draft Report, "External Quality Review of Dialysis Facilities, A Call For Greater Accountability" (OEI-01-99-00050) and "Two Promising Approaches" (OEI-01-99-00051)

Thank you for conducting a thorough review of the external quality oversight of dialysis facilities in the United States and the roles played by the Health Care Financing Administration (HCFA), the State survey agencies, and the End Stage Renal Disease (ESRD) Networks. HCFA welcomes the report's findings and views the findings as an opportunity to make the changes necessary to improve the oversight and quality of care in dialysis facilities participating in the Medicare program. We are committed to working with the State survey agencies and the Networks to ensure that dialysis patients receive high quality care.

Our efforts to improve performance of the dialysis facilities have had some measurable success. For example, between 1994 and 1998 the percentage of ESRD patients with adequate hematocrit (red blood cell) levels increased from 55 to 83 percent. Additionally, in the same time period, the percentage of patients receiving adequate dialysis increased from 49 to 74 percent. We also know from the U.S. Renal Data System, a joint HCFA and National Institutes of Health project, the one year mortality rates for dialysis patients decreased from 24.9 deaths per 100 patient years in 1990 to 22.8 in 1997.

These improvements are due in part to the leadership role HCFA took beginning in 1994 to develop clinical indicators that assess the quality of care for dialysis patients. This effort is now known as the Clinical Performance Measures Project (formerly the National/Network ESRD Core Indicators Project). HCFA, through the ESRD networks, collects clinical indicators on a national sample of dialysis patients in the areas of adequacy of dialysis, anemia management, and serum albumin (a protein in the blood that is an indicator of the patient's overall health). These data are collected, analyzed and described annually in a detailed report, the *ESRD Clinical Performance Measures Project Annual Report*. This report is distributed to all dialysis providers for their use in identifying opportunities for improvement. Using this national sampling approach, we have documented improvement every year in the number of dialysis patients achieving the benchmarks for these clinical indicators since 1994.

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Page 2 - June Gibbs Brown, Inspector General

We have also undertaken steps to begin collecting facility-specific data, something your reports advise HCFA to do. In 1998, HCFA directed the development of 16 clinical performance measures that we are collecting from a sample of facilities this year. This effort was initiated to implement a provision in the Balanced Budget Act of 1997 that requires HCFA to measure and report the quality of renal dialysis services. The 16 clinical measures are similar to those of the Core Indicators Project described above, with the addition of measures for evaluating vascular access (the point of access to the dialysis patient's blood stream). In 1999 this work was merged with the Core Indicators Project and the combined project is known as the ESRD Clinical Performance Measures (CPM) Project. The CPM Project is part of a larger ESRD Core Data Set that is under development. Through the ESRD Core Data Set, we are striving to determine and report accurate, meaningful facility-specific performance measures that will allow comparisons across dialysis centers and will ultimately increase facility accountability and patient choice. Facility-specific data profiles have been developed for the use of State Survey Agencies.

Despite our progress in improving the quality of care, there continue to be weak performing dialysis facilities. However, the Networks and States are working aggressively with these dialysis facilities to improve their care. We also intend to publish in early 2001 a proposed rule on new conditions for coverage for dialysis facilities that will strengthen requirements. In addition, the President's FY 2001 budget asked Congress to dramatically increase the funding level for surveys of ESRD facilities from $2.2 million to $6.3 million. By increasing the funding level, Congress would enable us to decrease the time between surveys from every six years to every three years and increase the number of surveys from 956 to 1,847 in FY 2001.

Our response to your comments, including HCFA's agency action plan and one technical comment, is attached.

Attachment
Agency Action Plan

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EXTERNAL QUALITY REVIEW OF DIALYSIS FACILITIES
A CALL FOR GREATER ACCOUNTABILITY
AGENCY ACTION PLAN

RECOMMENDATION 1. HCFA should hold individual dialysis facilities more fully accountable for the quality of care.

1.a. HCFA should revise the Medicare Conditions for Coverage for dialysis facilities so that they serve as a more effective foundation for accountability.

Strengthen the accountability of the dialysis facility governing body.

- HCFA agrees with this recommendation and will prepare a comprehensive proposed rule to revise the current ESRD conditions for coverage. The proposed rule would require facilities to collect and report performance measures so that HCFA can monitor the quality of renal dialysis services provided under Medicare. The governing body of the facility would be responsible for the collection and reporting of patient care data to HCFA. Increased emphasis on specific health and safety standards such as water quality and infection control, would be included also. HCFA expects to publish this proposed rule in early 2001.

- Under the conditions for coverage rule, HCFA will propose that a facility's governing body be held accountable for the development and monitoring of a quality assessment and performance improvement program (QAPI). The purpose of a QAPI program is to ensure that the ESRD facility focuses on continuous improvement of processes of providing health care services to meet the needs and improve the outcomes for dialysis patients rather than to rely solely on detection and correction of problems. The proposed QAPI program would require each facility to develop, implement, maintain, and evaluate an effective, data-driven program, under which facilities would collect and report clinical outcomes information to HCFA. We intend to establish minimum performance standards for certain clinical outcomes, such as adequacy of dialysis, nutritional status, anemia management, and other appropriate criteria. HCFA would also propose that facilities which fail to meet minimum performance criteria be required to take corrective actions to improve performance.

Reinforce accountability of dialysis facility medical director for patient care.

- HCFA concurs with this recommendation and will revise the existing procedures and interpretive guidelines that State survey agencies use to survey dialysis facilities. The survey procedures and interpretive guidelines will be revised in 2000 to reinforce accountability of the physician director for patient care

- Currently ESRD regulations hold the physician director accountable in 5 specific areas of patient care: participation in the selection of a suitable modality for each patient; assuring adequate training for dialysis nurses and technicians; assuring adequate monitoring of all patients and the dialysis process (including home dialysis patients); assuring the development and availability of patient care policies and procedures, including types of dialysis used in the

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unit, hepatitis prevention and procedures, and a disaster preparedness plan; and assuring that home dialysis training materials are available if the unit offers home dialysis training.

Require facilities to electronically report standardized performance measures determined by HCFA.

- HCFA has already begun to take steps that will implement this recommendation. Under a contract with PRO-West, HCFA developed 16 clinical performance measures (CPMs) in the areas of adequacy of hemodialysis, adequacy of peritoneal dialysis, anemia management and vascular access. The collection of these CPMs was pilot tested in 1999 by the ESRD Networks using a national sample of dialysis patients. In 2000, the Networks will again collect these CPMs on a national sample of patients. Importantly, HCFA also will collect the CPMs from a sample of dialysis facilities in 2000.

- As the OIG Report points out, we are developing the computer infrastructure that will electronically link dialysis facilities, Networks and HCFA. The proposed ESRD conditions for coverage rule would require facilities to electronically report data, including the 16 CPMs, to HCFA. The facilities would use a computer system, the Vital Information System for Improvement of Outcomes in Nephrology (VISION) to enter data and transmit it to HCFA. VISION is scheduled for implementation in January 2001.

Require facilities to conduct their own Quality Improvement program.

- As noted above, HCFA will be proposing a revised conditions for coverage rule that will require each dialysis facility to develop and monitor its own quality assessment and performance improvement program (QAPI). This program may include clinical measures such as adequacy of dialysis, nutritional status, anemia management, standard mortality data, emotional and social well-being, and rehabilitative status. The QAPI will address the needs of each facility, and foster a culture of continuous quality improvement within the facility.

Require facilities to establish internal systems for identifying and analyzing the causes of medical injuries and medical errors.

- HCFA agrees that internal tracking systems have the potential to help identify problems quickly so that corrections can be made promptly and patients protected. In recognition of the President's announcement in support of a nationwide system of medical error reporting that is State-based, we will explore the feasibility of using this system for ESRD facility oversight. In addition, under the proposed ESRD conditions for coverage rule, HCFA will encourage facilities to have ongoing error reduction programs in place as part of their Quality Assessment and Performance Improvement Program.

Require dialysis facilities to monitor patient satisfaction.

- HCFA concurs, and through the conditions for coverage rule, would propose the collection of

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patient satisfaction information as a reporting requirement. However, we have some concern about the response rate for patients on chronic dialysis and the validity of the results. The response rate for ESRD-patients in the latest Consumer Assessment of Health Plans (CAHP) survey was only 50 percent, whereas the rate for the general Medicare population was over 80 percent. CAHPs is a HCFA survey that asks Medicare beneficiaries questions about satisfaction with their Health Maintenance Organization (HMO). The results are used to evaluate HMO performance. Given our concerns with the response rate, we will examine ways to monitor patient satisfaction under the QAPI program that all dialysis facilities will be required to implement under the proposed rule.

1.b. HCFA should use facility-specific performance measures to encourage facilities to improve the quality of care and to help ensure facilities meet minimum standards.

Identify a core set of performance indicators to collect regularly on all patients from facilities.

- HCFA concurs with this recommendation. In 1994, HCFA took a leadership role in developing clinical indicators to assess the quality of care for dialysis patients. Through the ESRD Networks, we have collected clinical indicators/measures on a national sample of dialysis patients in the areas of adequacy of dialysis, anemia management, and serum albumin; vascular access measures were added in 1999. The data are collected annually and a detailed report describing the findings at the national and regional level is disseminated to all dialysis providers for their use in identifying opportunities for improvement. A national patient sampling approach, stratified by ESRD Network area for the hemodialysis patient sample, was chosen initially because of the workload burden on dialysis facilities and the ESRD Networks in using a hard copy reporting system.

- Using this national sampling approach, we have been able to document improvement in the number of dialysis patients achieving the benchmarks for these clinical indicators in every year since 1994. Dialysis providers have found these measures and the annual distributed report of findings to be a valuable tool in assisting them to improve care. By 2001, we plan to collect these measures on all patients from all providers. This will provide HCFA with facility-specific data that can be used to assess facility compliance, to assist facilities in improving care, and to report facility-specific performance to the public. We are developing a computer system, VISION, that will allow dialysis facilities to collect and report these data electronically to HCFA. We anticipate pilot testing this electronic system in 2000 with implementation by all facilities in 2001.

- The efforts described directly above are part of the larger ESRD Core Data Set that HCFA is developing. Dialysis facilities will be required to collect the Core Data Set, including the 16 Clinical Performance Measures, for all patients and report regularly through VISION. The first draft of Core Data Set elements is expected to be ready for stakeholder comment by July 2000.

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- We also would propose requiring facility-specific measures to increase facility accountability to HCFA in the ESRD conditions for coverage regulation such as, adequacy of dialysis, nutrition, anemia management, standardized mortality ratios, quality of life and rehabilitative status. HCFA will propose to establish minimum performance levels in the areas listed above and have this information reported by each facility on a regular basis.

- HCFA is using these facility-specific measures to create profiles of facilities which will include composite scores that rank facilities within the State. The profiles also will include data and information related to patient health and safety. This initiative is underway.

- HCFA will hold facilities accountable by requiring them to develop performance improvement projects to meet minimum federal standards.

Disseminate comparative facility-specific reports to facilities, Network, State survey agencies, and the public containing all of the performance indicators in the core set.

- HCFA supports this recommendation. We are currently working on developing an Internet based system to disseminate facility-specific reports to the public, similar to our Nursing Home Compare Site. A first set of facility-specific measures is being developed. These measures will describe facility characteristics and the quality of services provided that can be reported to the public.

  This first set of measures will be based on existing HCFA data and will primarily describe the facility, such as the name and address of the facility, the type of dialysis treatments offered by the facility and number of hemodialysis stations. This first set of measures will also include several clinical measures, such as the percentage of patients who receive adequate dialysis, the percentage of patients whose anemia was corrected, and the actual, compared to expected, patient survival rate. We anticipate that these first reports will be available to the public by the end of 2000. We plan to add additional measures to these reports as we collect data electronically from the dialysis facilities.

- Note that, in order to disseminate comparative facility-specific reports, HCFA will need to resolve several concerns including: issues relating to privacy restrictions on the release of data; issues relating to privacy restrictions regarding release of physician-specific data; and issues of what data can and will be released to specific groups and to the public without breach confidentiality.

1.c. HCFA should strengthen the complaint system for patients and staff.

Work with the Networks and the State survey agencies to establish an effective complaint system for dialysis patients and staff.

- HCFA concurs with the 8 elements presented in the report as a template for an effective complaint system: Accessibility, Objectivity, Investigative Capacity, Timeliness,

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Responsiveness to Complainants, Enforcement Authority and Follow-up, Improvement Orientation, Public Accountability. We have formed a workgroup to review the complaint process to make it easier and more responsive to dialysis patients, and a more manageable and integrated system for the Networks and State survey agencies. HCFA will also strengthen procedures for anonymous complaints to avoid the possibility of retaliation against patients.

- HCFA is developing a new regulatory basis for Network response to complaints that will support both more complete responses to complaints and alternative dispute resolution methods.

Conduct pilot projects to test ways in which the Networks and the State survey agencies could work together to create an integrated complaint system.

- HCFA agrees that pilot projects are most useful in developing a viable, structured complaint process. Networks have accompanied the State survey agencies occasionally on complaint investigations of dialysis facilities. HCFA will conduct pilot projects to develop an effective, integrated complaint process, as resources permit.

Develop a common instrument that facilities and others could use to assess patient satisfaction.

- During development of the proposed ESRD conditions for coverage rule, HCFA intends to explore the development of a patient satisfaction instrument. HCFA will review the patient satisfaction surveys that some dialysis facilities currently use and take into consideration the practical difficulties and potential burden on facilities that may result from requiring patient satisfaction information.

1.d. HCFA should enhance the role of Medicare on-site certification surveys.

Determine an appropriate minimum cycle for conducting Medicare certification surveys of dialysis facilities.

- HCFA agrees that there should be an appropriate minimum cycle for conducting Medicare surveys of dialysis facilities. The President's Budget for FY 2001 would substantially increase the funding level for surveys of ESRD facilities from $2.2 million to $6.3 million. This funding level would allow us to decrease the time between surveys from every 6 to every 3 years, and increase the number of surveys from 956 to 1,847 in FY 2001.

Require joint Network-State agency surveys for initial certification visits of dialysis facilities.

- HCFA disagrees that Networks and States should conduct initial certification surveys. As your report notes, the Networks are characterized by a collegial approach to oversight with a

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focus on educating and improving performance. In contrast, the role of the State survey agencies is regulatory with an emphasis on investigating and enforcing minimum requirements. We believe that it is important to distinguish these roles during the initial certification surveys. These initial surveys are an important step in the process that allows new dialysis providers into Medicare to treat vulnerable beneficiaries. In addition, the Networks are not structured or funded, nor is it their mission to perform initial certification on-site visits of dialysis facilities.

1.e. HCFA should facilitate the development of publicly accountable means for identifying serious medical injuries and analyzing their causes.

- HCFA agrees that efforts should be established to work with Networks and States to identify, monitor, and institute improvement projects regarding serious medical injuries and "near misses" in dialysis facilities. The Renal Physicians Association, in partnership with the Forum of ESRD Networks, has formed a Patient Safety Committee to define the types of errors of concern in dialysis facilities. This committee is also considering developing a data collection tool that would allow the tracking of medical errors in dialysis facilities. HCFA intends to seek statutory authority that would allow us to apportion Medicare Trust Fund money for this data collection activity.

RECOMMENDATION 2. HCFA should hold the Networks and State survey agencies fully accountable for their performance in overseeing the quality of care provided by dialysis facilities.

2.a. HCFA should issue policy guidance delineating the distinctive roles of the Networks and State survey agencies in quality oversight and providing direction on how they should collaborate.

Sharing facility specific data.

- HCFA agrees that certain facility specific data held by the ESRD Networks should be shared with the States To this end, HCFA is currently working with the Office of General Counsel to resolve issues stemming from section 1160 of the Social Security Act that deal with "Prohibition Against Disclosure of Information" by Networks.

Sharing State survey results.

- HCFA agrees that Networks would benefit from receipt of State agency survey findings and corrective action plans. To this end we will develop and promulgate a process to make survey findings more readily available to Networks. One option would be for HCFA to require State agencies to send survey results to Networks.

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Working together to addressing complaints.

- We concur that a structured joint complaint process coordinated between the ESRD Networks and the State survey agencies is desirable. HCFA will conduct pilot projects in this area to develop an effective complaint process, as resources permit. In order to implement this task, HCFA will ensure that both Networks and States have critical information on complaints.

- HCFA has developed a system for reporting standardized complaint information by all Networks through the Standard Information Management System (SIMS) which became operational January 2000. The implementation of SIMS is the first step in developing an electronic system of reporting and following a complaint as it is processed.

Consulting one another on areas of expertise.

- HCFA agrees and is working to facilitate collaboration between Networks and States. As described in your companion report "External Quality Review of Dialysis Facilities, Two Promising Approaches," a cooperative relationship between the Network and State agency has been established in Network 14. In 1995, the Texas State legislature enacted a law requiring all dialysis facilities to be licensed in order to operate in the State. The legislation established a formal relationship between the State's Department of Health and the Network's medical review board who, together with the renal community, developed and implemented standardized performance measures for dialysis facilities.

- HCFA will establish specific guidelines for coordinating, monitoring, and reporting to build a more cooperative relationship between States and Networks, especially in the area of sharing expertise to further protect ESRD patients. In addition, as funding permits, we plan to convene forums in which HCFA, Network and State officials can discuss ways to partner to ensure quality care for ESRD patients.

2.b. HCFA should foster greater accountability of the Networks.

Develop, with input from the Networks, a system for performance-based evaluations of the Networks.

Network accountability efforts should focus, in part, on how the Networks are drawing on standardized performance data to improve the overall clinical performance of facilities in their region and to ensure that poor performers meet minimum standards of care.

- We agree with this recommendation. HCFA has begun discussions on how we can move the Networks to performance-based contracting such as that recently instituted for the Peer Review Organizations. We will continue pursuing this contracting mechanism and intend to have this process in place by 2002. As noted elsewhere in this report, HCFA will require

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Networks to use standardized clinical performance measures to track and monitor facility performance, and to intervene with facilities that are poor performers.

Network accountability efforts should also focus on how effectively the Networks are using a complaint system as a quality-of-care safeguard.

- HCFA agrees that complaints should be a focus for Network accountability and the 8-step template proposed in the report is a good working model on which to build a structured complaint process. A workgroup is revising the ESRD Network Manual instructions to coordinate definitions and procedures with the State agencies to make the complaint process easier and more responsive.

Increase public disclosure of information on the Networks.

- HCFA will provide the public with more information about the role and activities of ESRD Networks through the Internet. We also intend to develop brochures about the ESRD Networks that would be available in facilities, at health fairs, and at other patient organization gatherings.

2.c. HCFA should foster greater accountability of the State survey agencies.

Establish a means to periodically assess the State surveys.

- State oversight for ESRD is unique because the survey process for dialysis facilities is technically and clinically complicated. HCFA will examine methods to increase onsite oversight of State activities. This will include reviewing the feasibility of increasing the number of observational surveys and using a contractor to assess the effectiveness of the State agency surveys.

Increase public disclosure of information on the State survey agencies.

- HCFA will explore methods for increasing the use of the Internet to publish survey results. We also will provide the public with more information about the role and activities of State survey agencies. The current patient information packet being developed for new ESRD patients will include information on the role and authority of State survey agencies.

Technical Comment

Page 42, footnote 43

The footnote on page 42 should be rewritten to change 15 months for nursing homes to 12 months, and to add Section 1819 of the Social Security Act to the statutory references.

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FORUM OF END STAGE RENAL DISEASE NETWORKS

May 18, 2000

June Gibbs Brown, Inspector General
Office of Inspector General
330 Independence Ave. S.W
Room 5250
Washington, D.C. 20201

Dear Ms. Brown,

The Forum of ESRD Networks appreciates the opportunity to comment on the reports of the Office of the Inspector General (OIG) entitled "External Quality Review of Dialysis Facilities, A Call for Greater Accountability" and "External Quality Review of Dialysis Facilities, Two Promising Approaches". The Forum Board of Directors, ESRD Network executive directors, and ESRD Network Medical Review Board chairs reviewed these reports. Many of us had the opportunity to interact with the OIG staff conducting the investigation, whom we found to be extremely knowledgeable and courteous. This response represents the synthesis of comments received from Forum and Network representatives, many of whom are physician volunteers. The reports are well researched and those involved in their preparation appear to have considered all resources. We found the reports to be quite perceptive and we agree with most of the findings of fact, although we have some concerns regarding the effective implementation of some of the recommendations.

We agree that the Conditions for Coverage must be strengthened and applied consistently throughout the country; however outcome targets for individual performance measures should not be specified in the Conditions of Coverage because of changing evidence-based medicine. Networks and state surveyors must use facility profiles to improve overall quality of care and assure that minimum standards are met. Facility-specific process and outcome data are already available and the Network role in quality improvement (QI) is well documented. The assessment of patient satisfaction and the documentation of adverse events are both very important areas that need attention and action by Networks and state surveyors. Care must be given, however, in the development of instruments and systems to address these two newer areas so as not to hinder the traditional non-punitive role of Networks to foster quality improvement and yet assure that patients are protected and standards of care are met.

We would like to offer the following comments for consideration by the OIG in the preparation of the final documents:

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email: forum@richmond.infi.net • http://www.esrdnetworks.org

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'1. Joint Initial Survey and Certification Activities

The OIG report concludes that ESRD Networks rarely target poorly performing facilities most in need of intervention. This is not entirely accurate; ESRD Networks do routinely work with poorly performing facilities. When poorly performing facilities are identified, ESRD Networks and state survey agencies may both be involved; however, the nature of the intervention may be vastly different. State survey agencies usually respond by conducting a site visit. Networks, because of personnel and resource limitations, respond with a variety of educational efforts, direct correspondence with facility leadership and occasionally with site visitation. Both approaches have been demonstrated to improve the quality of care and should continue to complement each other.

The OIG has made valuable contributions by advocating more cooperation between Networks and state agencies and by urging HCFA to give Networks the flexibility to use their limited resources in a way that can be tailored to address regional needs. Joint surveys to review poorly performing facilities may be an effective use of resources. However, we question the usefulness of joint surveys for initial survey and certification. At the time of the initial survey, very little exists at the facility in terms of records or programs for review and there is little demonstrated need for QI education or other actions Network staff might perform.

Initial, routine, and targeted facility surveys must be based on clear and documented criteria. Standards should be set that include input from all stakeholders. The selection process, review process and resources needed must be carefully considered before finalizing policies regarding on-site reviews.

2. Public Disclosure of Facility Information

The OIG report acknowledges that Federal regulations afford special liability protections for ESRD Networks. Federal regulations prohibit disclosure of grievance information, recognizing the importance of confidentiality protections for complaint investigations and peer review. Pressures for public disclosure must not dilute or supersede privacy laws and Federal regulations on confidentiality. Doing so would undermine the entire foundation of the ESRD Network organizations.

The efforts of the Consumer Information Workgroup, led by PRO-West, are not acknowledged in this report. In their initial recommendations to HCFA, PRO-West supported a minority opinion, advocating that facility specific outcome measures not be publicly reported at this time, due to questions concerning the validity and timeliness of the data, lack of case-mix adjustment, and the potential for "cherry-picking" of patients.

The Forum supports the responsible release of facility specific data that are proven to be valid, timely and presented at a level that is easily understandable by the ESRD patient community. If some of these data are collected through the Networks, validation strategies must be in place to assure their accuracy while preserving the non-punitive relationship between Networks and providers. Poorer performing providers will seek, rather than avoid, Network interventions to improve their public record.

3. Complaint System

The OIG noted the barriers to patients' complaints and acknowledged the current lack of consistent definitions for types of inquires. Accurate definitions that describe the nature and level of complaint (i.e. inquiry, complaint, formal grievance) must be established for facilities, Networks, state surveyors and HCFA. This will foster a greater understanding of the relevant issues and achieve greater consistency in the response to patients' concerns. Similar issues apply to complaints by dialysis facility staff. A more comprehensive system to reduce the fear of retribution (analogous to "whistle-blower" protections in other workplaces) is required.

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4. Accountability of Networks and State Survey Agencies

The OIG report envisions a performance-based evaluation system with a goal of "holding Networks more accountable for results that make a difference in patient care...". Networks (not state survey agencies) may be required to have their performance appraised by the degree to which they are able to effect performance improvements in dialysis facilities.

The OIG correctly states that Networks have limited authority to correct poor provider performance as documented by facility specific measures, yet later in the report the OIG explicitly recommends that improvement in facility outcomes be the yardstick by which Network performance is appraised. If Networks are held accountable for dialysis facility performance, they must have the authority and resources to effect change.

The OIG report does not advocate a performance-based evaluation system for state survey agencies. Rather, the states will have their work periodically assessed by a small group of experienced surveyors. State survey agencies have substantial power over dialysis facilities which, to date, has been inconsistently applied. They have the regulatory ability to invoke change and even close dialysis facilities. Paradoxically, the evaluation of the performance of state surveyors is not based on process or outcomes improvement of the facilities they have surveyed or on any sort of standardized instrument.

The Forum endorses the OIG's advocacy for greater cooperation between Networks and state survey agencies, the OIG's urging HCFA to give Networks the flexibility to use their limited resources in a manner that is tailored to regional needs, and the OIG's calling for mechanisms to be developed for evaluating performance of Networks and state survey agencies. The Forum is concerned, however, that Networks, which hold the lesser power of the two oversight entities, will be evaluated based on the degree to which they can effect voluntary change by dialysis providers. If performance is the agreed-upon benchmark, it should be applied to both agencies. Perhaps a more suitable approach may be to hold both agencies accountable for having methods to promote process and outcome improvement, while not holding either agency directly responsible for the improvements themselves. Such an approach is more likely to foster more creative and innovative intervention activities that can be implemented without fear that failure will jeopardize future funding.

5. Transplantation

The OIG report focuses on the review of dialysis facilities but makes no mention of the Networks' responsibility to work with renal transplant centers. Responsibility for oversight of transplantation programs must be articulated. Networks have established relationships with transplant centers, but the responsibility for transplant data collection and analysis was transferred to the United Network for Organ Sharing (UNOS) several years ago. UNOS falls short at evaluating program performance and providing interventions for process or outcomes improvement. It is currently unclear if any oversight is being provided to evaluate the quality of care provided to transplant patients. The Forum considers this a potentially dangerous lapse in accountability and one that should be addressed in this report.

In their QI-based intervention activities, Networks emphasize to providers that in order for quality to improve, the appropriate systems must be in place to collect, analyze, and respond to data so that processes can be evaluated in a way that will positively impact on outcomes. Facilities often respond that the resources required for QI (personnel and data systems) are expensive and they question whether this investment will pay for itself over the long term. Successful QI programs have demonstrated that quality is invariably cost-effective. Ironically, the ESRD oversight system is facing many of the same economic issues. Revising the current regulations and/or requirements for providers, Networks, and state survey agencies has the potential for improving performance but will also have a cost. Systems need to be created to effectively use as much already existing data as possible to provide the accountability recommended by the OIG reports. As requirements for data collection, transmission, analysis, and feedback increase, additional funding will be needed to support these efforts. Increased numbers of site visits in collaboration with state

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surveyors will require that resources be identified to support staff travel, education and training. Without increased resources, the recommendations contained in the OIG reports have very little chance for successful implementation. However, in the long run, cost savings from improved patient outcomes (decreased hospitalizations and use of other costly resources) should make an improved quality oversight system an extremely sound investment.

The Forum of ESRD Networks recognizes the tremendous effort by the OIG to produce these reports and supports the development of systems to improve the care and quality of life for patients with end stage renal disease. We endorse the dual oversight model of Networks to promote QI in a non-punitive environment and of state survey agencies to hold providers accountable for adhering to standards of care established by the Conditions of Coverage. Inevitably the separation of those functions will blur as data collected by the Networks are used to promote provider accountability by triggering state survey activities or by release into the public domain, and as Networks and state survey agencies share facility-specific data to collaborate on intervention activities. Nonetheless, if the proper systems are established which clearly define, properly fund, and provide accountability for Network and state survey agency activities, this model has the greatest likelihood of achieving the goal of improving the outcomes of patients with ESRD by bringing provider performance to a higher level. The success of innovative Network models of quality oversight as described in the "Two Innovative Approaches" report underscores the importance of allowing the Networks, through their Scope of Work, to exercise the discretion to tailor their programs to the needs and resources of the region and not using a "one size fits all" approach to the contract deliverables. The heart and soul of the quality agenda of each Network, its Medical Review Board (MRB), is a voluntary organization composed of renal professionals and patients from the region. Care must be taken not to straightjacket and alienate these MRBs with a restrictive and inflexible national quality agenda that stifles creativity and does not exploit the local expertise or address the unique process issues of a region. The Forum is proud of the achievements of the Network system to date and hopes that the OIG reports will be the stimulus for a reengineering that promotes even greater success.

Sincerely,

Jay B. Wish, MD
President

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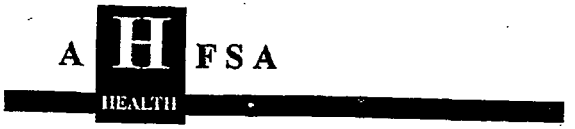

Association of Health Facility Survey Agencies

May 9, 2000

The Honorable June Gibbs Brown
Inspector General
Department of Health and Human Services
ATTN: Michael Mangam
330 Independence Avenue
Room 5246 Cohen Building
Washington, D.C. 20201

Dear Inspector General Brown:

Thank you for the opportunity to review the two draft inspection reports on the external quality review of dialysis facilities. The report is generally well presented. We do note that while the report points out and underscores what state agencies (SAs) need to be doing and need to improve in doing, there is a stark absence of any mention of the direct tie to funding levels.

We do agree with the findings and recommendations presented in the report. Further, we offer the following for your consideration:

- HCFA should secure appropriate additional funding to states for increased survey activity of ESRDs and implementation of the report recommendations.
- The ESRD Conditions of Participation (CoPs) should include the requirement to report medical injuries to SAs and specific data collection requirements for facilities to analyze and develop plans to fix the problem that caused the medical injury.
- Delete reference to announced surveys on page 7 of the OIG report.
- HCFA should clarify the role of the networks and the SAs, and require joint surveys/complaint investigations under certain circumstances.
- Networks and the SA should forward copies of all complaints and their results to each other.
- Networks should work collegially with facilities on identification of problems, however, if little or no improvement is seen, the Network should be required to notify the SA.

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The Honorable June Gibbs Brown
Inspector General
May 10, 2000
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- Require the SA to report CoPs not in compliance to the Network and require the Network to work with the facility in developing corrective action.
- Require HCFA to publish facility specific data on the Web that includes survey results, transplantation rates, adequacy rates (Kt/V) and Hct average levels for the facility.
- Require facilities to send satisfaction surveys to patients and return them to the Network and SA.
- Require facilities to, as part of patient rights, inform patients of the name and address of the Network and the SA in order to lodge complaints and post the name and address of the Network and the SA on a bulletin board in the waiting room.
- HCFA should develop specific criteria by which to consistently evaluate SAs and Networks and ensure implementation is consistent through its Regional Offices.
- New CoPs should include more QA components other than re-use and clarify more succinctly the accountability for the medical director.

Again, we appreciate this opportunity to comment. Please be assured of our willingness to work for improvements in quality of care for ESRD patients.

Sincerely,

Catherine Morris

Catherine Morris, President
Association of Health Facility Survey Agencies

cc: George Grob
Elise Stein

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aakp

The Voice Of All Kidney Patients

May 13, 2000

June Gibbs Brown
Inspector General
Office of Inspector General
Department of Health and Human Services
Washington, DC 20201

Dear Ms. Brown:

Thank you for the opportunity for the American Association of Kidney Patients to respond to the draft inspection reports on the external quality review of dialysis facilities. As the only national kidney patient association directed by patients for patients, we realize the important need to ensure quality of care and access for all dialysis and potential dialysis patients.

First of all we commend the Office of Inspector General for assessing the external quality review mechanisms currently in place and reviewing their strengths and weaknesses. We agree that there are inconsistencies in the program and are pleased by the amount of information your office has evaluated.

AAKP agrees with your recommendations that 1.) HCFA should hold individual dialysis facilities more fully accountable for the quality of care they provide and 2.) HCFA should hold the Networks and State survey agencies more fully accountable for their performance in overseeing the quality of care provided by dialysis facilities. We believe both of these recommendations could lead to better patient health outcomes and longevity. We strongly suggest that national standards be implemented to ensure that all Networks, State Survey Agencies and dialysis facilities follow the same guidelines.

With regard to the Networks and State Survey Agencies, AAKP has always remained concerned about the inconsistencies found throughout the ESRD Network system. While some Networks do outstanding jobs in developing continuous quality improvement programs, patient assistance and professional accountability, many Networks do not. With guidelines in place, we could expect greater reliability in how the two groups perform in the renal community.

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We wish to bring two points to your attention regarding your recommendations. You suggest there be a reporting mechanism for public dissemination of facility performance data. At this time, HCFA and Pro-West, with input from the renal community, are developing ways to report data to the general public. The availability of such data is scheduled for release by the fall of 2000. Second, though we realize your recommendations are not based on availability of Medicare funding, we are cognizant of the costs associated with such recommendations. We would encourage you to ensure that such funding does not come at the cost of current patient activities.

Thank you for the opportunity to respond to your excellent report. If you wish to discuss this in further detail, please do not hesitate to contact Kris Robinson, executive director, at 800-749-2257.

Sincerely,

Joseph D. White
President

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Endnotes

1. Section 1881(c) of the Social Security Act.

2. 42 C.F.R. sec. 405 subpart U.

3. Currently, there are about 19 States with licensure laws. Glenda M. Payne, "Licensed, Certified, Accredited: What are the Differences for the Dialysis Unit?" *Nephrology News and Issues*, September 1999, 47.

4. In order to qualify, individuals must be fully insured under Social Security or be a dependent of someone who is. In 1996, about 8 percent of individuals with ESRD who needed treatment did not qualify for Medicare coverage. U.S. House of Representatives, Committee on Ways and Means, *1998 Green Book*, (Washington, DC: Government Printing Office), 162.

5. 42 C.F.R. sec. 413.174.

6. For media accounts see: Kurt Eichenwald, "Death and Deficiency in Kidney Treatment," *The New York Times*, December 4, 1995, 1; K. Eichenwald, "At Big Kidney Chain, Deals for Doctors, Ruin for Rivals," *The New York Times*, December 5, 1995, 1; K. Eichenwald, "Making the System Work in Kidney Patients' Favor," *The New York Times*, December 6, 1995, 1; Wayne Woolley, "Dialysis Clinic Accused of Fraud: Ex-administrator Says Sinai Facility Had too Many Patient Deaths, Safety Infractions," *The Detroit News*, January 1, 1998, C1; Patrick O'Neill, "Complaints lead to look at dialysis centers, *Portland Oregonian*, October 19, 1998, B1; Patrick O'Neill, "Patients Get Wrong Mixture in Dialysis," *Portland Oregonian*, February 13, 1999, D1; Patrick O'Neill, "Dialysis problems increasing, official says," *Portland Oregonian*, February 17, 1999, A1; Patrick O'Neill, "Nerves Fray for Dialysis patients Cost-Cutting and Ownership Changes Highlight a New Breed of Treatment Centers," *Portland Oregonian*, February 23, 1999, B1.

7. It is a common practice for facilities to reuse hemodialyzers. Facilities that reuse must adhere to special protocols to prevent the spread of blood borne diseases.

8. U.S. Renal Data System, *USRDS 1999 Annual Data Report*, National Institutes of Health, National Institutes of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, April 1999: 26.

9. Health Care Financing Administration, Department of Health and Human Services, *Highlights from the 1999 Clinical Performance Measures Project*, http://www.hcfa.gov/quality/3m.htm, printed February 7, 2000.

10. Ibid.

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11. William M. McClellan et al., "Variable Mortality Rate Among Dialysis Treatment Centers," *Annals of Internal Medicine* 117 (1992): 332-336; William M. McClellan et al., "Facility Mortality Rates for New End-Stage Renal Disease Patients Implications for Quality Improvement," *American Journal of Kidney Diseases* 24 (August 1994) 2: 280-289.

12. Jeffrey C. Fink et al., "Hemodialysis Adequacy in Network 5: Disparity Between the States and the Role of Center Effects," *American Journal of Kidney Diseases* 33 (January 1999) 1: 97-104; Steven D. Helgerson et al., "Improvement in Adequacy of Delivered Dialysis for Adult In-Center Hemodialysis Patients in the United States, 1993 to 1995," *American Journal of Kidney Diseases* 39 (June 1997) 6: 851-861; James A. Delmez et al., "Hemodialysis Prescription and Delivery in a Metropolitan Community," *Kidney International* 41 (April 1992) 4: 1023-1028.

13. William M. McClellan et al., "Mortality in End-Stage Renal Disease Is Associated with Facility-to-Facility Differences in Adequacy of Hemodialysis," *Journal of the American Society of Nephrology* 9 (October 1998) 10: 1940-1947.

14. Pushkal P. Garg et al., "Effect of the Ownership of Dialysis Facilities on Patients' Survival and Referral for Transplantation," *The New England Journal of Medicine* 341 (November 25, 1999) 22: 1653-1660.

15. Ibid, 1659.

16. *USRDS Annual Data Report*: 165-167.

17. *USRDS Annual Data Report*: Reference Tables, Table I.13.

18. Mark E. Neumann, "A Buying Slowdown?" *Nephrology News and Issues* July 1999, 30-31.

19. The composite rate is not routinely updated like the rest of Medicare payments. The composite rate was established in 1983. It was reduced by $2 in 1986 and increased by $1 in 1991. Recent legislation increased it by 1.2 percent in January of 2000, and another 1.2 percent increase will occur in January 2001.

20. This project was previously called the ESRD Core Indicators Project. In 1998, HCFA contracted with PRO-West, a professional review organization, to develop performance measures based on the National Kidney's Foundation Dialysis Outcome Quality Initiative clinical practice guidelines. As a result, the previous clinical indicators under the Core Indicators Project were replaced with new but similar clinical performance measures.

21. *Highlights from the 1999 Clinical Performance Measures Project.*

22. ESRD Network of Florida (#7), *1998 Annual Report.*

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23. ESRD Network of Texas (#14), *1998 Annual Report.*

24. For examples of Networks that collect facility-specific data see *1998 Annual Reports* for: The ESRD Network of New England (#1), Southeastern Kidney Council (#6), The Renal Network (#9/10), and ESRD Network of Texas (#14).

25. Social Security Act 1881(b).

26. In all of 1997 and 1998, Networks made only two recommendations to HCFA to sanction facilities.

27. If a patient health and safety issue is involved the only sanction that HCFA or the States can take is to terminate the facility from the Medicare program. Other types of sanctions, such as denial of payments or reduction of payments, can only be taken when the problem identified does not jeopardize patient health and safety. See 42 C.F.R. sec. 405.2180 and 405.2181.

28. Networks reported that HCFA, in one case in particular, did not support a Network's recommendation for sanction. As a result the Network felt powerless to resolve future problems because facilities in the area perceived that HCFA would not support the Networks. Another Network recently tried to avoid this situation by successfully encouraging a facility to voluntarily withdraw from the Medicare program rather than recommend sanctions to HCFA. However, HCFA reported that they viewed this approach as the Network trying to protect the facility since the provider can still run another facility elsewhere. Many Networks are now reluctant to take this approach, leaving the Networks with little they can do to enforce standards beyond applying peer pressure.

29. Social Security Act 1881(b) (8).

30. See http://www.hcfa.gov/stats/pufiles.htm

31. Office of Inspector General, *"Know Your Number" Brochure: Perspectives of Dialysis Patients*, OEI-06-95-00320, January 1997: 7.

32. HCFA, Network Manual, section 755.2.

33. HCFA has established complaints as a top priority for the State survey agencies; it lists complaints third out of 12 workload priorities for the States. Fiscal year 2000 State Survey and Certification Budget Call Letter, July 7, 1999.

34. In response to our survey, the 18 Networks reported referring 49 complaints to the State survey agencies in 1998.

35. Until recently there was no national database for Networks to log their complaint activity. HCFA recently developed a central database system for the Networks, the Standard Information Management System (SIMS), that should help standardize complaint information across all Networks and provide national information in the future. Most Networks publish data on their own complaints in their annual reports and some Networks even provide a breakdown by type. The Forum of ESRD Networks conducted a national analysis on complaints in its 1997 summary report that contains data from all 18 Networks. See Forum of ESRD Networks, *End Stage Renal Disease Network Program Annual Report Summary 1997*: 20-21.

36. In order to conduct this review, we grouped complaints into five categories. 1) technical issues involving clinical expertise of staff and/or water treatment etc., 2) service quality issues involving patient comfort such as temperature, waiting times, friendliness of staff, the number of staff available, etc., 3) educational/informational issues involving calls where individual are looking for answers to specific questions, 4) disruptive patient issues involving violent or misbehaving patients, and 5) unknown issues involving contacts that we could not discern their nature from the documents we reviewed. Some complaints fit into multiple categories and were counted as such. It is also important to note that the comprehensiveness of the complaint logs we received varied substantially. We do not intend for this analysis to provide concrete numbers but rather to demonstrate an overall trend.

37. One Network wrote a letter to HCFA documenting the lack of collaboration between the State and the Network. Northwest Renal Network (# 17), *Recommendations for Improvements in the States of DHS and ESRD Networks Cooperative Relationship,* September 1999.

38. Networks occasionally visit facilities to provide technical assistance, look into specific problems, or investigate complaints. However, HCFA does not fund them to perform routine on-site surveys.

39. Our analysis is of ESRD facilities that includes both dialysis facilities and renal transplant centers. According to *USRDS 1999 Annual Data Report* p. 165, there were 241 centers providing renal transplants in 1997. This number has been relatively stable over recent years. Our analysis also includes both initial surveys and recertification surveys.

40. The data shows that as of the May 1999, the average time since the last survey was 3.2 years for free-standing facilities and 4.2 years for hospital-based facilities. This suggests surveyors may be targeting free-standing facilities, which may be subject to less external oversight than hospital-based facilities.

41. An unpublished HCFA-funded study found a similar trend. The study showed that in 1993, 59.4 percent of free-standing facilities received a certification survey; in 1994 36.1 percent; and in 1995, 22.6 percent. The Lewin Group, Inc. and Johns Hopkins University, *"Facility Accreditation and Certification for ESRD Study: Evaluation of the Effectiveness of the Current*

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End-Stage Renal Disease Survey and Certification and the Potential of Integrating Private Accreditation," unpublished draft May 30, 1997, for the Health Care Financing Administration.

42. Although we were unable from the data set we pulled from HCFA to determine the number of initial versus certification surveys, HCFA did provide us with the actual number of initial surveys conducted each year. We used the numbers of initial surveys provided by HCFA to calculate the number of recertification surveys and found that this backlog cannot be solely attributed to the recent growth in ESRD facilities. The number of initial surveys conducted each year increased only 24 percent since 1993, from 221 initials in 1993 to 273 initials in 1998. But we have seen a 72 percent decrease in the number of recertification surveys conducted each year since 1993. In 1993, over half of all facilities received a recertification survey. By the end of 1998, only 10 percent of all facilities received a recertification survey. At this rate of 10 percent a year, facilities will receive a recertification survey once every 10 years.

43. By statute, States must survey nursing homes once every 12 months and home health agencies once every 36 months. Sections 1819, 1919, and 1891 of the Social Security Act.

44. Fiscal year 2000 State Survey and Certification Budget Call Letter, July 7, 1999.

45. See 42 C.F. R., sec. 405.2136.

46. The Conditions do not give the medical director the authority to intervene in the care of a patient under another attending physician, although some facilities or corporations may give such authority. In a recent letter to a Network, HCFA stated, "Significantly, the end-stage renal disease regulations do not explicitly empower a physician-director with the authority to take independent action with respect to patients attended by other physicians." Correspondence to Glenda Harbert, Executive Director of Network 14, from Kay Hall, Project Officer, Division Clinical Standards and Quality, Health Care Financing Administration, on November 9, 1998.

47. HCFA, State Operations Manual, Section 4009.

48. HCFA offers basic and advanced training programs for surveyors regularly throughout the year. In fact, for fiscal year 2000 HCFA has four training classes scheduled specific to dialysis facilities. HCFA's basic training covers general topics related to the survey process in general, as well as, important technical information specifically related to dialysis facilities.

49. The most comprehensive study undertaken of medical injuries was the Harvard medical practice study. In that effort, the study team reviewed the records of about 30,000 patients hospitalized in New York State during 1984. It found that adverse events occurred in about 4 percent of the hospitalizations and negligent adverse events in about 1 percent of the cases. See Troyen A. Brennan et al, "Incidence of Adverse Events and Negligence in Hospitalized Patients," *The New England Journal of Medicine* 324 (February 7, 1991) 6: 370-76.

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A more recent study focusing on a large teaching hospital affiliated with a medical school and using a somewhat different methodology came up with even more disturbing results. It found that 17.7 percent of the 1,047 hospitalized patients reviewed received inappropriate care resulting in serious adverse events — ranging from temporary disability to death. See Lori B. Andrews et al, "An Alternative Strategy for Studying Adverse Events in Medical Care," *The Lancet* 349 (February 1, 1997) 309-313.

50. Some States licensure laws, such as Texas, require facilities to report adverse events to the State survey agency.

51. For more information see Department of Health and Human Services, Office of Inspector General, *External Review of Hospital Quality: The Role of Accreditation*, OEI-01-97-00051, July 1999.

52. Facilities do report events involving medical devices to the Food and Drug Administration and report outbreaks of infectious diseases to the Center for Disease Control and Prevention.

53. The Network evaluation form covers the 10 topic areas such as quality improvement projects, sanctions and referrals, patient grievance, and information management. The form does not contain any objective criteria for the project officer to use but rather leaves the evaluation up to the project officer's judgement. For example, "C.1 To the satisfaction of the project officer, the Network has developed and implemented at least one quality improvement project in option year 1, unless it was otherwise directed by HCFA." and "C.4.I. Where appropriate to the satisfaction of the project officer, the Network has assisted patients and facilities in resolving grievances."

54. The one Network that received two unsatisfactories involving sanctions and referrals. According to the comments attached by the project officer, this Network was not making appropriate referrals to HCFA for sanctions, was not sharing requested information with HCFA, and was inappropriately counseling a facility to withdraw from the Medicare program.

55. *Highlights from the 1999 Clinical Performance Measures Project.*

56. The HCFA name for validation surveys is Federal monitoring surveys.

57. In response to our series of reports on hospital quality oversight, HCFA has pledged to re-examine the SAQIP program and reevaluate its utility as a method for oversight for State survey agencies. In addition, HCFA intends to develop a performance measurement based system for evaluating State survey agencies. This system would provide more direct, timely feedback to States on clear criteria for performance. See the Office of Inspector General, *The External Review of Hospital Quality: A Call for Greater Accountability*, OEI-01-97-00050, July 1999.

58. Of course, the accreditation system has a number of deficiencies of its own. We addressed these in our recent reports on hospital quality oversight. See Office of Inspector General, *The External Review of Hospital Quality: A Call for Greater Accountability*, OEI-01-97-00050, July 1999.

59. It has been suggested that the current payment policies create disincentives for facilities and physicians to provide optimal care. Facilities receive a monthly composite rate regardless of the length or the complexity of the dialysis provided. Similarly, Medicare reimburses nephrologists at a monthly, capitated rate regardless of the complexity of the patient's condition or the frequency of visits. In addition, physicians may bill separately for inpatient hospital visits the same as other inpatient stays, which are not capitated. This often results in a financial benefit for nephrologists when their patients are hospitalized.

Others have also pointed out that the fragmented payment system makes it difficult to focus accountability. Facilities and nephrologists each receive separate payments from Medicare. Yet, each depends on the other to perform its function. The nephrologist must determine the appropriate treatment regimen and the facility must carry it out correctly in order for the patient to receive adequate care. Yet, Medicare payment policy does not hold the facility or the nephrologist accountable for working together.

In 1991, Congress asked the Institute of Medicine (IOM) to determine the impact that the reimbursement rate had had on the quality of care. Although the IOM found no demonstrative evidence that the reimbursement rate was impacting negatively on quality, it did find suggestive evidence. As a result, it recommended that "a quality assessment and assurance program should be implemented." In June of 1999, the Medicare Payment Advisory Commission recommended an increase in the composite rate in order to improve the quality of dialysis care. It further recommended that nutritional therapies for dialysis patients be under a separate payment in order to encourage facilities to provide the appropriate nutritional payments. More recently, in March 2000, the Medicare Payment Advisory Commission, again called for an increase in the composite rate, as well as to risk adjust payments for patients enrolled in Medicare+Choice.

For further discussion on this topic, see the following articles: Alan Hull, "Impact of Reimbursement Regulations on Patient Management, "*American Journal of Kidney Diseases* 20 (July 1992) 1 suppl. 1: 8-11; Allen Nissenson and Richard Rettig, "Medicare's End-Stage Renal Disease Program: Current Status and Future Prospects," *Health Affairs* 18 (January/February 1999) 1: 161-179; Eli A. Friedman, "End-Stage Renal Disease Therapy: An American Success Story," *Journal of the American Medical Association* 275 (April 10, 1996) 14: 1118-1122; Renal Physicians Association correspondence to Murray K. Ross, Executive Director of the Medicare Payment Advisory Commission, May 10, 1999; Medicare Payment Advisory Commission, *Report to the Congress: Selected Medicare Issues*, June 1999, 135-148; Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy*, March 2000, 129-

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147; Institute of Medicine, *Kidney Failure and the Federal Government* (Washington, D.C.: National Academy Press, 1991), 17.

60. Mark R. Chassin et. al., "The Urgent Need to Improve Health Care Quality: Institute of Medicine National Roundtable on Health Care Quality," *Journal of the American Medical Association* 280 (September 16, 1998) 11: 1000-1005.

61. In 1995 HCFA did rewrite the interpretive guidelines that offer directions to State surveyors to determine compliance with the Medicare Conditions for Coverage. The new guidelines increased the focus on patient-care processes and outcomes.

62. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards for hospitals articulate the responsibility of the governance body. The TransPacific Renal Network (#17) is actually looking to adapt the JCAHO standards for use for dialysis facilities in its region. HCFA proposed Conditions of Participation for hospitals also address this issue.

63. The June 17, 1996, draft of the Conditions for Coverage for dialysis facilities moves in this direction: "Condition: Governance. The dialysis facility is under the control of an identifiable governing body or designated person(s) so functioning, with full legal authority and responsibility for the governance and operation of the facility, the management and provision of all dialysis services, fiscal operations, relations within the ESRD Networks, the development of policies on patient health and safety, and the quality assessment and performance improvement program. The governing body must appoint a qualified administrator who is responsible for the daily operations of the facility."

64. The draft Conditions for dialysis facilities move toward holding the medical director more accountable by inserting, "The dialysis facility must have a medical director who is responsible for the overall delivery of patient care and outcomes." The current Conditions of Participation for nursing homes have similar language, and concerns have been raised about how to interpret this language: "The facility must designate a physician to serve as medical director. (2) The medical director is responsible for--(i) implementation of resident care policies; and (ii) The coordination of medical care in the facility." (42 C.F.R., sec. 483.75(i))

65. The draft Conditions for dialysis facilities address this issue, "Standard : Furnishing data and information for end-stage renal disease program. The dialysis facility furnishes data and information in the manner and at the intervals specified by the Secretary, pertaining to its patient care activities and costs for administration of the program." This may suffice as long as it is interpreted to include patient outcomes. We do not suggest that HCFA write into the Conditions specific outcomes or minimums facilities must meet. This will not allow for timely updates as scientific knowledge advances.

66. The draft Conditions for dialysis facilities also address this issue. "Condition: Quality assessment and performance improvement. The dialysis facility must develop, implement, maintain and evaluate an effective, data-drive, quality assessment and performance improvement program. The program must reflect the complexity of the dialysis facility's organization and services (including those services provided under arrangement). The dialysis facility must take actions that result in improvements in the facility's performance across the spectrum of care."

67. Several national corporations collect health status and patient satisfaction data routinely from facilities nationwide. Several Networks also view patient satisfaction as an important measure of quality. For example, The ESRD Network of New England (#1) developed a patient satisfaction survey for facilities to use and the ESRD Network of Florida (#7) requires facilities to monitor patient satisfaction in its "Criteria and Standards for Facilities."

68. HCFA currently has three projects underway to develop and implement an extensive computer system that will allow the electronic transmission of large quantities of data between facilities and Networks, and Networks and HCFA. The creation of the Renal Management Information System (REMIS) is the first project. This project will establish a new database to replace the outdated Renal Beneficiary and Utilization System (REBUS). REMIS will house all HCFA data on ESRD patients in one central database and allow for easier analysis of the data. According to HCFA's schedule, it will be up and running sometime during the summer of 2000. The Standard Information Management Systems (SIMS) is the second project in this arena. SIMS, which is scheduled to be as of December 1999, will connect all Networks with one another and HCFA through a computer network. The third project, the Vital Information System for Improvement of Outcomes in Nephrology (VISION), will develop software to electronically link facilities with the Network to facilitate electronic data reporting. HCFA anticipates pilot testing VISION early in the year 2000, with roll out to all facilities in 2001. This entire system will electronically connect dialysis facilities to Networks, Networks to other Networks, and Networks to HCFA.

69. HCFA has funded, through the Colorado Foundation for Medical Care, the University of Michigan Kidney Epidemiology and Cost Center to produce facility-specific reports similar to the unit-specific reports generated previously by the United States Renal Data System. See www.med.umich.edu/kidney for more information.

70. HCFA has contracted with the Colorado Foundation for Medical Care to develop facility-specific reports for State survey agencies to select facilities for surveys and to use to focus their survey when on site. In the spring of 2000, HCFA plans to pilot test these reports with 8 States. HCFA has contracted with PRO-West to develop facility-specific reports for the public. These reports will be available sometime in the year 2000.

71. The Institute of Medicine called for HCFA to relate "major Conditions for Coverage to patient outcomes." *Kidney Failure and the Federal Government*, 295. We are concerned that

the current language in draft Conditions may be too explicit. We suggest that HCFA not include in the regulations specific performance measures with specific minimums that facilities must meet. Instead, we suggest more flexible language that can allow for quicker revisions as medical knowledge progresses. The draft Conditions state: "Standard: Performance expectations. The interdisciplinary team must adjust the care plan and implementation strategies as assessment, response, and patient preference information requires. If the patient is unable to achieve the desired health outcomes, the appropriate member of the interdisciplinary team must provide an explanation. If the desired health outcome is achievable but is not being achieve, the interdisciplinary team must develop and implement an improvement program to achieve and maintain the patient's desired level of general health...The interdisciplinary team must assist and support the patient in achieving and maintaining a desired dose of dialysis. The patient must receive at least a delivered Kt/V not less than 1.2 (single pool) or a urea reduction ratio of at least 65 percent for a majority of treatments each hemodialysis patient."

72. For an argument in support of the release of mortality information see: John M. Newmann, "Why Should HCFA Release Center-Specific Mortality Information to Patients?" *Nephrology News and Issues*, November 1999, 13-14.

73. See HCFA's Medicare Compare at http://www.medicare.gov/comparison, and Nursing Home Compare at http://www.medicare.gov/nursing/home.asp.

74. Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy*, March 2000, p 142.

75. The Lewin Group, Inc. and Johns Hopkins University, *Facility Accreditation and Certification for ESRD Study: Evaluation of the Effectiveness of the Current End-Stage Renal Disease Survey and Certification and the Potential of Integrating Private Accreditation,* also called for a standard survey frequency and recommended it should be once every 1 or 2 years.

76. The President's proposed budget for fiscal year 2001 for the Department of Health and Human Services calls for a 14.4 percent increase over the fiscal year 2000 appropriated budget for survey and certification activities. This funding will HCFA "to decrease the survey intervals for ESRD facilities and non-accredited hospitals from once every six years to once every three years."p 87-88, released February 7, 2000.

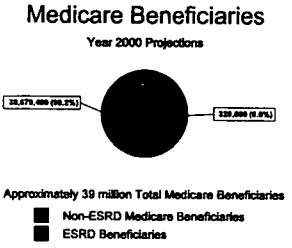
77. Institute of Medicine, *To Err is Human, Building a Safer Health System* (Washington, D.C.: National Academy Press 1999).

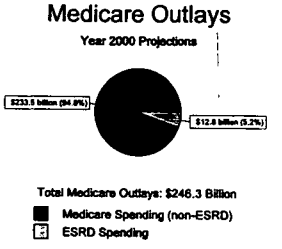
78. The Renal Physicians Association and the Forum of ESRD Networks have created a workgroup to examine issues of patient safety in dialysis facilities.

APPENDIX D

79. Colorado publishes on the Internet facility-specific reports on complaint investigations and "occurrences" which include medical injuries. These reports provide a description of the event and the facility's response and the State's evaluation.
See http://www/hfd.cdphe.state.co.us/info.asp.

Medicare's End Stage Renal Disease (ESRD) Program





SOURCE: United States Renal Data System: 1999 Annual Data Report
ESRD Medicare Beneficiaries and Program Expenditures, 1974-2002, Health Care Financing Administration, Office of the Actuary
Medicare Outlays, Fiscal Years 1967-2007, CBO Projections, Office of the President, 1997
1998 Green Book, Committee on Ways and Means, US House of Representatives

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administrati

The Administrator
Washington, D.C. 20201

The Honorable Charles Grassley
Chairman, Senate Special Committee on Aging
Washington, DC 20510-5400

Dear Chairman Grassley:

Thank you for your letter of April 24, 2000, regarding End Stage Renal Disease. Our End Stage Renal Disease (ESRD) networks, in partnership with the renal community, are working to improve quality in dialysis centers.

Overall, our efforts have had some measurable success. For example, between 1993 and 1998 the percentage of ESRD patients with adequate hematocrit (red blood cell) levels increased from 46 to 83 percent. Additionally, in the same time period, the percentage of patients receiving adequate dialysis increased from 43 to 74 percent. Finally, we know from the U.S. Renal Data System, a joint Health Care Financing Administration and National Institutes of Health project, the overall one year mortality rates for dialysis patients decreased from 24.9 deaths per 100 patient years in 1990 to 22.8 in 1997. This is largely due to the efforts of the Department of Health and Human Services and the renal community.

Despite this progress, there continue to be weak performing dialysis facilities. However, the networks are working aggressively with these dialysis facilities to improve their care. In addition, we intend to publish new conditions of coverage for dialysis facilities that will strengthen requirements in early 2001.

Please note, the President's FY 2001 budget would dramatically increase the funding level for surveys of ESRD facilities from $2.2 million to $6.3 million. This funding level would allow us to decrease the time between surveys from every six years to every three years and increase the number of surveys from 956 to 1,847 in FY 2001.

Below please find a list of your letter's specific inquiries, and the answers or the references to the attached materials, which correspond to those inquiries. I hope you find this information helpful. Please contact Don Johnson (202-690-5500) in my Office of Legislation if you have further questions.

Sincerely,

Nancy-Ann Min DeParle
Administrator

Attachments

We believe that you would like a high level of detail from primary source documents, and have attempted to provide the same in the following and the attachments.

1. **A detailed description of the relationship between the Health Care Financing Administration and the End Stage Renal Disease Networks.**

   ESRD Networks are under contract to HCFA to help the ESRD program under a set of requirements laid out in their statement of work. The specific conditions are described in the following items in the attached packet. They include information on contract oversight, performance review, and organizational conflicts of interest.

   1. Statement of Work (Section C-1 of the 7/1/97 – 6/3/00 ESRD Network contract)
   2. Exhibit F-1 (attached to C-1) -- Schedule of Deliverables
   3. Section G – Contract Administration Data – information on contract oversight
   4. Section H – Special Contract Requirements – information about performance review and organizational conflicts of interest
   5. Section 1881 of the Social Security Act
   6. ESRD Network Statement of Work for the period 7/1/00 – 6/30/03

2. **A list of the names, titles, divisions, addresses, and telephone numbers of those individuals within HCFA responsible for overseeing the ESRD Networks.**

   Our Administrator, Nancy-Ann Min DeParle, bears ultimate responsibility for HCFA's activities, and her Deputy Administrator is Michael Hash. Jeffrey Kang, M.D., is the director of our Office of Clinical Standards and Quality, wherein the day-to-day responsibility for overseeing ESRD Networks resides. His deputy director is Robert Streimer. Stephen Jencks, M.D. is the Director of the Quality Improvement Group within the Office of Clinical Standards and Quality, which oversees the ESRD Networks directly. In addition, our 10 regional offices and the four consortia into which the regions are grouped coordinate communications with the Networks.

   To better place these people in the context of HCFA as an organization, please see the following attachments.

   7. Organizational Chart for the Health Care Financing Administration
   8. Organizational Chart for HCFA's Office of Clinical Standards and Quality

3. **A detailed description of the structure of the ESRD Networks.**

   In reply to this request, we believe that the statement of work discussed above, as well as the following two attachments, provide a detailed description of the structure of the ESRD

Networks. In general, there are 18 Networks, each governed by an Executive Director, a Chairperson, and a Medical Review Board Chairperson. Additionally, they have staff such as Medical Quality Managers, Data Clerks, and Project Coordinators.

5. Section 1881 of the Social Security Act
9. Forum of ESRD Networks 2000 Directory

4. A description of the processes HCFA undertakes to ensure that the ESRD Networks are properly providing patient care.

Networks do not provide direct patient care, dialysis and transplant facilities do. HCFA contracts with 18 geographically designated Network Organizations for the purpose of improving the quality and effectiveness of ESRD patient care. They do not actually provide care to beneficiaries. They work with ESRD dialysis and transplant facilities within their respective regions. It is within these facilities that patient care is delivered. Patient care on an individual basis is further monitored within the facility by the beneficiaries' physicians. HCFA does oversee the networks through project and contract officers, who hold the Networks accountable.

3. Section G – Contract Administration Data, pages 11 - 12.

In addition, beginning in 1994 HCFA took a leadership role in developing clinical indicators to assess the quality of care for dialysis patients. Through the ESRD Networks, we have collected clinical indicators/measures on a national sample of dialysis patients in the areas of adequacy of dialysis, anemia management, and serum albumin; vascular access measures were added in 1999. The data are collected annually and a detailed report describing the findings at the national and regional levels is disseminated to all dialysis providers for their use in identifying opportunities for improvement. A national patient sampling approach, stratified by Network area for the hemodialysis patient sample, was chosen initially because of the workload burden on dialysis facilities and the ESRD Networks in using a hard copy reporting system. Using this national sampling approach, we have been able to document every year since 1994, improvement in the number of dialysis patients achieving the benchmarks for these clinical indicators. We believe that this approach has been successful in improving care for dialysis patients. Dialysis providers have found these measures and the annual distributed report of findings to be a valuable tool in assisting them to improve care.

By 2001, we plan to collect these measures on all patients from all providers so that we will have facility-specific data that can be used to assess facility compliance, to assist facilities to improve care, and to report to the public facility-specific performance. We are working on developing a system that will allow dialysis facilities to collect and report these data electronically to HCFA. We anticipate pilot testing this electronic system in 2000 with national implementation in 2001.

Additionally, as mandated by the Balanced Budget Act of 1997, HCFA (under a contract with PRO-West) developed sixteen clinical performance measures (CPMs) in the area of adequacy

of hemodialysis, adequacy of peritoneal dialysis, anemia management and vascular access. The collection of these CPMs was pilot tested in 1999 by the ESRD Networks using a national sample of dialysis patients. In 2000, these CPMs will again be collected by the Networks for quality improvement purposes, on a national sample of patients. Also in 2000, the CPMs will be collected from all dialysis facilities on all patients through the electronic reporting system. Once we are comfortable with the accuracy of the data, we would report to the public on facility-specific performance measures based on these 16 measures.

5. **A detailed description of the dialysis patient complaint resolution process.**

The dialysis patient complaint resolution process is described in the ESRD manuals that we have attached. They represent the current complaint resolution process, and we have a workgroup that is examining how to strengthen the complaint resolution process and alternative dispute resolution processes for beneficiaries and Networks.

10. ESRD Network Organizations Manual
11. Section 3280 of the State Operations Manual – Investigation of Complaints Against Other Than Accredited Organizations and Providers

6. **A copy of the HCFA reimbursement guidelines provided to ESRD Networks and their facilities.**

HCFA reimbursement guidelines are included in the attached Chapter of the Provider Manual. ESRD Networks do not play a role in payment to facilities. The manual explains in detail how the composite rate works, separately billable items, as well as the exceptions process, which allows the facilities to apply for reimbursement above the composite rate if they meet certain criteria.

12. Chapter 27 of the Provider Reimbursement Manual

7. **A copy of any HCFA guidelines given to the ESRD Networks and their facilities regarding re-use of dialyzers and any research or studies upon which these guidelines might have been based.**

Attached are the HCFA regulations on re-use of dialyzers. Additionally, attachment 20 contains information on what state surveyors would look for regarding re-use, beginning on page H-7. The attached American Journal of Kidney Diseases article will provide you with research information behind our guidelines.

13. 42 CFR Subpart U – Conditions of Coverage for Suppliers of ESRD – Section 405.2110-405.2113 relating to networks and section 405.2150 relating to reuse.
14. American Journal of Kidney Diseases Article, Am J Kidney Dis 23: 692-708

8. A copy of any HCFA guidelines regarding the amount of time a patient should be on dialysis, in terms of hours and times per week.

The amount of time a patient should be on dialysis is not addressed in HCFA guidelines. In fact, only a physician may write a prescription for the amount of time, based on his or her experience, the patient's condition and unique characteristics such as age and weight, and based on certain clinical guidelines. For an example of guidelines, we have included the 1999 Annual Report ESRD Clinical Performance Measures Project (in particular, pp. 28 – 29) and a complete set of Dialysis Outcomes Quality Initiative Clinical Practice Guidelines, which establish best practice guidelines.

15. 1999 Annual Report ESRD Clinical Performance Measures Project
16. Reference Page: Complete Set of Dialysis Outcomes Quality Initiative Clinical Practice located at http://www.kidney.org/professionals/doqi/doqi/
17. Highlights from the 1999 ESRD Clinical Performance Measures Project

9. A copy of any HCFA guidelines regarding conflict of interest where ownership of dialysis facilities is concerned.

HCFA guidelines regarding conflict of interest are being addressed in a proposed rule (attachment 17). That proposed rule implementing the Physician Self-Referral Law, which entails a much broader range of issues than just ESRD, has been the subject of much debate. We hope to finalize that rule this year. In addition to your requested information, organizational conflicts of interest are discussed in special contract requirements, which we have included for your review.

18. Physician Self-Referral Law Proposed Rule (63 Fed Reg 1659, Jan. 9, 1998) p. 1661, 1662, 1723, and 1724.
4. Section H.9 – Special Contract Requirements – contains information about organizational conflicts of interest

10. A detailed description of the survey process used for ESRD facilities, including but not limited to: the regularity of surveys, the survey methods and criteria used, types of citations, and statistics on facilities cited and/or terminated from the program.

As indicated above, we have funding in FY 2000 to perform surveys on a six-year cycle. Attached is a chart on the number of surveys performed in 1993 - 1999, as well as a list of deficiencies described in tag number order. Also, please see the HCFA survey procedures and guidelines, which provide detailed information on the administration of surveys.

19. Chart of ESRD Survey and Certification Data – Number of Surveys Performed
20. Comparison of Deficiency Patterns in tag Number Order for All 50 States and Nationally – Deficiency Listing for ESRD Facilities
21. Survey Procedures and Interpretive Guidelines for ESRD Facilities

11. A copy of any reports or studies comparing the various treatment modalities associated with ESRD (i.e., home hemodialysis, in-center hemodialysis, peritoneal dialysis).

To address the question of studies comparing various treatment modalities, we have included several attachments. These include a discussion of Medicare spending for each modality, comparative charts of the different treatments available (such as transplants, in-home and in-facility, by state, as well as total numbers on different modalities such as hemodialysis and several different types of peritoneal dialysis), and a broad discussion of modalities.

22. Chapter X of 1999 U.S. Renal Data Systems Annual Report
23. 1998 Facility Surveys Table from the HCFA ESRD Program Management and Medical Information System – Types of Transplants
24. 1998 Facility Surveys Table from the HCFA ESRD Program Management and Medical Information System – Facility compared with Home Treatments by State
25. 1998 Facility Surveys Table on Dialysis Treatment Modalities and Kidney Transplants – Total numbers on different modalities
15. 1999 Annual Report ESRD Clinical Performance Measures Project – Broad discussion of modalities

12. A breakdown of types of ownerships, i.e., for-profit, non-profit, non-profits associated with medical centers, or any other classification that HCFA may maintain for ESRD facilities.

The National Listing for Medicare Providers Furnishing Kidney Dialysis and Transplant Services January 1999 includes on Page 5 for Table 3 the Number and Percent of Approved ESRD Providers, By Type of Ownership. As you can see, the percentage of for-profit facilities has grown over the years.

26. National Listing for Medicare Providers Furnishing Kidney Dialysis and Transplant Services January 1999
27. Page 5 of the National Listing for Medicare Providers Furnishing Kidney Dialysis and Transplant Services January 1999

13. A list containing the names of all ESRD Facilities by state.

The following attachment presents all ESRD facilities by state. It was produced on March 22, 2000, from the Online Survey and Certification And Reporting System. Included are names, addresses, and telephone numbers, as well as county codes. There generally is about a 100 facility net increase per year.

28. Current List of All ESRD Facilities from the Online Survey and Certification And Reporting System as of 3/22/00.

14. A quantification of the total number of ESRD patients in the United States, also by state.

For a quantification of all ESRD patients by state, please refer to the following Facility Surveys Table. The number of ESRD patients has grown steadily at about 6% a year.

24. 1998 Facility Surveys Table – Dialysis Treatment Setting of ESRD Patients by State

15. Any other information you feel would be of assistance to our investigation.

It may be helpful for you to examine the ESRD Network Program Annual Report Summary. It is an excellent summary of the Annual Reports submitted to HCFA by ESRD Networks, and covers Calendar Year 1998.

29. ESRD Network Program Annual Report Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUN - 8 2000

The Honorable Charles E. Grassley
Chairman, Special Committee on Aging
United States Senate
Washington, D.C. 20610-6400

Dear Mr. Chairman:

Thank you for your letter of April 28, 2000, co-signed by Ranking Minority Member John Breaux, Special Committee on Aging, regarding investigation by the Special Committee on Aging of the Medicare program and the quality of care provided by its End State Renal Disease Program. We regret the delay in responding to your letter.

The information you have requested follows.

1. **A description of the process by which hemodialysis dialyzers are approved for use (and under what conditions) by the Food and Drug Administration (FDA).**

FDA classifies medical devices into one of three classes on the basis of risk, Class I being the class of least risk and Class III being the class of greatest risk. A Class I or II device must have a cleared Notification of Intent to Market a Device (510(k)) prior to marketing (unless exempted from this requirement). A Class III device must have an approved premarket approval application (PMA) prior to marketing.

Hemodialyzers are classified as either Class II or Class III as defined by 21 CFR 876.5820 or 876.5860. The determination as to whether a dialyzer is placed into Class II or Class III is based on the permeability of the dialyzer membrane to water. Dialyzers with water permeability greater than 12 ml/hr-mm Hg are called "high permeability dialyzers" and are placed in Class III. This classification was based upon the increased risk for excessive fluid loss posed by these devices. Dialyzers with water permeability less than 12 ml/hr-mm Hg are called "conventional dialyzers" and are Class II. FDA has proposed to reclassify high permeability dialyzers from Class III to

Class II. This decision was based upon our increased experience and knowledge of these devices, and upon our ability to devise special controls for these devices that address the risks to health identified by the original classification panel.

Recommendations for the content of 510(k)s for dialyzers are outlined in a guidance document enclosed at Tab A. This guidance is currently in draft form.

Since 1997, FDA has required manufacturers who market dialyzers to clinics that reuse their dialyzer (on the same patient) to label the dialyzer for multiple use. The labeling requirements are described in a guidance document, entitled "Guidance for Hemodialyzer Reuse Labeling." Manufacturers are required to provide the results of bench and clinical testing of the dialyzers after the first use, and after 1, 5 and 15 reuses. A summary of this information appears in the device labeling, along with instructions for reprocessing the dialyzers by at least one validated method. Additional guidance on how to best conduct the bench and clinical tests was provided in an accompanying document entitled "Frequently Asked Questions on the Guidance for Hemodialyzer Reuse Labeling" that was widely disseminated to industry and other interested parties. Both of these documents are enclosed at Tab B.

To date, FDA has received 12 premarket notification submissions from five different manufacturers that contain hemodialyzer reuse labeling.

2. Any studies relating to the merits of the reuse of dialyzer.

Numerous studies have appeared in the published literature that address the risks and benefits of dialyzer reuse. In particular, the National Institutes of Health (NIH) is involved in two large, multicenter studies on the safety of dialyzer reuse. Literature articles describing these are enclosed at Tab C.

FDA has conducted an analysis of all available data on hemodialyzer reuse, including data that were submitted in the hemodialyzer reuse premarket notification submissions. This study was funded under a special CDRH review research initiative. The purpose of the study was to evaluate the potential effects of reprocessing and reuse on dialyzer performance. The analysis will also be used internally to guide future revisions of the hemodialyzer reuse guidance document referenced above. The findings from this study were presented

in abstract form at the American Society for Artificial Organs Annual Meeting in April 1998, and in an internal scientific presentation on hemodialyzer reuse in April 2000. A description of the abstract and a copy of the presentation materials are enclosed at Tab D.

3. Any guidelines the FDA has provided to medical practitioners regarding the reuse of dialyzers.

The hemodialyzer reuse guidance document referenced above requires manufacturers to provide users with instructions on how to safely reprocess their dialyzers using at least one method. This labeling was extensively reviewed by FDA during the premarket review process. The availability of dialyzer reuse labeling should improve the safety of hemodialyzer reuse in the United States by giving the prescribing physician instructions for how to perform reprocessing on each manufacturer's dialyzer. In addition, by providing a summary of the bench and clinical data on the labeling, the physician can quickly assess the effects of a particular reprocessing method on key hemodialyzer performance characteristics.

4. An explanation of when a dialyzer manufacturer may label its product "one time use only" and the clinical significance of the use of such a label beyond one use.

Manufacturers may elect to label their dialyzers "single use only", however, they should not then knowingly market their dialyzer to clinics that they know practice reuse of their dialyzer. If a physician chooses to reprocess and reuse a dialyzer labeled "single use only", it would fall under the "practice of medicine" and therefore would be the responsibility of the individual physician or clinic to ensure that reprocessing and reuse is properly conducted.

5. Any guidelines the FDA has provided to medical practitioners regarding the sterilization/cleaning (reprocessing) of dialyzers.

FDA has provided guidance on reprocessing of hemodialyzers in a document entitled "Quality Assurance Guidelines for Hemodialysis Devices" (February 1991). A copy of the relevant section, Chapter 10, Hemodialyzer Reuse, is enclosed at Tab E. In addition, as discussed above, the FDA has worked extensively with dialyzer manufacturers to include reprocessing instructions on their device label.

Page 4 - The Honorable Charles E. Grassley

6. A description of the process by which a defective dialyzer is reported to the FDA and what actions the FDA takes once such a report is made.

Medical Device Reporting (MDR) (21 CFR 803) is the mechanism for FDA to receive significant medical device adverse events from manufacturers, importers and user facilities, so they can be detected and corrected quickly. Medical device user facilities and manufacturers must report deaths and serious injuries to which a device has or may have caused or contributed, and manufacturers must also report certain device malfunctions. Additionally, user facilities and manufacturers must establish and maintain adverse event files and must submit to FDA specified follow-up and summary reports. FDA uses these reports to identify unknown or rare adverse events and trends, among other things, that would warrant corrective action. Ultimately, a device may be recalled.

7. A list of incidents reported to the FDA regarding defective dialyzers. Please include a brief description of the complaint and the steps that were taken to resolve the complaint.

FDA does not investigate and resolve every individual complaint received about any device. A summary of hemodialyzer adverse event reports found in the Manufacturer and User Device Experience (MAUDE) database is enclosed at Tab F.

8. Any other information you feel would be of assistance to our investigation.

In September 1999, FDA held a scientific symposium to discuss the latest clinical and scientific findings on hemodialyzer reuse. Speakers were invited from academia and NIH. A copy of the handouts from the symposium is enclosed at Tab G.

Thanks again for contacting us about this matter. If you have further questions, please let us know. A similar letter has been sent to Senator Breaux.

Sincerely,

Melinda K. Plaisier
Associate Commissioner
for Legislation

Enclosures (7)

Statement of Carol A. Keller, MPA, Omaha, Nebraska

I am writing to share my opinions regarding the current state of dialysis care. For over 25 years I have had end stage renal disease (ESRD) with experience as a hemodialysis patient for approximately 8 of those years. For more than 3 years now I have been a home hemodialysis patient. I have also had two transplants, one in 1977 lasting 13 years and the other in 1993 lasting less than four years. From my initial dialysis experiences to the present day I have observed a remarkable difference in the quality of care provided at some dialysis units. I would like to emphasize that my current providers give me excellent care. Unfortunately I have had dialysis treatments at other units in the past and when I travel I have experienced significant quality of care issues. For the past 17 years I have worked in hospital administration positions. During the past 7 years I have been working as the Performance Improvement Coordinator for the Veterans Affairs Nebraska-Western Iowa Health Care System. My experience in the renal community has included: National Kidney Foundation Trustee and Officer in local affiliates; American Kidney Fund Committee Chair; Founder and Donations Coordinator for a children's kidney camp; and, serving on the Medical Review Board of an ESRD Network and conducting an exercise rehabilitation program.

There are many issues that your Committee could address regarding the quality of care for dialysis patients. I believe that the following topics are priorities for improving the state of dialysis care to enhance patient outcomes, which I believe should be the primary goal of providing dialysis services. While I work in the quality improvement field and support improvement initiatives for dialysis care, many of the dialysis processes still need to have quality control issues monitored and reviewed to ensure consistent care is provided.

- Patient Safety: Consistent staffing levels for all shifts and training requirements for all staff. Standardized infection control and surveillance practices, including general cleaning and sanitation procedures. Reuse practices and patient right of refusal to reuse.

- Patient Education: Access to information and health care staff (dietitians, social workers, and physicians). Ongoing use of quality of life assessment tools and outcome measures. Ongoing patient involvement in care plan. Access to support groups or other mechanism for patient assistance. Availability of all treatment options. Provision of rehabilitation services at units including vocational rehabilitation, exercise, and self-care options.

- Medicare Provisions: Review length of time before Medicare becomes primary insurer (now 30 months for employed patients). Review patient compliance issues (shortened treatments, diet & fluid intake, skipped treatments, etc.) as patient's responsibility for Medicare to make payment. Review patient quality of life issues (nursing home patients, futile treatment) when providing treatments. Review receipt of other government benefits for patients without employment and refusing rehabilitation services. Include component specific to patient rights and responsibilities for patients and units to comply.

Please feel free to contact me for additional information. Thank you.

Statement of Dale Ester

I have been thinking about ways to make the dialysis experience a better environment for all ESRD patients. I have enclosed my views/opinions and am certainly willing to discuss them at a later date. These notes can be used for testimony too.

1) ALL patient care technicians need to be certified (registered in a manner similar to Registered Nurses) to become eligible to work in a dialysis setting providing medical service to patients. Current patient care technicians can come from anywhere and require no medical background or a high school diploma. A hair-dresser has more certification and schooling-training to go through to be able to provide service to clients than do the dialysis technicians who have real "lives" in their untrained hands.

2) Patient to Patient care technician ratio should never exceed a maximum of 4:1 due to the inability of being able to properly render adequate medical attention to the safety of the patient in a crisis of life-threatening consequence. Currently, the ratio goes up to 8:1 and no one seems concerned except for the patients who are fearful of the risk they are being forced to endure.

3) There is no incentive for dialysis units to perform better as there is little intervention from the government to make them perform better. Although DOQI is a voluntary guideline, it is not mandated to be delivered to patients as law, thus many service providers simply continue do as they please because the government established such low levels of "minimum care" as the only standard they have to meet to receive payment for services rendered. The bare-minimum standards need to be raised so patients receive a better health standard report enabling them to enjoy some quality-of-life issues.

4) An improved grievance policy needs to be constructed. I suggest a national grievance committee to hear complaints from patients and then acts upon those complaints in a responsible and effective manner. Too often the ESRD Networks side with the dialysis providers to ease the complaint strife on hand. Who really currently stands up for the dialysis patient when they have a legitimate complaint? No one. And if by chance someone does look into the complaint, the patient is eventually labelled as a troublemaker in their chart and from that point onwards, rarely receives any improvement in care. In fact, reprisals and repercussions usually are forced upon a patient who makes a complaint, in essence, to keep the patient in provider control. The threat of harm is the most often used reprisal. and yet, no one outside of the dialysis industry listens to realize the practice is real. It does happen. It happened to me. We need to establish a systematic way of handling complaints without fear of reprisal for making suggestions aiming to improve dialysis care. The ever omnipotent dialysis provider needs to realize the patient is

not the last thing on their list of priorities, but should be the first.

5) I believe dialysis patients should sign for their daily, weekly, or monthly dialysis treatment sessions before the bills are sent in for payment. Too often I fear many bills go to Medicare and are potentially invalid as to drugs used or services rendered (in other words, fraud likely exists but who ever checks?). Who would be better able to justify what happened at the treatment session than the patient who was in the treatment firsthand. If patients were able to treat their Medicare dollars as if was their own out-of-pocket money, I doubt such elusive bills for untold amounts of hipocracy would ever occur. The Medicare system could rightfully save billions of dollars annually just by having the patient "confirm by signature" what is being billed to their medicare number substantiating the services billed/drugs administered actually occurred.

6) More governmental inspections of dialysis units should occur, and they should be thorough inspections which arrive unannounced at any time during the working schedule. There is too much failure in the system when it allows a dialysis provider/unit to "know" when an inspection is about to occur, generating the unit to administrate an immediate ability to clean up the area and get everything in order as if this one day inspection makes the unit able to pass muster for years worth of vagrant medical failures and lack of aseptic conditions/techniques. The idea is to make the unit more responsible so patients can enjoy the atmosphere of cleanliness and safety with no fear about potential health risk because the unit simply is busy and doesn't care enough to practice better bio-hazard handling standards. Blood on the floor, poor glove changing and or washing of hands, are things which need to be better controlled. When a patient makes comment about such poor practice, it simply angers the unit personnel and then reprisals are set in action. It is real.

7) More dialysis night time hours should be available so patients can return to work without fear of missing too much work because dialysis treatment is not available at the time needed. If you want more ESRD patients to go back to work, it is urgent to make a remedy available which is easy to accomplish.

8) Regular servicing of dialysis chairs should be a requirement too. Chairs are often broken, seats torn, springs sticking out, or seat bottoms broken and the unit seems to not care. Yet patients are forced to sit in these hazards as if their comfort is not to be maintained. It is frustrating. I suggest one try sitting in a broken down chair strapped up like a mouse in a trap for 4 hours and see how uncomfortable the situation becomes and the mistrust which develops because of same. The units simply don't care about patients or the condition under which they must survive, even if it is only for a few hours. It is horrible to realize a treatment is much like a torture time .. all because the patients voice goes unheard or disregarded by the personnel as if to say, "we can not hear you nor do we want to hear you. Simply sit there and get whatever we give you without question." This too, is a dialysis patients inhumane reality.

9) It would be ever so nice if a social worker was actually available to handle the social and mental affairs of patients who request assistance. Currently the social worker is doing the preparation to establish the Medicare billing to go through and is so overworked (with a ratio of 1 social worker to approximately 150 patients) there is no time to "socialize" to learn about the real person and the problems which could be resolved. The fault lies in the units not having enough social workers (and dieticians too) available to handle the patient workload of those who need adequate assistance. More staff should be hired to diminish this oversight and render the ESRD patient the means to improve their outcome.

10) Travel from center-to-center, state-to-state, is a not-so-funny joke. This travel, called transient dialysis, is extremely frowned upon as it is the social worker who is inevitably left to to manage the arrangements. Even when the patient tries to help, the service is poor and the assistance needed to make the arrangements are so spotty it is extremely difficult to make any travel or vacation "tentative" plans. Yet the industry promotes unjustly informing patients not to worry, dialysis won't stop your ability to travel. Who are we kidding if not ourselves? Travel because of lack of interest at the unit level of personnel is horrible. There needs to be a better way of accessing transient dialysis by the patient directly without so much rigorous intervention by the staff making travel arrangements almost an impossibility, especially if the patient pushes onward to accomplish the task. Better long-term confirmation needs to be available too.

11) A scientific study should be performed to determine if an elevated hematocrit above the current 33%-36% level, would better serve to get ESRD patients back to a better quality-of-life and potentially get them back to the mainstream of society and part of the working strata. Patients now are currently kept at a low level of energy -- is it to keep them repressed so they don't create social outcry or is it because we are unwilling to make them whole again? If dialysis is acceptable as the treatment to keep ESRD patients alive when the kidneys fail, we should make it our determined goal to make the technology we have available today perform at its highest potential rendering the goodness it is capable of delivering. If raising the hematocrit level could achieve this goal, it should be pursued and acted upon with vigorous enthusiasm. The technology is available to make this happen, why don't we make its benefits to mankind become a recognizable reality actually achieved? Lives ultimately depend upon it. Believe it.

12) Risky as it may seem, I think the government should ward off allowing dialysis to be rendered from subcontractors (dialysis providers) who have learned to manipulate cost and performance, diminishing the delivery of quality-driven service to patients at the cost of the health of the patients themselves, all in the name of making a better profit margin for its shareholders. When a unit scores a big gain in profit, many dialysis patients lost with their lives in some fashion to render the gain the unit proudly displays. Maybe a non-profit status would better serve patients, but only if payroll restrictions were monitored to diminish the huge outlay of cash to corporate high level employees as if to suggest the bulk revenue was going towards

patient care when in effect, it was being saddled up in the CEO's wallet and benefits portfolio. Patients suffer with the current system of how profit is derived from the dialysis unit strategy, who try endless ways to stretch out every dollar paid in from Medicare as if profit was the only real reason for rendering dialysis treatment, and certainly not for improving the well-being of the patients it has contracted to provide life-saving service. It is sad to learn patients have a monetary value when a unit decides to sell itself to another company -- patients are worth approximately $50,000 a year and are "sold" in mass as if they were slaves by a pompous trader who is only interested in what the "patient dialysis commodity" will deliver in profit standards to their wallets. We have a long way to go yet when we can't realize these dialysis slaves are people who simply have a treatable disease. Patients are family too. No one deserves to be treated with such indignity or inhumane practices. Until it is stopped or better controlled, profit will be the ugly manipulative pimp taking money from the quiet unobstructed raping of people who themselves are in need but have no way to fight back effectively. Profit within the dialysis industry is not the way to deliver good treatment to patients. Profit has proven itself unable to deliver goodness as we are now exploring the reasons why such an effective medical technology is so misunderstood and charged with such anger and mistrust. No one wants to change the paradigm, especially those who are cleaning up excessive profit on an unregulated and often overlooked medical situation. The Medicare system is at fault for not being more restrictive on how service is delivered and at what profit level should be considered acceptable as normal for the treatment has become a part of the national good and paid faithfully by the work force in the Nation today. I doubt many people would respect the current method of how dialysis is rendered to those in need. Change is desperately needed.

I again offer my assistance to brainstorm finding viable ways to satisfy and remedy this ongoing dialysis crisis dilemma. The solutions are there if we take the appropriate action needed to change the current paradigm and make dialysis a treatment strategy, not a money making scheme. The goodness of quality treatment is lost to those in the industry who have manipulated the payment method to reap benefits largely into their hands at the expense of delivering less than perfect care to patients who rely upon them to live, and the industry not caring one single bit about the patient being seriously hurt or loss of life in the whole process.

Change is desperately needed. I certainly hope and pray the Senate meeting this Monday sets the eyes on America to investigate the misdeeds and malpractices of the current dialysis industry for all to bear witness to a crime against humanity. There must be justice in the civilized world and I know we can find it quickly. Many patients can help too.

Sincerely,

Dale Ester

Statement of Frank Brown

I have been a dialysis patient since 1977, at six different clinics around the country. In that 23 years, my life has been made much more difficult than it ever had to be, by a system that seems to operate on the principle of benign neglect, that treats people as commodities to be profited from, rather than as patients to be cared for.

My well-being and rehabilitation have never been a priority for these clinics: rather, it's get on the machine, off the machine, accept your fate, and don't complain. Any problems not immediately threatening the course of dialysis are commonly disregarded. Never one to passively accept avoidable problems, I have been labeled, harassed, and many times pressured to leave.

Since most patients are too intimidated to press an issue, it seems that common clinic policy is to get rid of the minority who will speak up, rather than to solve problems or make changes they might find inconvenient.

I have experienced so many incidents of neglect and outright exploitation, it would take hours to relate. My first kidney doctor, probably the best one I ever had, quit the practice when reuse with formaldehyde was begun in 1977, against FDA regulations.

While on peritoneal dialysis in 1984, a careless procedure by a nurse caused peritonitis, which the doctor did not treat properly for two whole days, leading to early failure of the treatment, and two subsequent bowel obstruction operations. While back on hemodialysis, in 1994, I discovered that an increase in the bicarbonate level in the dialysate would eliminate severe aftereffects of treatment that I had been suffering for years. My doctors refused to change it, saying it was impossible, too difficult, dangerous, against their lawyer's advice, and that I was grasping at straws. Eventually, they raised it slightly, but kept changing it back. After six years, with a new nephrologist, it has now been raised to a minimally comfortable level. There are a number of studies available showing that higher dialysate bicarbonate levels are better for patients' health.

The worst abuses in my case have involved the mismanagement of anemia, and the administration of Epogen, the anti-anemia drug. In 1997 my clinic began allowing my blood count to fall drastically, after it reached the arbitrary level of 36.5% hematocrit. I warned the nurses ahead of time that this would likely cause problems, but they refused to listen, telling me that they were "just following orders." The first time this happened, in June 1997, I experienced the most severe pain in my hands and arms, as the dropping hematocrit exacerbated the

preexisting conditions of neuropathy and carpal tunnel syndrome. I also became extremely exhausted for two solid months. My complaints were scorned and derided, and I was told to find another clinic if I was not "happy" with their methods. The National Kidney Foundation did a survey around this time, and heard from about 100 patients who had problems with drastically falling hematocrits, and this was also a hot topic on the Internet. The NKF-DOQI has ten citations concerning improved health in dialysis patients with normal hematocrits.

By October, I was somewhat recovered, and my hematocrit reached 42%, the first time it had ever reached normal range, and I experienced an amazing increase in energy and endurance. This did not last, as they again decided to let it drop, to 32%. I again warned them that this would cause problems, and again, I was ignored. This time it was worse, coming on the heels of the previous incident, and, in addition to another two solid months of exhaustion, I experienced progressive loss of the use of my hands. Again, I was told to find another clinic if I was not happy. I appealed to every agency I could, up to HCFA, but they all gave the clinic a free pass. I have been left with greatly diminished use of my hands, amounting to a whole new disability. The doctor later gave me an exemption, to 42%, from the standard anemic hematocrit of 32-36% but the clinic has been unable to maintain that level, with wide fluctuations. In November of 1999, my hematocrit reached 42%, and I warned them that the Epogen must be decreased significantly, to maintain that level. They ignored me again, following their standard protocol. This caused my hematocrit to rise to a dangerous level, causing severe shortness of breath, and illness, because I could not dialyze properly, and it again took two months to recover. They ignored this, pretending they couldn't understand it, and, of course, none of my difficulties were ever charted. In fact, after the first two incidents, Medicare investigator Ken Simpson told me that nothing untoward had happened, since there was nothing charted about it, it would be illegal for them not to chart it, and of course, they wouldn't do that. I had previously written some of my complaints in the patient care plan, but that was ignored, too. This has been an ongoing violation of my inherent and explicit right to participate in treatment planning, and it has caused me serious harm.

There is a lot more to my story, and I know many around the country that have had similar experiences.

When I go into the clinic, I never know what to expect. One time, about a year and a half ago, a woman sitting across from me died during dialysis. They just laid her out on the floor, half covered by a sheet, right in front of me and another patient, and then left the room until the coroner came, over an hour later. It is like a war zone.

All I and other dialysis patients want is a fair chance to have worthwhile and enjoyable lives, and to participate and contribute to society.
Thank you.

Mr. Swamidoss-

This is a partial record of events at my clinic from 1993-1994. I have kept such records intermittently over the years, but would get frustrated and stop, as it appeared no-one was listening, and it was doing no good.

>>
SEPTEMBER 13, 1993, MONDAY Regular machine (Fresenius) is broken, so I am put on the old machine (Cobe). I tell them I will refuse reuse on old machine. They say the Fresenius will be fixed by Wed. 15. Blood is drawn for monthly lab reports. Total time about 3:30 Feel like treatment is inadequate.

SEPTEMBER 15, WEDNESDAY Fresenius still broken; on Cobe with reused dialyser. I told them I did not want reuse with old setup, but it would have shortened my time even more, so I went ahead with it. Total time 3:00. Felt sick after treatment; worse after eating--nausea and heartburn. Same Thursday and Friday.

SEPTEMBER 17, FRIDAY Still on old machine. Dialyser on third use. I tell charge nurse (Kerri) 'I want a new one' but she refuses because she 'doesn't have time.' Dialyser is already half clotted. I tell her that my time should be extended to compensate, but she says she needs a doctor's order. She refuses to call the doctor and refuses to let me use the phone to call him myself. Lab reports are in from Monday Sept. 13. The URR (urea reduction rate) was 54% (normal is at least 60%), and that was on the FIRST use. Arrived 2:40, on 3:45, off 7:00. Total time 3:20. Feeling very sick after treatment, and very sick all weekend.

SEPTEMBER 20 MONDAY Arrived 2:40, on 3:45, off 7:00. Total time 3:15 Still sick. I tell Dr. Wilson what happened. He chews out nurses, tells them 'they know they are to extend time when this happens'. A week or so later, word comes down from Zohlman (medical director) that the nurses did nothing wrong. One nurse (Teeta) tells me that a report must be filed because of inadequate dialysis (low URR). This was never done.

SEPTEMBER 22 WEDNESDAY Arrived 2:30, on 3:30. At 6:00, venous blood chamber is clotting, the nurse (Kerri) waits too long to change it, by the time she tries to return my blood, it has turned dark, and I get bad symptoms, so must be taken off machine at 6:30. Total time 3:30.

OCTOBER 25 MONDAY I am finally starting to feel better after one month. I ask Kerri if there was an incident report filed for inadequate dialysis for the week of Sept. 13-17. She says no. She says 'I should be grateful for "any" treatment.' It would be easy to blame Kerri for these and other incidents,

but the fact is that she was just carrying out company policy, although in a more obnoxious manner than usual.

OCTOBER 27 WEDNESDAY Cathy Ellis, the head nurse, tells me they were "just following Doctor's order" in not extending my time while on old machine.

NOVEMBER 1993. The machines have been breaking down sporadically throughout the year, the worst event being in September when I was on the old machine for three treatments in a row and was sick for a month afterward. In November, the TMP (trans membrane pressure) meters on the machines seemed to have been set too low, so that they often would fall out of range, usually in the last hour of treatment, necessitating lower blood flow and thereby poorer treatment. Sometimes the blood flow had to be set so low that I started feeling sick and had to stop early. I requested that they get someone from the machine company (Fresenius) to look at it, but R.J. the chief technician said there was nothing wrong, so nothing was done. At one point, a technician from Fresenius did come into the clinic, and determined that the machines were not properly calibrated, but this was ignored, and nothing was done. One of the staff members, Gary, told me he was frustrated by all the machine problems and the water supply shutting down so often that he couldn't do his job properly. He has since quit.

DECEMBER 1993. I started taking notes to have some record of events.

MONDAY DEC. 27 -Arrive 2:30, machine occupied. On at 3:35, off at 7:00, 3:25 total time TMP bottomed out last hour of run. Blood flow reduced from 400 to 270 to keep TMP above zero -third time in a row this has happened.

WEDNESDAY DEC 29 arrive 2:40, on 2:50, full time TMP still not fixed.

FRIDAY DEC 31 arrive 1:40, on 1:50, off 5:50, full time TMP still not fixed.

MON. JAN 3 arrive 2:35, on 3:20, off 6:50, 3:30 total TMP still not fixed.

WED JAN 5 arrive 2:30, on 2:40, 4:00 total. TMP still not fixed blood flow down to 250 in last 1.5 hours of treatment down to 230 last forty-five minutes.

THURS JAN 6 I called Suzi Fregeau, BMA administrator told her about the TMP, she said she would talk to Nora, (head nurse) and have her talk to me.

FRI JAN 7 arrive 2:45, machine being worked on 3:30, off 7:00, 3:30 total. TMP working

MON JAN 10 arrive 2:30, waited one hour, on 3:45, off 7:15, 3:30 total

WED JAN 12 arrive 2:30, on 3:10, off 7:10, 4:00 total machine working OK

FRI JAN 14 arrive 2:35, on 3:10, off 7:00, 3:50 total

MON JAN 17 arrive 2:40, on 3:30, off 7:10, 3:40 total time. clinic very hot

WED JAN 19 arrive 2:30, on 2:50 air-conditioning on- clinic freezing 5:15 I wake up from nap, notice that the TMP is malfunctioning and blood flow has been reduced from 400 to 200, with nothing about it on the chart. 5:30 switch to different machine 5:50 same problem on different machine, blood flow 220-250 6:00 Zohlman comes by, apologizes for the way things have been going, says things are changing for the better. 6:10 blood flow to 210, feeling bad, off by 6:20 total time about 2 hours effective dialysis.

FRI JAN 21 run 4.5 hours to compensate for Wednesday machine working

NON JAN 24 4:00 total
WED JAN 26 4:00 total

FRI JAN 28 arrive 2:20, on 3:00 4:00 machine shuts down with no noise or alarm, I happen to be watching at the time. nurse turns it back on 5:00 tech (Russ) says it's unsafe, says 'switch to other machine' 6:00 other machine still not ready--never switched off at 7:00, 4 hours total

MON JAN 31 arrive 2:20, machine just now being worked on.
on at 3:20
6:20 TMP dropping, blood flow to 300
6:40 blood flow to 250
6:50 blood flow to 200, come off at 6:50
total time 3:30, effectively 3 hours

WED FEB 2 arrive 2:25, on 2:35
3:20 TMP starts dropping, blood flow to 350, then 300
blood flow down to 200 by 6:00, come off machine
3:30 total, very poor quality

FRI FEB 4 arrive 2:25, switched to different machine, must wait 3:15 water goes out, all patients' blood returned
4:00 on machine
6:15 clotting in bloodline, line is changed and clots again now dialyser is clotted, dialyser and line are changed, dialyser and line clot again, are changed again. LOST ABOUT ONE PINT OF BLOOD
7:00 back on after 45 minutes
8:00 off machine, 3:15 total.

MID-FEBRUARY Doctors and staff decide that there is nothing wrong with the machines, so there must be something wrong with me. They send me to have a fistulagram, to see if there is narrowing of the vessel, which can be expanded by a balloon. The fistulagram finds nothing wrong, but the technician decided to expand the balloon far up in my shoulder, where the vessels were normal. It hurt too much, and I made him stop. Another patient had a vein torn by the same technician.

Things continued as usual at the clinic for quite a while, until eventually, the chief tech was replaced, and the TMP problem was resolved.

Dialysis Senate Subcommittee

Thank you for this opportunity to be heard. The foregoing testimony represents how End Stage Renal Disease and Kidney Dialysis has evolved into a **National Use** and **Abuse** of **Medicare Dollars** and **Dialysis Patients.** This National Abuse frequently includes unreported patient deaths that are not related to their chronic disease, but to unethical and immoral practices of facilities.

Like so many others in the dialysis field, I was just a healthcare worker who received "on the job" training. I am not licensed or registered with any state or healthcare organization. I had direct and complete hands on care responsibilities for patients including inserting needles into their veins or graft in order to connect them to their dialysis machine to initiate their lengthy treatment. I, like many others at this level, did not have a comprehensive understanding of the renal diseases and process, the psychosocial problems, and most of all, the dangers of the equipment used and problems associated with the chemicals used in the reprocessing of dialyzers.

After months and months of witnessing the improper use of equipment, supplies, drugs and above all watching licensed professionals to permit these acts to proceed at the cost of the patients health and welfare brought numerous concerns. I followed the chain of command with no results. My conscience would not let me be silent and I filed my complaints with the Region 10 HCFA Office, which violated my confidentiality, and advised the Renal Network to handle my complaint that ironically was about them. I did file a formal complaint with the State Department of Health in which the investigation discovered that the State does not regulate End Stage Renal Disease Facilities and, therefore, could not impose sanctions.

This is a matter of conscience and ethical wrongdoing by those in charge of Kidney Dialysis in this country. I have documentation, letters, phone calls and interviews from patients, their families, dialysis employees and even from professionals that will prove, without a doubt, that urgent regulations need to be mandated in providing the dialysis community with healthcare that has morals, ethics, legal boundaries and above all the care and respect that patients deserve.

As a Nation we have always lent a helping hand to other countries far and wide. We encompassed human rights issues and were angered at man's inhumanity to one another. **Senators, the inhumanity is alive and thriving in the industry called dialysis.** These dialysis corporations have the finances to purchase lobbyist and public relation firms to sway you to their side. These corporations have become inhuman as to their scheming continues in profiting at the expense of public physical and mental health and receiving only a slap on the hand for their wrongdoing.

It is time we expose and confront the dialysis industry. Many a brave patient has stood up to no avail. Patients have learned that a democracy is not allowed in some dialysis

units. Many are afraid to complain because it is their very lives that are held in this delicate balance. You don't complain to the Warden because he will leave you with his guards. It saddens my heart to think that these patients are putting their most sacred possession "Life" in the hands of an industry that only has one thing in mind and that is **financial gain.** Patients have no where to turn outside of the industry and are placed in a "Do or Die" situation. The industry owns all the cards in this poker game and at this point has all the chips on their side of the table.

For Profit Dialysis has the only group of physicians who are immune from the Anti-kickback Statute and the Stark Law, which means physicians, can profit from their patient's care in more ways than one. This has led to huge cash and stock options given to the physicians from the for-profit corporations. Physicians are given x amount of dollars to refer patient's to a clinic. The cheaper a clinic is run shows up in maximum benefits of the profit sharers. Our patients now are on the Stock Exchange since their physician is now in business with the Dialysis Corporation. These large corporations will try to convince you their budget is being sacrificed because the government hasn't given them a raise. The dialysis industry knows that this is the only medical disease that the government pays as primary 80% of all costs for everyone and the patients insurance is secondary. Then to top it off the government is charged an extra fee of $200.00 or more per month from physicians for acknowledging his patient is still alive. Check the Stock Market and it will confirm that these physicians and dialysis corporations are making millions of dollars in profit off of government expenses and patients lives. I must ask you, "Are our patients lives up for Public Trading?" This is simply conflict of interest.

HCFA set up what is call the Networks. These Networks are responsible to give the statistics to the government and to handle all dialysis oriented complaints. When I complained to HCFA, Medicare and the Attorney General it went straight to the Network without any whistle blowing immunity. I questioned who was on the Network Boards, and there were three board members of the company I wanted investigated since and that's when I found out all patient's complaints were sent back to the patient's unit to be resolved.

Discovering that the statistics the government was given was on the honor system wasn't surprising. To date, Dialysis has **No Standards, No oversight and No Accountability**. You only have the DOQI Guidelines that disclaim the same guidelines from the Kidney Foundation. (???) A patient's dialysis treatment is based on lab findings and some companies even own the laboratories. Many times a patients treatment is based upon the accuracy of the dialysis machine, and again who owns, operates and calibrates these machines? All we know to date is the more dialysis the better. The patient's quality of life is the true indicator of proper dialysis.

This now brings me to the focus of the healthcare workers who are burned out and actually an assembly line worker. The facility dictates when a patient's treatment starts and ends and seldom is time allowed in between to assure patient safety. Their health

and welfare is jeopardized all for the sake of numbers and profit.

Dialysis clinics are paid for a full treatment even if the patient dialyzes only a minute. So clinics can cut a patients time and then justify adding an additional run a week creating more profit. Company profits are based upon the ability to measure and limit the use of supplies. Low quality supplies are purchased to Maximize their profits. Patient safety suffers due to using "a one size fits all treatment plan."

And speaking of patient safety...let's look at the training or education that is supplied to the new employee that has no previous experience. In most facilities the training is inadequate. New employees are out on the floor without even a clue to what lies ahead after a brief training. Strict training regulations must be put in place because our patients are paying the price with their lives on the balance. Patients are not given the choice in facilities to dictate who takes care of them for their treatment. Put yourself in their shoes--living with chronic renal disease, having constant fear for your life and wondering if the person dictating your treatment has adequate education in this field and knows how to use it. Now add to this situation, **fear** because you are in a situation in which you have no choices and you have no control over your treatment due to the doctor telling you where you dialyze.

Now lets take a look at the equipment used in every hemodialysis treatment. As intricate and sophisticated as our computerized technology is, it is only as smart at the person operating it. Even with all the bells and whistles, I have seen many healthcare workers ignore, question or not even understand these alarms and warning signs that are all a function of the dialysis machine.

Let's not forget the dialyzer, which is the artificial kidney used to filter the patient's blood. This piece of equipment is intended and labeled by the manufacturer for <u>single use only,</u> but these single-use dialyzers are used an average of 30 times sometimes reaching up to 50 uses before disposing just to save money. The chemicals used to reprocess the dialyzer can be extremely harmful and even fatal if it isn't rinsed out properly and are mixes with the patient's blood. Yes, this does happen all too often! How safe and effective can reprocessed dialyzers be especially since the accountability of the processing is another factor. Many times reused dialyzers do not pass pressure test the first time, but are still used. Another factor is the chemicals used for disinfecting the dialyzers are not only dangerous to the patients, but to the healthcare workers.

Units get inspected anywhere from once every 4-10 years and inspection is done by Nursing Home Inspectors. No matter how bad the facility failed an inspection no one is held accountable. This industry has no oversight, accountability, and no standards to date. They are self-policing.

Patients in the dialysis industry are Scared to Death. This industry has the highest mortality rate in the world. The dialysis industry is the owner of a 25% mortality rate, and remember this is just what they are admitting to not even counting the first 90-days

or HIV deaths. Europe's mortality is 7 to 9 percent and they do the over 55 age group also.

Dialysis Corporation's are cashing in huge fortunes off the money that was intended for patient care. Just pick up any Wall Street Journal and the figures are in black and white. Quite often, we are not compelled to listen or act on another's problems unless we have been touched by those problems. Beware, kidney failure and disease is on the rise and may be just around the corner for you or your loved ones.

As Thomas Jefferson once said, "Give the People the Facts, and They Will Do What's Right."

Thank you for your time,

Arlene Mullen

6/18/00

Senate Special Committee on Aging
G31 Dirksen Senate Office Building
Washington, DC 20510

Attention: Joanne Francis

Dear Ms. Francis:

Please excuse the handwritten nature of this letter as I do not have access to my computer. However, I believe the matters I will address in my letter are too urgent to wait. I ask that my comments be made part of the record of testimony which you have been taking concerning dialysis.

As I discussed with you by phone June 9th, there are important issues surrounding dialysis. These include but are not limited to patient safety, adequate care by physicians, for-profit versus not-for-profit, billing Medicare and Renal Network.

Patient safety is of primary concern in my role as nurse at our dialysis center. I believe our ratio of four patients to one technician and 12 patients to one nurse is woefully inadequate. People on dialysis lose blood pressure rapidly at times, may develop signs/symptoms of dialyzer reaction, hemolysis, air embolism, adverse medication reaction and more and all of these falls rapidly. Constant monitoring is essential. We need to have three patients to one technician and at least two nurses for every 12 patients. Basic training for a technician is 8 weeks but in addition, technicians

should be required to get a basic, state or federal certification in the core curriculum for dialysis technicians e.g. is offered by the National Association of Nephrology Technicians. There is no basic standard now, just whatever training the company wants to offer.

Adequacy of care by physicians means to me that the doctors visit the dialysis unit at least once a week for every shift of patients. Currently, in our unit the doctors come to a Care Conference held in a back room once a week and the team (social work, nurse, dietary) discuss those patients for whom one of the disciplines has a specific concern. The doctors look at charts, not live patients. If a doctor is not able to make Care conference, nursing faxes or phones to his office the concerns and awaits a reply. Adequacy of care also means to me that physicians look at the monthly labs drawn on patients, not just those labs for whom nursing has a concern. I seriously doubt that in the units chronically short of help that nurses have enough time to adequately address laboratory value issues, e.g. high calcium and high phosphorus. Also doctors should be going over long term care plans with patients so patients know what modality options they have. This shouldn't be left up to nurses after the fact. Doctors need to be educating patients before they start hemodialysis about options for dialyzing at home with homehemodialysis or peritoneal dialysis and also options for transplantation.

Dialysis needs to be not-for-profit or nonprofit. As soon as a company wanting to make a profit takes over a dialysis unit, all medical individualization ceases. Everyone gets put on the same dialyzer

regardless of whether or not it is best for them. Patients' times on dialysis are cut if they are late through no fault of their own so the schedule can continue. Patients are not allowed to decide whether or not they want a reused dialyzer; they must reuse their dialyzer or be put on a less efficient conventional dialyzer. Plus many other items which might help them, e.g. use of self-adhering bandage to wrap up needle sites after dialysis, are put on their own expense.

Billing medicare for dialysis has become an art to for-profit companies to take advantage of all loopholes. For example, if a patient's needles are in, he is hooked to the blood lines, blood gets to the dialyzer in the first minutes of dialysis and for whatever reason such as an infiltrated needle the dialysis must be stopped, even if he does not do any more dialysis other than that first minute, medicare is charged for that run. as long as the blood hits the dialyzer regardless of whether or not any more dialysis takes place that day, medicare is charged. Little known to patients I have spoken with, if the patient has insurance other than medicare, they (insurance company) is being charged for heparin. medicare apparently covers heparin under the composite rate. Heparin is used to keep the fibers in the dialyzer from clotting so nearly all patients use some heparin. My question is whether or not charging for heparin is eating into the lifetime maximum amount payable by a patient's insurance and why aren't our patients being told that they are being charged for heparin.

Nearly all patients I have spoken with do not feel safe making a complaint to the nursing staff, administration of the company nor to Renal Network. Too many of the people on Renal Network have had

a vested interest in keeping dialysis the way it has been all these years. Representatives of major companies e.g. Fresenius, and physician are on the Renal Network board. This would seem like a conflict of interest. There should be an ombudsman e.g. with the nursing home programs in the state of Oregon who can be called to represent a patient in his complaint who is a totally unaffiliated person with no ties to the dialysis industry.

Joanne, there is much more I could say about the changes the dialysis industry needs. We who serve the dialysis population are hoping for dialysis to become regulated, not by doctors or companies who make dialysis products, but by caring individuals e.g. Senator Grassley, family members of patients, patients themselves and caring dialysis nursing staff members. Standards e.g. DOQI standards, are not enough.

Thank you for your part in helping the dialysis patients receive the best care that possibly can be given.

Sincerely,
Meredith Long
4408 N.W. 127th St.
Vancouver, WA 98685

July 5, 2000

To: Senator Charles E. Grassley
Fax # 202-224-6020

From: Sholom & Jeanie Joshua
1205 N. Signal St
Ojai, California 93023
Phone; 805-646-0458

Rea Dialysis abuse and violation of Federal law

Dear Senator Grassley,

We are medically trained dialysis technicians.

Jeanie Joshua has been on dialysis for over 17 years. For the past 8 years she has done her dialysis at home; I am her medical assistant.

In 1999, Jeanie Joshua's health was severely compromised by her federally funded dialysis providers.

We repeatedly asked for an investigation and intervention from the Renal Network, the federally funded watchdog for dialysis in the United States. But there was no investigation, no intervention, and no response.

The office of Senator Dianne Feinstein requested records on Jeanie Joshua, for 1999, from Renal Network #18. Renal Network #18 refused, even though their contract with the Federal Goverhment states clearly and explicitly that all records and documents are to be made available to the Federal Government for whatever reason the Government wants them.

Jeanie Joshua is alive and stable today because she was able to transfer her care to another provider. She worked out the transfer under circumstances of unimaginable hardship, with no help from the dialysis system.

To date there has been no investigation of what was done to her in 1999.

I am enclosing an 18 page summary of Federal laws broken by Renal Network #18.

Dialysis care must be one of the best kept secrets in the Medicare program. A fiefdom has been created, paid for by Medicare with no accountability. The Government depends on Renal Networks to tell them what is right and wrong, but the Renal Networks are not doing their job. And something is very wrong. For all the $13 billion spent annually on dialysis, Americans with end stage renal failure are dying, on average, 3 times as frequently as their peers in Europe, Japan, and Israel.

Lastly, HMO administration of dialysis would be a disaster for dialysis patients.

Please contact us so we can hep you to help all dialysis patients.

Sincerely,

Sholom Joshua

Attachments (18 pages)

VIOLATIONS OF FEDERAL LAW BY RENAL NETWORK #18

FAILURE OF RENAL NETWORK #18 TO MEET FEDERAL GOVERNMENT CONTRACT REQUIREMENTS

PATIENT ENDANGERMENT BY RENAL NETWORK #18 RESULTING FROM NEGLIGENCE OF RESPONSIBILITIES AND NOT FOLLOWING STANDARDS AND GUIDELINES OF FEDERAL LAW

Approximate Time Frame: February, 1999 to May, 1999

Background: In February, 1999, Mrs Jeanie Joshua, Medicare beneficiary and home dialysis patient, was given orders by her federally funded nephrologist, David Abrams, M.D., which were contrary to the medical standard of care. The orders, which were related to hypertension, endangered Jeanie Joshua's health and life. Mrs Joshua and her husband, Sholom Joshua, appealed, in writing, for help from the Federal Renal Networks. The appeal/grievance was sent to the head of the Federal Renal Networks, Ida Sarsitis, who forwarded it to the Networks' western regional office and from there to Renal Network #18.

Simultaneously, Dr Abrams informed Jeanie Joshua he was ending their doctor-patient relationship without provision for Mrs Joshua to have access to her home dialysis. Dr Abrams informed Mrs Joshua that he was transferring her care to another doctor, who practiced 80 miles away from where Mrs Joshua lived. Mrs Joshua would then have to drive 80 miles each way to receive dialysis treatments in a dialysis treatment center, commonly known as a unit.

The above-described events were known to Renal network #18 (hereafter referred to as RN 18) and approved by RN 18. There was no response by RN 18 to the appeal/grievance from Mr and Mrs Joshua.

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The federal laws pertaining to dialysis are outlined in the Code of Federal Regulations (CFR), Title 42, Chapters 4 and 7. In turn, those laws form the basis for the specific Renal Network responsibilities described in RN 18's contract with the federal government's Health Care Financing Agency.

OBJECTIVES OF THE FEDERAL GOVERNMENT'S END STAGE RENAL DISEASE PROGRAM (ESRD).

Section 405.2101: The objectives of the end-stage renal disease program are:

(a) To assist beneficiaries who have been diagnosed as having end-stage renal disease (ESRD) to receive the care they need;

(b) To encourage proper distribution and effective utilization of ESRD treatment resources while maintaining or improving the quality of care;

(c) To provide the flexibility necessary for the efficient delivery of appropriate care by physician and facilities; and

(d) To encourage self-dialysis or transplantation for the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for such treatment.

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The federal government's program for the delivery of renal services divides the United States into 18 geographical areas. These areas are called "Networks." Each network is headed by an organization funded by the federal government through a contract with HCFA to oversee dialysis activities in its geographical area.

The federal regulations define network organizations in Section 405.2102: "The administrative governing body to the network and liaison to the federal government."

RN 18 is the designated organization for the southwest portion of the United States which includes southern California.

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RENAL NETWORK 18's CONTRACT WITH HCFA

RN 18's current contract with HCFA is for the time period ending 6-30-2000.

RN 18, in its contract, states the following as its first primary goal:

Section C.1.C Goals: Improving the quality of health care services and the quality of life for ESRD benficiaries.

RN 18's contract with HCFA contains responsibilities and

procedures to be fulfilled on behalf of its stated goal. This document will reference which contractual obligations were broken by RN 18.

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RN 18's VIOLATIONS OF FEDERAL REGULATIONS AND CONTRACTUAL OBLIGATIONS FALL INTO 5 AREAS:

(1) The handling of grievances from dialysis patients.

(2) Assuring safety and appropriate care for dialysis patients.

(3) The role of home dialysis in the federally funded ESRD program.

(4) Patients rights.

(5) Records, Reports, Notices and Referrals

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1. Patient Grievances

The following federal law was violated by RN 18:

(Chapter 7, Section 1395rr (c) (2) (D)): "The network organizations of each network shall be responsible...for implementing a procedure for evaluating and resolving grievances."

Comment: RN 18 did not respond to the Joshuas' grievance sent to the Networks in February, 1999. RN 18 did not contact the involved patient, Jeanie Joshua.

The following federal contract obligations were violated by RN 18:

(Section C.4.I., Patient Grievances): The Network shall follow the HCFA national policy in the Draft ESRD Network Organizations Manual at Attachment J-2-d, for evaluating, resolving and reporting patient grievances. The Network shall assist patients and facilities in resolving grievances and complaints, including referring immediate and serious grievances to the appropriate HCFA Regional Office and State Survey Agency, within 24 hours of receipt. Guidelines for these activities are contained in the Draft ESRD Organizations Manual instructions at Attachment J-2-d.

The network shall also assist, when appropriate, the State

Survey Agency in the investigation of a complaint as requested by HCFA, the State Survey Agency, the Peer Review Organization, the provider/facility, or the patient."

Comment: RN 18 did not follow the HCFA policy for responding to patient grievances. (The specific violations, as they correspond to sections of the HCFA national policy found in the ESRD Network Organizations Manual, will be described later in this document). Rn 18 did not assist patient Jeanie Joshua with her grievance; RN 18 did not respond at all. RN 18 did not refer Jeanie Joshua's grievance, though it was both serious and immediate, to the appropriate HCFA Regional Office or other designated agencies within 24 hours of receipt. RN 18 made no investigation and no referrals.*

(Section 745.1) Network Responsibility in Grievances: "You are responsible for implementing a procedure for evaluating and resolving grievances involving patient care, conducting on-site reviews of facilities as necessary (as determined by the Medical Review Board or the Secretary), and utilizing standards of care established by the network organization to assure proper medical care."

Comment: RN 18 failed to implement any such grievance procedure for Jeanie Joshua even though she was being exposed to improper and life threatening medical care.

(Section 745.3) Reviewing Grievances: "Your responsibility is to review the issue(s) raised by the grievance and determine the action required (e.g. investigation and/or referral).

Comment: There was no investigation or referral for Jeanie Joshua.*

(Section 755.3) Determination of Network Involvement: "Only become in investigating and resolving grievances when the complaint affects a Medicare-eligible beneficiary..."

Comment: Jeanie Joshua is a Medicare beneficiary but did not receive the mandated response to her grievance.

(Section 755.4) Life Threatening Situations. "If the grievance you receive appears to present an immediate and serious threat to patient health and safety, forward the grievance immediately (within 24 hours of receipt) to the appropriate state agency and regional office associate regional administrator. Always notify your project officer of the situation. Your initial contact with the appropriate regional office may be via telephone and immediately followed by a

*See part 5, page 14, paragraph 6

written confirmation of the situation. If the regional office requests your assistance, make your services available in a consultative manner. Inform the patient that in addition to your involvement, his/her grievance has been forwarded to the regional office for review."*

Comment: Jeanie Joshua's grievance explained with specifics the life-threatening nature of the care ordered by David Abrams. M.D. RN 18 took no action and made no inquiry with Jeanie Joshua.*

(Section 765.2) Written Acknowledgment of Grievance: "When you receive a written or other grievance, provide written acknowledgment to the complainant within 15 calendar days. If you determine that a patient's grievance is more appropriately handled by another agency, inform the complainant of the referral in writing.* The letter must include the reason for the disposition, and provide the name, address, and telephone number of an agency contact person."

Comment: RN 18 made no response to Jeanie Joshua's grievance, not in 15 days, not ever.

(Section 765.3) Investigation of Grievance: "Process grievances/complaints. Assist in the resolution of the grievance by acting in the appropriate capacity (investigator, referral agent, coordinator, or facilitator) between the complainant and the facility, provider, or supplier. Interview patients, providers, and facility staff as appropriate. To facilitate the investigation/resolution process, when necessary, Network staff or consultants review medical or other records to make determinations about the quality of care provided. When necessary and appropriate, a grievance may be resolved by negotiating an improvement plan (IP) with the facility and monitoring the progress the facility makes to improve the problem area."

Comment: There was no investigation by RN 18 of Jeanie Joshua's grievance. There was no interview or contact with the patient, Jeanie Joshua.

(Section 765.4) Conclusion of Investigation: "Conclude your investigation within 90 calendar days of receipt of the inquiry, and issue a written report that maintains the confidentiality of the complainant. The name of the complainant can be made available to the State Agency on request. Send the report to the complainant.* (See Section 770). In those rare instances where more then 90 days are required, notify all parties in writing, including the HCFA project officer of the reason for the delay and the anticipated date for conclusion of the activity."

*Ibid

Comments: There was no investigation by RN 18. See Section 765.5, following.

(Section 765.5) Exception: "In life threatening situations, refer the grievance to the appropriate state agency and regional office within 24 hours of receipt. If the Network is requested to investigate the grievance, begin your investigation immediately and render a determination about the quality of care within 60 calendar days of the receipt of the grievance (See Section 755.4)."

Comment: Jeanie Joshua was being exposed to blatantly improper medical care which was life-threatening (See copy of grievance, dated February, 1999, attached). RN 18 took no action.

(Section 770.2; C) Potential Outcomes of Grievance Process. "Grievances are resolved when the complainant is satisfied that his/her concern(s) have been investigated, and an acceptable explanation or solution has occurred."

Comment: There was no resolution. Jeanie Joshua was systematically stripped of the rights and protections found in the federal regulations and the HCFA contract with RN 18. Jeanie Joshua was left with no support from any part of the dialysis system. In isolation, she sought the resolution which RN 18 had denied her.

(Section 775) Improvement Plans (IPs): "Request IPs whenever you have determined that a single problem or pattern of questionable care exists which has, or may have, an impact on the health or well-being of a patient. The intervention designed must correct the problem you identified..."

Comment: None of this was done, even though Jeanie Joshua's health was already undermined by the time of the grievance and the doctor's orders she was given put her in a life-threatening situation.

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2. Assuring Safety and Appropriate Care For Dialysis Patients.

The following federal laws were violated by RN 18:

(Chapter 7, 1395rr, C II 2 G): "(A Network) shall identify facilities and providers that are not cooperating toward meeting network goals and assisting such facilities and providers in developing appropriate plans for correction and reporting to the Secretary on facilities and providers that are not providing appropriate care."

Comment: The primary goal of the ESRD Network Program, as expressed in the RN 18's "Statement of Work," is "Improving the quality of health care services and quality of life for ESRD beneficiaries." The health care services given Jeanie Joshua by David Abrams, M.D. were contra-indicated and dangerous. Dr Abrams' services did not meet Network goals and needed to be reported. RN 18, apparently, made no such report.*

(Chapter 4, Section 405.2138 (b) (1): "Patients are afforded the opportunity to participate in the planning of their medical treatment and to refuse to participate in experimental research."

Comment: RN 18 allowed Jeanie Joshua to be exposed to reckless medical experimentation. Jeanie Joshua informed the Networks that the medical orders she was given by Dr Abrams were causing her serious harm. RN 18 made no response or intervention.

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The following federal contract obligations were violated by RN 18:

(Section 515.4. Developing a Network Intervention Activity): "Your specific intervention activity/or strategy must be based on practice guidelines, published literature; or community consensus. Focus your intervention plan on the following:

--Stimulating facilities/providers to develop their own improvement efforts...

--Stimulating behavior changes of individuals (for example; educating patients to obtain flu shots, or to not sign off dialysis early; educating physicians if dialysis treatment is under-prescribed)."

Comment: The Joshuas' grievance informed the Networks that Jeanie Joshua was given doctor's orders for treatment of hypertension which were contrary to the standard of care and which exacerbated her condition. The dynamics of hypertension--and its treatment--are fundamental. Home dialysis patients, by federal law, are trained to identify and respond to hypertension . (Reference: CFR, Title 42, Chapter 4, Sub-chapter B, Section 405.2137, (b) (7) (vi)). Further, in following the orders given by Dr Abrams, Jeanie Joshua's hypertension was made substantially worse, a fact that was reported both to the doctor and the Networks. But Dr Abrams would not change his orders and RN 18 made no intervention.

(Section C.1.A.): RN 18's responsibilities, as described in its Statement of Work, are to be based on "...the requirements of Section 1881 (c) of the Social Security Act, the Health Care Financing Administrations' (HCFA) Health Care

*Ibid

Quality Improvement Program (HCQIP) and other directives related to improving the quality of care of patients with end stage renal disease(ESRD)."

(Section C.1.D. The Health Care Quality Improvement Program): "The mission of HCQIP is to promote the quality, effectiveness and efficiency of services to Medicare beneficiaries by strengthening the community of those committed to monitoring and improving quality of care. The HCQIP's mission also includes communicating with beneficiaries and health care providers in order to promote informed health care choices, protecting beneficiaries from poor care, and strengthening the health care delivery system.

"The HCQIP supports the strategic goals of HCFA to assure health care security for Medicare beneficiaries. Health care security means:

--Access to quality health care;
--Protection of the rights and dignity of beneficiaries;
--Dissemination of clear and useful information to beneficiaries and/or their representatives, providers/facilities, and practitioners to assist them in making health care decisions.

"For the purposes of this contract, we are using the Institute of Medicine's definition of quality, which is: 'The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.' Using this definition, quality care under the HCQIP includes access to care, appropriateness of care, desired outcomes of care and consumer satisfaction."

Comment: RN 18 abandoned the federal government's guidelines referred to above. RN 18 afforded Jeanie Joshua no protection from poor care and no protection of her fundamental rights as a Medicare beneficiary and ESRD patient. In addition, RN 18 made no investigation or intervention even though it had been informed of patient Jeanie Joshua being given medical orders which were inappropriate and dangerous, produced only undesirable outcomes, and terror instead of consumer satisfaction. The care Jeanie Joshua was given, and which was described with specifics in the Joshuas' grievance, was not "consistent with current professional knowledge."

(Section C.4.G. Sanctions and referrals): "The Network's responsibilities for alternative sanction recommendations and referrals include the following:

--1....(Not directly applicable)
--2. Referring to the Peer Review Organization or the office of the Inspector General information collected while

conducting contract activities which indicates that a physician may be failing to meet his/her obligation to provide quality care.*

Comment: RN 18 did not follow its own instructions (see Patient Grievances, earlier in this document). RN 18 offered no assistance to patient Jeanie Joshua. RN 18. apparently, made no referrals though the issues in Jeanie Joshua's grievance were serious and immediate.* The 24 hour time limit for referral of serious and immediate grievances was not complied with. Instead of acting within the time limit guidelines, RN 18 didn't respond at all. There was, apparently, no investigation by any other agency as RN 18 did not inform the Joshuas of the option for involving any other agency and RN 18, apparently, did not contact any other agency on the Joshuas' behalf.*

(Section 705): "...Physicians who fail to comply with Network goals to such a degree that they are considered to be failing to meet their obligation to provide quality care must be referred to the Peer Review Organization (PRO) or the office of the Inspector General and/or the Board of Examiners of Physicians.

"All fraud and abuse cases should be referred to Federal or State fraud and abuse enforcement agencies responsible for the investigation or identification of fraud or abuse in the Medicare or Medicaid programs."

Comment: The medical abuse which Jeanie Joshua was subjected to by Dr David Abrams was blatant and serious. But RN 18 made no investigation and, apparently, no referrals."*

(Section 755.4) Life Threatening Situations. "If the grievance you (i.e. RN 18) receive appears to present an immediate and serious threat to patient health and safety, forward the grievance immediately (within 24 hours of receipt) to the appropriate Survey Agency and Regional Office Area Regional Administrator. Always notify your Project Officer of the situation. Your initial contact with the appropriate Regional Office may be via telephone and immediately followed by a written confirmation of the situation. If the Regional Office requests your assistance, make your services available in a consultative manner. Inform the patient that in addition to your involvement, his her grievance has been forwarded to the Regional Office for review."

Comment: The grievance the Joshuas sent to the Networks was explicit in the immediacy, seriousness and life-threatening circumstances Jeanie Joshua was put in by David Abrams, M.D. But RN 18 did not act within 24 hours; did not act at all. RN 18 never informed the Joshuas of any referral or action.

* See Part 5, page 14, paragraph 6

3.Home Dialysis

The following Federal laws were violated by RN 18:

(Chapter 7, Section 1395rr (II) (6)): "It is the intent of the Congress that the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for home dialysis or transplantation should be so treated."

Comment: RN 18 approved a transfer of Jeanie Joshua's care which would have ended her access to home dialysis. Jeanie Joshua had been on home dialysis for 3 years with a perfect record of safety and great overall success. RN 18's approval of an unwarranted transfer was in contradiction of the intent of Congress expressed in Chpt 7, Sec. 1395rr (II) (6).

(Chapter 4, Subchapter B, Part 405, Subchapter U, Section 405.2138 (b) (2)): "(Patients) are (to be) transferred or discharged only for medical reasons or for the patient's welfare or that of other patients, or for nonpayment of fees (except as prohibited by title XVIII of the Social Security Act),.."

Comment: There was no medical basis to transfer Jeanie Joshua's care. The proposed transfer, approved by RN 18, was not for Jeanie Joshua's welfare. The transfer would have ended Mrs Joshua"s home dialysis for no reason whatsoever, and would have required that she travel 80 miles in each direction to obtain dialysis in a unit. There was no issue of non-payment of fees. There were no other patients involved who could have benefitted from the transfer. Jeanie Joshua's grievance included specifics on her preference for and success on home dialysis.

(Section 405.2137: Condition: Patient long-term program and patient care plan). "Each facility maintains for each patient a written long-term program and a written patient care plan to ensure that each patient receives the appropriate modality of care and the appropriate care within that modality. The patient, or where appropriate, parent or legal guardian is involved with the health team in the planning of care. A copy of the current program and plan accompany the patient on interfacility transfer.

(a) Standard: Patient long term program. "There is a written long-term program representing the selection of a suitable treatment modality (i.e., dialysis or transplantation), and dialysis setting (e.g., home, self-care) for each patient.

(1)"The program is developed by a professional team which includes but is not limited to the physician director of the

dialysis facility or center where the patient is currently being treated, a physician director of a center or facility which offers self-care dialysis training (if not available at the location where the patient is being treated), a transplant surgeon, a qualified nurse responsible for nursing services, a qualified dietitian and a qualified social worker.

(2)"The program is formally reviewed and revised in writing as necessary by a team which includes but is not limited to the physician director of the dialysis facility or center where the patient is presently being treated, in addition to the other personnel listed in paragraph (a) (1) of this section at least every 12 months or more often as indicated by the patient's response to treatment...

(3)"The patient, parent, or legal guardian, as appropriate, is involved in the development of the patient's long-term program, and due consideration is given to his preferences.

(4)"A copy of the patient's long-term program accompanies the patient on inter-facility transfer or is sent within one working day."

Comment: The transfer of care approved by RN 18 violated and wrongly nullified Jeanie Joshua's long-term program and patient care plan. The most fundamental component of the plan, home dialysis, was discarded. Jeanie Joshua was not allowed input to her own care plan; no due consideration was given to her preference for home dialysis.

No social worker input existed in the change of plan or change of long term program.

The patient care plan made no mention of the treatment plan for Jeanie Joshua's hypertension, the treatment plan ordered by David Abrams, M.D.

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4. Patients' Rights

The following Federal laws were violated by RN 18:

(Title 42, Chapter IV, Subchapter B Part 405, Sub-part U, Section 405.2138 (b): Standard: Participation in planning.

(1) "Patients are afforded the opportunity to participate in the planning of their medical treatment and to refuse to participate in experimental research."

Comment: Jeanie Joshua was denied the opportunity to participate in the planning of her medical treatment. Her long-term plan, which called for home dialysis, and which had been in existence for 7 years, was unilaterally changed by David Abrams, M.D., with the approval of Renal Network 18.

Experimental, contra-indicated treatment of hypertension was ordered for Jeanie Joshua by David Abrams, M.D. The Joshuas informed the Networks of their extreme alarm at these developments but there was no response from RN 18.

(Section 405.2138 (b) (2)): "Patients are transferred or discharged only for medical reasons or for the patient's welfare or that of other patients, or for non-payment of fees (except as prohibited by Title XVIII of the Social Security Act) and are given advance notice to ensure orderly transfer or discgarge."

Comment: RN18 approved a transfer of Jeanie Joshua out of home dialysis and into a treatment center 80 miles from her home. There was no medical reason for the transfer and the transfer was not for Jeanie Joshua's welfare. As no other patients are involved in Jeanie Joshua's home dialysis, the transfer could not benefit any other patient. There was no issue with non-payment of fees.

(Section 404.2138 (c)): "Standard: respect and dignity. All patients are treated with consideration, respect and full recognition of their individual and personal needs, including the need for privacy in treatment. Provision is made for translators where a significant number of patients exhibit language barriers."

Comment: Jeanie Joshua was not treated with consideration or recognition of her needs. In the midst of a crisis created by inappropriate medical care, her request for assistance from the Networks (i.e. RN 18) was ignored. Instead of speaking to Jeanie Joshua, RN 18 spoke only to Mrs Joshua's providers. RN 18 then approved the transfer of Jeanie Joshua's care. The transfer would have closed off Mrs Joshua's access to home dialysis, forcing her to travel 80 miles in each direction to obtain dialysis in a unit. This plan was not only an unworkable burden for Mrs Joshua, it is also contrary to the intent of Congress expressed in Federal regulations, Title 42, Chapter 7, Section 1395rr (II) (6): "It is the intent of the Congress that the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for home dialysis or transplantation should be so treated."

At no time did RN 18 communicate with the Joshuas.

RN 18 approved a transfer of care which is prohibited under Federal Regulation 405.2138 (b) (2). (See 2nd paragraph, this page).

(Section 405.2137: Condition: Patient long-term program and patient care plan. "Each facility maintains for each patient a written long-term program and a written patient care plan to ensure that each patient receives the appropriate modality ofcare and the appropriate care within that modality. The patient, or where appropriate, parent or legal guardian

is involved with the health team in the planning of care. A copy of the current program and plan accompany the patient on interfacility transfer."

(a) Standard: patient long-term program. "There is a written long-term program representing the selection of a suitable treatment modality (i.e., dialysis or transplantation) and dialysis setting (e.g. home, self-care) for each patient."

Comment: The treatment plan given by David Abrams MD to Jeanie Joshua for treatment of hypertension was inappropriate and exascerbated Mrs Joshua's condition. She requested intervention from the Networks but received no attention.

Jeanie Joshua's long-term program called for home dialysis. The transfer approved by RN 18 would have ended Mrs Joshua's home dialysis.

(b) Standard: patient care plan. "There is a written patient care plan for each patient of an ESRD facility (including home dialysis patients under the supervision of the ESRD facility; see 405.2163(c)), based upon the nature of the patient's illness, the treatment prescribed and an assessment of the patient's needs.

(1) "The patient care plan is personalized for the individual, reflects the psychological, social, and functional needs of the patient, and indicates the ESRD and other care required as well as the individualized modifications in approach necessary to achieve the long-term and short-term goals.

(2) "The plan is developed by a professional team consisting of at least the physician responsible for the patient's ESRD care, a qualified nurse responsible for nursing services, a qualified social worker and a qualified dietitian.

(3) "The patient, parent, or legal guardian, as appropriate, is involved in the development of the care plan, and due consideration is given to his preferences.

(4) "The care plan for patients whose medical condition has not become stabilized is reviewed at least monthly by the professional patient team described in paragraph (b) (2) of this section. For patients whose condition has become stabilized, the care plan is reviewed every 6 months. The care plan is revised to insure that it provides for the patient's ongoing needs"

Comment:Jeanie Joshua's patient care plan and long-term program were arbitrarily overturned by David Abrams, MD, depriving Mrs Joshua of the standards and rights listed in (b) and (b) (1), (3), and (4).The Joshuas requested intervention by the Networks on the issues of inappropriate medical care and improper transfer of care. The Joshuas received no response from RN 18. RN 18 made no investigation and proceeded

to approve a transfer of care which took away Jeanie Joshua's rights.

A social worker was never included in the changes to Jeanie Joshua's patient care plan and long-term program.

Information about the hypertension treatment orders made by David Abrams, MD was omitted from Mrs Joshua's patient care plan.

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5. Records, Reports, Notices and Referrals

RN 18 has refused to release their records concerning Jeanie Joshua. This situation has existed since May, 1999, when Mrs Joshua signed a release statement requesting that the records be provided to her U.S. Senator, Dianne Feinstein.

In February, 2000, a request was made for RN 18 to provide a copy of its 1998 Annual Report and copies of its 1999 Quarterly Reports to Senator Feinstein. The request was denied.

The refusal of RN 18 to turn over the requested documents is a violation of the contract between Health Care Financing Agency and RN 18. From that contract:

> "All data and analyses produced under this contract shall become the exclusive property of the Government which may make, without any recourse to the Contractor, any use thereof as may be deemed appropriate. Furthermore, the Government shall have the right to review and copy any documentation accumulated and developed by the contractor in performance of this contract." (Section H, Special Contract Requirements, 7, (c)).

The contract between RN 18 and HCFA contains requisite procedures for handling patient grievances. Grievances of a serious nature, such as the one from the Joshuas in February, 1999, require that RN 18 make specific referrals to other agencies as steps toward grievance resolution. The contract also requires that the patient be notified of the referrals.

The absence of notices to Jeanie Joshua is the criteria used in this document to conclude that, apparently, no referrals were made in response to her grievance.

The Quarterly Reports from RN 18 for 1999 are required to include information on grievances received during the year. Those reports cannot be accurate because of the non-response of RN 18 to the Joshuas' grievance.

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Addendum

Addiitonal laws related to dialysis were broken by RN 18 in the time period February,1999 through May, 1999. To understand how those laws applied, it may be helpful to explain the circumstances in which they occurred.

At the time of her grievance (February, 1999), Jeanie Joshua had been on home dialysis for 7 years. She had a perfect record of safety and excellent treatment results. She had a productive, active life, including tutoring students in math.

Jeanie Joshua and her husband, Sholom, were trained by licensed medical staff to perform hemo-dialysis at home. They were also trained in the dynamics of hypertension, as required by Federal law (Chapter 4, Sub-chapter B, Part 405, Subpart U, Section 405,2137 (b)(7)(vi)). That training included the causes of hypertension and its remedy.

In December, 1998, Jeanie Joshua developed hypertension for the first time. Various medications were only minimally effective. Her hypertension did improve when her fluid volume was lowered. Because she has no kidney function, Mrs Joshua essentially can remove fluid only by dialysis..

In late January, 1999, Dr Davis Abrams gave Jeanie Joshua orders to deliberately add extra fluid volume and to decrease the frequency of dialysis.

The orders given were the opposite of the training Mrs Joshua had received.

The orders exascerbated Jeanie Joshua's hypertension to an extreme degree.

David Abrams, MD was informed repeatedly by Mrs Joshua that his orders were exascerbating her hypertension. Dr Abrams told Mrs Joshua to continue with his orders.

In February, 1999, Jeanie Joshua filed a grievance with the Renal Networks. She told the Networks that her health was worsening due to Dr Abrams orders and asked the Networks to intervene. There was no response to Mrs Joshua's grievance.

During the time period March, 1999 through April, 1999, Mrs Joshua tried to find another nephrologist to take over her care, a nephrologist who would sponsor home dialysis. Her efforts were handicapped by two factors: (1) There was no way she could explain what Dr Abrams was doing without confounding a prospective nephrologist (2) Jeanie Joshua's health was so undermined by Dr Abrams that she had little strength to do anything.

In April, 1999' Jeanie Joshua went to a meeting at her dialysis back-up unit. She was told that RN 18 had approved the transfer of her care out of home dialysis to a unit in Los Angeles, 80 miles away from her home. Jeanie Joshua protested that the transfer was against the law and consequently she would not agree to it. She asked to speak with the unit's medical director.(an M.D.). She asked him to

temporarily take over her care so she could continue to look for a nephrologist for her ongoing care. The medical director refused. Mrs Joshua asked the medical director to let her tell him what had happened to her since February, 1999. The medical director said he didn't want to hear the account.

Mrs Joshua was told there would be no provision for temporary coverage by any physician associated with the unit. Then she was told one unit doctor might be willing to be her regular doctor, if she passed an interview. All the other unit doctors had already decided amongst themselves that they would not be available to provide any care (Most of these doctors had never met Mrs Joshua).

Jeanie Joshua's experience with her unit's medical director contrasts with the following Federal laws:

--Section 405.2136 (g) "Standard: Medical supervision and emergency coverage. The governing body of the ESRD dialysis or transplant facility ensure that the health care of every patient is under the continuing supervision of a physician and that a physician is available in emergency situations."

--Chapter 7, Subchapter XVIII, Section 1395a. Free choice by patient guaranteed. (a)"Basic freedom of choice. Any individual entitled to insurance benefits under this subchapter may obtain health services from any institution, agency, or person qualified to participate under this subchapter if such institution, agency, or person undertakes to provide him such services."

Jeanie Joshua was given no freedom of choice as she was given no temporary coverage necessary to exercise that freedom. In effect, Jeanie Joshua was being told that she had no rights in the whole situation.

Jeanie Joshua informed the medical staff at the unit meeting that she could not give up her rights. In response she was told she would no longer be given any medications or laboratory tests; that she was on her own.

The dialysis delivery system, with the participation and approval of RN 18, had created a situation of extreme trauma for Mrs Joshua, and violated multiple Federal laws meant to protect dialysis patients.

In May, 1999, with no assistance from RN 18 or anyone involved with her care, Jeanie Joshua was able to make arrangements with a doctor of her choosing. Through these new arrangements, she has been able to continue with her home dialysis.

In Jeanie Joshua's 8 years on home dialysis, she has met or exceeded all Federal and common sense goals for an ESRD patient. Throughout her years on home dialysis, she has required little time or involvement from her dialysis providers.

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Final Thoughts

Patients who are not treated properly are encouraged, in

the Federal regulations, to file grievances with the Renal Networks. The law states:

(Chapter IV, Subchapter B, Part 405, Subpart U, Section 405.2138 (e): Standard: grievance mechanism. "All patients are encouraged and assisted to understand and exercise their rights. Grievances and recommended changes in policies and services may be addressed to facility staff, administration, the network organization, and agencies or regulatory bodies with jurisdiction over the facility, through any representative of the patient's choice, without restraint or interference, and without fear of discrimination or reprisal."

If a network does not respond to a grievance--as happened to Jeanie Joshua--or responds inadequately, the patient has, in practical terms, nowhere to turn.

The many Federal laws enacted to protect ESRD patients are of no avail if a Network does not fulfill its responsibilities. A dialysis patient cannot, realistically, pack his bags and go somewhere new to get proper care. Most dialysis providers are for-profit entities and tend to function as a business where the complaining "customer" is generally perceived to be wrong--no matter what. Reputations follow the patient from one provider to another. Because patient rights tend not to be enforced (Jeanie Joshua's experience is a graphic example), providers can decide to refuse dialysis to a patient. This is a frightening scenario. (One noted exception to this practice is in the case of prisoners who require dialysis. Because prisoners have the assistance of law enforcement, they are not turned away by providers. Even prisoners known to be violent will be escorted right into a facility, with guards provided as a protection against trouble).

But for the lone dialysis patient, most of whom are older individuals with poor or failing health, there is no assistance. If the dialysis delivery system decides to close its doors, the patient's only recourse is an emergency room and the courts.

Additionally, dialysis providers are frequently formed into groups. Often there is only one group where the patient lives. The patient, for fear of no dialysis, tends to be quiet about poor care.

Another important issue is the under-utilization of home dialysis. Only 1% (approximately) of hemodialysis patients receive treatments at home, even though it is an established fact that patients do better, feel better, and have healthier, happier lives on home dialysis.

The Renal Networks are entrusted to "Improving the quality of health care services and quality of life for ESRD beneficiaries." A fundamental responsibilty of the Networks, to fulfill its stated goal, is the investigation and resolution of grievances. Failure to do this is a betrayal of the public trust.

The Federal regulations provide for the termination of a Renal Network that has failed to fulfill its responsibilities:

(Chapter 7, Subchapter XVIII, Part D, Section 1395rr (c)(ii) (II): "An agreement with a network administrative organization may be terminated by the Secretary only if he finds, after applying such standards and criteria, that the organization has failed to perform its prescribed responsibilities effectively and efficiently. If such an agreement is to be terminated, the Secretary shall select a successor to the agreement on the basis of competitive bidding and in a manner that provides an orderly transition."

ATTN: Mr. Cecil Swamidoss - per our recent phone conversation, I am forwarding this material

I am a Professor of Psychology at Cleveland State University and have been a dialysis patient starting in 1995.

I receive my B.A. at Harvard College in 1965 and my Ph.D. in Psychology at Columbia University in 1974.

I will be happy to provide more information if it would be helpful.

Best wishes, RJS
Bob Sollod

Senate Office Building
Washington, D.C.

Dear Senator Grassley

It is only a couple of days ago that I became aware of your hearings on the U.S. dialysis crisis. I have not have time to present a complete response for the hearings, but I have put together as much as possible within the brief time allotted.

I started dialysis about five and a half years ago. Since that time, I have been on hemodialysis a total of four years, a transplant almost one year and peritoneal dialysis about a half a year. I will restrict my comments here to hemodialysis as administered in a dialysis center.

I am a 58 year old college professor of psychology. I have continued teaching, writing, research and other activities during this period although not at the level I could achieve earlier. I am currently putting in three afternoons and early evenings a week to receive dialysis (15 hours in all at the dialysis center).

Most recently, I noticed a large staff turnover at our dialysis center. This was not atypical, but not only were technicians turning over this time, but so were nurses and

supervising nurses. The new technicians were poorly trained. For a month,I did not notice anyone washing his or her hands. Technicians would go from one patient to another without changing gloves. This is an extremely dangerous practice as it may involve preading deadly viruses and bacteria from one patient to another. One technician had long fingernails and a lot of jewelry at the same time I was watching a television show about the dangers of the spread of infection in just such a manner with premature infants. Technicians would be working on a patient and paying attention at the same time to someone else ten yards away and carrying on a conversion. Technicians would (and still do) engage in loud banter when patients are trying to sleep. There seemed to be little or no regard for a sterile field as after the needle site was swabbed with alcohol, technicians would carelessly touch it.

Patients did not wash their own hands or fistulas prior to treatment. Food sharing between patients was allowed.

I complained to the center's national headquarters, and the CEO emailed me and promised he would take action. There was subsequently some improvement, but most of it resulted after I printed up a large card saying, "Please be sure your hands are clean and that you have new gloves on before working on me or on touching tubes containing my blood. Thank you for your consideration." In a few cases, I would not let technicians approach me until they had washed their hands. They were not pleased, but I knew I had to protect myself.

The scenario's detailed above are symptomatic of a system in crisis.

Here are some - only a few - of the many problems of which I am aware.

The technicians are overworked. They are assigned four patients at a time. Only a few years ago, they had only three. The history here is educative. Once doctors, then mostly nurses and now technicians are mostly administering dialysis.

Medical consultations are few and far between. My doctor sees me at most ten minutes a month. Various medical conditions can and do slip between the cracks even though I make every effort to keep up with what is going on. For example I was losing much bone mass as a result of hyperparathyroidism (common in kidney failure). Some two or more years went by before I realized that I needed a partial parathyroidectomy. By the time it was done, I had severe osteoporosis. My doctor had mentioned it once earlier and I had not followed up as a result of other complications at the time. He did not take it upon himself either to have me check my bone density again or to suggest that I have the surgery done. Many

patients develop life threatening osteoporosis when it could have been prevented with a parathyroidectomy.

To generalize, dialysis patients usually have problems with many systems. A few minutes a month of medical consultation is not enough for them to get adequate care.

As far as I can see, there is no-one working to support dialysis patients in obtaining or maintaining employment. The scheduling of dialysis does not easily accommodate people working a normal schedule.

There is no effort towards rehabilitation of patients - period.

Psychological counseling or referrals for patients seems nil.

There is little or no preparation for patients prior to dialysis. They receive little or no information about dialysis or how to cope with it. They no little about the procedures or about the medical aspects of dialysis. There is often very little orientation - and no continuing education about how to cope with dialysis.

Subsequently, I routinely see patients taking off too much fluid and having cramps or becoming faint (or fainting) without either they or a technician realizing that the settings have to be adjusted for weight change. Many patients do not even know that the best way to avoid fluid accumulation between sessions is to avoid salt. "Water follows salt" is a dictum with which most are not familiar.

There is little awareness about the benefits and drawbacks of transplants.

Supplies are inadequate. Sometimes supplies are second-rate. Dialyzers are reused to save a few dollars, but with major consequences for the safety and health of patients. Reuse of dialyzers is rare in Europe, where the mortality rate is considerably lower.

Doctors are referring patients to centers in which they have a financial stake. This very factor alone mitigates against any real effort to improve a center.

Citizens cannot find out the comparative mortality, hospitalization or infection rates among centers. One does not know if one is entering a comparative death trap or not.These figures MUST BE MADE PUBLICALLY AVAILABLE. They could be adjusted for type of patient and pre-existing severity of complicating

conditions.

There is no Medicare incentive for centers to improve the health of a patient or to help him or her improve the level of functioning - including employment status. There must be INCENTIVES for this type of effort.

Centers are inflexible in treatment schedules. It is an assembly line. Efforts to have all-night therapy, four-day a week therapy and other varieties as have proven successful in other countries are not even considered. Programs to teach patients to administer their own dialysis are far and few between.

There is little incentive or opportunity for new dialysis protocols.

Senators, this is a crisis. Of our 350,000 dialysis patients, about 20% die annually. This 70,000 is greater than our losses in Vietnam. Our death rate should be at least 1/3 lower to match the rate in other Western countries. Saving 21,000 extra lives a year is a worthy goal. But improvement in dialysis would also enable the lives of many of the 350,000 to be happier and more productive. Many immediate family members are also harmed at present. There is every reason to believe that, with current technology, even more lives can be prolonged.

In an attached document, I have summarized in narrative form my experiences with the health system and, in particular, those relating to treatment of kidney failure and ESRD. It is a personal document, but I hope it will be relevant and useful in conveying some of the experiences that may occur in our struggling dialysis care system.

Sincerely,

Robert N. Sollod, Ph.D.
Professor of Psychology
Cleveland State University

attachment: Beyond the Safety Net

Living Beyond the Safety Net: Narrative of a Dialysis Patient

Robert N. Sollod, Ph.D.

I am a middle-aged academic and practicing clinical psychologist in the Mid-West ("middle-aged, middle class and in the Mid-West") with a background of helping people with many problems in different clinical settings. As a university professor, my scholarly activities have been in the area of the history of psychotherapy, the integration of different approaches to psychotherapy and the relation of psychology to religion.

In 1990, I spent part of my Sabbatical in Cyprus, where I studied with Daskalos, a Greek Orthodox mystic, healer and teacher. His teachings vitalized the spiritual dimension of my life. He had a deeply transformative presence, and his convictions seemed to come directly from experience. He asked his students, "Do you have a soul? No, you are a soul and you have a body." He urged people to accept whatever life brought as part of a Divine plan and to learn from all life's experiences. He perceived death as not an end to life but as a "change of state". Overcoming egoism through daily self-examination was a central theme. He taught that we are responsible for our thoughts and feelings and could develop an awareness of spirit. He conveyed and promoted an egalitarian attitude toward others. I learned much about the relation of spirituality to psychology and was looking forward to the possibilities ahead of me. I believed I was not only a seeker but also a "finder" and could convey some nuggets of truth to others. I thought that I would be able to pursue real psych-ology, literally, in Greek, the study of the soul. I did not realize that these teachings would shortly become essential for me.

I returned to the states in December 1990, in time to avoid the onset of the Gulf War, which shortly would ensue near Cyprus. was sweaty, exhausted and dizzy by the end of the

airplane trips home. I suffered from fatigue and often became exhausted during the next few weeks. I was very irritable. Jeanine and I joined a health club to improve our fitness. On the first try- out of the assigned weight-training exercises, I became out-of- breath, very sweaty and had to stop. Jeanine was concerned when she saw me lying down, exhausted, on a bench at the health club. I reassured her that I was just out of shape. I did not imagine anything serious and certainly did not link this with my experience in Cyprus. An exercise supervisor required me to get a doctor's approval before returning.

I visited to my primary-care doctor, who examined me and ran some blood tests. He phoned me a few days later and informed me that my creatinine level was high - an indication of kidney failure. At a subsequent appointment, he told me that my prognosis was end-stage renal disease (ESRD) - with either dialysis and/or a transplant in the offing. I was stunned and at first did not fully believe or accept this abruptly conveyed diagnosis. During the next few weeks, I spent long periods alone in order make sense of my situation. I thought of illness and death while life around me went on as usual. Others were concerned with summer vacations, departmental politics, automobile repairs, minor medical problems and the news of the day. I sought the strength to cope with what might be in store.

I felt blind sided because no doctor had informed me that I was a candidate for kidney failure. I had hyperlipidemia and moderately high blood pressure for many years. These conditions had been treated symptomatically. No-one had pointed out their connection with or the seriousness of an underlying chronic nephrotic syndrome. My HMO physicians had never referred me to a nephrologist. Even if my condition and prognosis had been adequately formulated, however, there was no indication that any treatment could have prevented a

downward slide.

Oddly enough, the very next day one of my students reported that her cat had been diagnosed with kidney failure and would shortly have to be "put to sleep." The cat had been urinating "all over the place" for many months and had finally been diagnosed by a veterinarian as having kidney failure. I was surprised and amused by the coincidence or synchronicity involved, identified with the cat and offered, jokingly, "Would you ever consider cat dialysis?"

I learned that kidneys could deteriorate for many years without symptoms of uremia, a serious condition caused by the buildup of waste products in the blood and body tissues. A person could live normally on as little as 20 percent of kidney capacity. Apparently, my kidneys had been deteriorating for many years but had been functioning at more than this essential 20 percent.

A few months later, in July 1991, I switched from my primary care doctor in an HMO to a major medical center for a more complete appraisal. After an initial interview and evaluation, I was marking time in the cafeteria. ("They don't call us patients for nothing.") An announcement on loudspeakers indicated that I should return to the nephrology clinic. A staff person there said that it was important to for me to be seen right away. He said that they had put out an "all points bulletin" for me. "What's the urgency?" I asked a doctor. "We want to be able to see you next week." He said that, if I continued to take vasotec, I might die suddenly. Vasotec was the antihypertensive medication I had been prescribed for many years. The doctor indicated that vasotec raises the potassium levels in people with kidney failure. In my case, I was informed, blood values of potassium were at a potentially lethal level. The first symptoms of too much potassium in the bloodstream, I was told, are cardiac arrest and sudden death. I was given some

samples of a different anti-hypertensive to take. I was stunned by the doctor's abruptness as well as by what he had to say.

I reported the information to my affable primary care physician, who had been responsible for the vasotec prescription. In a barely audible voice, he indicated that he was unaware of vasotec's potentially lethal side effect in kidney patients. His ignorance might well have resulted in my death, and nobody would have discovered the cause. As I left his office, I had mixed emotions. I was disappointed and angry. I had been let down by someone I liked and had trusted. His warmth and concern did not compensate for gaps in his knowledge.

I realized that I could not completely rely on physicians' advice nor ever again automatically trust their conclusions or regimens. I decided to become more self-reliant in my approach to medical care. I wrote some letters to newspapers about the inadequacies of HMOs, but they were not published - possibly because HMOs were popular in the early 1990s and considered a progressive solution to the rising costs of health care.

The next few years involved living with increasingly severe kidney failure. I became more and more uremic but did not yet need dialysis, my symptoms being fatique, weakness, incessant itching, poor appetite, bloating, irritability, and difficulty concentrating. I had not known anyone who had kidney failure. felt isolated in my struggle with this uremic syndrome. Not surprisingly, Jeanine was concerned about my deteriorating condition.

Using my scholarly habits and skills, I tried to become an expert on kidney failure. I asked doctors and nurses many questions, did computer searches and read articles in medical journals. I remember commenting, "My brain is trying to save my other organs." With the concurrence of my new primary physician, I concluded that it was

worth trying massive doses of cortisone in order to protect my remaining kidney functioning.

Mood changes, fluid retention and weight gain are among the side effects of cortisone treatment. The alternate-day regimen of cortisone resulted in elation on days when I was taking cortisone. Withdrawal symptoms of enervation and great fatigue occurred every other day. My academic productivity alternated from day to day. I was able to write some publishable articles during the good days. Given my sense of a limited future, I was committed to focusing on topics close to my heart - which might be of real benefit to others. One article, which received much favorable attention, was entitled "The Hollow Curriculum". it discussed the omission of teaching about religion in higher education. Invitations to speak nationally followed, but I was too exhausted much of the time to be willing to accept them. I also wrote an article about the utility of techniques and concepts drawn from healing and spiritual traditions in psychotherapy.

Full of hope, I tried some alternative treatments, including hands-on healing touch. A practitioner would presumably send "chi"or prana, forms of subtle energy unknown and unaccepted by modern science, into the kidneys. The chi was thought to open up any energy blockages that might have contributed to the kidney failure. This alternative approach was beneficial in that it increased my somatic awareness and helped me access some suppressed emotions. It helped me understand some of the connections between my emotions and physical states. I traveled to see a Chinese herbalist in New York and an Eastern European "healer" practicing in Bethesda - one recommended by a friend and the other in a newspaper article. A healing group intended my healing and well-being. I believed that spiritual healing might arrest or reverse my condition. But neither conventional medical treatment with cortisone nor alternative healing methods prevented the ongoing and inexorable deterioration of my kidneys.

I did find that practicing meditative self-observation and sometimes reaching an inner awareness or presence lightened my mood. I felt better without actually becoming better. I continued to pray for healing, if that was God's will. I wondered what the purpose of this illness might be.

Some of my friends and acquaintances indicated that they thought my illness was a result of a personal failing of some sort. I found myself in partial agreement. They said that, if I changed my thoughts and emotions, my kidneys would improve. Having normal kidneys and being in good health, they exuded a distinct sense of superiority and self-satisfaction. They also recommended numerous forms of herbal and vitamin medicine, acupuncture or tai chi that had worked for them. One confidently suggested that I drink a lot of water - bad advice for a person excreting little urine.

After a while, I realized that, in practically every case, those who recommended and swore by alternative treatments had not confronted anything more than malaise or mild symptoms of depression. I found their attitudes to be poorly informed, judgmental, condescending and irritating. Some acquaintances, I found, actually started to avoid me. I was told that my illness made one of them uncomfortably aware of his mortality. I often spoke about the general nature of my disorder but preferred not to go into details unless I felt relaxed, and particularly open, with someone.

I continued teaching but stopped seeing psychotherapy clients except for brief consults. This was the first time in my career that I was not engaged in the practice of psychotherapy. This activity was an early causality of kidney failure. I had to acknowledge the potency of this illness and the importance of physical health. I was also too sick to continue in a pro bono inner life support group I had formed. It went on without me. I did not trust, given my concerns about

medical problems, that I could function as an effective psychotherapist. Nor was I able, as I jettisoned downhill, to elaborate creative ideas in scholarly journals. I had enough intellectual stamina to write short reviews, comments and letters for professional journals, but scholarly articles were too taxing to complete. Nonetheless, I wanted to continue to work for a positive legacy.

During this period, I committed myself to initiating community service efforts at the university. I was feeling very itchy, tired and nauseous much of the time. In spite of numerous obstacles and indifference on the part of some administrators, I was able to organize many faculty, staff and students to promote community service and service learning on our large urban campus. I was trying to make a difference in the limited time that appeared to be left to me. It was an often lonely quest. I often tried to emulate the dying protagonist in Carissa's film, Acer, who struggled to have a playground built in spite of terminal cancer and bureaucratic obstacles.

I became very involved in helping to form a new faculty union. Even though not feeling well much of the time, I became the Chief Negotiator at the beginning of a difficult initial negotiation. Dealing with my illness had somehow helped me have the courage and toughness to face an unpleasant administration Chief Negotiator. My continuing struggle with a chronic illness cast a bright shadow in the high regard that many others felt for me. The teamwork and camaraderie with other faculty union members boosted my morale and helped me overcome a sense of isolation.

We did achieve our first union contract. It included equitable proposals that would not help me personally but would have a positive impact generally. It was a remarkable achievement to convince the faculty to go without an across-the-board pay raise for one year in order to

provide funds to establish minimum salaries per rank. Our negotiations, from which I had to withdraw for health reasons, resulted in greater salary equity - particularly for female faculty members. Greater professional security was written into the contract. Some colleagues were encouraged to give up their moonlighting jobs outside of academia.

Returning now to my illness, I wondered what personal failings if any had contributed to my kidney failure. A renal biopsy indicated cellular sclerosis (scarring). The most likely etiology was a strep infection many years earlier followed by consequent inevitable deterioration of my damaged kidneys. I was relieved that my personality did not appear to be at fault.

I saw an article in a scientific journal about an experimental treatment for kidney failure involving a genetically-engineered insulin-like human growth factor. This growth factor had stimulated kidney regeneration in laboratory animals. Its effects on humans were unknown. I decided to apply to be a subject in this program conducted at a medical center in St. Louis - about a thousand miles from my home in the suburbs of Cleveland. My condition turned out to be suited to the experimental protocol. I was one of a handful of people to be accepted into the program. In Spring of 1994, I spent more than seven weeks as a guinea pig while receiving large doses - worth about a million dollars ($20,000 per injection) - of the experimental human growth factor. I became a valuable research subject. I hoped to prevent or at least forestall the need for dialysis.

Roles as scholar and therapist emerged in addition to my roles as experimental subject and patient. Aside from times for specific tests, I was given the run of the hospital and the city. I often went to the medical library among the researchers and medical students, where I spent many hours reviewing the latest nephrology journals. I was also writing a study guide for a

personality theory textbook on a laptop computer. One of the doctors involved in the research project was extremely knowledgeable, friendly, informative and compassionate. He treated me as an equal. I spent some time almost every day finding out more about the vicissitudes of kidney disease, dialysis and transplantation.

I felt a sense of kinship with the other kidney-failure patients I met. We used the abundant free time to discuss the ins and outs of kidney failure. One patient had undergone a successful kidney transplant from a living donor. I saw this patient's result as one that would likely occur in my future. I had been assured by my sister that she would donate a kidney to me.

I also met other research patients with different conditions and experimental protocols. As George Burns quipped about old age, I " . . . had the opportunity to learn about all kinds of diseases that I didn't know existed." One patient, a Peruvian teenager, had a rare genetic disorder that made his skin so sensitive to light that he could not go outdoors. His face was scarred with numerous cancerous and pre-cancerous lesions. I listened to his concerns and cheered him up with some fanciful suggestions such as being completely covering himself with opaque garments. I tried to be helpful to other patients and often reflected upon our comparative fates. Oddly, I found myself enjoying my combination of roles as a patient-experimental subject-investigator-helper. This hiatus was a reprieve from the pressures of daily life. I was able to meditate, to practice self-observation and to experience an inner presence on a regular basis.

My kidneys did start to improve from the growth factor - with marked increases in my energy and stamina. It seemed miraculous to reverse the course of the disease - to feel less itchy and more energetic. I became hopeful that progress would continue. I visualized healthy kidneys and used autosuggestion to enhance the effects of treatment. I was pleased to discover that I had

become able to walk miles without fatigue when I participated in a Kidney Foundation march to encourage kidney donations.

The therapeutic effects of the experimental treatment, however, shortly faded. My kidney failure symptoms increased. The doctors concluded that further treatment was useless and decided to stop administering the growth factor. I was disappointed in this development and likened myself to Cinderella when the clock struck twelve. My condition reverted back to what it had been. The magic was over. Side effects of the research project included noticeable thickening of my skin. In addition, for the first time, doctors detected a heart murmur.

Upon my return home, I decided to postpone dialysis as long as possible. This could be accomplished by following a strict low protein diet - to keep the level of blood urea nitrogen low. This approach was controversial but had been mentioned favorably in some medical journals and by one of the doctors in the experimental program. My nephrologist disapproved. He insisted that I arrange for vascular surgery to make dialysis possible immediately and begin dialysis as soon as possible. He said that he would not see me any more until this had been done. My trust in the infallibility of medical advice had already been shattered. I called back the next day and told his answering machine that I was determined to go without dialysis as long as possible. He did not call back. Later I learned that he was known to have an authoritarian style - made worse because he had just recovered from surgery himself and was not at his best. I quickly found another nephrologist, who agreed to help me stay off dialysis as long as possible.

My understanding of the world and of myself was shifting profoundly. Few areas of my thinking or interacting were unaffected. I was already irrevocably marked like a butterfly whose wings had been touched. I was growing less concerned about the approval of others. I became

more open and direct in my approach to teaching. My weighing of priorities had changed in light of my sense of a limited future. I realized I would have a different approach in the way I could work with and help others, but I was not sure exactly how. Some people urged me to formulate and write down my observations and insights. I did not feel I had the luxury to stand back and thoroughly analyze how I was changing. I was vigilant regarding the changing nature' of my medical condition.

As the waiting list for a cadaveric kidney was very long, my last hope to avoid dialysis was that my sister would donate her kidney before I needed to begin. I told a number of friends and acquaintances that I would not need dialysis as I was fortunate that my sister who would donate a kidney. This was reasonable as, very early, she had volunteered to donate a kidney. Her compatibility was positive. But she kept putting off the scheduled surgery. She and her husband began to become more fearful about the anticipated discomfort and risks of surgery and inconvenience of travel away from home (My insurance policy would not cover hospitals in her region.). She also indicated that her mild hypertension disqualified her.

I obsessed about whether she was unwilling or unable to donate a kidney. My doctor told me not to think about it ("Don't go there"). I went along with his terse advice even though I considered it lacking in psychological sophistication. my sister would not or could not rescue me. It was her choice to make, for whatever reason. I felt abandoned by her. My sense of isolation and separation from the flow of life became stronger. A few weeks later, she revealed that she had an unsettling dream in which I had died because I did not receive a compatible kidney transplant. I was not reassuring when I replied, "It could happen." She paused and went on to the next topic.

I was surprised at what I had said but did not feel I should apologize. Other "places" I knew not to go too often were the self-pitying place and the morbid-imagining-of-dire-futures place. I realized that these attitudes were wrong from a spiritual point of view. They also deflected my limited energy from the goals of maintaining my morale, continuing my necessary activities, and coping with daily life. It was essential for me to maintain a certain mental and emotional discipline. when others wanted me to get upset about something, I learned to reply, "Worry is a luxury I cannot afford." Daily periods of self-awareness and practicing a spiritual presence were vital for maintaining an inner sense of well-being. I tried to nurture positive and life- enhancing thoughts and to avoid most negativity.

I was able to postpone dialysis until March, 1995. This was almost two years since it had almost been forced on me. In spite of the continuing "healing hands" treatment and the low protein diet, I became increasingly uremic. I remember that, during this period, I often engaged in meditative awareness of my body's movements as I trudged slowly and breathless to meet my classes. I started having frequent nosebleeds, one symptom of severe uremia. My skin developed a yellowish tinge and, as Jeanine let me know, I had a pronounced urine-like odor. My doctor and I finally agreed that I had to begin dialysis. My diagnosis was now end-stage renal disease (ESRD), a term that assuredly is not a euphemism.

Starting dialysis would mean the end of my life as I knew it. A social worker informed me that a large percentage of relationships break-up and many people are no longer able to work as a result of the burden of dialysis and its complications. Both Jeanine and I felt apprehensive and disoriented when we first heard the details of dialysis. It triggered fears of illness, loss and death. Neither of us was confident about the future. As I approached the onset of dialysis, Dante's

phrase for the sign on the entrance to hell occurred to me: "Abandon hope, all ye who enter." The future appeared bleak as I began to yield to hopelessness. I felt as if I was drifting, untethered, out into space - like the astronaut in 112001". While ordinary life went on as usual around me, my mind was centered on the meaning of my life and on human mortality. I knew that I would shortly die, were it not for the invention of dialysis.

My nephrologist suggested that I start dialysis without missing a beat - without missing any work or activities. He was right. I was able to proceed with dialysis quickly and without interruption of my teaching schedule. It looked as if I could maintain my university responsibilities. I was pleased.

I entered a world that I had imagined only vaguely but dreaded nonetheless. I found myself sitting next to a dialysis machine in a room full of medical personnel and patients - with tubes attached to very large needles inserted into a fistula in my arm. A fistula is a vein which receives arterial blood flow as a result of surgically splicing an artery to it. My blood flowed out of my fistula through the tubes of the machine and the artificial kidney and back into my body. At times, I felt faint or had severe cramps. There were often problems with my fistula, including infiltration (the needle punctures the wall of the fistula leading to blood flowing in a painful bulge under the skin) or blood clots. The needles were often very painful. It was difficult to sit in a chair for four hours. The procedure was simultaneously awesome, frightening and reassuring. I felt more energetic and was less uremic after the first sessions. A machine could keep me alive.

I was knowledgeable about kidney disease but found that most of the patients had received little information about their condition or treatment. One patient said that he had been feeling bad, saw a doctor, was tested and then told he had to start dialysis. There was not even

time to insert a fistula. Instead, he a tube was placed into a subclavian vein. Patients often did not know the causes of cramps (usually sodium depletion), the need to control fluid intake between sessions, the necessity to limit phosphorous intake to avoid bone loss and the importance of regular and adequate dialysis.

Most of my fellow patients were ~~Afro~~ African Americans from the inner city. A few were functionally illiterate. Some were not employed and were on some form of disability or Medicaid. Nationally, the poverty rate for dialysis patients is 50%, and the programs do little to enhance employability. We related in a friendly way. They called me, "Doc" and often asked for advice about their condition. They seemed to feel reassured that I, an "elitist." was participating in the same treatment as they received. We were all in the same boat.

Dialysis nurses and technicians varied in experience, competence and in their ability to relate in a respectful way toward patients. They often were overworked, undertrained and under a great deal of pressure. They were usually inadequately supervised. Some were caring, sensitive and competent. Others were not. A sadistic nurse refused to remove a needle she had inserted into a nerve plexus - in spite of my protestations of pain. Some rigidly adhered to dialysis prescriptions in spite of the fact that too much fluid was being removed. I saw a frail and elderly fellow-patient faint and lose consciousness from reduced blood volume. one technician remonstrated patients for their attempts to diverge from a doctor's outdated orders. Dialysis technicians often conversed with one another while they were inserting or removing needles or adjusting the machine. Some technicians refused to inform patients when they adjusted dialysis machines. As my fistula developed slowly and some technicians were inexperienced, there were some difficult sessions. One time three additional needle sticks perforated the fistula. This led to

significant painful swelling under the skin. Like the other patients, I often felt helpless and frightened at the dialysis center.

During dialysis, I developed a bizarre behavioral disorder, pica (which consists of the ingesting of non-nutritive substances). Pica is known to occur when there are vitamin or mineral deficiencies or toxicity. Many dialysis patients develop a desire for ice. In my case, I started chewing on and often swallowing paper and cloth, for which I had developed a strong craving. I had little shame regarding pica. At one period, I actually bought a dozen high quality cotton handkerchiefs for the purpose of chewing on them and ingesting them. I remember telling the retail clerk, "These handkerchiefs look good enough to eat!"

A few technicians were horrified when I started eating paper during dialysis. One nutritionist checked out the content of the paper I was eating paper to ascertain that I was not damaging myself. Some patients were made uncomfortable by the sight of me eating paper. I recall one patient repeating in a loud voice, "Our doctor is a quack! our doctor is a quack!" After a few minutes he explained, "How come he don't let me eat chicken (during dialysis) but lets that man eat paper?" A few hours later, he asked me, "What color is it when it comes out?"

Research indicated that I would increase my chances of survival by having longer sessions than average. Even though my physician concurred, the technicians found that my longer sessions slowed them down. They often teased me for taking so long and tried to rush me. I stubbornly stuck to my dialysis prescription. I felt much better with the longer sessions.

I spent about fifteen hours a week at the dialysis center. Interaction with other patients became a regular part of life. Dialysis patients tend not to socialize outside of treatment. The possibility of attachment and loss, one patient said, kept him from wanting to get too close to

others in the same boat. If not friends, they become very familiar acquaintances. I found that I was able to be helpful to them by listening and with information as well as emotional support.

I was stunned when I discovered that the middle-aged person's average expected lifespan of about 30 years was reduced to seven years for those on dialysis. Mortality rates among dialysis patients are high - about 20% a year in the United States. This is equivalent to mortality during combat. Death may come from many factors - especially those that are dialysis- related. Infection (usually from the dialysis process), cardiovascular complications and the voluntary withdrawal of patients from dialysis are the major causes of death. Refusal to begin or continue dialysis is, curiously, not considered suicide.

I learned something about the economics of dialysis. Medicare had covered the expenses of dialysis patients since 1972. At that time, Vance Hartke of Indiana introduced a bill to put dialysis patients, regardless of age, on Medicare. Prior to the passage of this bill, about half of those needing dialysis died because they could not afford treatment. Expenses are currently over $25,000 per patient each year. My bills, paid entirely by Medicare and insurance, are about $60,000 a year. My bills are higher than average because I need very large doses of an expensive genetically-engineered medication, Epogen, used to treat the anemia that accompanies kidney failure. These expenses are greater than my income after deductions. I often wondered how many lives in third-world countries could be saved by my $60,000 per year. A presidential candidate I formerly would have supported came out for "medical savings accounts", which would have been laughable in my case.

For the most part, dialysis centers have become profit- making institutions with fixed fees established by Medicare. They are rewarded for cutting costs in order to maximize profits. They

are not rewarded for improving the quality of life of their patients nor penalized for poor treatment. As dialysis centers do not reveal their mortality rates, a patient has no way of finding out if he or she is entering a good center or a virtual death trap. I discovered these and other problems with the health delivery system for dialysis. I contacted a local reporter and Congressional legislative aides, drew their attention to many of the problems surrounding dialysis care, and discussed possible solutions with them.

Subsequent to the events related to the onset of ESRD and dialysis, I developed a considerable medical history. Many of the incidents included life-threatening medical emergencies. These are par-for-the-course for dialysis patients. My medical emergencies were anxiety provoking and exhausting for Jeanine. She sometimes started trembling when I was having a medical crisis. I felt despair as I did not see how I could reassure her. I knew that my situation was weighing very heavily on her and wondered if we could stay together.

I began peritoneal dialysis, a method that can be carried out at home, is more flexible and offers more autonomy to the patient than in-center hemodialysis. After six months, as is often the case, I developed peritonitis - caused by bacteria entering the abdominal cavity - and had to resume hemodialysis. Jeanine was relieved because she did not like the intrusion of the equipment and the need to do medical procedures at home. She was increasingly concerned about my vulnerability to infections.

A routine colonoscopy, an intrusive diagnostic evaluation of the colon, led to my having an outpatient removal of a non- premalignant polyps or growths. All seemed to go well but, a few hours after discharge from the hospital, I discovered profuse rectal bleeding. What seemed to be diarrhea was actually composed mostly of dark-red blood. Apparently, an intestinal blood vessel

had been perforated during the surgery. I was rapidly becoming faint and was lucky to be able to get to the emergency ward and intensive care just in time to avoid going into shock. Intravenous fluid was immediately administered, and I received three units of blood.

Once in intensive care, I wanted to sit up because I felt uncomfortable lying down. The discomfort stemmed, without my realizing it, from fluid in my lungs from congestive heart failure. This is a common symptom of congestive heart failure. The hospital staff also did not seem to be aware of my condition. The intensive-care nurses were unhappy with me sitting up in bed. They wanted me to lie down in the bed and use a "potty". I refused. I wanted to get out of bed and use a portable toilet next to my bed. My nurse said I could not be allowed to stand up because I might faint. I said I could stand up and judge if I got dizzy. The nurse did not approve. In desperation, I engaged in "civil disobedience." I stood up on the bed and, feeling steady, danced a little jig. I thought, "This is out-of character." My behavior was clearly an intensive-care rule violation.

I said, "See, I can stand up on the bed. I can even dance. Look!" I felt much better standing as I could breathe more easily. My nurse repeatedly ordered me to get down, but I refused. She looked distressed and backed out of my alcove. I did not see her again. A few moments later three other nurses and two attendants appeared in my section. Expressionless, they observed me standing on the bed. I was afraid they would put me in restraints. I repeated, "You see. I can stand on the bed. Certainly I am able to use the portable toilet." After a few minutes of observing me, they left. A different nurse returned. She allowed me to get out of the bed and finally use the portable toilet. I felt relieved (excuse the expression) and vindicated.

I was scheduled for diagnostic catheterization to discover the cause of the bleeding. over

night, however; the bleeding had stopped. Early the next morning, I was taken to an operating room where a team composed of an anesthesiologist, some nurses, a doctor, a resident and others were ready to conduct this procedure. I had already been moved to an operating table and prepped for the procedure when the radiologist-in-charge came over and spoke to me. He informed me of the purpose of the procedure and the risks involved. I thought for a few minutes. I did not understand what point there was in trying to locate the source of bleeding that had stopped the night before. I refused to provide consent for the procedure. I said I would not agree to a procedure the purpose of which made no sense to me. The doctor replied that the team had come in especially early on a Sunday morning (7:30 A.M.) just to do the procedure. They were eager to begin.

Lying on the operating table, I used my best negotiating skills. I indicated in a friendly manner how commendable their behavior was and that I appreciated their dedication. I maintained that, nonetheless, there was still no point in conducting a useless and risky procedure. The radiologist left - saying he wanted to make a phone call. He returned shortly and reported that the Chief of Gastroenterology agreed with me. I was relieved and thanked him whole-heartedly. I felt triumphant when I found out that I would not have to undergo this procedure. I was broken the mold of the helpless patient. I would have submitted to an unnecessary invasive procedure if I had been less informed or assertive.

About fifteen months having started dialysis, by the late Spring of 1996, symptoms of congestive heart failure were becoming apparent. During this time I also developed a stubborn case of pneumonia. I was finally referred to a cardiologist. My ability to function was impaired, and I often was exhausted and short-of-breath. The cardiologist diagnosed me as having a

problem with the mitral valve and enlargement of the left ventricle, with reduced cardiac output. At the end of his examination, he said that my condition was inoperable - with inevitable deterioration and likely death in a few years! I was stunned by this abruptly presented information. I found it hard to accept the notion that I would die before most of the dogs I knew. The next few days, I contemplated the implications of this medical appraisal. My situation reminded me of the case histories of voodoo death that I had mentioned in Abnormal Psychology courses. I was condemned..

I was given an echocardiogram, a noninvasive diagnostic technique using computer analysis of reflected sound, the next week. After perusing the results, the cardiologist revised his opinion and said that my heart condition was operable. He recommended mitral valve repair. I had received a reprieve.

I did not understand the cause of the rapidly developing mitral valve problem. One of my doctors said that my rapid onset of heart trouble might have been caused by the insulin-like growth factor that I had been given in the research project. This growth factor may have caused growth and deformation of the heart. The initiative I had taken with so much enthusiasm to attempt to restore my kidney functioning might have caused severe and irreversible heart damage. I realized that my initiatives to stave off kidney failure

The medical center had been publicizing a newly developed minimally invasive approach to heart surgery. I indicated my willingness to try it. I would be about the 150th patient ever to have this approach. Instead of splitting the chest, a small hole is made in the breastbone and special instruments were used for the surgery. The time of recovery is reduced and the chances of infection minimized by this minimally invasive technique. I was not informed of any particular

dangers of this approach. During the minimally invasive procedure, however, the heart-lung machine is attached through a vein in the lower right part of the abdomen, the external inguinal vein. I was informed only weeks after the operation that this part of the procedure presents present risks that do not occur in conventional surgery.

"The operation was a success but the patient almost died." Perhaps the problem was that the surgery occurred in early July, a month when new and inexperienced-surgical residents arrive. The mitral valve repair went well. Right after surgery, a large vein - the external iliac vein - that had been used to connect the heart-lung machine, ruptured. Intensive care nurses noticed that my abdomen was swelling from profuse internal bleeding. My vital signs were deteriorating. I was taken back into an operating room, and "opened up" again to sop up the blood and repair the damage. During the process, I received - transfusions equaling more than my entire blood supply. The records indicated that my heart stopped during this period. No surgeon or doctor met with me or Jeanine post-surgery to explain what had gone wrong. I discovered the truth only by perusing my file. A few years later, a colleague informed me that the ambitious and world-famous surgeon who presided over the operation that nearly killed me was dubbed "Satan" by the hospital staff.

The recovery was long, painful, and dangerous. Initially, I was later told, my vital signs were, "all over the place." A nurse told Jeanine, brusquely , "He is a very sick man." There was no elaboration or reassurance. I had already lost well over fifty pounds and was looking frail and skeletal. The hemorrhage had resulted in many blood clots in my right leg, which was swollen to almost twice its diameter from the accumulated blood. It was very heavy. I had to cut the right leg of my underpants for them to fit. Totally blocked circulation, gangrene and a leg

amputation were possibilities. A dedicated, caring and worried peripheral vascular specialist visited me every hour or two for a few days. The doctors were clearly concerned about the possibility of a blood clot moving to the lungs and had my legs tied down. My swollen leg was very painful.

Jeanine spent twelve to fourteen hours a day trying to comfort and protect me. I was not allowed to drink as I still needed dialysis. She gave me small chunks of ice to wet my mouth. She was profoundly physically drained and emotionally shattered by my condition, but she fought courageously for my survival in the hospital. She felt isolated and beleaguered. Her legitimate concerns about my treatment were often dismissed by the staff. For example, she witnessed a doctor say that I had to continue on a blood thinner administered intravenously for ten days. An hour later a nurse came in and removed the I.V. She ignored Jeanine's pleas even though Jeanine informed her about the doctor's orders. Another time, a painful catheter remained in my nose for a whole day past when it was needed in spite of her repeated requests for its removal.

Many of the nurses were cold and cliquish. One day, I had the delusion that they comprised a coven of witches. I did not notice any disconfirming evidence. I was not allowed to get up or even move my leg for fear of loosening a blood clot. Some doctors considered an operation to install filter in my vena cava to prevent clots from reaching my lungs. In spite of morphine, I continued in agony. One night, at 2:00 A.M., I phoned some friends and asked them to help me escape from the hospital. As I had anticipated, they politely refused and left me in restraints in the frightening hospital. I cried in desperation.

I was delirious and delusional from the effects of the anesthesia and medication - which stayed in my system longer than usual because of kidney failure. At one point, I thought I was an

American in Russia and queried the patient sharing my room about his attitude toward Yeltsin. Jeanine felt even more drained by my disorientation. It did not trouble me. I thought that if the staff put the name and address of the hospital in each room, patients would know where they were. I suggested the day and date should also be posted.

I was very sick for over a year. I was able to manage to continue teaching. I was short of breath, easily exhausted and often bloated. My leg remained swollen for half a year. I used the electric cart or moved in the "slow lane" at supermarkets. I greeted many elderly people I would otherwise not noticed as I quickly walked by them. I taught my classes sitting down. one student's evaluation accurately critiqued that I just sat at my desk and did not use the blackboard. During this period, I thought of a dog, Taffy, we had when I was a teenager. Recovering from an automobile accident, she went through her paces slowly and stoically. I hoped for the strength to be as simple as she was in my co-existence with pain and physical limitations.

My colleagues reacted in a variety of ways. Some avoided me and seemed threatened by my physical condition. Others were friendly or at least appropriate. Some asked probing questions without ascertaining that I was in the mood to talk about my physical condition. Two colleagues, both prominent full professors, continued to smoke in their offices in proximity to me, in spite of my requests. This was especially galling because I was just back from the hospital. I had even informed them that I was suffering from congestive heart failure, anemia, pneumonia and end-stage renal disease. I was obviously short-of breath and easily fatigued. They indicated that they were "trying to stop." I was angry at their callous indifference and insensitivity. I reported both of them to the university's Affirmative Action officer, in charge of rights of the disabled, who ordered them to stop smoking in the building.

Jeanine and I discussed the possibility of my death. we prepared for it psychologically and in terms of specific plans and necessary preparations - such as writing a will and getting my papers in order. Given the difficulties of my recent surgery, death did not seem far away. I found I was not afraid of death but regretted that I would be separated from Jeanine. I also feared pain and loss of control, which I had already experienced in the hospital. Many days I felt too weak to meditate or engage in self-observation. I prayed for the strength to carry on and slept a lot.

My transplant was put on hold because I was showing symptoms of ascites (fluid in the abdomen). The first treatment consisted of a needle inserted into my abdomen. Over eight liters of fluid the color of beer was removed within an hour. It was collected in one-liter vacuum bottles. The procedure was painless. I was delighted with the results. I lost about eighteen pounds of abdominal bloat and could tighten my belt four notches.

The downside was that the gastroenterologist who conducted the procedure became convinced, in spite of negative blood tests, that I had liver failure. My experienced nephrologist disagreed and said that ascites often occurs in dialysis. A clash of egos resulted in the decision to perform a biopsy on my liver. As a result of the fluid around my liver, the biopsy had to be done with a wire in a catheter passed down a trans-nasal route - i.e. "through the nose". This was very painful, and, even though sedated, I shouted at one point to stop. At home, a few hours after discharge, I started experiencing the most excruciating pains of my entire life. I felt as if I was being struck every few minutes across the abdomen with a two by four. Screaming at the top of my lungs, I called 911 Emergency Services. Between screams, I said that, even though my call sounded like a homicide in progress, I was just suffering from a post-biopsy reaction and needed to get to an emergency room quickly. Later, my doctor informed me that the pain had probably

been caused by a liver bleed through the gall bladder. Happily, the biopsy results proved to be negative! The gloom-and-doom gastroenterologist stubbornly continued to insist that I must have liver failure and that I therefore did not qualify for a transplant. His erroneous opinion was finally ignored by the pre-transplant team. my ascites did not return.

In February 1997, two years after the onset of dialysis, I received a cadaveric kidney donation. I was tearfully grateful and thought of the donation as a Christ-like sacrifice. But the kidney did not take well. There were signs of significant rejection. I was delirious again from the effects of surgery and delusional for a time as well. I was disoriented as to time and place. members of the faculty union's executive team visited me during this hospitalization and decided to replace me as grievance officer. For a couple of weeks, I was not considered competent to approve medical decisions. I was diagnosed with atrial fibrillation, and was treated with a process called "cardioversion", which consists of strong electric shocks to the chest to correct the heart's rhythm. "If you have to choose between light or heavy sedation, please choose heavy," I requested.

After three weeks, I was discharged prematurely with septicemia, blood poisoning, from bacterial infection. My body could not counter this infection because of the immunosuppressants needed to maintain the transplant. Jeanine was out-of-town when I was discharged. Two days later, I was found - incompletely robed and wandering in a weak and disoriented state - by my condominium neighbors. I returned to the hospital for an additional three weeks. I finally needed extensive treatment with an expensive last-ditch intravenous antibiotic, Vancomycin. It caused a painful burning sensation in my veins when administered.

Some close friends and special colleagues came to my aid with many visits and with real

assistance. Hospital and insurance company policies would have resulted in another premature discharge. A colleague's wife made an impassioned appeal to a medical director. He questioned her standing in her advocacy of my cause. She invoked her experience as a holocaust survivor to explain her attitude toward bystander responsibility. Jeanine accused the hospital of "butchering Bob,, and argued for my transfer to a rehabilitation unit. The nephrology head commented, "She doesn't mince words." He was convinced to make the necessary efforts to enable me to remain in a treatment environment.

I had to spend almost two weeks in a rehabilitation program. I did not need rehabilitation but was very weak from septicemia. The physical therapists there did not acknowledge this fact but made me go through extensive tests and exercises in spite of my protests. I remember saying, "You want me to stand on one foot when I don't even have the strength to stand at all." The explanation was that they had to meet insurance treatment guidelines in order for me to remain there. One Monday, I felt stronger and passed all the tests I had flunked the previous Friday. I felt vindicated and told a therapist, before discharge, that I had been right all along. I didn't need physical therapy - only rest and antibiotics.

The transplanted kidney, damaged from partial rejection, functioned marginally. During this time, I had symptoms of kidney failure all over again. I was bloated, itchy, smelly and yellowish, but freed from the need to spend many hours each week in dialysis. I was nauseous for over an hour every day from the many pills I had to take to maintain the transplant. I traveled from Shaker Heights with Jeanine to a psychology convention in Chicago and took a brief Thanksgiving trip to New York. After about a year, the transplanted kidney was functioning so poorly that I had to return to dialysis again. I felt that now familiar sinking feeling of despair. I

told people that I felt "devastated". A few weeks later, in March, 1998, more surgery was necessary to remove the transplanted kidney, which had started swelling and was on the verge of rupturing. This time, I requested to see the anesthesiologist in advance and questioned the type of anesthesia I had been given. I convinced him to something different. My mind was, for the first time, clear and rational after surgery.

Dialysis treatments have continued for the past year and a half. Dialysis is proceeding smoothly at present. I am allowed to set the controls for the machine on my own. My heart has improved. My right ventricle is no longer enlarged, no more signs of congestive heart failure are present, and my cardiac capacity is normal. The severe anemia associated with kidney failure has been corrected, and I have been free of pneumonia and other infections. My activity-level is increasing, although at times I feel more fatigue than formerly. I have returned to active teaching, scholarship and psychotherapeutic practice. I have the energy to meditate and often experience feelings of inner joy and tranquility.

Jeanine said she felt closer to me because I was "so courageous and uncomplaining" in dealing with my illness. She said that I had not shown a nasty side - even when I was in great pain and delirious. we got married in August, 1998. We picked a day when I did not need dialysis. Our increased commitment to each other is a silver lining. I deeply admire Jeanine's loyalty and courage in staying with me while having to deal with my chronic, changing, often life-threatening and painful medical condition. Watching a loved one who is ill is often more difficult than being ill yourself. Her life as much as mine has been changed fundamentally. My ordeal has significantly diminished her sense of well-being and almost totally destroyed any feeling of security that I could provide. The incessant emergencies we encountered during the last

eight years have robbed her of a sense of tranquility. I live with the knowledge that my illness has lessened the quality of her life.

My sister reduced her blood pressure through diet and exercise and discovered a minimally invasive surgical approach for kidney donors. She finally volunteered to donate a kidney, but it was too late. I had developed additional antibodies during the failed transplant. These reacted against her tissues in laboratory tests. It was no longer possible for me to receive her kidney. Again, I felt adrift. I felt checkmated by the disease situation; the living-donor solution was not possible.

In looking back over this medical "surprise package" that I opened at around the age of fifty, I realize that one consequence has been a period of precipitous personality change - one that has affected everything I do. I now tend to be more egalitarian and am less trusting of authority. By the same token I am less likely to be authoritarian in my dealings with students and clients. I have lost most of the desire to control the behavior of others. Much of my previous sense of superiority over others due to a good education and intellect has vanished. I often dwell on the fact that I would gladly trade places with most people in good health, regardless of their talents or abilities. I have become more aware of the fragility of our life here on earth than many of my professional and social peers. I have felt a strong bond with many of the other dialysis patients and continue to spend more time with them than with any professional colleagues. Perhaps these changes reflect some lessons I needed to learn.

Presently, I feel I have changed and been changed by the experiences of the past eight years. It is yet too early to know how these experiences will be integrated into my life and my activities. I have again begun working with a few psychotherapeutic cases since I have been

feeling better, I have found my approach to be more accepting and direct. I have crossed some bridges others my age have not, and I feel ready to help others from a position of perhaps premature maturity and a deeper perspective than before my discovery of kidney failure. Dealing with life-threatening crises has helped my therapeutic approach mature in ways my previous supervision and clinical experience could not.

I learned that it was helpful not to make a drama out of the ups and downs of my medical condition, but to take them in a matter-of-fact way. The ideal of accepting life events and learning whatever one can from them has proven vital. Meditative practices and prayer were proved helpful. This was true even when I was weakened from congestive heart failure, pneumonia, anemia and renal failure. Spiritual openness sometimes led me to a sense of a benevolent higher Presence. An attitude of lack of identification with external and extrinsic aspects of myself - what Jung called the persona - was of benefit. The spiritual teaching that I was a soul and had a body was vital to me. The ideal of accepting and learning from all life's experiences was important also. A useful concept that I discovered recently was of psychologist Blair Justice's (A Different Kind of Health: Finding Well-being Despite Illness) idea of being healthy in a sick body. I found that even when my body was frail and weak, I could still be happy and optimistic.

Larry LeShan's idea of illness as a stimulus for transformation (Cancer as a Turning Point), that he developed for cancer patients, applied to me as well. I have learned that I am stronger than I had thought, that I could survive devastating experiences and continue on with a positive attitude. I discovered that I did not fear death. This lack of fear was a gift I did not work for. I found I was tougher than I would have guessed I might be. At the same time, I learned to

ask for and accept help from others. My belief in the importance of transcending the physical realm has helped. I feel I have tested some spiritual principles and found them valuable. Prayer and other spiritual practices and forms of meditative awareness did not cure my kidney failure. They did serve to help me maintain an inner sense of well-being and a sense of the universality of Divine love, regardless of any difficulties I had to endure.

I believe that my experiences have enabled me to glimpse some truths about the mortality of the body and the value of life, a sort of "Daskalos" redux. I became disillusioned with institutions and with relationships and learned to sort out what was valuable from what was false in both areas. Hospitals emerged as technologically advanced but also as flawed and cruel institutions. Health professionals varied in their expertise and compassion. Some seemed robotic and soulless. The concern and help of others helped me during difficult series of trials. Jeanine came through with flying colors. My sister did not, at least not when her gift of a kidney would have been most helpful. Some friends were reliable, others not. The upside of disillusionment is that I have found that it is not necessary to live with every illusions and that dis-illusionment can be liberating.

RENAL LEADERSHIP COUNCIL

Providers of Quality Dialysis
for the Nation's ESRD Community

July 10, 2000

The Honorable Charles E. Grassley
Chairman
Special Committee on Aging
United States Senate
G31 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Grassley:

Thank you for the opportunity to provide the Committee with the response of the Renal Leadership Council (RLC) to the June 26, 2000 hearing held by the Committee on quality of care of renal dialysis patients. We request that these comments be made part of the record of the hearing.

The RLC is an association representing five of the major renal dialysis providers. The RLC's members provide renal replacement therapy to more than 100,000 individuals with End Stage Renal Disease (ESRD). The RLC's members provide dialysis care to ESRD patients in over 1,000 dialysis facilities in 42 states and the District of Columbia. ESRD patients receive dialysis treatments in RLC member free-standing and hospital-based dialysis facilities that are located in urban and rural areas.

Sincerely,

Raymond M. Hakim, MD, PhD.

Raymond M. Hakim, M.D., Ph.D.
on behalf of the Renal Leadership Council

RMH/cgc

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RENAL LEADERSHIP COUNCIL

Providers of Quality Dialysis
for the Nation's ESRD Community

TESTIMONY OF THE

RENAL LEADERSHIP COUNCIL

IN RESPONSE TO THE

JUNE 26, 2000

SENATE SPECIAL COMMITTEE ON AGING

HEARING ENTITLED

"KIDNEY DIALYSIS PATIENTS:
A POPULATION AT RISK?"

SUBMITTED FOR THE RECORD
ON JULY 10, 2000

444 North Capitol Street, Suite 532, Washington, DC 20001 • Phone: (202) 544-6264 • Fax: (202) 544-3610

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We wish to make the following points:

1. There have been continuous improvements in the quality of care of dialysis patients, as documented by the Health Care Financing Administration (HCFA) and the ESRD Network reports.

   - For example, the number of patients meeting the recently recommended dose of hemodialysis increased from 43% in 1993 to 80% in 1998. We believe this percentage to be even higher in 2000.

   - Another example is the achievement of recommended anemia targets (Hematocrit > 30%), which increased from 46% in 1993 to 83% in 1998.

   - A third example is the continued improvement in the measurement of the adequacy of dialysis for peritoneal dialysis patients.

All of these improvements and many more were well-documented in HCFA's January 31, 2000 report issued by Dr. Jeffrey Kang, director of the Office of Clinical Standards and Quality.

In particular, we wish to emphasize that these improvements occurred because of the interest of providers in working with HCFA to improve outcomes through an educational and continuous quality improvement process, using Renal Physicians Association (RPA) and Dialysis Outcome Quality Initiative (DOQI) guidelines. It is also important to note that these improvements did not happen because of more HCFA regulations, more Medicare inspections, or more punitive (intermediate or otherwise) measures. Fundamentally, more regulations will result in facilities just meeting minimal standards instead of focusing on continuously improving the outcome of dialysis care.

2. The General Accounting Office (GAO) report released at the hearing lists the top five deficiencies of conditions of participation and their potential adverse

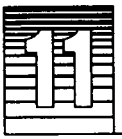
effects. While the RLC is committed to meeting all conditions of coverage in their facilities, it is also important to note that these deficiencies are primarily deficiencies in paperwork documentation and the "potential adverse effects" are, to most objective reviewers, a leap of logic and reasoning. Except for rare anecdotes, the GAO does not, and we believe, cannot point to any actual adverse effects.

3. The GAO report suggests additional punitive inspections and intermediate "monetary" penalties. This is similar to what regulators and the GAO have encouraged with nursing homes, resulting in a near extinction and bankruptcy of the industry. We submit that additional resources be directed not to more regulations or punitive damages, but to a collaborative program between industry, HCFA, the Networks and the State inspection system to develop processes for continuous quality improvement and to improve the inadequate knowledge base and training of state inspectors in such processes. If we continue insisting that facilities meet only "minimal standards", patients and patient outcomes will suffer. We should work together to continuously ask ourselves "Can we do better?" through accurate data and education.

4. Several of our physician-medical directors commented on the lack of relevance and anecdotal nature of the patients' testimony. These testimonies reflected much more issues on patient compliance or current HCFA regulations that do not reimburse for dialysis more than 3 times a week regardless of patient's needs.

The major improvement in the delivery of care for dialysis patients has occurred in the face of static reimbursement, with almost no inflationary adjustments since 1973. This has resulted, according to the Medicare Payment Advisory Committee (MedPAC) and the Institute of Medicine, in an effective reduction of constant dollar reimbursement from $138 in 1973 to $36 in 1998, and payments that are less than the cost of care in all, but the largest dialysis facilities, since 1998. Further increases in personnel, supply and overhead costs have aggravated this variance between Medicare reimbursement and costs. We respectfully submit that GAO should comment on the MedPAC report and report to your committee on this persistent inequality.

In summary, the RLC respectfully submits that the keys to improving outcomes in this "population at undue risk" lies not in more regulations or more punitive damages, but instead in a collaborative process of continuous quality improvement and a better process of interaction between HCFA, industry, and the state inspection process. Finally, we wish to emphasize that, unless reimbursements equal at least the true cost of care and includes an annual inflationary adjustment on an ongoing basis, the ability of the members of the RLC to attract, educate and train qualified dialysis staff and our ability to retain such staff by paying them appropriate wages will suffer, and their ability to continue to pursue further improvement in patient care will deteriorate.



Renal Network of the Upper Midwest, Inc.

End Stage Renal Disease (ESRD) Network 11

Serving Michigan, Minnesota, North Dakota, South Dakota, and Wisconsin

July 11, 2000

Senator Charles Grassley, Chairman
Senate Special Committee on Aging
G31 Dirksen Senator Office Building
Washington, DC 20510

RE: 6/26/00 Public Hearing on "Kidney Dialysis Patients: A Population at Undue Risk?"

Dear Senator Grassley:

ESRD Network 11's Executive and Medical Review Committees met on June 29, 2000 for our regularly scheduled quarterly meetings. The 6/26/00 public hearing was one of the agenda items discussed, and we would like to submit some additional comments for consideration.

1. The goal to improve the quality of care provided to individuals with end stage renal disease (ESRD) is shared by the Health Care Financing Administration, Congress, and Network 11, and ESRD Networks are continuously working toward this goal.

2. In particular, the last two meetings of the Medical Review Committee and Executive Committee (Network 11's Board of Directors) have centered around reviewing profiles for nearly all Network 11 dialysis facilities. These confidential profiles and quality improvement projects have focused on vascular access, dialysis adequacy, anemia management, nutrition, and prevention and treatment of bone disease. Peer review processes are in place to monitor and improve care. Network 11 uses such profiles to educate providers and support improvements. Yet if satisfactory improvements are not made, Network 11's review processes follow up and specifically focus to ensure improvement and facility accountability.

3. Network 11 publishes *Common Concerns*, a quarterly patient education newsletter, which is distributed directly to patients' homes. Network 11 resources and the grievance process are made known to patients through this newsletter and grievance posters posted in all ESRD facilities in Network 11. Network 11 processes about 300 patient concerns annually.

We have copies of letters submitted to you from the Forum of ESRD Networks, and we support the positions stated in those letters. We wanted to offer, as a member of the Forum, another voice and resource. If we can provide additional information, please feel free to contact us.

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Thank you for your consideration of these comments.

Sincerely,

Consumer Members on behalf of
Network 11's Executive and Medical Review Committees

Mary Lynn Deraas
Chairperson, Consumer Committee, Network 11

Diane Carlson
Executive Director, Network 11

Robert Provenzano, MD
President, Network 11

TESTIMONY OF

RMS DISEASE MANAGEMENT INC.

AND

RMS LIFELINE INC.

BEFORE

THE SPECIAL COMMITTEE ON AGING

UNITED STATES SENATE

JUNE 26, 2000

Contact:
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Overview of RMS Disease Management Inc.

RMS Disease Management Inc. is a disease management organization that provides high-quality renal care that improves patient outcomes and quality of life while managing costs. RMS Disease Management focuses on developing relationships with nephrologists and other key renal providers that allow for a nationwide delivery system of integrated renal care. This network and delivery system offer participating health plans an opportunity to better manage the continuum of care of their end-stage renal disease (ESRD) patients and the associated financial risk. RMS Disease Management signed the first national ESRD disease management contract with Humana, under which RMS Disease Management has responsibility for coordinating and managing the care for over 1,200 Humana patients in markets throughout the United States. Recently, the company was awarded the contract for Florida Medicaid's 2,000 pre-ESRD and ESRD patients and is expected to implement the program in the fourth quarter of 2000.

Overview of ESRD Program

RMS Disease Management is concerned about the future health and continued success of the End-Stage Renal Disease Program under Medicare (the ESRD Program). The ESRD Program currently represents less than 0.5% of all Medicare beneficiaries, yet comprises almost 6 percent of the annual Medicare costs. Currently, Medicare payment is available to qualifying beneficiaries diagnosed with ESRD, regardless of age. Medicare assumes primary payer responsibility for ESRD patients three months after diagnosis, unless the patient has group health insurance, in which case Medicare assumes secondary payer status after three months and primary status after 30 months. Typically, Medicare pays for ESRD patient benefits in two separate ways: in part as fixed or composite payment and in part fee-for-service. Because of the routine nature of chronic dialysis costs, HCFA has set a fixed composite rate for chronic outpatient dialysis therapy, which includes all supplies and services related to an outpatient dialysis treatment, and monthly physician fees for nephrologists who treat patients requiring dialysis in an outpatient setting. However, because of the numerous complications prevalent among ESRD patients (more than 75 percent have severe co-morbid conditions, including diabetes and hypertension), costs related to ancillary testing, drugs such as Epogen, hospitalizations and attendant provider costs are made on a fee-for-service basis.

With most chronic illnesses, the advent of managed care has demonstrated significant financial cost improvements, although admittedly not always with a complementary increase in quality of care. Managed care has received less than favorable reviews from critics in the public and press in recent years. Nevertheless, the RMS experience demonstrates that, when developed and implemented in a coordinated fashion with a focus on clinical outcomes, disease management strategies can effectively reduce many healthcare costs and, more importantly, improve the quality of patient care. Nowhere is this concept more apparent than in ESRD, where RMS' focused and specialized coordination of care has effectively reduced costs and improved care relating to chronic afflictions, such as diabetes, asthma, and mental disorders. Unfortunately the ESRD

community has been effectively insulated from disease management or any other managed care. That is because the majority of ESRD patients are Medicare beneficiaries and Section 1876 of the Social Security Act prohibits ESRD patients from joining Medicare+Choice programs.

Disease State Management

Organizing the delivery of care for chronically ill patients is essential for optimal clinical outcomes and cost control. Recognizing the need for focused, specialized coordination of care, managed care companies are developing or partnering with organizations, such RMS Disease Management, to build disease management programs that improve clinical outcomes, patient satisfaction, and quality of life while managing costs.

Recent efforts by Congress and HCFA demonstrate a commitment to having ESRD beneficiaries receive better quality care at lower costs to Medicare. Such efforts are good for the renal community because they support a financially healthy ESRD program. However, Congress and HCFA must take steps that are well-founded and do not unfairly burden ESRD beneficiaries, the renal providers--particularly the nephrologists and dialysis centers--or private health plans. The ESRD Program and ESRD beneficiaries are entitled to the benefits inherent in a focused, disease state management approach.

ESRD patients, however, are prohibited from enjoying the benefits of these innovative managed care programs as a result of Section 1876 of the Social Security Act. This prohibition was originally promulgated in order to protect vulnerable ESRD patients and to ensure the quality and high-level of care required for this complex patient population should managed care organizations withhold or limit access to services. Yet today, there are extensive quality oversight measures in place that ensure quality care for ESRD patients.

- The End-Stage Renal Disease Network monitors the quality of care for all ESRD patients.
- The Health Care Financing Administration (HCFA) developed the Core Indicators Project to profile ESRD patient care in dialysis facilities.
- The National Kidney Foundation's Dialysis Outcomes Quality Initiative (NKF-DOQI) is converting its clinical practice guidelines into performance measures to be used as CQI tools for overseeing and improving quality of ESRD patient care.

In addition, at the Renal Physician Association's Annual meeting in March 1999, Paul Eggers, Office of Strategic Planning at HCFA, made the following statement; "HCFA is concerned that patients should have the right to enroll in Medicare (Senior Risk Programs). Patients with Cancer, Alzheimer's, HIV and other chronic diseases have the right to enroll. It is possibly discriminatory for HCFA to not allow ESRD patients to have the expanded benefits."

Although removal of Section 1876 in the Social Security Act will improve ESRD patients' access to quality care, biases in the current AAPCC rate will make it difficult for Medicare+Choice managed care organizations to sustain the proactive programs for improving care delivery and patient quality of life. In December 1998, The Lewin Group

conducted an independent study, funded by RMS, to better understand the limitations of the AAPCC and its impact on ESRD care. They found that:

- The current AAPCC does not include key risk adjustments for patient demographics, treatment modality, Medicare Secondary Payer status, or county of residence;
- The current AAPCC, because of the lack of these risk adjustments, significantly underpays for older, sicker dialysis patients--patients currently most likely to be in Medicare Senior Risk plans;
- The consistent under-funding is likely to lead to a disincentive for health plans to provide consistent, high-quality care as well as access to care.

An analysis prepared for RMS by Dr. Allan Collins M.D., F.A.C.P, Associate Professor of Medicine, University of Minnesota School of Medicine, Hennepin County Medical Center and Director of Nephrology Analytical Services in Minneapolis, demonstrates that the age and modality biases in the AAPCC rate under-compensate health plans by as much as 28 percent (Attachment A).

HCFA recently developed a capitated-payment ESRD demonstration project, under which three participating health plans receive a single monthly payment for all costs incurred by their participating ESRD patients. The capitated-payments are calculated using risk-adjusted capitation rates, with adjustments for patient age as well as the presence of diabetes. By structuring the Demonstration Project payment system in this way, it lends credence that the current AAPCC system is flawed. Unfortunately, it will be several years before the project is completed and all of the data generated is analyzed.

Finally, in its March 2000 Report to the Congress, the Medicare Payment Advisory Commission (MedPAC) included the following recommendations for "Improving payment for end-stage renal disease services" (chapter 6 pgs. 127-147):

1. As soon as possible, the Secretary should risk-adjust payments for patients with end-stage renal disease (ESRD) enrolled in Medicare+Choice.

2. The Congress should require HCFA to annually review the composite rate payment.

3. For fiscal year 2001, the composite rate for outpatient dialysis services should be increased by 2.4 percent.

4. HCFA should collect information on ESRD patients' satisfaction with the quality of and access to care.

5. Once HCFA has implemented a risk-adjusted payment system and a system to monitor and report on the quality of care, the Congress should lift the bar prohibiting patients with ESRD from enrolling in Medicare+Choice.

6. ESRD patients who lose Medicare+Choice coverage because their plan leaves the area should be permitted to enroll in another Medicare+Choice plan.

Thus, ESRD offers a perfect opportunity to utilize disease state management approaches with promising results, and it is important that Congress and HCFA recognize this as the ESRD Program incorporates more and more managed care. If Congress and HCFA do not recognize the importance of focused, coordinated and specialized delivery system approaches, the results may reduce costs, but to the detriment of the ESRD beneficiary and the quality of care.

Proposed Actions Necessary by Congress and HCFA

Medicare's ESRD Program now faces an important opportunity to take advantage of efficiencies that will mean better care for ESRD beneficiaries at reduced costs to The ESRD Program. To do this, Congress and HCFA must implement changes to the current ESRD Program that monitor quality of care, adequately reimburse providers, and provide access to care. RMS therefore recommends that Congress take the following steps:

1. ***Congress should establish quality standards for ESRD patients.*** A "Renal Advisory Panel" should be created and empowered to develop, implement, and regularly update and review clinical performance measures by which the care delivered by Medicare Senior Risk programs to ESRD patients would be monitored. Such a panel would work with the Department of Health and Human Services and would represent the interests and input of the renal community organizations, including patient advocacy groups, clinicians, and renal care providers.

2. ***Congress should revise the current AAPCC rate for ESRD patients.*** The payment should be structured using the same methodologies as the Demonstration Project payment system, which adjusts for patient age and presence of diabetes. In addition, the rates should be calculated after removing patients with kidney transplants and those with Medicare as a Secondary Payer, both of which dilute the rates overall and penalize health plans caring primarily for dialysis patients.

3. ***Section 1876 of the Social Security Act should be eliminated.*** In conjunction with appropriately revising the AAPCC and guaranteeing that patient protection measures are put in place, Congress should permit ESRD patients to enroll in managed care plans, if they so choose. With lifting of the 1876 prohibition, ESRD patients would be offered the same choice of joining Senior Risk plans as are other Medicare beneficiaries.

ATTACHMENT A

ANALYSIS OF ESRD PATIENT DATA RELATED TO AVERAGE ADJUSTED PER CAPITA COST (AAPCC)

By

Allan Collins, M.D., F.A.C.P
University of Minnesota School of Medicine

Attachment A

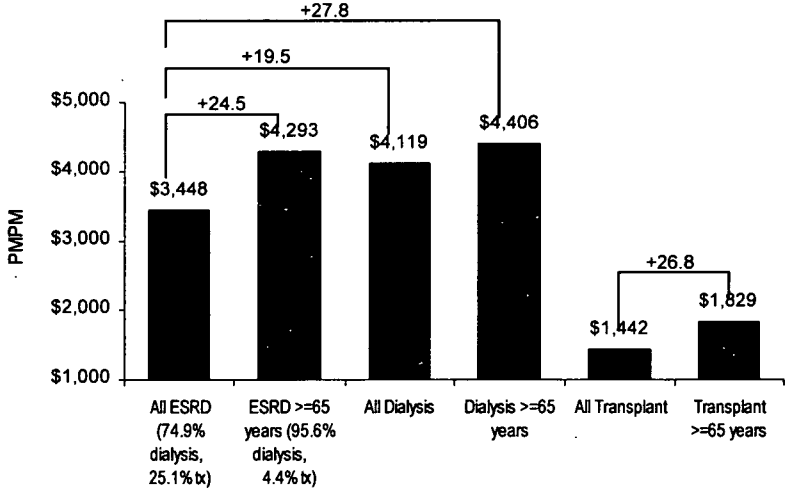
Attachment A demonstrates the substantial differences in the rates when the age and modality distributions are taken into consideration. The analysis was prepared specifically for RMS Disease Management by Allan J. Collins, M.D., F.A.C.P, Associate Professor of Medicine, University of Minnesota School of Medicine, Hennepin County Medical Center and Director of Nephrology Analytical Services in Minneapolis.

Dr. Collins' analysis looks at the age and modality rate comparisons for all ESRD patients (75 percent dialysis, 25 percent transplant) as well as ESRD patients over 65 years old (95.6 percent dialysis, 4.4 percent transplant). Additional comparisons were made between all dialysis patients, dialysis patient over 65 years old, all transplant patients, and transplant patients over 65 years old.

It appears Medicare is significantly under paying for all senior risk ESRD patients over 65 years old (inclusive of transplant) by 24.5 percent and under paying by 27.8 percent for the senior risk ESRD dialysis patients over 65 years old. On the other hand, the transplant patients in the senior risk Medicare program are over paid—by 26.8 percent--given there are a comparable percent of transplant patients (4.4 percent) in the risk program

These figures best demonstrate the biasing of the current rate structure for the senior risk Medicare HMO patients who develop ESRD. Of additional note, the ESRD patients over 65 years old have virtually no Medicare Secondary Pay (MSP) issues compared to the ESRD patients under 65 years old.

Comparison of PMPM Medicare Payments Based on Age & Modality Mix, 1992–1996*



Data computed from USRDS 1998 ADR Tables K-5. Dialysis, transplant, and age group rates are based on the actual patient months contributing to the Per Member Per Month

TESTIMONY OF

RMS LIFELINE INC.

BEFORE

THE SPECIAL COMMITTEE ON AGING

UNITED STATES SENATE

JUNE 26, 2000

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Overview of RMS Lifeline Inc.

RMS Lifeline is a managed network of dedicated outpatient centers that provide end-stage renal disease (ESRD) patients with coordinated, quality-driven access care. These centers focus on the interventional care of the access sites of dialysis patients in an outpatient.

As background, ESRD patients, other that those with transplants, are individuals who must receive dialysis therapy. The most common form of dialysis is hemodialysis, a procedure that generally takes place several times a week at a hospital or clinic. In hemodialysis, blood is withdrawn from the patient's arm or leg and pumped through an external "dialyzer," or filter. The cleansed blood is then returned to the patient. The process takes approximately three to four hours.

Before patients can begin hemodialysis, they must have an "access" site to provide access to the bloodstream. A surgeon will either create an "autologous A/V fistula" from the patient's own artery and vein, or implant a teflon-like tube, usually in the forearm. It is through this access site that the patient's blood leaves and re-enters the body during hemodialysis. These accesses must be subsequently cared for and maintained to insure continuous access to the patients' bloodstream during the dialysis procedure. In addition to the initial placement, a number of interventional procedures, including thrombectomies and angioplasties, are performed to maintain vascular access function. The initial placement procedure require a surgeon, usually a vascular specialist, while subsequent interventions a performed by surgeons, radiologists, and more recently by specially trained interventional nephrologists.

Over time, it is not uncommon for the access site to accumulate plaque or develop a clot inside, causing it to narrow and slow the flow of blood, rendering the dialysis therapy less effective. Ultimately, if it becomes completely clogged, the patient faces an emergency situation and often must be hospitalized. In fact, access-related complications are the No.1 cause of hospitalizations for ESRD patients and account for as much as 25 percent of total ESRD patient costs.

RMS Lifeline was developed to address the problems associated with vascular access care. The company develops and manages a network of outpatient access care centers dedicated to improving the delivery and outcomes of access-related problems.

Overview of ESRD Program

The ESRD Program currently represents less than 0.5% of all Medicare beneficiaries, yet comprises almost 6 percent of the annual Medicare costs--a projected $9.2 billion charge to Medicare in 1998. Individuals afflicted with ESRD face two alternatives: they must either have a kidney transplant--an option which is available only to a small fraction of ESRD patients due to the organ donor shortage--or they must undergo regular chronic dialysis therapy, a process for removing waste and toxins from the bloodstream.

Currently, Medicare payment is available to qualifying beneficiaries diagnosed with ESRD, regardless of age. Medicare assumes primary payer responsibility for ESRD patients three months after diagnosis, unless the patient has group health insurance, in which case Medicare assumes secondary payer status after three months and primary status after 30 months. Medicare pays for ESRD patients in two separate ways: in part as fixed or capitated payment and in part fee-for-service. Because of the routine nature of chronic dialysis costs, HCFA has set a fixed composite rate for chronic outpatient dialysis therapy, which includes all supplies and services related to an outpatient dialysis treatment. Physician fees are capitated on a monthly basis for nephrologists who treat patients requiring dialysis in an outpatient setting. However, because of the numerous complications prevalent among ESRD patients (more than 75 percent have severe co-morbid conditions, including diabetes and hypertension), costs related to ancillary testing, drugs such as Epogen, hospitalizations and attendant provider costs are made on a fee-for-service basis.

Hemodialysis Vascular Access Care

Today, the delivery of vascular access care is reactive, fragmented and uncoordinated because there is no incentive to identify and treat access problems early. As a result, patient quality of life suffers, outcomes are poor and the costs are high. In fact, vascular access represents 15 percent to 30 percent of aggregate pre-patient ESRD medical costs at $2.5 billion annually. The majority of vascular access procedures are performed in hospital setting since most ESRD patients only get treated once their access fails. At that point patients cannot receive dialysis again until their access site is repaired, resulting in emergency room visits and hospital stays. With inpatient vascular access care more than four times as expensive as outpatient care this becomes a significant cost to the healthcare system.

The RMS Lifeline managed network of outpatient centers that provide ESRD patients with dedicated, focused vascular access care. The entire patient care team is educated in access monitoring and diagnostic testing that identifies access problems early. This eliminates numerous emergency room visits and hospitalizations. Consistent monitoring and early interventions by a dedicated team create improved outcomes and increased patient satisfaction while managing costs. However, RMS believes that the current list of approved ASC vascular surgical codes omits a significant number of procedures which could and should be utilized in performing vascular access site interventions as ASC procedures in order to improve patient outcomes and lower costs to Medicare.

On June 12, 1998, the Health Care Financing Administration (HCFA) requested comment on a proposed rule to make various changes to the ambulatory surgical center (ASC) payment methodology and the list of Medicare covered procedures. In order to make the full range of vascular access care in an ASC a viable and cost-saving reality, RMS prepared a response to HCFA stating that the current ASC/APC regulations should incorporate an expanded list of covered surgical codes. Attachment "A" identifies the vascular access codes along with a description and an explanation as to why we contend that these codes should be on the list of covered ASC surgical procedures and similarly, on the list of Ambulatory Payment Classification groups which are proposed to eventually replace the ASC list.

In early 1998, RMS Lifeline Inc. contracted with Allan J Collins, M.D., FACP, an Associate Professor of Medicine in the Division of Nephrology at the University of Minnesota School of Medicine, to conduct an analysis of vascular access events performed during 1996 on an inpatient versus an outpatient basis. A copy of the completed report is included as supplemental documentation to support our recommendations and is labeled "Attachment B." The results of this analysis demonstrate the seven- to eight-fold difference in vascular access payments that are performed on an inpatient basis versus on an outpatient basis.

RMS spent significant time and resources analyzing patient data related to dialysis access care, and as a follow-up to these formal comments we would be pleased to meet with representatives from your agency to review the results of these efforts. In short, RMS can show that:

(1) Medicare ESRD program costs related to vascular access expenses have risen steadily since 1991 and are estimated to be nearly 2.5 billion in 1998.
(2) Hospital inpatient and outpatient admissions related to access care have increased well beyond the growth in the overall ESRD patient populations.
(3) Costs related to vascular access care account for almost 25 percent of the total annualized costs of ESRD dialysis patients.
(4) In recent years the number of access interventions required per ESRD patient has steadily increased to 1.2 procedures per year and even higher for patients in their first year of dialysis.

In addition, at the request of the Medicare Payment Advisory Commission, the Renal Physicians Association (RPA) and the American Society of Nephrology (ASN) reviewed the safety and efficacy of expanding the list of access procedures allowed to be performed in an ASC setting. The RPA and ASN determined that vascular access procedures can be performed safely at freestanding vascular access centers. Additionally, the RPA/ASN found that receiving care at ambulatory surgical centers offers a number of advantages to dialysis patients, including convenience, decreased waiting time, less disruption of the normal dialysis schedules and an experienced staff sensitive to the unique concerns and fears of this chronically ill and vulnerable population.

Recommendation

HCFA should add the 31 additional vascular access codes to the ASC list when it issues the final regulation on ASC payment methodology and Medicare covered procedures.

In 1991 inpatient vascular access procedures accounted for 80% of the total procedures, compared to 20% outpatient. By 1996, inpatient vascular access procedures had fallen to 54%, with a proportionate increase in outpatient services. Nevertheless, while initial access and maintenance access intervention procedures are now commonly performed in an outpatient setting, a significant number of these procedures are still not on the approved ASC facility listing.

When deemed appropriate by the treating physician, expanded coverage of access care performed in an ASC setting will have two immediate and dramatic effects:

1. First, there are immediate cost savings available by moving these procedures to an ASC setting. As demonstrated in Attachment B, inpatient procedures are obviously more expensive than similar hospital outpatient procedures. By providing for coverage of these services in an ASC setting the overall costs will be reduced even further. Moving these procedures from hospital outpatient billing to ASC billing will also save patients from paying the high co-payments they are now charged without any loss of quality in patient care.

   We also contend that the vast majority of access procedures, including initial placement of the vascular access, could and should be safely performed as outpatient procedures in an ASC setting. According to an analysis by Dr. Collins (Attachment C) the majority of these codes are currently being performed and paid for in some type of outpatient setting. Most pure vascular dialysis access procedural events, unencumbered by any other medical complications (i.e., acute MI, pneumonia, major surgery), are clearly appropriate and safe for the outpatient ASC treatment setting. While many of these procedures are already found on the list of current or proposed covered ASC surgical codes, we firmly believe it is necessary to expand the list of covered ASC surgical codes to include the other vascular access procedures which are not currently included.

2. Second, by expanding the list of covered ASC surgical codes to include all of the recommended vascular access surgical procedures, we believe that the overall quality of patient care will be improved. In addition, patients will have a choice in vascular access procedure options without the burden of incremental out-of-pocket costs. The end result is not only lower costs, but also improved patient quality of life.

ATTACHMENT A

REQUESTED CODE ADDITIONS TO THE JUNE 12, 1998 FEDERAL REGISTER ASC/APC LISTING

Requested Code Additions to the June 12, 1998 Federal Register ASC/APC Listing

Included below are the vascular access surgical procedure codes which we firmly believe need to be added to, or retained on the ASC/APC listing in order to provide appropriate compensation for the full scope of viable treatment options for renal patients. For some of the services, volume data were available to us as an extract from the1996 HCFA Part B Physician/Suppliers Standard Analytical File. This data was provided to Dr. Allan Collins of Nephrology Analytical Services in Minneapolis, Minnesota, in response to a special request he made of HCFA. Dr. Collins was kind enough to share his data with us for the purposes of this report. Where available, the data are incorporated beneath the specific code to which they apply, and boxed for clarity.

While we were only able to access data for 10 of the 31 codes on the attached list, it is clear from the data reflected below that these types of access related codes are being performed safely and effectively on a regular basis in a hospital outpatient setting. It is also clear from the relatively small percentage of services being performed in all other locations, which includes the office, that these surgical procedures are relatively complex, and are not being done routinely in a physician's standard office setting. We fully expect that when HCFA reviews the data available for the other codes on this list for which data were not available to us, the same type of distribution between outpatient and inpatient places of service will be observed. It is our contention that services which are safe and effective for performance in an outpatient hospital setting are fully appropriate for an ASC/APC setting, and should be included on these lists going forward.

34101 Embolectomy or thrombectomy, with or without catheter; axillary, brachial, innominate, subclavian artery, by arm incision

34111 Embolectomy or thrombectomy, with or without catheter; radial or ulnar, artery, by arm incision

34490 Thrombectomy, direct or with catheter; axillary and subclavian vein, by arm incision

35190 Repair, acquired or traumatic arteriovenous fistula; extremities

# and % of Procedures Performed Inpatient		# and % of Procedures Performed Outpatient		# and % of Procedures Performed in Other Locations	
1,305	*72.3%*	*466*	*25.8%*	*35*	*1.9%*

35458 Transluminal balloon angioplasty, open; brachiocephalic trunk or branches, each vessel

35460	Transluminal balloon angioplasty, open; venous				
# and % of Procedures Performed Inpatient		# and % of Procedures Performed Outpatient		# and % of Procedures Performed in Other Locations	
1,36656.5%		*1,022*	*42.3%*	*30*	*1.2%*

35475 Transluminal balloon angioplasty, percutaneous; brachiocephalic trunk or branches, each vessel

35476	Transluminal balloon angioplasty, percutaneous; venous				
# and % of Procedures Performed Inpatient		# and % of Procedures Performed Outpatient		# and % of Procedures Performed in Other Locations	
13,539	*26.1%*	*35,350*	*68.2%*	*2,947*	*5.7%*

35903	Excision of infected graft; extremity				
# and % of Procedures Performed Inpatient		# and % of Procedures Performed Outpatient		# and % of Procedures Performed in Other Locations	
7,010	*74%*	*2,205*	*23.3%*	*261*	*2.8%*

36005	Injection procedure for contrast venography (including introduction of needle or intracatheter)				
# and % of Procedures Performed Inpatient		# and % of Procedures Performed Outpatient		# and % of Procedures Performed in Other Locations	
6,440	*45%*	*7,478*	*52.3%*	*387*	*2.7%*

36010 Introduction of catheter, superior or inferior vena cava

36011	Selective catheter placement, venous system; first order branch (eg, renal vein, jugular vein)				
# and % of Procedures Performed Inpatient		# and % of Procedures Performed Outpatient		# and % of Procedures Performed in Other Locations	
2,291	*56.3%*	*1,583*	*38.9%*	*193*	*4.7%*

36120 Introduction of needle or intracatheter; retrograde brachial artery

36140 Introduction of needle or intracatheter; extremity artery

36145	Introduction of needle or intracatheter; arteriovenous shunt created for dialysis (cannula, fistula, or graft)				
# and % of Procedures Performed Inpatient		# and % of Procedures Performed Outpatient		# and % of Procedures Performed in Other Locations	
21,236	*27.8%*	*51,166*	*67%*	*3,972*	*5.2%*

36215 Selective catheter placement, arterial system; each first order thoracic or brachiocephalic branch, within a vascular family

36216 Selective catheter placement, arterial system; initial second order thoracic or brachiocephalic branch, within a vascular family

36217 Selective catheter placement, arterial system; initial third order or more selective thoracic or brachiocephalic branch, within a vascular family

36218 Selective catheter placement, arterial system; additional second order, third order, and beyond, thoracic or brachiocephalic branch, within a vascular family (List in addition to code for initial second or third order vessel as appropriate)

36831 Thrombectomy, arteriovenous fistula without revision, autogenous or nonautogenous dialysis graft (separate procedure)

36832 Revision, arteriovenous fistula; with thrombectomy, autogenous or nonautogenous dialysis graft (separate procedure)

36834	Plastic repair of arteriovenous aneurysm (separate procedure)				
# and % of Procedures Performed Inpatient		# and % of Procedures Performed Outpatient		# and % of Procedures Performed in Other Locations	
468	*52.3%*	*413*	*46.1%*	*14*	*1.6%*

37201	Transcatheter therapy, infusion for thrombolysis other than coronary				
# and % of Procedures Performed Inpatient		# and % of Procedures Performed Outpatient		# and % of Procedures Performed in Other Locations	
8,126	*34.2%*	*14,717*	*61.9%*	*944*	*4.0%*

37204 Transcatheter occlusion or embriolization (eg, for tumor destruction, to achieve hemeostasis, to occlude a vascular malformation), percutaneous, any method, non-central nervous system, non-head or neck

37205	Transcatheter placement of an intravascular stent(s), (non-coronary vessel), percutaneous; initial vessel				
# and % of Procedures Performed Inpatient		# and % of Procedures Performed Outpatient		# and % of Procedures Performed in Other Locations	
2,090	*46.1%*	*2,312*	*51%*	*130*	*2.9%*

37206 Transcatheter placement of an intravascular stent(s), (non-coronary vessel), percutaneous; each additional vessel (List separately in addition to code for primary procedure)

37207 Transcatheter placement of an intravascular stent(s), (non-coronary vessel), open; initial vessel

37208 Transcatheter placement of an intravascular stent(s), (non-coronary vessel), open; each additional vessel (List separately in addition to code for primary procedure)

37250 Intravascular ultrasound (non-coronary vessel) during therapeutic intervention; initial vessel (List separately in addition to code for primary procedure)

37251 Intravascular ultrasound (non-coronary vessel) during therapeutic intervention; each additional vessel (List separately in addition to code for primary procedure)

49423 Exchange of previously placed abscess or cyst drainage catheter under radiological guidance (separate procedure)

ATTACHMENT B

EXECUTIVE SUMMARY
ANALYSIS OF PATIENT DATA RELATED TO DIALYSIS ACCESS CARE

By

Allan Collins, M.D., F.A.C.P
University of Minnesota School of Medicine

Overview of Analysis of Patient Data Related to Dialysis Access Care
A vascular access analysis was undertaken and completed for RMS Lifeline Inc. ("RMS"), a subsidiary of Baxter Healthcare Corporation, by Allan J Collins, M.D., FACP, Associate Professor of Medicine in the Division of Nephrology at the University of Minnesota School of Medicine, to identify trends in vascular access events, sites of service, overall associated allowable expenditures, and costs per event and procedure.

Vascular Access Events
Among the various findings in Dr. Collins' analysis, the most striking find is the seven- to eight-fold difference in inpatient (Exhibit A) versus hospital outpatient (Exhibit B) vascular access costs. Both the institutional services and the physician vascular access procedure charges are much less when performed in an outpatient setting. As demonstrated, Part A inpatient costs are 85 percent more than outpatient costs, while Part B inpatient costs are 75 percent more than outpatient costs.

Exhibit A

Vascular Access Events with Inpatient Matches	Part A Net $/Event	Part B Net $/Event
Insertions Only	$9,956	$592
Insertions + Complications	$10,756	$858
Complications Only	$10,222	$461

Exhibit B

Vascular Access Events with Outpatient Matches	Part A Net $/Event	Part B Net $/Event
Insertions Only	$1,137	$373
Insertions + Complications	$1,218	$521
Complications Only	$847	$344

Overall Methodology:
This analysis examined Part B physician service codes, which identify vascular access events as insertions or complications. These codes identify the place of service, allowing identification of those physician services performed on an inpatient versus a hospital outpatient basis. Subsequently, the site of service physician Part B code claims were linked to inpatient and outpatient events.

A total of 693,586 claims for Part B Vascular Access were reviewed and then narrowed to insertions occurring only during the first six months of 1996 so that both the initial events and subsequent follow-up events were captured. These claims were grouped based on service dates and resulted in 192,000 identified vascular access events--all occurring within a three-day period. It was then determined that 96,000 of these vascular access events could be associated with inpatient institutional services and 90,000 with outpatient institutional services, and 6,000 are associated with services outside of the hospital but not considered inpatient. Of the 96,000 inpatient institutional events, 31,640 could be matched with Part B physician procedural claims. Likewise, only 36,341 of the 90,000 outpatient events could be matched with Part B claims.

The matching of institutional events and Part B physician procedural claims is critical for identifying a pure vascular access related event, therefore the analysis was based on the 31,640-inpatient events and 36,341 outpatient events.

ATTACHMENT C

ESRD PART B PAYMENT DATA FOR MEDICARE PAID CLAIMS BY PLACE OF SERVICE MEDPAR FILE 1998

By

Allan Collins, M.D., F.A.C.P
University of Minnesota School of Medicine

Payment Data for Medicare Paid Claims by Place of Service[1]
ESRD Part B – MEDPAR File 1998

				Outpatient			
ode	Description	Total	IP Hospital	Hospital	Office	ASC	Other[2]
34101[3]	Embolectomy/thrombectomy;ax,brach,subcl artery;arm incision	5,471	2,791	2,558	13	84	25
34111	Embolectomy/thrombectomy;radial,ulnar artery;arm incision	669	343	273	35	2	16
34490	Embolectomy/thrombectomy;axiallary,subcl vein;arm incision	1,475	716	718	6	27	8
35190	Repair fistula-Extremities*	1,530	1,066	422	10	21	11
35458	Transluminal angioplasty,open-brachiocephalic trunk or branch	1,032	589	415	4	20	4
35460	Transluminal Angioplasty-venous	3,500	1,797	1,674	4	8	17
35475	Transluminal angioplasty,perc.-brachiocephalic trunk or branch	11,637	2,714	7,814	943	5	161
35476	Transluminal Angioplasty, percutaneous-venous	83,375	17,181	60,706	3,798	53	1,637
35903	Excision of infected graft-Extremity	10,242	7,504	2,472	56	71	139
36005	Injection procedure for contrast venography	22,907	9,191	12,977	290	16	433
36010	Introduction of catheter-sup or inf vena cava	17,601	9,807	6,677	690	28	399
36011	Selective Catheter placement-1st order branch	5,571	2,796	2,561	33	5	176
36120	Introduction of needle or intracatheter-retrograde brachial art.	1,817	394	1,071	329	3	20
36140	Introduction of needle or intracatheter-extremity art.	6,772	3,932	2,667	42	2	129
36145	Introduction of needle or intracatheter-AV shunt(Dialysis)	120,980	26,050	88,279	4,175	66	2,410
36215	Selective Catheter placement-1st order thoracic or brachiocehalic	4,670	2,797	1,724	52	8	89
36216	Selective Catheter placement-2nd order thoracic or brachiocehalic	3,940	2,281	1,374	238	3	44
36217	Selective Catheter placement-3rd order thoracic or brachiocehalic	1,778	1,021	726	5	1	25
36218	Selective Catheter placement-3rd order or more selective	494	361	124	2	1	6
36831	Thrombectomy, AV fistula w/o revision, graft	25	13	11	-	-	1
36832[4]	Revision of A/V fistula	50,836	23,867	25,147	234	681	907
36833	Revision of A/V fistula w thrombectomy (NEW CODE-1999)	24	13	10	-	-	1
36834	Plastic repair of AV aneurysm	1,244	689	534	9	11	1
37201	Transcatheter therapy - infusion for thrombolysis	28,258	8,037	18,861	675	12	673
37204	Transcatheter occlusion or embriolization	709	545	141	16	-	7
37205	Transcatheter placement of stents; percutaneous, initial vessel	7,253	3,253	3,739	155	3	103
37206	Transcatheter placement of stents; percutaneous, additionial vessel	867	478	344	28	-	17
37207[5]	Transcatheter placement of stents; open, initial vessel	-	-	-	-	-	-
37208	Transcatheter placement of stents; open, additionial vessel	40	27	9	3	1	-
37250	Intravascular ultrasound during therapeutic intervention, initial	134	84	46	4	-	-
37251	Intravascular ultrasound during therapeutic intervention, additional	28	24	4	-	-	-
49423	Exchange of drainage catheter	242	126	111	-	-	5
Totals[6]		387,506	126,637	240,640	11,795	1,019	7,415

[1] Final Medicare Adjudicated Claims Data for 1998.

[2] All other locations (I.e. Indian Reservation, Skilled Nursing, Facility, Home Health Agency, Hospice).

[3] Code 34101 is currently on the ASC approved list, but scheduled to be removed.

[4] Code 36832 is currently on the ASC-approved list, should be 36833 - a new code & "sub-code" of 36832.

[5] There is no data on code 37207, but is a procedure that could be performed in either IP or OP.

[6] Dr. Collins estimates that pure vascular access services performed inpatient cost Medicare 75 percent more than in an outpatient facility.

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Testimony for the Written Record

Submitted by: Joel D. Kopple, M.D.
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"Kidney Dialysis Patients: A Population at Undue Risk?"

SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE

June 26, 2000

The National Kidney Foundation (NKF), the country's oldest and largest voluntary health agency devoted to the needs of Americans with kidney disease, appreciates the opportunity to provide testimony for today's hearing. NKF has long been dedicated to advancing the quality of care delivered by dialysis clinics in the United States, including providing information and resources to renal professionals, kidney patients and their families. For example, on November 14, 1994, NKF President Neil Kurtzman, M.D. hosted a media event at the Washington Press Club to highlight opportunities to improve outcomes for dialysis patients. This was followed up with a comprehensive program for the development of practice guidelines (the National Kidney Foundation Dialysis Outcomes Quality Initiative, or NKF/DOQI). These guidelines, initially published in 1997, were designed to enhance dialysis adequacy, anemia management and vascular access placement and preservation by assisting decision making by clinicians. NKF/DOQI is being implemented in dialysis facilities throughout the United States.

Fourteen years before the publication of the NKF/DOQI, the Foundation pioneered in the development of guidelines for the multiple use of hemodialyzers. The statement issued at that time emphasized testing for effectiveness of residual function of reprocessed dialyzers before their subsequent use. The NKF has updated its position paper on dialyzer reuse periodically since then, with subsequent reports published in 1988 and 1997.

In addition to providing tools for renal health professionals, the Foundation has followed a parallel course, in an effort to empower dialysis consumers with information and encourage them to participate in making decisions that will affect their overall quality of life. Some landmarks in this effort have been the video series: ***People Like Us*** and the programs: ***People Like Us, Live*** and

Rehabilitation, Information, Support and Empowerment **(RISE).** This multifaceted approach is the hallmark of the National Kidney Foundation, reflecting the organization's diverse constituencies. At the present time we count 26,283 members, including dialysis and transplant patients (and their loved ones), nephrologists, renal dietitians, nephrology social workers, and nephrology nurses and technicians.

On two occasions during 1999 the National Kidney Foundation presented testimony suggesting that the ESRD Networks should make all dialysis patients aware of the programs which are offered by NKF, mentioned above, as well as the wealth of printed materials available from NKF and other renal patient groups, such as the American Association of Kidney Patients. The first presentation was at a HCFA town hall meeting on the new Network Scope of Work in Baltimore on August 31, 1999 and the second opportunity was presented at a meeting of the Medicare Payment Advisory Commission on October 14, 1999. Informed patients are more likely to adhere to their health care regimen and that will lead to improved outcomes, reduced hospitalization and better controlled health care costs.

The National Kidney Foundation has continually emphasized the relationship between staffing of dialysis units and desired outcomes for dialysis patients. Since there have been only modest raises in the Medicare reimbursement rate for dialysis treatments during the last 20 years and since Medicare is the predominant payer for dialysis services in the United States, dialysis providers have tended to increase staff loads and reduce the educational level of the mix of personnel employed to provide renal replacement therapy and related services. The attached National Kidney Foundation Position Statement, ***Quality of Dialysis Care,*** calls for "[a]dequate staffing for the provision of care

by qualified, certified, competent and caring personnel (nephrologists, nurses, technicians, dietitians, social workers) at a level appropriate to the acuity of the patient population." For this reason, NKF supports the retention and expansion of the structure and process requirements relating to personnel in HCFA's Conditions for Coverage of Suppliers of End-Stage Renal Diseases (ESRD) Services. In addition, the NKF Council of Nephrology Social Workers and the NKF Council on Renal Nutrition have developed algorithms that can be used to assist units in assessing staffing patterns. Finally, the National Kidney Foundation Dialysis Technician Task Force has issued recommendations with respect to the level and content of training for dialysis technicians. Its report, issued in 1993, is also attached.

HCFA has relied upon state survey agencies to assure quality of care. Unfortunately, because of budgetary restrictions, the number and frequency of site visits at dialysis clinics has declined. For that reason, the National Kidney Foundation supports the provision in the Administration's FY 2001 Budget Request which is designed to decrease intervals between site visits of dialysis clinics from once every six years to once every three years. We hope that the Senate will appropriate the funding that has been requested.

Finally, much remains to be done to fulfill the promise that the National Kidney Foundation Dialysis Outcomes Quality Initiative offers for reducing mortality and morbidity in this country's dialysis patients. While HCFA's ESRD Clinical Performance Measures (CPM) Project has advanced the implementation of the NKF/DOQI Guidelines, there is a crucial role that HCFA can play to facilitate the goals of the NKF/DOQI Project by updating coverage policy for laboratory tests for dialysis patients. Current regulations for laboratory tests are confusing and unevenly interpreted by carriers

and fiscal intermediaries. As a result, reimbursement policy for testing impairs the physician's ability to ensure safe and effective care for ESRD patients, in general, and, in particular, makes it difficult to order the tests recommended by NKF/DOQI. HCFA should initiate a review of the appropriateness and frequency of covered lab tests and revise policies for reimbursement of lab tests based on current scientific knowledge.

Attachments

National Kidney Foundation Position Statement

Quality of Dialysis Care

Until 1960, end-stage renal disease (ESRD) was a terminal illness. Experience in the 1960s documented the feasibility of affecting the outcome of ESRD with chronic dialysis. The Social Security Amendment of 1972 (PL 92-603) extended Medicare coverage to those with ESRD requiring dialysis and transplantation, and thereby made this lifesaving technology available to all Americans. When this model legislation was enacted in 1973, only about 11,000 patients were its beneficiaries. Today, some 200,000 ESRD patients are alive because of this program. By the turn of the century 300,000 citizens will be its beneficiaries.

Individuals, who only 30 years ago would have died, now have the potential to lead a fulfilling life made possible because of the availability of financial support from the federal government and a committed and responsible health care delivery system. Thus, for the past 23 years, ready access to dialysis care has successfully and effectively prolonged the lives of hundreds of thousands of individuals and made it possible for the transplantation of kidneys to tens of thousands of them. However, its widespread availability and compounding social and fiscal factors have raised problems that were not foreseen at the inception of this most successful program. Essentially, the process of keeping individuals afflicted with a terminal illness alive as long as possible has not been free from complications and problems.

Concern over these issues has prompted the ESRD community, in general, to embark on a concerted effort to seek solutions that would allow for the delivery of the highest possible quality of care to the beneficiaries of the program. The National Kidney Foundation, in its long-term commitment to this goal, has developed the following statement of what constitutes high-quality dialysis care. In a fiercely competitive marketplace, driven by cost containment, this statement on the quality of care is intended to serve as a catalyst to:

1. Protect the care and welfare of the patient while facilitating the process of providing optimal treatment outcomes.
2. Assume fiscal responsibility to hold costs at a minimum while at the same time assuring the quality of the services rendered.
3. Provide a basis for an integrated information system that will allow the development of a partnership between consumers, professionals, and providers who share the common goal of optimal care.

To achieve these goals will take the cooperative effort of all three constituents of the system: the patient, the delivery system, the provider.

The Patient

ESRD patients receiving dialysis must be treated in a holistic manner by a qualified and adequately staffed multidisciplinary health care team, which includes the patient as a responsible member of the team. The care delivered must be predictable, comfortable, and compassionate, and should maximally increase life expectancy and reduce the need for hospitalization. To this end, patients must be active and informed participants in all aspects of their care, including the choice of treatment modality. As active members of the health care team, they must in turn be responsible and accountable for treatment outcomes, so far as they are psychologically and physically capable.

Several patient-related factors cannot be changed, but with due recognition and diligence can be ameliorated. As a rule, they will demand increased attention, closer monitoring, and committed resources to optimize quality of care:

- Age, at its both extremes, with its attendant social, fiscal and physical demands.
- Comorbid conditions such as coronary artery disease, congestive cardiomyopathy, hypertension, diabetes, hyperlipidemia, arrhythmias, and malignancies.
- The patients' perception of their physical and emotional needs and their satisfaction with the quality of dialysis care. These can and should be assessed by proper tools, compared with facility staffing characteris-

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tics, and satisfactorily resolved to the extent possible.
- Social and nutritional needs, either preexisting or brought about by the demands of ESRD and its treatment must be addressed by qualified, trained, and licensed individuals with access to the crucial resources that are necessary to resolve them.

The Delivery System

Factors that affect the quality of care but are related to the delivery of dialysis care itself are more readily amenable to change than patient-related factors, but will require additional resources, scientific validation, and improved technology. Some of the standards of adequacy of dialysis have been established, several are in the process of being formulated, and others must await scientific data to be established. None of these standards or guidelines, however, will be able to improve the quality of care optimally unless they are monitored closely and supported adequately. To this end a uniform system of continuous quality improvement measures should be in place and supported by adequate instructional information, and, where justified, accountable increased funding resources. The ultimate outcome must be continued reduction in mortality and morbidity. The principal issues that require immediate attention are:

- Dose and duration of dialysis, which is optimal, individualized, and adequately monitored. ($Kt/V > 1.2$ for hemodialysis, weekly $Kt/V > 1.85$ for peritoneal dialysis). The appropriate Kt/V dose for pediatric patients remains to be determined.
- Water purity and individually tailored dialysate composition.
- Controlled ultrafiltration systems that minimize adverse reactions on hemodialysis.
- Reuse procedures that conform to AAMI standards.
- Optimal membrane characteristics of biocompatibility and flux.
- Improved functioning of vascular access with adequate preventative measures that are essential to reduce hospitalization.
- A hematocrit level that is physiologically optimal (34% to 36%).
- Adequate protein (≥ 1 g/kg/d) and caloric (≥ 30 to 35 kcal/kg/d) intake, closely monitored nutritional status (albumin > 3.5 g/dL), and stable weight.
- Careful monitoring and appropriate treatment for bone disease.
- Adequate staffing for the provision of care by qualified, certified, competent, and caring personnel (nephrologists, nurses, technicians, dietitians, social workers), at a level appropriate to the acuity of the patient population.
- Easy access to functional and vocational rehabilitative training programs.
- Improved technology and training to reduce infectious complications.
- Adoption of a program for Advanced Directives.
- Institution of an educational program covering treatment options, initiation, and withdrawal of renal replacement therapy.
- A system for continuous quality improvement for all of the above.

The Provider

A third set of factors that affects the quality of dialysis care is related to the regulatory and funding component. The ESRD program in the United States has been our first experiment with principally a single-payer medical care. It is also our first example of potential pitfalls of this approach. The annual costs of this program have increased steadily only because the number of patients kept alive by it has increased. The actual reimbursement rate per individual course of treatment has steadily declined. Past reductions in reimbursement have been instituted without due consideration or analysis of their impact on outcome, morbidity, and mortality. This must be reevaluated and resolved.

The following people were on the committee that developed the policy statement:

Garabed Eknoyan, MD, Chair
Debra Barkman, RN, BS, CNN
Joyce Ezaki-Yamaguchi, RD, CS
Joseph Letteri, MD
Nathan Levin, MD
Peter Lundin, MD
William McClellan, MD
Rosa Rivera-Mizzoni, MS, RD, LD

National Kidney Foundation Dialysis Technician Task Force†

AT ITS SEPTEMBER 14, 1990 meeting, the National Kidney Foundation (NKF) Public Policy Committee focused on the increasing proportion of patient care services delivered by technicians. Similarly, the committee for the Study of the Medicare End Stage Renal Disease Program appointed by the Institute of Medicine noted:

> "Data strongly suggest that decreased reimbursement has led to decreased staffing in dialysis units (and) to shifts from nurses to technicians . . . There is no evidence that these changes in staffing patterns have affected quality (of patient care). However, professional opinion favors this contention.

At the conclusion of its deliberations, the NKF Public Policy Committee recommended that the President of the Foundation appoint a special task force on dialysis technicians. Such a group would be asked "to review public policy options and make recommendations concerning job descriptions for dialysis technicians, as well as standards for training and possible mechanisms for certification."

Based on this recommendation, Saulo Klahr, MD, then President of the NKF, appointed a group representative of nursing, technology, medicine, and administration, which met on Sunday, December 2, 1990, and was chaired by Tom Parker, MD. At the same time, the American Nephrology Nurses' Association (ANNA), and the National Association of Nephrology Technologists (NANT) assembled a task force to study this issue.

At December 1990 meetings, these groups agreed to study State Nurse Practice Acts, sample job descriptions and outlines of representative training programs for dialysis technicians, and summaries of the ways other specialties have dealt with the issue of unlicensed practitioners. The NFK committee drafted a technician patient care role description and a list of minimum curriculum components based on a position statement developed earlier by NANT. The drafts were widely circulated, heavily revised, and presented to the ANNA/NANT group. At November 1991 meetings, the ANNA/NANT task force also decided to investigate practice models with the goal of preparing global recommendations on the roles of all care givers in nephrology. The goal was to prepare a joint statement on technician practice early in 1992.

At a meeting held in Chicago on April 30, it was announced that the ANNA board of directors had decided not to continue with the technician project. Instead, the association would concentrate on developing a research-based practice model for nephrology nursing. NANT announced that its board of directors had decided to issue a position paper encompassing the entire scope of the nephrology technologist role. Neither organization objected to an NKF publication of the patient care role description and curriculum, as long as revisions made by the task force were kept.

INTRODUCTION

A review of State Nurse Practice Acts indicates that no legal barriers exist to the articulation of a role description for dialysis technicians based on existing practice patterns. The notable exception is the administration of medications. The NKF does not take exception to the administration of routine medications by dialysis technicians, but understands that local law may prohibit some activities. The NKF Committee recognizes differences in state nursing and medical practice acts and regulations promulgated by state legislatures and health departments. This document is meant to support existing laws and regulations. Each facility will, of course, comply with applicable regulations. While it is possible to agree on an outline of components for a model training program for dialysis technicians who function in patient care roles, it may be premature to make recommendations concerning certification.

The dialysis patient care technician role description and curriculum outline that follow attempt to define a person who, under supervision, performs safe, effective, and adequate hemodi-

From The National Kidney Foundation.

Received April 2, 1992; accepted in revised form October 7, 1992.

† Task Force Members: Thomas F. Parker (Chairman), Raymond K. Hakim, Jeffrey B. Hover, Sally Burrows Hudson, Jean Kammerer, Nathan W. Levin, and Anthony Messana.

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alysis treatments. The technician is not intended to be a "nurse substitute," or an economical alternative to a biomedical specialist. The elements of the job description and training outline are meant to supply basic skills and knowledge to people who provide dialysis treatments as part of a team. The NKF Technician Task Committee was charged with determining a job description and outline of training program that refers to a person who provides safe and adequate dialysis treatments under supervision. It is the goal of the NKF that such supervision be provided by a registered nurse.

In the interest of defining the technician as broadly as practical, to permit flexibility over time, and allow individualization, detail in job elements and curriculum outline is minimal. Certain items are included because background information is necessary for the technician to understand the broader picture of hemodialysis, not because it is expected that they will be expert in these concepts. For example, anatomy, physiology, and pathophysiology as referred to in the outline are intended to provide a basic understanding of what it is dialysis is supposed to accomplish. A technician must understand what patients will be dealing with in terms of symptoms and clinical signs if that person is to report effectively to the supervising Registered Nurse. If the technician is to provide safe and effective dialysis treatments, he or she must have a global understanding of the systems and processes involved.

Individual facilities will adapt the outline to their programs, but basic knowledge of causes and outcomes related to end-stage renal disease (ESRD) is within the scope of unlicensed personnel. The intent is not to create a category of care-giver or infringe on practice domains of others. That some technician duties outlined in the job description overlap with parts of some states' definitions of nursing is coincidental. There is overlap in most health care roles. Nurses recognize, for example, a safe dose of a narcotic analgesic, or a drug level in a toxic range, or abnormal electrolytes, or symptoms of a "medical" emergency. That knowledge does not make them physicians, nor does appropriate response mean that they are practicing medicine. The important concept is that a team cares for the patient. If the technician is to report unusual occurrences to team members, he or she must be able to differentiate the usual from the unusual.

Water treatment, quality assurance, and quality control may not be the purview of patient care staff in larger units. In smaller units, professionals and nonprofessionals may overlap duties in many patient care and some plant safety areas. Everyone who dializes needs to know what constitutes safe water, problems with quality, and safety issues. We may not all need to know how to achieve American Association of Medical Instrumentation (AAMI) water, but surely we should understand the complications that can occur when water is impure, when sterilant is not carefully rinsed, when conductivity errors occur, or when safety systems malfunction. The purpose of including these elements in the outline is to provide broad guidance to facilities, organizations, or others involved in technician education in order for curricula to be tailored to individual facility needs.

The Committee believes that the included elements listed need to be addressed for all patient care technicians. The depth will be determined by the original preparation of the orientee, the actual working job description of the dialysis technician, and the needs of the facility.

DIALYSIS TECHNICIAN PATIENT CARE ROLE DESCRIPTION

Dialysis technicians practice in multiple roles. In patient care roles, the technician's primary responsibilities include assisting, under supervision, in the care of patients undergoing hemodialysis treatments. It is the goal of the NKF that such supervision be provided by a registered nurse.

Qualifications: High school diploma or equivalency.

Experience: Courses in basic sciences. Previous health care experience (such as Certified Nurses' Aide or medical technician/technologist).

Reporting relationships: Reports directly to the registered nurse. Adheres to all applicable regulations, statutes, and practice acts.

The technician:

1. Assembles necessary supplies.
2. Prepares dialysate according to established procedures and the dialysis prescription.
3. Assembles and prepares the dialysis extracorporeal circuit according to protocol and dialysis prescription. Installs and rinses di-

alyzer and all necessary tubing. Tests monitors and alarms, conductivity, and absence of residual sterilants. Sets monitors and alarms according to unit and manufacturer protocols.

4. Obtains predialysis vital signs, weight, and temperature according to unit protocol and informs the nurse of unusual findings.
5. Inspects access, administers local anesthesia, performs venipuncture, and initiates dialysis according to established protocol, prescription, and universal precautions as permissible by state law. Reports unusual findings to the registered nurse.
6. Determines clotting times and administers anticoagulants according to unit protocols and prescription as permissible by state law.
7. Measures and adjusts blood flow rates following established protocols and prescription.
8. Calculates and adjusts fluid removal rates according to established protocols and prescription.
9. Monitors patient and equipment, reporting unusual occurrences to the registered nurse. Changes fluid removal rate, patient position, and administers replacement saline as directed by the nurse, physician order, or unit protocol.
10. Documents findings and actions on the appropriate flow sheet per unit protocol.
11. Monitors equipment for safe and proper functioning. Responds to alarms, making appropriate adjustments.
12. Responds appropriately to dialysis-related emergencies such as cardiac or respiratory arrest, needle displacement or infiltration, clotting episodes blood leaks, air emboli, etc. Initiates cardiopulmonary resuscitation (CPR).
13. Discontinues dialysis and establishes hemostasis following unit protocol. Inspects, cleans, and dresses access according to unit protocol. Reports unusual findings and occurrences to the registered nurse.
14. Obtains and records postdialysis vital signs, temperature, and weight.
15. Discards supplies and sanitizes equipment according to manufacturer and unit protocol.
16. Communicates emotional, medical, psychosocial, and nutritional concerns to the registered nurse.
17. Maintains professional conduct, good communication skills, and confidentiality in the care of patients. Participates in the multidisciplinary process.
18. Collaborates with the registered nurse in identifying and meeting patient education goals.

DIALYSIS TECHNICIAN MINIMUM CURRICULUM COMPONENTS FOR THE TECHNICIAN PROVIDING PATIENT CARE

The following outline lists elements necessary in a curriculum for preparing technicians in the patient care aspects of the dialysis technician role.

1. Introduction to dialytic therapies: History and major issues
   - A. History of dialysis
   - B. Definitions and terminology
   - C. Communication skills
   - D. Ethics, confidentiality
   - E. Multidisciplinary process
   - F. Roles of other team members
   - G. Information about related organizations
2. Principles of hemodialysis
   - A. Principles of dialysis
   - B. Access to the circulatory system
   - C. Anticoagulation, local anesthetics, saline
3. The person with kidney failure
   - A. Basic renal anatomy, physiology, elementary pathophysiology
   - B. The effect of renal failure on other body systems
   - C. Symptoms and findings related to the uremic state
   - D. Modes of renal replacement therapy, including transplantation
   - E. Elementary renal nutrition
   - F. Psychosocial aspects of ESRD: concrete vs counseling services
4. Dialysis procedures
   - A. Technical aspects of dialysis: operation and monitoring of equipment, initiation and termination of dialysis
   - B. Glucose monitoring, hemoglobin/hematocrit monitoring, anticoagulation monitoring

C. Elementary bacteriology, aseptic technique, sterile technique, specimen handling, universal precautions
D. Emergency procedures and responses such as CPR, air embolism management, line separation response
E. External and internal disasters: fire, natural disasters, emergency preparedness
F. Safety, quality control, quality assurance
G. Basic documentation

5. Hemodialysis devices
A. Conventional, high efficiency, high flux: theory/practice
B. Dialysate composition, options, indications, complications, safety
C. Monitoring and safety
D. Disinfection of equipment

6. Water treatment
A. Standards and regulations
B. Systems and devices
C. Monitoring
D. Rationales

7. Reprocessing, if applicable
A. Principles of reuse
B. Safety, quality control, universal precautions, water treatment
C. Issues: overview

8. Patient teaching
A. Role of the technician in supporting patient education goals
B. Principles of learning
1. Hemodialysis principles
2. Interpretation and reporting of symptoms during dialysis (ie vital signs)

9. Infection control and safety
A. Risks to patients—nosocomial infections, accidents
B. Risks to employees—universal precautions
C. Electrical, fire, disaster, environmental safety, hazardous substances

10. Quality assurance/continuous quality improvement (QA/CQI)
A. Role of the technician in quality assurance activities
B. Principles of QA/CQI
C. Importance on ongoing quality control activities in dialysis

ANNA
Celebrating 30 Years of Service to the Nephrology Community
American Nephrology Nurses' Association

STATEMENT OF THE

AMERICAN NEPHROLOGY NURSES' ASSOCIATION

TO THE

SENATE SPECIAL COMMITTEE ON AGING

Kidney Dialysis Patients: A Population at Undue Risk?

June 26, 2000

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The American Nephrology Nurses' Association (ANNA) is the largest professional nephrology group in the United States representing over 11,000 nurses dedicated to improving the care of nephrology and kidney transplant patients. ANNA welcomes the opportunity to submit a written statement to the Special Committee on Aging regarding the quality of care provided for End Stage Renal Disease (ESRD) patients in the United States. We want to work with Congress to increase the quality of care for the 300,000 ESRD patients throughout this country.

ESRD patients are sicker today and have more co-morbidities than in the past. The ESRD population will also increase due to our aging population. In addition, this entire country is facing a severe nursing shortage and it is doubtful this will end. Due to this shortage and pressure for budgetary cuts, there is more reliance on technicians in dialysis facilities. Over the past few years, the nephrology community has had to cope with Medicare payments to dialysis facilities that have outpaced inflation. This has affected the provision of a sufficient and appropriate mix of labor resources in dialysis facilities. Reimbursement levels are imposing upon the provision of services and supplies. All of these factors jeopardize ESRD patients' access to services and care. Because of these changes, we have seen increased patient-staffing ratios; more technicians utilized; and reuse of some supplies. The renal community is constantly coping with maintaining high standards of care despite increasing restraints in which to maintain this same quality of care.

As nurses caring for nephrology patients, we are particularly concerned with

- maintaining quality care;
- who is providing the care and education that ESRD patients receive;
- ESRD patients' access to care in rural areas;
- the scope and timeliness of data collected by the ESRD networks; and
- the provision of quality care in dialysis facilities.

ANNA's Recommendations for Improvements to the ESRD Program to Assure Quality of Care

1. **Improve data gathering and sharing of information between the 18 ESRD Networks and state survey agencies.** The means of gathering and sharing data among the ESRD Networks is out-dated. Better use by computer for the collecting and sharing of data must be made available. There must be accurate maintenance of records and statistics of the number of patients receiving dialysis, along with the number of admissions and reasons for ESRD patients' admittance to inpatient units. There must be better tracking of the complications that patients have while on dialysis, such as access problems, cardiac complications, strokes, gastrointestinal bleeds and other morbidities that they experience in community settings that may cause hospital admissions.

   All data gathered must be timely to be truly helpful in changing procedures, protocols and policies for ESRD patients. Data that is two years old cannot effectively provide quality care. Data collection on who is providing care for dialysis patients, including the number

of advanced nurse practitioners and their responsibilities, in the various settings is crucial. Data that is gathered must be shared in more efficient and meaningful ways than what is currently in place. ANNA also wants to assure that those providing care to ESRD patients is appropriate and safe. Who is providing care to patients and staffing ratio information is crucial.

2. **There should be a better means to ensure state surveyors are well trained, that there is timely and sufficient monitoring of dialysis facilities, and that meaningful follow-up for facilities with deficiencies is carried out.** There must be means to provide surveyors with more power to investigate complaints and provide meaningful follow-up and revisions for known violations found in facilities. ANNA is extremely concerned about the lack of power given to surveyors and the backlog that exists for surveys of dialysis centers. If a patient reports questionable activities or concerns at a dialysis center and a surveyor makes a site visit validating a problem, the surveyor is powerless to enforce any needed changes. The current system does not assist in meaningful transformation of centers giving less than quality care, solutions to obvious problems or assure necessary changes are enforced for centers with violations.

Many states are experiencing a backlog of facilities that should be surveyed. There are not enough trained surveyors to carry out needed work, and surveys should be done approximately every three years. In order for ESRD patients to receive quality care and continue that quality, there must be a mechanism for enforcement once a surveyor finds violations. Education and follow-up of facilities' staff is necessary to assure change. The

possibility of statutory requirement of ESRD facilities would assure that certification surveys and follow-up inspections occur. Increased options for dealing with deficient facilities must be tackled with better follow up and education or penalties. ANNA is hesitant to recommend monetary penalties due to its possible detriment to patients and access of care.

2. **ANNA believes that RN's must be the health care professionals directing the education process for ESRD patients regarding dialysis, peritoneal dialysis and the education of technicians.** RN's provide essential education to ESRD patients regarding their diagnosis, dialysis, prevention of complications, treatments, medications and care of access devices. Those patients using peritoneal dialysis should receive their information from a RN. In addition, RN's must be the key individuals to provide education and oversight to technicians. Because RN staffing ratios are stretched to the limit in many facilities, it is becoming increasingly difficult to provide all the education that patients need initially and on a continual basis. This education should not be delegated to technicians.

ANNA is also concerned about the training, standards and qualifications that technicians must have and the variances that occur from state to state. ANNA believes that RN's must oversee the educational standards for technicians to ensure competency and quality control for the care technicians provide.

ANNA also acknowledges the increased staffing problems that may occur in rural areas. ANNA urges Congress to make meaningful inroads to address the nursing shortage by increased educational funding for schools of nursing and advanced practice nurses. In addition, an annual inflation formula applied to the composite rate, resulting in an annual update of this payment, would assist in compensating for staff salaries and administrative costs. This would assist in providing an adequate number of RN's in dialysis facilities. HCFA has no authority to do this. This change in the formula for an annual update must come from Congress.

3. **ANNA is concerned with the rate of infections in the various access devices for dialysis.** There are insufficiencies in tracking the number of infections and clotting problems for the access devices used in ESRD patients. There must be more data on this issue to effectively assess the types of patients who develop infection, lapses in sterility, reasons for infection and prior or on-going patient education to prevent infection to better identify problems and overcome them. In addition, other morbidities, such as diabetes, make a significant difference in the rate of infection in ESRD patients. If improvements in teaching, care and prevention of infection are to take place, the renal community must know how other issues and morbidities interact with the rate of infection in various devices. In addition, clotting problems have increased for various reasons. Timely correction of clotting problems or other vascular access problems must occur, such as doppler flow studies and timely referrals.

4. **ANNA wants to assure the quality of care for ESRD patients enrolled in managed care, and opposes a repeal of Section 1876 of the Social Security Act prohibiting Medicare ESRD beneficiaries from participating in managed care plans.** ANNA wants to assure that ESRD patients have access to specialty care in a timely and consistent manner, appropriate referral processes and early intervention for those who are in a pre-renal state.

ANNA looks forward to working with Congress and HCFA to accomplish these important goals to improve the care provided for ESRD patients. Thank you for this opportunity to present our comments here.

Fresenius Medical Care

June 23, 2000

The Honorable Charles Grassley, Chairman
Special Committee on Aging
United State Senate
Washington, DC 20510

Dear Mr. Chairman:

I am writing on behalf of Fresenius Medical Care–North America to express our support for a thoughtful re-evaluation of the current Medicare End Stage Renal Disease (ESRD) program.

As you know, Subpart U of the Medicare regulations establishes the basic operating standards for dialysis facilities in this country. These standards have not been significantly modified for more than 20 years. As a result, the regulatory structure which currently governs the day-to-day operation of U.S. dialysis facilities has not kept pace with advances in patient care and management. Similarly, the composite rate paid by Medicare to support basic dialysis services has only been increased twice since 1983. In real dollar terms, the rate of reimbursement has actually declined substantially over that period.

Clearly, the time has come for the Congress and HCFA to join with the dialysis community in undertaking a broad-based re-evaluation of the structure and focus of the Medicare ESRD program. The goal of this effort should be to bring the program up to date with recent medical and technical innovations as well as outcomes-oriented evaluation. Although great progress has been made in the last decade in improving the quality of care furnished to ESRD patients, further improvements can and should be made. To achieve this end, it is important that both regulatory and reimbursement policies be carefully aligned to promote innovation and improved quality outcomes for ESRD patients.

Some of the recommendations that we expect to be presented to the Committee during its hearing on ESRD quality next week should offer a foundation for a constructive discussion of program improvements.

1. Standardization of Outcome Measures. We support the use of standardized outcomes-based quality measures to assess the performance of individual dialysis facilities. Dialysis providers, nephrologists and other renal healthcare professional should be involved with HCFA in developing such measures based on recognized medical and clinical criteria. Measures should focus on key indicators of medical outcomes and patient well-being. The clinical performance measures developed by HCFA, as well as the parameters addressed in the Dialysis Outcomes Quality Initiative (DOQI) supported by the National Kidney Foundation, should be used as a starting point for discussion. At a minimum, parameters addressing the adequacy of dialysis treatment (both hemodialysis and peritoneal dialysis), anemia management, nutritional status, patient mortality and hospitalization, and vascular access should be included in any new program.

Mechanisms for collecting and reporting data should be transparent to, and fully understood by, all affected parties. Reasonable opportunities to correct data input or reporting errors should be built into the process.

2. Accountability for Patient Outcomes. We support the proposition that dialysis facilities and treating nephrologists should be held accountable for the quality of renal care delivered to patients. It would be appropriate to revise the Medicare conditions of coverage described in Subpart U to confirm this important principle. Providers and nephrologists should be involved in developing effective administrative mechanisms for enforcing accountability through site surveys as well as public disclosure of comparative quality performance measures. We believe that making standardized performance data on individual dialysis facilities publicly available to patients and physicians will exert a powerful incentive for quality improvement by those facilities.

3. Patient Complaints. Dialysis facilities should work cooperatively with the existing Renal Networks and State agencies to address patient concerns and complaints in a fair and timely manner. We support a further integration and coordination of these efforts. HCFA and the Networks should work with dialysis providers and nephrologists to improve patient education and awareness of grievance options. For example, patients should have the ability to bring questions or concerns about the operation of a dialysis facility to the Director of Nursing or the Medical Director. Patients also need to be informed of available dialysis facilities near their homes and to have a mechanism to voice concerns when they are referred past nearby dialysis units for the convenience or economic benefit of physicians or medical centers. In addition, we believe that dedicated renal "Hotlines" should be established at a State or Network level to give patients an additional option for voicing concerns on a confidential basis if they wish.

   It is important that complaints and grievances be evaluated by qualified healthcare personnel. The focus should be on problem-solving, not paperwork. Where complaints are based on patients misunderstanding of the treatment process (i.e. frustration with the length of dialysis sessions prescribed by the nephrologist), physicians and dialysis facility staff should be encouraged to place more emphasis on patient education and communication. In other instances, involving failure to meet established standards of practice or care, more direct remedial action may be required. Dialysis facilities should be expected to maintain complaint files in good order and with proper documentation of effective investigation and follow through.

4. Site Surveys. We support the establishment of minimum cycles for conducting Medicare site surveys of existing dialysis facilities. Many State agencies lack the resources to hire qualified personnel to perform surveys on a regular basis. This must be corrected and HCFA must be prepared to assume appropriate financial responsibility for doing so. We also support greater involvement by the ESRD networks in the survey process. Nephrologists, dialysis providers and other renal healthcare professionals should be encouraged to take an active role in improving the effectiveness of the survey process to ensure a tighter focus on issues directly affecting the quality of patient care.

Standards should be strengthened for the qualifications and competence of State surveyors, including experience in the care of ESRD patients. Survey results should be reviewed by the Networks and recommendations put forward for improving the effectiveness of the process. Feedback should also be encouraged from dialysis providers, nephrologists, other renal healthcare professionals, and patients to ensure that the process is functioning properly and is addressing matters most relevant to patient outcomes.

5. Identification and Analysis of Medical Errors and Injuries. We have long supported programs designed to identify and analyze the causes of medical errors and injuries. This should be part of the Continuous Quality Improvement (CQI) program at every dialysis facility. While each dialysis facility's goal should be the elimination of treatment errors and medical injuries, the human element in clinical and medical practice makes this an elusive goal. Nevertheless, organized vigilance in investigating errors and following through on corrective measures will help minimize their effect on patients.

   To support this effort, a medical information system should be available to collect data on significant medical injuries on an industry-wide basis. Such a system should be developed jointly with HCFA, the Networks, and dialysis providers. We support proposals for the Networks to take the lead in establishing pilot projects in this area and are prepared to participate in these projects. We urge HCFA and the Networks to ensure that planning for these pilot projects is open to dialysis facilities and nephrologists, and that the projects build upon medical information systems already in place.

These initiatives are consistent with Fresenius Medical Care's longstanding commitment to the quality of the renal products and services that it provides to patients and providers on a worldwide basis. Fresenius Medical Care has been a leader in the dialysis field for more than 20 years. In the late 1970s it developed and introduced dialysis machines that, for the first time, were able to control effectively the removal of water during the dialysis process. This breakthrough technology also allowed the use of new, biocompatible membranes which reduced the level of stress associated with dialysis treatments. Since acquiring the dialysis services and products operations of National Medical Care in 1996, Fresenius Medical Care has implemented a number of programs and initiatives which demonstrate our continuing commitment to the delivery of quality medical care to ESRD patients and our acceptance of accountability for meeting that objective.

We have established parameters and goals for a designated set of key clinical quality indicators and outcomes. These measurements include: mortality, standard mortality ratio (SRM), standard hospitalization ratio (SHR), length and number of hospitalizations, adequacy of dialysis (URR and Kt/V), adequacy of nutritional therapy, adequacy of anemia management, adequacy of bone disease treatment, vascular access placement, measurement of patient compliance with treatment orders and yearly measurement of patient satisfaction. This data is compiled centrally and comparative performance data is distributed to regional and facility clinical staff. Through this process, the Medical Director and clinical staff at each facility are able, on a continuous basis, to access their achievement of pre-established Company goals and to compare their performance to other units in their region and to national averages.

Fresenius Medical Care also has developed a system for collecting and addressing complaints from patients and clinical staff. Both patients and staff may lodge complaints to facility administrators or Medical Directors as well as management personnel and corporate executives. In addition, clinical staff have access to a confidential "Hotline" staffed by an independent organization. Company employees and managers are expected to take patient and staff complaints seriously and are required to follow Company procedures for evaluation and follow-through, including appropriate documentation. We believe that listening carefully to patient and staff concerns provides an important "early warning system" for problems that could become more serious if undetected or not addressed in a timely manner.

Fresenius Medical Care has developed a mechanism for monitoring a broad range of clinical variances (medical errors or adverse events) which are reviewed and trended at the corporate and regional level. Significant adverse events are analyzed to determine root causes and define appropriate corrective actions. A reporting system measures upper and lower control limits and trends. Clinical variances that exceed upper control limits or show trend increases are analyzed in greater detail by clinical personnel at regional and corporate levels. It has been our experience that rigorous attention to this system has played an important role in reducing the frequency of clinical variances at our facilities since the program was initiated.

Overall, we believe that these data collection and reporting systems are unique in the dialysis industry in their scope and detail. We believe that they have made a measurable contribution to improvements in medical outcomes for our patients. Implementation of national data collection systems to track medical outcomes, as well as patient complaints and clinical variances for all dialysis facilities, would permit them to compare their performance to that of their peers on a regional and national basis. Public disclosure of standardized performance data would also permit patients and physicians to select a dialysis facility based on objective quality and outcome measures. We have already met with staff representatives of HCFA and the Office of Inspector General to describe our systems and to show their cumulative effect on measurable quality indicators. We would be pleased to provide a similar briefing to the members and staff of this Committee.

As the Committee moves forward with its consideration of recommendations for improving the quality of ESRD care, we hope that it will not overlook the important role played by Medicare reimbursement policies. Since its inception in 1983, the bundle of services covered by the composite rate for ERSD services has remained essentially unchanged. Over time the reimbursement rate for these services has actually declined substantially in real dollar terms. While providers have been able to offset some of this revenue loss through lower equipment and supply costs and other productivity improvements, this cannot continue indefinitely. Recent proposals to reduce reimbursement for several intravenous drugs that are commonly used in renal therapy will only exacerbate this problem and continue to erode the ability of providers to pursue the quality goals that we all believe are achievable.

We believe that it is time for the Congress and HCFA to take a hard look at both the structure and level of ESRD program funding. The current system is neither quality oriented nor fiscally sound. It is unsatisfactory for providers, patients, and HCFA. It needs to be changed.

Advances in ESRD treatment have led to an increase in the number and variety of services that are separately billable to Part B of the Medicare program. MedPAC estimates that approximately 35 percent of Medicare ESRD expenses are now paid outside the composite rate bundle. As these separately billable expenses have grown, Medicare carriers and intermediaries have become increasingly aggressive in challenging physician orders and provider claims for such services. While some of these challenges have had merit, others have not. The current scope and methodology of these financially-driven challenges have begun to have implications for the quality of patient care.

Fresenius Medical Care shares the frustration of providers, physicians, and HCFA in addressing these issues. Time and resources that are now devoted to claims administration activities could be better focused on patient care. Accordingly, we have been working for the past three years on legislative proposals to include two categories of separately billable ESRD services – clinical laboratory tests and oral and intravenous nutritional therapy – into an expanded composite rate bundle. This can be achieved on a budget neutral basis by transferring costs currently associated with these separately billable services to an enhanced composite rate payment. The House Ways and Means Committee Report on the Balanced Budget Refinement Act of 1999 directed MedPAC and HCFA to report on "whether the quality of care could be improved" and payments be made more appropriately if billings outside the composite rate were revised to include an appropriate mix of additional services, including laboratory tests and nutritional therapy.

We believe that enactment of this proposal will eliminate second-guessing of physician treatment decisions by Medicare contractors without sacrificing fiscal integrity. Tied to a broad national initiative to improve collection and reporting of patient outcomes (to ensure continued patient access to medically necessary services), it would represent an important first step toward building the composite rate to a level commensurate with the congressional and HCFA commitment to medical quality improvement. It is also important that the benefits of the modest increases in the composite rate that were enacted by the Congress last year be preserved through future annual rate adjustments tied to an appropriate medical cost index. There should also be a commitment to periodic review of the adequacy of the composite rate based on unforeseen or uncontrollable changes in provider costs. A more detailed summary of our proposal is being provided to the Committee staff.

We appreciate the Committee's interest in calling attention to the need for a stronger partnership among the government, dialysis providers, physicians and other renal healthcare professional, and patients to improve the quality of ESRD care. We hope that the Committee will support the further development of quality-oriented initiatives already underway by HCFA and the renal community. Adoption of the data collection and reporting proposals described above would represent an excellent start. However, attention must also be paid to reimbursement reform so that financial incentives are properly aligned with the achievement of improved patient outcomes.

We would welcome the opportunity to present our views to the Committee at a future hearing or to work with members of your staff to assist in your further consideration of these important issues.

Sincerely yours,

John Markus
Senior Vice President

JM/mep

cc: The Honorable John Breaux

ATTACHMENT 4

1: *J Clin Epidemiol* 1999 Mar;52(3):209-17

Association of dialyzer reuse with hospitalization and survival rates among U.S. hemodialysis patients: do comorbidities matter?

Feldman HI, Bilker WB, Hackett MH, Simmons CW, Holmes JH, Pauly MV, Escarce JJ

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The objective of this study was to determine whether the associations between reuse of hemodialyzers and higher rates of death and hospitalization persist after adjustment for comorbidity. This was a nonconcurrent cohort study of survival and hospitalization rates among 1491 U.S. chronic hemodialysis patients beginning treatment in 1986 and 1987. The impact of dialyzer reuse was compared across three survival models: an unadjusted model, a "base" model adjusted only for demographics and renal diagnosis, and an "augmented" model additionally adjusted for comorbidities. We found that reuse of dialyzers was associated with a similarly higher rate of death in analyses unadjusted for confounders (relative risk [RR] 1.25, 95% confidence interval [CI] 0.97-1.61), adjusted for demographics and renal diagnosis (RR 1.16, 95% CI 0.96-1.41), and analyses additionally adjusted for comorbidities (RR = 1.25, CI, 1.03, 1.52). Reusing dialyzers was also associated with a greater rate of hospitalization that was stable regardless of adjustment procedures. We conclude that higher rates of death and hospitalization associated with dialyzer reuse persist regardless of adjustment for demographic characteristics or baseline comorbidities. These findings amplify concerns that there exists elevated morbidity among hemodialysis patients treated in facilities that reuse hemodialyzers. Although the association we observed was not confounded by comorbidity, a cause-and-effect relationship between dialyzer reuse and morbidity could not be proved because of the inability to control for aspects of care other than dialyzer reuse.

ATTACHMENT 5

1: *Am J Nephrol* 1999;19(6):641-8

Related Articles, Books, LinkOut

Full Text

Association of dialyzer reuse and hospitalization rates among hemodialysis patients in the US.

Feldman HI, Bilker WB, Hackett M, Simmons CW, Holmes JH, Pauly MV, Escarce JJ

Center for Clinical Epidemiology and Biostatistics and Department of Biostatistics and Epidemiology, University of Pennsylvania Medical Center, Philadelphia, PA, USA.

OBJECTIVES: To determine if reuse of hemodialyzers is associated with higher rates of hospitalization and their resulting costs among end-stage renal disease (ESRD) patients. METHODS: Noncurrent cohort study of hospitalization rates among 27,264 ESRD patients beginning hemodialysis in the United States in 1986 and 1987. RESULTS: Dialysis in free-standing facilities reprocessing dialyzers was associated with a greater rate of hospitalization than in facilities not reprocessing (relative rate (RR) = 1.08, 95% confidence interval (CI), 1.02-1.14). This higher rate of hospitalization was observed with dialyzer reuse using peracetic/acetic acids (RR = 1.11, CI 1.04-1.18) and formaldehyde (RR = 1.07, CI 1.00-1.14), but not glutaraldehyde (p = 0.97). There was no difference among hospitalization rates in hospital-based facilities reprocessing dialyzers with any sterilant and those not reprocessing. Hospitalization for causes other than vascular access morbidity in free-standing facilities reusing dialyzers with formaldehyde was not different from hospitalization in facilities not reusing. However, reuse with peracetic/acetic acids was associated with higher rates of hospitalization than formaldehyde (RR = 1.08, CI 1.03-1.15). CONCLUSIONS: Dialysis in free-standing facilities reprocessing dialyzers with peracetic/acetic acids or formaldehyde was associated with greater hospitalization than dialysis without dialyzer reprocessing. This greater hospitalization accounts for a large increment in inpatient stays in the USA. These findings raise important concerns about potentially avoidable morbidity among hemodialysis patients. Copyright Copyright 1999 S. Karger AG, Basel

ATTACHMENT 3

Impact of Disease Severity and Hematocrit Level on Reuse-Associated Mortality

James P. Ebben, BS, Fred Dalleska, MS, Jennie Z. Ma, PhD, Susan E. Everson, PhD, Edward G. Constantini, MA, and Allan J. Collins, MD

• Prior studies on reuse-associated mortality have presented conflicting results and included few adjustments for disease severity or hematocrit levels. To evaluate the impact of patient and provider characteristics on reuse-associated mortality, we developed a period-prevalent model with a 6-month entry period. Five cohorts of Medicare hemodialysis patients surviving from July 1 through December 31 of the entry year (1991, 60,985 patients; 1992, 63,081 patients; 1993, 76,018 patients; 1994, 82,899 patients; 1995, 91,761 patients) were followed up for the next year. Using a basic Cox regression survival model (M-1) including age, sex, race, renal diagnosis, prior end-stage renal disease time, unit age, unit size, water treatment, dialysate, and germicide, results were compared with those using a more inclusive model (M-4) adding dialyzer type (conventional or high efficiency/high flux), unit designation (hospital based or freestanding), unit profit status, comorbidity, disease severity, and hematocrit. The previous association of for-profit units with increased mortality was not present after 1994. Whereas the M-1 analysis showed better survival in reuse units after 1991, the more complete M-4 analysis showed no difference in the risk for mortality between reuse and no-reuse units. We conclude that mortality rates in the United States from 1991 to 1995, when adjusted comprehensively for patient and unit characteristics, were not different in units that practiced reuse and those that did not.

INDEX WORDS: Reuse; hemodialysis; hematocrit; mortality; comorbidity; outcomes; germicide; disease severity.

HEMODIALYZER reuse continues to be an economic reality in US dialysis units, and concerns about its effect on patient safety and outcomes continue to be raised in the dialysis community. Three recent studies of reuse-associated mortality, examining different time periods and using varying methods, have reported conflicting associations between germicides and mortality.

A study by Held et al,[1] published in 1994, examined prevalent Medicare hemodialysis patients in freestanding units that primarily used conventional dialyzers. Two cohorts of approximately 32,000 patients each, those alive on January 1, 1989, and those alive on January 1, 1990, were followed up for a full year. As in the later studies, all patients were on end-stage renal disease (ESRD) therapy for at least 90 days before the beginning of the entry period. The study considered age, sex, race, and primary renal diagnosis but did not include comorbidity; the investigators therefore restricted the study population to patients in freestanding units because of the more homogenous patient mix and lower levels of comorbidity in these units. Study results showed that mortality rates in freestanding units using peracetic acid, hydrogen peroxide, acetic acid mixture, or glutaraldehyde were greater than those in freestanding units using formalin or not-practicing reuse.

HELD RES 1'

Criticizing the prevalent-based method of Held et al[1] because it excludes patients who die soon after the onset of ESRD, Feldman et al,[2] publishing in 1996, studied 28,000 incident Medicare patients who began hemodialysis in 1986 and 1987. This study included both hospital-based and freestanding units and, because high-efficiency/high-flux dialyzers were just arriving on the market, was also limited primarily to units practicing conventional dialysis. The investigators detected no significant mortality-rate difference in hospital-based units between those that reused dialyzers and those that did not. In freestanding units, although not observing the greater mortality associated with glutaraldehyde use in the study of Held et al,[1] the investigators confirmed results of the earlier study showing that

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peracetic and acetic acids were associated with greater mortality than formaldehyde or no reuse.

Each of these large national studies centered on basic patient demographic and provider characteristics. Neither included unit profit status, and both were limited by the sparse data available on disease severity, hematocrit, and outcomes associated with high-efficiency/high-flux therapy.

In 1998, our own research group examined period-prevalent Medicare patients in units practicing conventional dialysis.[5] The two cohorts included patients from 1989 to 1990 (n = 13,926) and 1991 to 1993 (n = 20,422). Adjusting for comorbidity, unit characteristics, and profit status, we found a greater mortality risk for patients in freestanding for-profit units using peracetic acid manual reuse during 1989 to 1990. In the later period of 1991 to 1993, increased risks were detected in hospital-based nonprofit units practicing formaldehyde automatic reuse and in freestanding for-profit units using gluturaldehyde. These unit types, however, each accounted for less than 5% of the total number of units. For all other interactions of reuse germicide and technique, we observed no significant difference in mortality rates between reuse and no-reuse units.

These results suggested that other factors associated with patient survival, including severity of disease, comorbidity, and hematocrit level, might have a greater influence on mortality than reuse practices themselves. Our analytic group recently developed epidemiological models to assess such factors.[4,6] We have applied them here in a new assessment of reuse-related mortality in US dialysis units, examining both conventional dialysis therapy, the focus of earlier studies, and high-efficiency/high-flux therapies, on which the majority of patients now dialyze. This report summarizes our results.

METHODS

Patient Selection

We studied prevalent Medicare hemodialysis patients who were alive during the last 6 months of an entry year from 1991 to 1995, with follow-up for 1 additional year (60,985 patients in 1991, 63,081 patients in 1992, 76,018 patients in 1993, 82,899 patients in 1994, and 91,761 patients in 1995). Patients survived at least 90 days beyond the first ESRD service date, a criterion that normalizes the Medicare entitlement period based on patient age,[7] and each patient had four or more erythropoietin claims during the entry period to calculate a representative mean hematocrit.[3] Patient characteristics were determined from the Health Care Financing Administration (HCFA) Medical Evidence Form 2728, which provides date of birth, sex, race, renal diagnosis, and first ESRD service date. Mortality information was obtained from the HCFA Death Notification Form 2746, which reports all-cause and cause-specific categories of death.

Comorbidity

Because comorbidity has been shown to have an association with patient survival,[4,9] we adjusted for it in our analysis. Comorbid conditions before the follow-up period were determined from Medicare Part A and B claims and included atherosclerotic heart disease, congestive heart failure, peripheral vascular disease, cerebrovascular accident/transient ischemic attack, other cardiac disease (valvular heart disease, arrhythmias, and pacemakers), cancer (excluding skin malignancies but including malignant melanoma), chronic obstructive pulmonary disease, and gastrointestinal disease (including liver disease, gallbladder disease, and gastrointestinal tract diagnoses associated with bleeding). Our methods for this comorbidity profiling have been published previously.[3,5]

Disease Severity, Hematocrit Level, and Unit Variables

Disease severity measures included the number of vascular access procedures (obtained from the Part B Physicians' Current Procedural Terminology codes/services), blood transfusions (from the Part A codes), and hospital days during the entry period. Patients were grouped by mean entry-period hematocrit: less than 27%, 27% to less than 30%, 30% to less than 33%, 33% to less than 36%, and 36% and greater. Unit-level characteristics were obtained from the Centers for Disease Control and Prevention annual National Surveillance of Dialysis-Associated Diseases in the United States[10] and included profit status, unit designation (freestanding and hospital based), percentage of patients undergoing high-efficiency or high-flux dialysis, and germicide use (formaldehyde, peracetic acid, gluturaldehyde, and no reuse). We defined conventional units as those in which 25% or less of the patients were treated with high-efficiency/high-flux therapy.[5]

Statistical Methods

Demographic and disease severity characteristics of no-reuse units and of units using each type of germicide were analyzed by chi-squared and least significant difference pairwise t-tests, with P significant at less than 0.05. Mortality risk was assessed with a Cox regression model, stratified on diabetic status to address proportionality[11] and stratified as well on age group, sex, race, and renal diagnosis. We evaluated four different and increasingly complex survival models. In the basic model (M-1), we adjusted for age within each strata, prior ESRD time, unit age, unit size, water treatment, dialysate, and germicide, using no-reuse units as the baseline. In the second model (M-2), we added profit status (baseline, nonprofit units), unit designation (baseline, hospital-based units), and membrane type (baseline, units with ≥25% of patients undergoing high-efficiency/high-flux dialysis). The third model (M-3) also included comorbid-

ity and disease severity measures (the number of vascular access procedures, blood transfusions, and hospital days in the entry period). The final model, M-4, was adjusted for each of the previously mentioned factors and for entry-period hematocrit value, as well. We used the M-2 model for an initial assessment of outcomes in for-profit, freestanding, and conventional units over time. To illustrate the impact of the more complex adjustments, we then compared germicide-specific mortality risks using the basic model (M-1) and the model adjusted most extensively for disease severity, comorbidity, and hematocrit (M-4).

RESULTS

Whereas only 40% of patients in 1991 were treated in units using high-efficiency/high-flux therapies, this number had increased to more than 75% by 1995 (Table 1). The percentage of patients treated in for-profit units between 1991 and 1995 remained relatively stable (60% to 66%), and more patients (71% to 76%) were treated in freestanding units than in hospital-based units during the same period.

Figure 1 shows the relationship of demographic and disease-severity factors to germicide use in 1991 and 1995, showing the statistically significant differences. Mean patient age, for example, increased over the 5-year period and, in 1995, was older for patients in units using peracetic acid than for those in units using formaldehyde or not practicing reuse. The number of comorbid conditions also increased between 1991 and 1995, and in 1995 was significantly different in each comparison of reuse groups. Prior ESRD time was significantly different for all groups except formaldehyde/no reuse in 1991, peracetic acid/no reuse in 1995, and formaldehyde/glutaraldehyde in 1995. The percentage of women and patients with diabetes was significantly different for all groups in both years, and, with the exception of glutaraldehyde/peracetic acid in 1991, the same was true for mean hematocrit levels. Whereas the number of vascular access procedures in each year was generally similar across most reuse practices, the number of blood transfusions was significantly different between most reuse groups. The difference in the number of hospital days is perhaps the most striking outcome of these comparisons. Patients in no-reuse units in 1991 had significantly more hospital days than those in units that reused dialyzers. In 1995, although the number of hospital days had decreased overall and was similar in no-reuse and glutaraldehyde units, patients in no-reuse units continued to have significantly more hospital days than those in units using formaldehyde or peracetic acid.

Table 1. Patient Distribution by Unit Characteristics

	Percentage of Units		
	High Efficiency/ High Flux	Profit	Freestanding
1991	40.5	60	71
1992	48.9	65	76
1993	57.8	63	73
1994	66.1	64	74
1995	77.3	66	75

To analyze mortality risks in for-profit, freestanding, and conventional units (Fig 2), we used the M-2 model, adjusted for profit status, unit designation, and membrane type, in addition to the factors included in the M-1 model. Compared with nonprofit units, for-profit units had significantly greater risks from 1991 to 1993. In 1994 and 1995, however, profit status was no longer a significant risk factor. Freestanding units were associated with significantly less risks than hospital-based units in every year but 1994. These findings have been reported previously by Collins et al.[3] Risks associated with conventional dialysis therapies fluctuated over time; they were not different from the baseline (high-efficiency/high-flux units) in 1992 and 1994 but were significantly greater in the remaining years.

The variable results found with the M-2 model led us to analyze the impact of additional patient factors of comorbidity, disease severity, and hematocrit level on reuse-associated outcomes. In Fig 3, we used both the basic M-1 model and the full M-4 model, adjusted for the complete set of patient and unit factors, to calculate the relative risk for death for each germicide compared with the baseline of no reuse. The M-1 analysis showed reuse germicides to be associated with better outcomes overall. Results for peracetic acid and glutaraldehyde varied over time, whereas the risks associated with formaldehyde were consistently less. However, when complete adjustments for unit characteristics, comorbidity, disease severity, and hematocrit level were added to the analysis, these associations disappeared, and there was no significant difference in outcomes between patients in units that reused dialyzers and patients in units that did not.

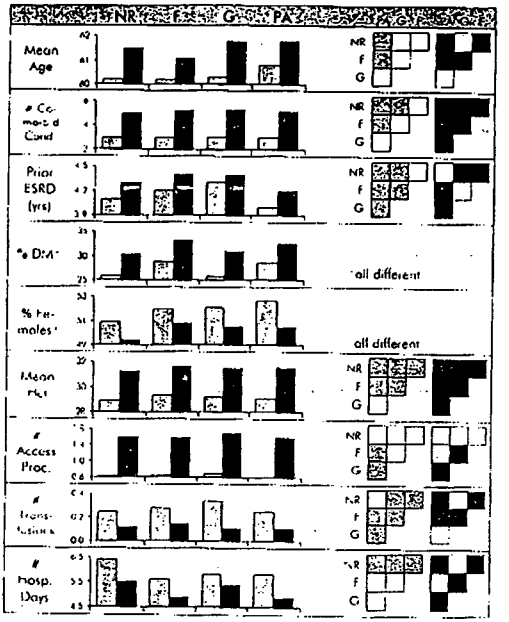

Fig 1. Comparison of reuse groups, 1991 to 1995. Statistical significance ($P < 0.05$) for germicide pairs is indicated by shaded areas on the grids. (□), 1991; (■), 1995. Abbreviations: NR, no reuse; F, formaldehyde; G, glutaraldehyde; PA, peracetic acid; DM, diabetes mellitus; Hct, hematocrit.

DISCUSSION

This study points out the vulnerability of an analysis of reuse-associated outcomes to unit and patient characteristics and membrane type. Previous studies, for example, have focused solely on units practicing conventional dialysis. Whereas these units accounted for the majority of all US dialysis units at the time of the earlier studies, the number of nonconventional units, ie, those in which greater than 25% of patients are undergoing high-efficiency/high-flux treatment, grew from 40.5% in 1991 to 77.3% in 1995. Because of this dramatic increase, outcome studies focused on conventional units can no longer be viewed as representative of the entire patient population. We therefore examined both conventional and nonconventional units in a broad national study, eliminating the potential bias created by the limited patient cohorts of earlier analyses.

Our initial findings that patients in freestanding units had a significantly lower mortality risk than those in hospital-based units in 1991, but only a marginally lower risk in 1995, suggested that basic adjustments for demographic factors, unit designation, and profit status (our M-I model) were not sufficient to explain the mortality trends noted in earlier studies. In our subsequent survival models, we therefore added descriptive characteristics of comorbidity, disease severity (including vascular access procedures, blood transfusions, and entry-period hospital days), and

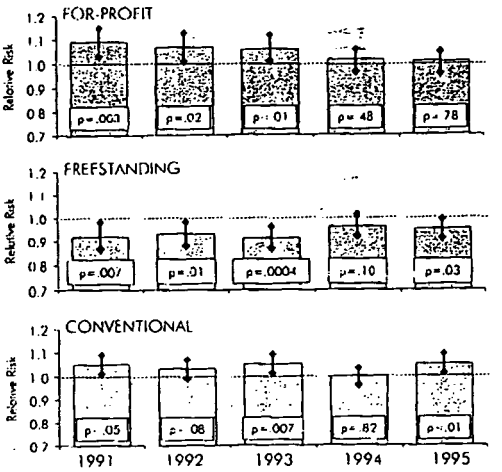

Fig 2. Trends in mortality risk by dialysis unit designation. M-2 model, adjusted for age, sex, race, renal diagnosis, prior ESRD time, unit age, unit size, water treatment, dialysate, germicide, unit profit status, unit designation, and membrane type.

hematocrit level, factors that we have shown to be significantly associated with patient outcomes but that have been absent from earlier reuse studies. With these more comprehensive adjustments, mortality risks in reuse units were not significantly different from those in no-reuse units, a result that remained consistent across 1991 to 1995.

Our application of this more complete method to reuse-associated outcomes substantially influ-

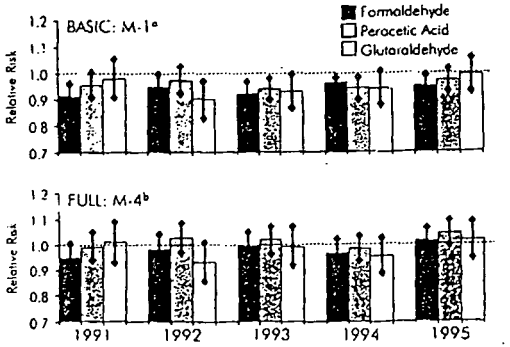

Fig 3. Impact of germicide on mortality, 1991 to 1995, using basic and full models, adjusted for unit status, disease severity, and hematocrit (baseline, no reuse). aAdjusted for age, sex, race, renal diagnosis, prior ESRD time, unit age, unit size, water treatment, dialysate, and germicide. bIn addition to M-1 adjustments, includes unit designation, unit profit status, membrane type, comorbidity, disease severity, and hematocrit.

ences conclusions drawn from studies using only the basic parameters of age, sex, race, renal diagnosis, and basic unit characteristics (unit age and size, water treatment, dialysate, germicide, and profit status), including our own earlier study and those by Held et al[1] and Feldman et al.[2] We found that comorbidity, disease severity, and hematocrit level do not appear randomly distributed across reuse germicides, suggesting that these factors strongly influence the association between germicide and mortality and should be carefully considered in an analysis of germicide-related outcomes.

This current analysis contains several limitations that might be addressed in future studies. Although it is reasonable to assume that dialysis therapy, a known risk factor, is also not randomly distributed across the germicide groups, we were unable to include this factor in our analysis because reporting of the urea reduction ratio on dialysis claims did not begin until 1998. Direct data on nutritional status, including albumin levels and other biochemical measurements, are currently unavailable as well. However, we adjusted for disease severity, which we have previously shown to be similar in impact to nutritional status,[4,5] and we included hematocrit level as an additional disease severity measure, one not evaluated in previous studies of reuse-associated outcomes. Finally, because the length of time from the onset of ESRD influences mortality, a prevalent-based study may be affected by the inclusion of patients with dissimilar ESRD exposure times. Although we adjusted for prior ESRD time, reports by other researchers of variable results in incident and prevalent studies suggest that incident-based studies should be performed to confirm our results.[12,13]

In conclusion, the adverse outcomes associated with certain germicides in 1989 to 1990 are no longer apparent in the US data, and reuse and no-reuse outcomes appear similar after 1992. We found that the adverse outcomes previously linked to profit status were no longer present in 1994 and 1995 and that reuse and no-reuse outcomes were not significantly different after adjustments were made for comorbidity, disease severity, unit characteristics, and hematocrit level. More careful evaluation of incident patients and the effect of comorbidity, disease severity, hematocrit, and, if possible, dialysis therapy and nutritional status is needed to confirm our findings.

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SPECIAL REPORTS

Lessons From the Hemodialysis (HEMO) Study: An Improved Measure of the Actual Hemodialysis Dose

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• The Hemodialysis (HEMO) Study is a multicenter, prospective, randomized, 2 × 2 factorial clinical trial designed to evaluate the efficacy of the dose of dialysis delivered ("standard" v "high") and dialysis membrane flux ("low" v "high") in reducing the morbidity and mortality of patients. The study is nearly half complete. Although both patients and investigators are blinded to the overall findings, which will not be available for another 3 years, important data have been generated from which a more accurate expression has been derived for the dose of dialysis received by each patient in the trial. This new expression of the effectiveness of dialysis, eKt/V, is a two-pool approximation derived from the traditional single-pool Kt/V (spKt/V) and time on dialysis. The dialysis prescription for the HEMO Study subjects is individualized to achieve the target dose for each patient and is closely monitored by measuring the more accurate and validated expression of eKt/V. Comparisons of the HEMO Study dose of dialysis with other studies have been confused by this unique expression (eKt/V) of the dialysis dose and adequacy adopted for the HEMO Study. The target eKt/V dose in the "standard" arm of the Study is 1.05 and in the "high" arm is 1.45 per dialysis thrice weekly. Based on data available from 426 subjects randomized to each arm, the target of 1.05 in the "standard" dose of the HEMO Study is equivalent to an spKt/V of 1.32, and that of the "high" dose, 1.67. Thus, volunteers in the "standard" arm of the Study are receiving a tightly controlled and closely monitored dose, which is above the current national mean spKt/V, and above that of the accepted minimum standard spKt/V of 1.2. When completed, the HEMO Study will show whether there are merits of a tightly controlled hemodialysis dose that is consistently delivered over a prolonged period and whether a high dose is beneficial and safe to prescribe.

INDEX WORDS: Hemodialysis; adequacy of hemodialysis; Kt/V; HEMO Study; National Institutes of Health (NIH); National Institute of Diabetes, Digestive, and Kidney Diseases (NIDDK); clinical trial.

THOMAS GRAHAM (1805-1869), a physical chemist, has been dubbed the "Father of Dialysis" for his work on the forces that govern the diffusion of gases and the movement of water across a semipermeable membrane.[1] He used thin sheets of paper impregnated with starch as semipermeable membranes.[2] The application of the principle of diffusion to the removal of substances from blood had to wait 50 more years before a pharmacologist, John Abel (1857-1938), and his associates reported in 1915 on the use of celloidin tubes immersed in a dialysate bath housed in a glass jacket to dialyze rabbits and dogs.[3] It was John Abel who introduced the term "artificial kidney."[1] During the following decade, Georg Haas (1886-1971), a surgeon, first used the artificial kidney to dialyze a human in October of 1925.[4] Another 20 years were to pass before dialysis was introduced to the clinical arena through the pioneering work of Willem J. Kolff (b. 1910).[5] The introduction of a permanent blood access device in 1960 by Belding Scribner (b. 1920)[6] allowed extension of the procedure to sustain the life of patients with end-stage renal disease. During the ensuing two decades, the clinical use of dialysis evolved from that of a life-supporting procedure for patients with acute renal failure to a life-sustaining one for patients with chronic renal failure, after the terminal features of uremia were shown to respond to dialysis.

With increased application of dialysis, it has become evident that the amount of dialysis needed for good health is greater than that necessary to maintain life in patients with end-stage renal disease (ESRD). It is this observation that has

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provided the impetus for much of the work on dialysis over the past three decades. The major advances made in the science and technology of dialysis during this period have saved the lives of thousands of patients with ESRD. Yet, despite this preservation of life, mortality and morbidity have remained unacceptably high for patients with ESRD, especially in the United States.[7] The scientific and public concern about these results stimulated the Division of Kidney, Urologic, and Hematologic Diseases of the National Institute of Diabetes, Digestive and Kidney Diseases to initiate a clinical trial (called the HEMO Study) to evaluate the efficacy of the hemodialysis treatment regimen to reduce morbidity and mortality in hemodialysis patients.

During the protocol development phase of the HEMO Pilot Study (October 1992 to February 1994), several interventions deserving investigation were considered, including time on dialysis, dose of dialysis, membrane flux, and nutrition. Because of the prohibitively large sample size that would be required to address all of these important variables, the interventions selected for study were limited to the dose of dialysis and membrane flux. The full-scale trial, launched in March of 1995, is a randomized multicenter clinical trial evaluating the effectiveness of the dose of dialysis using a 2 × 2 factorial design ("standard" *v* "high") and membrane flux ("low" *v* "high").[8] The Study was designed to minimize the variance of the two target Kt/V values to help to ensure that a "no difference" between the groups is an interpretable result that can be easily translated into practice. The final results of the HEMO Study are likely to have important practical and theoretical implications for dialysis patients and care providers. On the practical side are the design of dialyzers, the patient's dialysis schedule, targeted blood and dialysate flow rates, and cost. The theoretical implications may have profound effects on the way dialysis is delivered in the future. At the moment, the study is nearly half complete, and although both investigators and patients are blinded to the overall findings, valuable lessons have been learned from this clinical trial. One of these lessons is the validation of an improved expression for quantifying hemodialysis, allowing a more precise prescription that is individualized to achieve the target dose for each patient. This novel definition of the dialysis dose has been a source of misunderstanding and of concern about the actual dose of dialysis prescribed for study participants. This report details the background, derivation, validation, and advantages of the new expression compared with the conventional measures now in use, with particular attention to the standard arm of the HEMO Study.

DEFINING THE DOSE OF DIALYSIS

Among the prevailing measures of dialysis, the most exact is the effective urea clearance per dialysis treatment, expressed as a fraction of the volume of urea distribution in each patient. The resulting expression of dosage, "Kt/V," is truly a clearance despite the absence of the familiar units for clearance (mL/min). The units of measurement in the expression [K (mL/min)][t (min/dialysis)]/[V (mL)], can be expressed as a fraction of body water cleared of a given solute per dialysis. It is more commonly expressed as just a fraction without giving the units of measurement. Fortunately, Kt/V for urea can be measured easily, primarily from the fractional fall in blood urea nitrogen (BUN) from the start to the precise end of dialysis, modified by volume changes caused by ultrafiltration during the course of dialysis, and by urea generation. To maintain precision and accuracy, the latter modifications require an iterative mathematical modeling process that is simple in concept but requires a computer to calculate.[9] The resulting value is expressed as "spKt/V," because it is derived from a model of urea kinetics that describes the patient's urea volume as a perfectly equilibrated single pool (sp). This assumption is incorrect; as shown in Fig 1, a disequilibrium in urea concentration develops during hemodialysis with lower urea concentrations in the blood compartment compared with peripheral compartments such as muscle, skin, and the intracellular environment. Because the dialyzer removes urea only from the blood, the concentration seen by the dialyzer is lower than the overall average urea concentration in the total body water. As a result, the efficiency of dialysis is less than that predicted by the single-pool model. Mathematically, the dialyzer clearance term (K), in the expression for single-pool Kt/V, overestimates the average "whole body" clearance. Consequently, single-

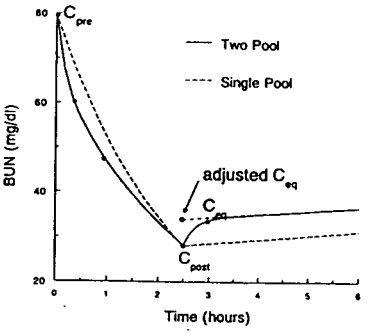

Fig 1. Blood urea concentrations (BUN) measured during and immediately after dialysis in a single patient. The greater fall in BUN during dialysis and the rebound after dialysis results from urea disequilibrium within the patient. Disequilibrium is caused by differences in blood flow and a delay in diffusion of urea among body compartments. C_{pre} = BUN before dialysis, C_{post} = BUN immediately after dialysis, C_{eq} = BUN 30 minutes after the end of dialysis, adjusted $C_{eq} = C_{eq}$ after subtracting the effect of urea generation for 30 minutes.

pool Kt/V overestimates the actual dose of dialysis received by the patient.

It is important to emphasize that although the delivered dialyzer clearance is usually accurate when measured using the predialysis and immediate postdialysis BUN, delayed diffusion of urea from the peripheral compartments of the patient (urea disequilibrium) reduces the actual delivery of urea to the dialyzer. This reduced delivery of urea does not lower the dialyzer clearance but reduces the urea concentration at the dialysis membrane relative to the total body urea pool. Hence, the urea gradient and therefore the rate of urea diffusion is reduced, and the actual amount of urea removed from the patient is less than it would be in the absence of disequilibrium. As a result, the overall effectiveness of delivered dialysis falls below that predicted by the single-pool model (Fig 1).

It is this flaw of spKt/V, as an expression of the effectiveness of hemodialysis, that led the HEMO Study investigators to adopt a measure of the effective patient clearance of urea (eKt/V) during dialysis that corrects for disequilibrium by using the equilibrated level of urea concentration. Like spKt/V, this expression is also a measure of the fractional clearance of urea per dialysis, but the clearance is no longer that of the dialyzer. The "K" term in the expression "eKt/V" is often termed the "patient clearance," because it represents the effective clearance of urea after equilibration is taken into account. Because urea equilibrates completely throughout the body, usually within an hour after completion of dialysis,[10] the actual benefit of dialysis to the patient is better measured from the equilibrated rather than the immediate postdialysis BUN. To measure eKt/V conventionally, one must measure or estimate the equilibrated postdialysis urea concentration (Ceq). Once Ceq is determined, eKt/V is calculated in the same way as spKt/V except that Ceq is substituted for the immediate postdialysis BUN in the calculation.

MEASUREMENT OF eKt/V

Unfortunately, measuring Ceq is impractical because of the added time required of the patient and of the staff to obtain the 1-hour postdialysis blood sample. The resulting inconvenience and attendant cost are difficult to justify. To resolve this problem, a concerted effort was made during the pilot phase of the HEMO Study to circumvent the requirement for actually measuring Ceq from a 1-hour postdialysis BUN. Alternative methods that were studied and compared included measurement of dialysate urea losses,[11,12] measurement of additional single or multiple BUN levels during the course of treatment,[13] and a simple linear formula for estimating eKt/V from the rate of urea removal during dialysis (rate method). Results of these alternative methods were compared with the true Ceq and eKt/V determined from a blood sample taken at 30 minutes postdialysis.[14] In addition to providing comparative data, these efforts validated a simple linear equation based on the fractional rate of urea removal[15]:

$$eKt/V = spKt/V - 0.60(K/V) + 0.03 \quad (1)$$

where K/V is expressed in hours^{-1}. This equation, which had been derived independently of the HEMO Study,[15] shows that for the same spKt/V, eKt/V will decrease as the intensity of dialysis (K/V) increases and the time on dialysis is shortened. When applied to the data collected during the pilot phase of the HEMO Study, eKt/V calcu-

lated from Equation 1 matched the true value of eKt/V, determined from the measured Ceq, at least as well as any of the other methods requiring multiple BUN measurements. This close match with the true eKt/V validated the accuracy of equation 1 and justified its adoption for the HEMO Study.[16]

The physiological implications of equation 1 are that urea rebound and therefore urea disequilibrium are predictable and that the major determinant of urea disequilibrium is K/V, the intensity of dialysis. A practical advantage of equation 1 is that no additional samples of blood or dialysate are necessary. This eliminated the inconvenience to patients and the cost to dialysis facilities otherwise incurred in attempts to accurately measure urea clearance during dialysis. Another advantage of deriving eKt/V using equation 1 is that spKt/V must be calculated; spKt/V is the initial measure of dialysis dose, and eKt/V is derived from it. This allows a comparison of the current single-pool standard (spKt/V) with the more accurate dose based on the patient clearance and equilibrated urea concentrations (eKt/V). It should be emphasized that the monthly measurement of dialysis dosage obtained in each HEMO Study subject is the standard spKt/V derived from the predialysis and postdialysis BUN. The difference is in how the patient is managed from that point forward in light of a better appreciation of the physiology of urea removed during dialysis. This is the rationale for the adoption of eKt/V as the targeted standard for HEMO Study patients, an improved and more accurate measure of dialysis rather than the perpetuation of the more limited spKt/V.

The HEMO Study compares a standard dose of delivered dialysis (eKt/V) of 1.05 per treatment with a higher dose of 1.45 per treatment delivered three times per week. The dialysis dose for each patient is based on a set of prescriptions provided by the Data Coordinating Center (DCC) aimed at setting a high urea clearance (K), and varying time on dialysis (t) to achieve the target for each patient. Time is constrained only at its low end, to a minimum of 2.5 hours. Adjustments of dialyzer surface area and blood and dialysate flow rates are recommended by the DCC according to the size of the patient (V) for each prescription.

THE "STANDARD" ARM OF THE HEMO STUDY

The standard dose of dialysis was of most concern to the investigators of the HEMO Study and members of the External Advisory Committee (EAC). This dose of dialysis was chosen to reflect what was and continues to be the current standard, agreed on by most of the professional and voluntary renal organizations, based on both evidence and judgment. The standard adopted by the National Institutes of Health, the Renal Physician's Association, and the National Kidney Foundation-Dialysis Outcomes Quality Initiative (NKF-DOQI), is a minimum spKt/V of 1.2/dialysis thrice weekly.[17-19] This level is well above the dose that has been shown to be unequivocally substandard[9,20] and is above the dose delivered to most dialysis patients.[21]

The average spKt/V achieved in most dialysis centers has increased gradually and is now over 1.2 per treatment, due at least in part to the national recommendations just mentioned. This increase in the average dialysis dose observed in the United States has resulted in several observational studies comparing the outcomes in patients receiving "higher" dialysis doses with those of patients receiving "lower" doses.[21-23] Unfortunately, such uncontrolled studies cannot conclude that a higher Kt/V is beneficial because of a phenomenon known as "the error of the mean."[24] Figure 2 shows this error in interpreta-

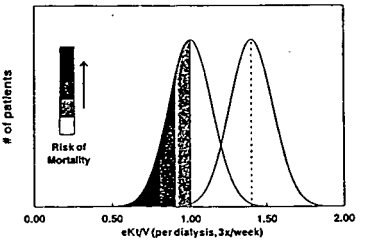

Fig 2. Illustration of the phenomenon of the error of the mean. In a random cross section of patients, even if no additional benefit is achieved by increasing eKt/V above 1.00 per dialysis, the group mortality will decrease when the mean eKt/V is shifted upward from 1.0 to 1.4. The reason for this improvement in mortality is illustrated here. Patients in the lower half of the bell-shaped distribution curve are at risk for higher mortality. When the mean for the entire group shifts to 1.4, these patients escape the risk.

tion of the data by illustrating a hypothetical distribution of eKt/V values. As the average eKt/V increases, the proportion of patients falling within the substandard region decreases, giving a false impression that the higher dose is beneficial. The available evidence for a benefit from a limitless increase of hemodialysis dose is controversial. Larger studies such as the United States Renal Data System (USRDS) case mix mortality study show little or no benefit.[21] Conversely, smaller studies suggest some benefit.[22,23] Unfortunately, none of these studies are randomized, all rely on incomplete historical data, and comparative information is derived from a progressive and sequential improvement in the average spKt/V. Furthermore, the methodology, and therefore the accuracy, of Kt/V measurements reported in the literature is variable, and a valid comparison of results is not possible.[24,25] In fact, careful examination and statistical analyses of reports suggesting continued benefit from increased dialysis doses have questioned the validity of the conclusions derived in those reports.[24] Additionally, in deriving conclusions from uncontrolled and nonrandomized studies, consideration must be given to patients with higher morbidity who are more difficult to dialyze and consequently achieve a lower Kt/V. For example, seriously ill and terminal patients may have a higher incidence of failing access devices and require more central catheters that impose limitations on the amount of dialysis delivered. In addition, the contribution of residual renal function is not considered in any of the published reports. Whether a higher dose of dialysis is beneficial and safe for hemodialysis patients can be answered only by a carefully designed and conducted randomized clinical trial (Fig 2).

Randomized clinical trials represent a major advance over the historically time-honored method of judging new treatments by trial and error. The methodology derives from principles developed for agricultural research that include calculations to allow for variability in results attributed to chance alone. The current model for these studies, molded over the past several decades, is considered the gold standard for testing medical treatments. This lofty status notwithstanding, randomized clinical trials do have limitations, not the least of which are the restraints necessary to limit risk to the subjects drafted into a study. This is the major reason that clinical trials must be monitored by an external body and require the understanding and support of the public and the profession. Patients who unselfishly choose to subject themselves to the risks of any therapeutic trial deserve responsible supervision and understanding support from their community. Otherwise, it is relatively easy to undermine this type of project by using intimidation tactics.[26]

The volunteers for the HEMO Study are protected by an independent EAC that monitors the outcome of randomization, because the investigators are blinded to these outcomes. In addition, constant feedback from the DCC ensures that individual patients do not stray too far from their prescribed doses from month to month.

ENSURING SAFETY OF THE STANDARD Kt/V INTERVENTION

If the current recommended minimum spKt/V of 1.2/dialysis, three times per week is accepted as a de facto, albeit soft, standard, how are patients who are randomized to the lower dose arm of the HEMO Study protected from underdialysis? The targeted dose is an eKt/V of 1.05 per dialysis. Equation 1 indicates that if spKt/V is constant, eKt/V decreases when the intensity of dialysis (K/V) increases. For this to happen, the time on dialysis must shorten. The reduction in eKt/V as time is shortened is intuitively predictable because disequilibrium is more pronounced and dialysis is less efficient when the same dose, expressed as total dialyzer clearance (spKt/V), is given over a shorter interval. Because K/V = (spKt/V)/t, a rearrangement of equation 1 will give:

$$spKt/V = (eKt/V - 0.03)/(1 - 0.60/t) \quad (2)$$

Equation 2 shows that an eKt/V of 1.05/dialysis translates to different values of spKt/V depending on dialysis time. Examples of the relationship, derived from equation 2, between patient clearance (eKt/V) and dialyzer clearance (spKt/V), as time on dialysis increases, are shown in Table 1. It can be seen that for the target eKt/V of 1.05 the corresponding spKt/V falls below the minimum only for patients dialyzed for 4.5 hours or longer. Because prolonging dialysis at the same spKt/V improves its efficiency, eKt/V better reflects the true dialysis dose. For HEMO

Table 1. Values for spKt/V Calculated From eKt/V and Dialysis Time Using Equation 2

Dialysis Time (hr)	eKt/V 1.00	1.05	1.45
2.0	1.39	1.46	2.03
2.5	1.28	1.34	1.87
3.0	1.21	1.28	1.78
3.5	1.17	1.23	1.71
4.0	1.14	1.20	1.67
4.5	1.12	1.18	1.64
5.0	1.10	1.16	1.61

NOTE. Both values for Kt/V are expressed as a fractional clearance per dialysis 3×/week.

Study patients, the mean difference between spKt/V and eKt/V in the standard arm was 0.23 ± 0.04 and in the high dose arm was 0.25 ± 0.04.

As noted above, the initial measure of dialysis dose in the HEMO Study is the single-pool Kt/V (spKt/V) from which eKt/V is derived using equation 1. Because spKt/V is calculated, the mean spKt/V is precisely known for all patients enrolled in the study. The mean spKt/V, after 2 years of recruitment, in 426 patients randomized to the standard Kt/V arm was 1.32 per dialysis, as shown in Fig 3, which compares the distribution of the mean spKt/V values of the patients in the two dialysis dose arms of the HEMO Study with that of the values obtained in the Phase I prevalence study conducted by the USRDS in 1993. The curve for the standard Kt/V arm of the HEMO Study patients skewed slightly to the right so that less than 4% fell below the minimum spKt/V of 1.20. This very narrow range reflects the concerted efforts of the HEMO Study investigators to maintain the statistical power of the study by separating and tightly controlling the two randomized dialysis dose prescriptions. The mean spKt/V is well above the current recommended minimum standard and above that currently achieved in most dialysis centers in the United States. It should be noted that the USRDS data shown in Fig 3 represent that of the most recently available national sample of prevalent dialysis patients in whom spKT/V is measured. Data from the Health Care Financing Agency indicate that between 1993 and 1995 mean urea reduction ratio (URR) has increased from approximately 63% to 66%. This change corresponds to an increase in mean spKt/V of approximately 0.1 units. However, because of the much lower variability of spKt/V in the standard arm of the HEMO Study, the proportion of the Study subjects whose dialysis dose falls by chance below 1.2 per treatment is significantly lower (4%). These interim data indicate that the dose of dialysis delivered in the standard Kt/V arm of the HEMO Study is tightly controlled, and provides evidence that HEMO Study patients are well protected from underdialysis based on current criteria for hemodialysis adequacy.

URR AS A MEASURE OF DIALYSIS DOSE

The URR, defined as the decrease in BUN divided by the predialysis BUN, includes the most significant factor that determines Kt/V, the ratio of postdialysis to predialysis BUN, and has been used as a simplified measure of the dialysis dose. The mean value for URR in the 426 HEMO patients randomized to the standard dialysis dose was 67%. Although highly correlated with Kt/V in population studies, URR fails to reflect the actual dose received by an individual patient

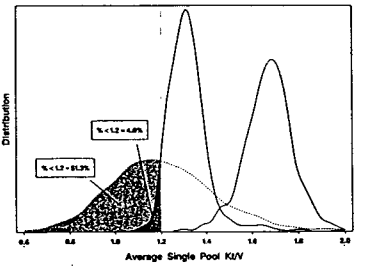

Fig 3. Distribution of delivered single pool Kt/V for patients in the standard arm (middle curve) and in the high arm (right curve) of the HEMO Study who were followed-up for more than 4 months through May 1997. Data from the 1993 US Renal Data System (USRDS) case mix mortality study (left curve) are included for comparison. In each study, the analyses were restricted to patients with four or more measurements of Kt/V to reduce the effect of measurement error. To produce the distributions in this figure, all available single-pool Kt/V measurements were first averaged for each patient. A nonparametric density estimation procedure with normal kernals was then used to describe the distributions of the mean single-pool Kt/V values. For the USRDS data, 51.3% had Kt/V values less than 1.2. In the HEMO Study, only 4% in the standard arm and none in the high arm fell below the 1.2 spKt/V minimum.

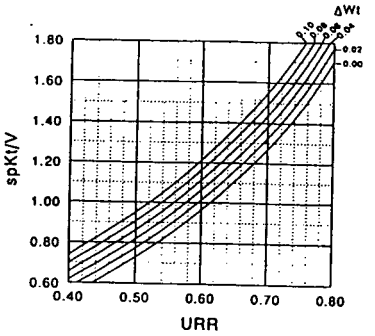

Fig 4. For a single patient, URR can vary despite constant values of Kt/V. The different values for URR result mostly from differences in weight gain between and requisite weight loss (ΔWt) during hemodialyses.

because of variable amounts of fluid lost during dialysis which generally depends on that gained between dialyses (Fig 4). As a consequence of ultrafiltration during dialysis, it is possible for a patient to receive adequate treatment when the URR is below standard or, conversely, to receive inadequate treatment when the URR is above standard. Furthermore, URR, in contrast to Kt/V, does not provide a measure of protein catabolism and offers no logical method for correcting a prescription that is inadequate. For these reasons, URR, which is calculated in the HEMO Study, is not used as a standard for dialysis. Similar recommendations favoring Kt/V in preference to URR were recently made by the NKF-DOQI Hemodialysis Adequacy Work Group.[19]

ETHICAL ISSUES IN THE HEMO STUDY

Because there are risks associated with all clinical trials, fully informed consent is required from all study participants. Volunteering for a therapeutic trial is a noble, unselfish, and altruistic act that can place a volunteer at personal risk for the greater benefit of mankind. Ironically, for the HEMO trial, it is not the lower but the higher dose of dialysis that represents the unproven therapy and therefore presents a potential risk to the patient. Although uncontrolled evidence suggests that this is not the case, the conceptual scientific argument remains valid until unequivocal evidence is provided. The HEMO Study was designed to examine both the safety and the efficacy of the higher dialysis dose compared with an acceptable dose reflecting the current standard of care. The limited data presented in this preliminary report show that the latter goal has been achieved; the standard Kt/V arm is well within the standard of practice and above the accepted minimum. As in all clinical trials, if differences in outcome are found between the two arms of the study, then in retrospect the arm of the study with a poorer outcome would be considered relatively "more harmful." The answer to the question must await completion of the clinical trial. To assume that answers to the questions posed by the HEMO Study are known without testing them puts all dialysis patients at risk. There is no substitute for a randomized clinical trial to answer these vital questions.

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Special Article

The Hemodialysis (HEMO) Study: Rationale for Selection of Interventions

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End-stage renal disease (ESRD) and its treatment are among the critical and growing health-care issues in the United States. Despite advances in the prevention and management of renal disease, the annual growth rate of the ESRD population averaged 10% between 1986 and 1989 (1). The mode of renal replacement therapy for the majority of these patients has been hemodialysis. With the increasing number of patients, the cumulative cost of this life-saving therapy has become staggering. However, the human cost of morbidity and mortality transcends the dollar cost of the delivery of treatment. Mortality rates among dialysis patients in the U.S. are the highest in the developed world (2). Several factors, implicated as causes of this rise in mortality, need to be prospectively examined and characterized. These variables include patient-related factors (age, race, gender, comorbidity, nutritional status, etc.) and treatment-related variables (dialysis dose, membrane type, etc).

Treatment-related variables, especially the dose of dialysis, are particularly important as they strongly influence survival and can be manipulated. In fact, it has been questioned whether the high mortality rate in the U.S. reflects inadequacy in the amount of dialysis prescribed and actually delivered. Data on adequacy of dialysis can be inferred from the results of the National Cooperative Dialysis Study (NCDS). The NCDS, although limited by the exclusion of patients with high levels of comorbid conditions, defined a dose of dialysis below which adverse events frequently occurred (3). This minimum dose was subsequently defined as a Kt/V for urea of 1.0 (where K is the clearance of urea by the dialyzer, t is the dialysis session length or time, and V is the volume of distribution of urea). Further analysis of the results of the NCDS suggested that there is a continuous relationship between Kt/V and patient outcome, rather than a "step-function" with a specific level of Kt/V beyond which no further improvement in outcome is observed (4).

There is also other evidence to suggest that as the dose of dialysis is increased, at least to a certain poorly defined point, there is a continuous reduction in death rate. Recent retrospective studies demonstrate that survival continues to improve as Kt/V increases beyond 1.0 (5–7). Indeed, longer survival of hemodialysis patients has been reported to be associated with Kt/V ranging from 1.6–1.9 (8). As a result, several professional organizations and a consensus panel have established a minimum required dialysis dose (9). The recommended minimum Kt/V of 1.2 translates approximately into a urea reduction ratio (URR, defined as pre BUN-post BUN/pre BUN) of about 0.65. Although many dialysis units in the U.S. have targeted these higher Kt/V and URR levels, data from the United States Renal Data System (USRDS) shows that in 50% of the population the delivered Kt/V remains less than 1.1 (10). These guidelines and the resulting change in dialysis practice are indicative of the empiricism that has characterized the evolution of dialysis therapy. It is unlikely that higher amounts of dialysis beyond those levels will be given routinely until the benefits are established more convincingly.

The use of Kt/V for urea to define the dose of dialysis is based on the assumption that urea (molecular weight 60 daltons) can be used as an index for low molecular weight substances that contribute to mortality and morbidity. The recent introduction of new membranes with greater permeability to large molecules (i.e., 5,000–40,000 daltons) has led to an increasing awareness of their possible contribution to mortality and morbidity of hemodialysis. However, the benefit of removing large molecules has not been evaluated in a prospective study where dose (removal of small molecules) is controlled. In addition, these newer membranes differ in their composition, biocompatibility, and cost. Presently, there is no consensus on the indications for the use of these newer membranes.

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The continuing growth of the ESRD population, the high cost of treatment, and the poor outcomes of renal replacement therapy, as judged by high mortality and morbidity among hemodialysis patients, set the stage for a prospective clinical trial that would establish an optimal dose of dialysis for removal of both low and high molecular weight substances.

The Hemodialysis (HEMO) Study

Background

The Hemodialysis (HEMO) Study, the beginning of the full-scale phase of the multicenter clinical trial, firmly reestablishes government-supported biomedical research for ESRD. From the mid-1960s to the early 1980s, the National Institutes of Health (NIH) supported a number of the significant medical advances made in the treatment of patients with ESRD, most notably continued development of the artificial kidney (11) and the NCDS (3). Shortly after publication of the results of the NCDS, NIH support for research in ESRD decreased substantially until there was no organized government-supported effort to address the medical problems of hemodialysis patients. Based in part on data from the USRDS, which revealed the unacceptably high mortality rate among hemodialysis patients, the NIH in concert with representatives of the American Society of Nephrology, the Renal Physicians Association, the National Kidney Foundation, and the American Nephrology Nurses' Association, conducted workshops in 1991 and 1992 to better define research priorities for ESRD patients (12). Of highest priority was the need to determine whether a greater than usual dose of delivered hemodialysis could significantly decrease the mortality and morbidity experienced by patients undergoing this life-sustaining procedure. In 1991 this prompted the NIH to issue a Request for Applications (RFA) for pilot clinical centers and a data coordinating center to develop the protocol and test the feasibility of a clinical trial that would reduce mortality and morbidity in hemodialysis patients. The pilot study, then known as the Mortality and Morbidity in Hemodialysis (MMHD) Study, was initiated during the summer of 1993 and preliminary results of that phase of the trial have been reported (13, 14). In December 1993, a second RFA was released to expand the trial into a full-scale phase. Fifteen clinical centers and a data coordinating center were selected to participate in the full-scale trial (Table 1). The pilot protocol was reexamined in the fall of 1994 and the full-scale protocol was completed by the end of that year. After review and approval by an External Advisory Committee (consisting of experts in nephrology and biostatistics) early in 1995, recruitment began on March 20, 1995 with follow-up scheduled through March 2001.

Given that a fixed budget was available from the NIH to support the HEMO Study, both the pilot and full-scale trial investigators were required to make difficult choices concerning the number and type of interventions to be implemented. Initially, several interventions were considered, including dose of dialysis, dialysis time, nutrition, membrane flux and membrane biocompatibility. The scientific justification of each of the proposed interventions was vigorously debated during frequent meetings of the Steering and Planning Committee. Ultimately, it became necessary to prioritize the importance of these factors based on likelihood of their improving the survival of hemodialysis patients and whether they could be implemented within the financial resources allocated. In the pilot study, dose of dialysis (as measured by equilibrated or eKt/V that accounts for post-dialysis urea rebound), membrane flux and biocompatibility were tested as interventions in a small number of patients. In the full-scale trial, the minimum recommended dose of dialysis will be compared to a higher dose; and the effect of

TABLE 1. Clinical centers and central facilities participating in the pilot and full-scale phases of the HEMO study

Center #	Name of Center
Pilot study	
Center 1	Beth Israel Medical Center New York, New York
Center 2	Harbor—UCLA Medical Center Los Angeles, California
Center 3	New England Medical Center Boston, Massachusetts
Center 4	Vanderbilt University Medical Center Nashville, Tennessee
Full-scale study	
Center 1	Beth Israel Medical Center New York, New York
Center 2	Bowman Gray School of Medicine Winston Salem, North Carolina
Center 3	Brigham and Women's Hospital Roxbury, Massachusetts
Center 4	Duke University Durham, North Carolina
Center 5	Emory University Hospital Atlanta, Georgia
Center 6	Lankenau Hospital and Medical Research Center Wynnewood, Pennsylvania
Center 7	New England Medical Center Boston, Massachusetts
Center 8	University of Alabama at Birmingham Birmingham, Alabama
Center 9	University of California, Davis Sacramento, California
Center 10	University of Illinois Chicago, Illinois
Center 11	University of Rochester Rochester, New York
Center 12	University of Texas Southwestern Medical Center Dallas, Texas
Center 13	University of Utah Salt Lake City, Utah
Center 14	Vanderbilt University Medical Center Nashville, Tennessee
Center 15	Washington University St. Louis, Missouri

Data Coordinating Center for the Pilot and Full-Scale Studies: The Cleveland Clinic Foundation, Cleveland, Ohio

Chair, Steering Committee for the Pilot and Full-Scale Studies, Baylor College of Medicine, Houston, Texas

other comorbid conditions, serum albumin, and serum creatinine. These variables have been explicitly modeled in the power estimates discussed. Other variables that will be assessed include: cause of renal disease, health status, socio-economic aspects, prior peritoneal dialysis or renal transplantation, status awaiting transplantation, treatment with angiotensin converting enzyme inhibitors (ACEI) or β-blockers, treatment with erythropoietin, complications during dialysis, blood pressure control, and fluid removal during dialysis.

Justification of Urea as the Low Molecular Weight Solute

At present the quantification and prescription of hemodialysis is based on measures of urea removal. Urea is only a "mild" uremic toxin, in that elevated plasma levels of urea *per se* have been reported to cause no detectable clinical effects (15). However, urea is a surrogate for other water soluble, poorly protein-bound compounds of low molecular weight which do accumulate in renal failure and are known to exert toxic effects. Most published studies of dialysis adequacy have used Kt/V as the measure of urea removal (16). The URR has been suggested, but not proven, as an alternate and equally reliable indicator of the adequacy of dialysis measurement (17). However, the relationship between Kt/V and URR is exponential, with large increases in Kt/V above 1.5 resulting in only small increases in URR. For example, increasing the Kt/V from 1.5 to 2.0 would be associated with an increase in the URR from 73% to only 82%. The URR is therefore less sensitive to changes in dose than is Kt/V. Thus, if levels of Kt/V above 1.5 do provide additional clinical benefit, it is logical to surmise that the beneficial effect is due to removal of low molecular weight solutes other than urea. The widespread availability of high efficiency dialyzers offer the possibility of providing even higher Kt/V levels with conventional dialysis times of 3–4.5 hours per treatment.

In the HEMO Study, the target eKt/V for the standard therapy group will be 1.0 with a compliance range of 0.9–1.1. Because the trial primarily uses high efficiency dialyzers, the average K/V will be about 0.4, and ΔKt/V (difference between equilibrated and single-pool Kt/V) will be (0.6 × 0.4) − 0.03 = 0.21 Kt/V units (18). Thus, it is anticipated that the mean single-pool Kt/V in the usual Kt/V group will be about 1.2, which is the level recommended by the recent consensus recommendations. For the high Kt/V group, the target eKt/V is 1.4, with a compliance range of 1.3–1.5. Again, because the average K/V will be about 0.4, and therefore the ΔKt/V will be about 0.21 the single-pool Kt/V for the high Kt/V group will average about 1.6. This value is appropriate because it is substantially higher than is currently achieved in practice. The Pilot Study demonstrated that an eKt/V of 1.4 could be achieved in ≤4.5 hours in patients with urea distribution volumes of up to 47 liters (13, 14).

Justification of β_2-Microglobulin as the Middle Molecular Weight Solute

Whereas urea removal is now the accepted standard for quantification of dialysis, there is evidence that removal of solutes having larger molecular weight may also be important. Since the normal kidney clears substances with molecular weights up to 60,000 daltons, it is possible that removal of large molecular weight substances by dialysis may be beneficial. Currently available dialyzer membranes with comparable ability to remove urea vary to a very great extent in their ability to remove large molecular weight substances, e.g., in the 5,000–40,000 dalton range. Preliminary evidence suggests that use of membranes which remove large molecular weight substances may be of some clinical benefit (19–22). On the other hand, it is possible that increased removal of amino acids and larger molecular weight solutes might be detrimental. In addition, the use of membranes with high permeability may increase the transfer of bacterial proteins and other noxious byproducts in the dialysate to the patient, with potentially deleterious side effects.

Although the spectrum of uremic toxins, both small and large, remains largely undefined, β_2-microglobulin has emerged as a marker for the evaluation of large molecular solute accumulation and removal during dialysis. With a molecular weight of 11,900 daltons, β_2-microglobulin is removed to a negligible extent by so-called "low flux" membranes; however, reductions of up to 40% in circulating β_2-microglobulin levels can be achieved during dialysis using a high flux membrane.

The specific choice of β_2-microglobulin as a surrogate large uremic toxin is valid for several reasons. First as the important precursor molecule linked to dialysis-associated amyloid syndrome, β_2-microglobulin is a clinically relevant large molecular weight uremic toxin. Second, reliable assays are available for the rapid determination of serum β_2-microglobulin concentrations. Third, rigorous kinetic models accounting for the dialytic removal, generation, and intercompartmental transfer of β_2-microglobulin can be developed. Finally, because the removal of β_2-microglobulin by high flux membranes occurs by a combination of diffusion, convection, and adsorption, it is generally a dependable representative of large molecular weight proteins. The complexity associated with characterizing large molecular weight protein removal has led to the use of the percent reduction or whole body clearance of the serum β_2-microglobulin concentration as a method of estimating β_2-microglobulin removal during a dialysis session, with the clear understanding that extensive post-dialysis rebound of β_2-microglobulin may occur.

TABLE 2. Target times (minutes) for usual and high equilibrated Kt/V goals

Volume	Usual Kt/V	High Kt/V
24–26	150	158–176
26–28	150	167–187
28–30	150–151	177–198
30–32	150–159	187–209
32–34	150–167	196–221
34–36	157–175	206–232
36–38	163–183	216–243
38–40	170–191	226–254
40–42	177–199	235–265
42–44	184–206	245–276*
44–46	191–214	255–288*
46–48	198–222	264–299*
48–50	205–230	274*–310*
50–52	212–238	284*–321*

* Required time above the upper 4½ hours dialysis time limit.

require treatment with either low blood flow rates or low-efficiency dialyzers, which represent a departure from current practice. Thus, if no difference in survival emerged between the usual and high Kt/V groups, the study would not answer the clinically relevant question: Can high efficiency dialyzers be used to maintain usual Kt/V while shortening dialysis time? In addition, this strategy confounded blood flow rate and dialyzer size with dialysis dose which could lead to unanticipated differences between the usual and high Kt/V groups. Finally, patients randomized to the usual Kt/V groups would be deprived of a potential benefit, namely a shorter dialysis time.

For these reasons, in the Full-Scale Study, it was decided to dialyze patients in the usual group for a shorter time than patients in the high Kt/V group. To standardize the difference in time between the Kt/V groups, high-efficiency dialyzers will be employed for both Kt/V groups, thus maximizing K/V. The shortest dialysis treatment time required to achieve the Kt/V goal will be prescribed in both Kt/V groups, with a minimum session length of 2.5 hours, unless limitations are present due to inability to achieve target blood flow, ultrafiltration, dry weight or normal blood pressure. A maximum time of 4.5 hours has been adopted to conform to usual procedure in most dialysis units. Target times for the usual and high Kt/V groups are shown in Table 2. The selected target time ranges correspond to the dialysis session length required to achieve the required Kt/V using a blood flow rate of 400–500 ml/min, a dialysate flow rate of 800 ml/min, and a dialyzer mass-transfer area coefficient of 800 ml/min.

This strategy deliberately confounds time and Kt/V. Thus, at the conclusion of the study, if the higher Kt/V group has a better outcome, it will not be certain whether the benefit is due to a higher dose or a longer dialysis time. Although not ideal from an analytical point of view, this answers the most clinically relevant questions. To achieve the beneficial effect observed in the high Kt/V group, it would be necessary to utilize both high-efficiency dialyzers and longer time. On the other hand, if there is no beneficial effect of the higher Kt/V, high-efficiency dialyzers and shorter times could be safely used.

Dialyzer Reuse

Reuse and Optimal Dialysis

Reuse of the artificial kidney has been employed in some fashion as long as patients have been treated for chronic renal failure with hemodialysis. In the United States, the majority of hemodialysis centers have programs in place for reprocessing of dialyzers. In 1993, more than 70% of centers reported that they reused disposable dialyzers. Approximately 50% of the centers use formaldehyde or glutaraldehyde and 50% use a mixture of peracetic acid-hydrogen peroxide (Renalin) as the sterilant (27). In units where formaldehyde or glutaraldehyde are used, bleach is used in over half of them. Bleach is not routinely used with Renalin, however, as residual bleach may inactivate Renalin. Reuse chemicals affect many aspects of the hemodialyzer that may be related to optimal dialysis, including small and large molecule clearance and biocompatibility. In the future, heat sterilization without chemical disinfectants may become an option for dialyzers composed of polysulfone.

The impact of reuse on urea clearance has been found to be small and acceptable as long as dialyzer fiber bundle volume is regularly measured and dialyzers with more than a 20% fall in fiber bundle volume are discarded (28, 29). There is no information suggesting that use of certain reuse chemicals or sterilants is particularly beneficial or harmful with regard to maintenance of dialyzer urea clearance. There remains the possibility of idiosyncratic decreases in urea clearance due to insufficient heparinization, for example, dialysate channeling with certain lots of dialyzers, or other technical problems.

Reuse also affects the clearance of larger molecules, such as β_2-microglobulin. For example, after about 10 reuses with reprocessing methods that include bleach, there are marked increases in ultrafiltration, β_2-microglobulin clearance, and protein leakage through polysulfone membranes (30). Reuse with Renalin, without bleach, causes a slight to moderate diminution of β_2-microglobulin clearance through PMMA and AN69 membranes and decreased adsorption of β_2-microglobulin to AN69 membranes (31). In contrast, β_2-microglobulin clearance through reused polysulfone membranes reprocessed with Renalin does not appear in some studies to change with the number of reuses (32). In membranes that show a decrease in β_2-microglobulin clearance with reuse, the postulated mechanism is decreased adsorption and/or sieving due to protein deposition on the membrane surface.

Finally, reuse impacts on the biocompatibility of membranes. When cuprophane membranes are reprocessed with formaldehyde, glutaraldehyde, or Renalin without bleach, biocompatibility (defined

maintain a protein and energy intake of ≥1.0 g/kg/day and ≥28 kcal/kg/day, respectively. At baseline, anthropometry, 2-day food record recalls, appetite assessment and diet satisfaction will be recorded and patient demographics, socioeconomic status and comorbidity will be fully described. During follow-up, changes in weight and biochemical parameters, such as albumin and PCR, will be tracked. In the event of weight loss or declining serum albumin, the HEMO Study dietitian will work with the dialysis unit dietitian to augment the patient's protein and energy intake using oral and/or intradialytic supplements. These nutritional "action items" are defined as follows: decrease in serum albumin of ≥0.3 g/dL from the baseline level to a value ≤3.9 g/dL; and undesired weight loss of 2.5 kg or 5% of post dialysis body weight during any time of follow-up. Secondary analysis of the data will allow a number of the questions listed above to be answered. The trends determined by the HEMO Study should help frame new questions to investigate in future prospective studies.

Cardiovascular Disease

Cardiovascular Disease and Optimal Dialysis

Comorbid conditions, not uremia, cause most deaths in hemodialysis patients. Indeed, heart disease (myocardial infarction, congestive heart failure and sudden death) accounts for 30 to 50% of deaths reported in various series (38–40). The high prevalence of heart disease among patients initiating hemodialysis in the U.S. certainly contributes to the subsequent cardiovascular mortality (41). Moreover, left ventricular hypertrophy (LVH), left ventricular dysfunction, hypertension and hyperlipidemia, which are strong independent risk factors among the general population, are also prevalent among patients treated by hemodialysis and are associated with higher mortality. The presence of these risk factors, and the efficacy of a variety of medical therapies to ameliorate them in the general population, led to the consideration of whether a program of cardiovascular risk factor reduction should be undertaken in the HEMO Study.

Left Ventricular Hypertrophy and Dysfunction

One echocardiographic survey of 153 hemodialysis patients found normal cardiac structure and function in only 23%. LVH was found in 55%, left ventricular dysfunction without LVH was found in 19%, and each finding was associated with more than a two-fold increase in mortality (39). Some of the factors associated with these abnormalities were the same as in the general population: older age, higher blood pressure, and smoking.

One of the interventions considered in a cardiovascular risk factor reduction program was the use of angiotensin converting enzyme inhibitors (ACEI) because of their salutary effects on both LVH and left ventricular dysfunction (42). Although prior studies have not included hemodialysis patients, the beneficial effect of ACEI is thought to be reduction in left ventricular wall tension, which should be applicable in hemodialysis patients. Despite low systemic plasma renin activity in many patients with renal disease, the renin-angiotensin system is not suppressed appropriately for the extent of volume expansion (43). Furthermore, ACEI are frequently prescribed and are well-tolerated in hemodialysis patients. Rarely, ACE inhibitors may cause anaphylactoid reactions in patients dialyzed with certain membranes (e.g., AN69), and more rarely, in patients treated with other reused synthetic membranes (44). In the HEMO Study, ACEI and other drugs will be used as necessary to treat hypertension or heart disease. The number of patients treated with ACEI, as well as beta-adrenergic blockers and other drugs for cardiovascular disease will be tracked. Secondary analysis of this data should allow for a partial answer to this question.

Hypertension

Hypertension affects approximately 80% of individuals with renal disease and patients initiating hemodialysis (45). However, with fluid removal, more frequent monitoring of blood pressure and adjustment of anti-hypertensive medications, only about 30% of patients on renal replacement therapy have elevated pre-dialysis blood pressure (45). In the NCDS, average pre-dialysis blood pressure was 148/89 mm Hg (46). Although normalization of blood pressure during dialysis may be taken as an indication of effective antihypertensive treatment, continuous ambulatory blood pressure monitoring in hypertensive dialysis patients reveals interdialytic hypertension in 80% (47), and pre-dialysis hypertension remains a risk factor for death from cardiovascular disease (45). Even in dialysis patients who are normotensive during the day, nocturnal blood pressure is higher than normal (48). These findings suggest the possibility of exposure to higher than-usual levels of blood pressure in a large fraction of hemodialysis patients, which may contribute to the high prevalence of LVH and cardiovascular mortality.

A second intervention considered was to control blood pressure to lower than usual levels. There are no specific recommendations for arterial blood pressure for hemodialysis patients. The guidelines set forth by the Joint National Committee (JNC) for Detection, Evaluation and Treatment of Hypertension (49) are a blood pressure ≤160/90 mm Hg for patients >60 years old, and ≤140/90 mm Hg for patients ≤60 years old. There are no data on optimal blood pressure levels in hemodialysis patients. For the HEMO Study, the adopted standard of care was a pre-dialysis blood pressure of ≤160/90 mm Hg and a post-dialysis blood pressure of ≤140/90 mm Hg. Since pre-dialysis blood pressures are

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COMMENTS ON DIALYSIS ADEQUACY AND OPTIMAL DIALYSIS

DIALYSIS ADEQUACY

When hemodialysis for ESRD first started in Seattle in 1960, patients were dialyzed for 24 hours once weekly. It quickly became obvious that this resulted in a major build up of toxins, fluid and symptoms during the ensuing six days, and so the schedule was altered to 12 to 16 hours twice weekly. Patients improved. With more experience, in 1963 this was changed to 8 to 12 hours thrice weekly. Patients and their complications improved even more. We stopped at thrice weekly because of the hassle involved in more frequent travel to the center and in having to build the dialyzers more often and because of the cost of dialysis. On this regimen, adequacy was judged from patient well-being, their clinical appearance and simple blood tests – this worked very well.

After the National Cooperative Dialysis Study (NCDS) report in the 1970s, kinetic modeling of urea removal was developed as a measure of adequacy of dialysis - the quantity called Kt/V was derived. This represents dialyzer clearance, time on dialysis, and volume of distribution of urea in the patient's body. The concept is good, but unfortunately the NCDS results were extrapolated to argue that a Kt/V of 1.0 was adequate hemodialysis. With the availability of larger disposable dialyzers, it was possible to shorten dialysis and maintain a Kt/v of 1.0. This was seized on by many dialysis units and patients – the former for economic reasons and the patients because they liked less time on dialysis. Unfortunately, a Kt/V of 1.0 was only barely minimal hemodialysis as became obvious over the ensuing years (Attachment 1). For example, Europeans did not use Kt/V at that time, and in the late 1980s a study of data from the U.S. Renal Data System and the European Dialysis and Transplant Association Registry showed that European hemodialysis patients were getting some 20 percent more dialysis than their U, S. counterparts. This may have been one factor related to the higher mortality reported in U.S. dialysis patients.

More recently it has become accepted that with thrice-weekly hemodialysis the target Kt/V for each dialysis should be at least 1.3. The problem of dialysis adequacy has been extensively studied in recent years and about three years ago the National Kidney Foundation's Dialysis Outcomes Quality Iniative (Attachment 2) came up with such a recommendation together with a number of other recommendations to improve adequacy of both hemodialysis and peritoneal dialysis. Also in recent years, HCFA and the ESRD Networks have undertaken a major quality iniative to review clinical performance measures annually and provide feedback to individual dialysis units. The most recent report, based on 1998 data, shows that adequacy as measured by a number of parameters is continuing to improve (Attachment 3). We can always do better; I think that we are on the right track.

MORE FREQUENT DIALYSIS

As noted above, thrice-weekly dialysis was a practical compromise. However, normal kidneys work continuously, and so more frequent dialysis, by

smoothing out the chemical and fluid changes in the body, would more closely approach normal kidney excretory function. More dialysis can further increase adequacy. This is in fact the case.

A number of programs in the U.S. are dialyzing some patients five or six times weekly. This can be done either by short intensive dialysis or by slow nocturnal dialysis, at a center or more commonly at home. Similar programs are underway elsewhere, especially in Canada and Italy – all told several hundred patients worldwide are doing this. For example, in Seattle we have 12 patients dialyzing five and six times weekly. Within a week of starting this, the change in patient well-being is obvious. Two of these patients vacationed in Hawaii where they could only dialyze thrice weekly. Within a week of starting less frequent dialysis they began to notice adverse effects. All twelve patients have experienced the benefits of decreased symptoms and improved quality of life that are described in detail in the accompanying publications. As one of our patients said:"If I have to go back to three dialyses a week you will have to drag me there, and my finger nails will leave marks in the concrete"

The issue here is that Medicare only pays for thrice weekly dialysis except in very rare circumstances. There is data showing that more frequent dialysis is associated with reduced hospitalization and lower doses of medications, including the very expensive erythropoietin (EPO), and so looking at Part A and Part B together, Medicare would save with more frequent dialysis (Attachment 4). The Ontario Provincial Government is now supporting several more frequent dialysis programs because it has been shown that the overall costs of six times weekly home hemodialysis are no more than those of continuous ambulatory peritoneal dialysis.

The other advantage of more frequent dialysis is that it will increase the use of home hemodialysis. This is important, as home dialysis provides the best patient survival, quality of life and opportunity for rehabilitation of all dialysis modalities. Medicare regulations require that the option of home hemodialysis be presented to patients, but few programs offer this now. Physicians experienced with home hemodialysis have suggested that with the right equipment and support as many as twenty percent of all dialysis patients could elect home hemodialysis in the future.

The June 1999 Medpac Report to Congress addresses both adequacy and frequency of dialysis and specifically recommends the Secretary determine clinical criteria for patients to receive increased frequency or duration of dialysis (Attachment 5)

More frequent hemodialysis is a treatment regimen with marked advantages medically and in quality of life (See other Attached papers). If we are concerned about adequacy of dialysis, there is no doubt that dialysis five or six times weekly, depending on body size and medical factors, provides the most adequate dialysis, and should be an option available under the Medicare ESRD Program.

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WRITTEN TESTIMONY FOR THE RECORD
SENATE SPECIAL COMMITTEE ON AGING HEARING : KIDNEY DIALYSIS PATIENTS: A POPULATION AT UNDUE RISK?
HEARING DATE: JUNE 26, 2000

Presented by Professor Robert A. Wolfe, Ph.D.

The Honorable Senator Grassley and Members of the Committee:

Thank you for holding the recent informative Senate Special Committee on Aging Hearing on "Kidney Dialysis Patients: A Population At Undue Risk?". As the director of the Kidney Epidemiology and Cost Center at the University of Michigan (UM-KECC), I am writing to emphasize the important contributions that independent researchers, at both Universities and other non-profit organizations, are making to assure and improve the quality of care of ESRD patients. Although we do not have an organizational voice, as do other ESRD groups, we have been active in providing crucial information to the dialysis community for many years. These contributions include not only basic research that will have long-term impact on ESRD care, but also include very practical continuous quality improvement (CQI) and quality assurance (QA) components that have immediate impact upon patient well-being. In addition, your hearings clarified the need for information about individual dialysis facilities, reuse practices, and dialysis chains. This letter reviews some efforts that we have already made in these and other areas.

A research perspective serves well to optimize patient care, as it is motivated by fact rather than by self-interest or by preconception. The tools of scientific research are useful not only for basic science, but also for achieving goals of quality assurance and quality improvement in the care of ESRD patients in the U.S.

The UM-KECC research team has made a professional commitment to research that improves the care of ESRD patients. These contributions have saved patient lives, improved the quality of life for ESRD patients, and saved millions of dollars by focusing and targeting the efforts to achieve these goals.

I believe there are at least four steps that should be taken to assure that this important research perspective can continue to make contributions to advance the welfare of ESRD patients:

1) Fund independent researchers to help to assure data integrity, identify ways to improve care, and provide data to focus and motivate CQI / QA efforts.
2) Continue to collect relevant patient outcome and clinical practice data at provider facilities and use those data for QA, CQI, and research efforts.
3) Seek independent unbiased review and evaluation of all ESRD programs and efforts so that the programs themselves are continually improved.
4) Assure access to all relevant data by researchers, consumers, surveyors, Networks, and policy makers.

Some of the most important tools that are currently being used to improve patient care were not clearly described by the panel members in your hearings. Two issues, [A] unit-specific reports and [B] reuse studies, are described in more detail below.

[A] Unit-Specific Reports: During the last 5 years, the researchers at the UM-KECC were contracted by HCFA to send over 13,000 individual unit-specific reports (USRs) to dialysis facilities in the nation (over 3,000 facilities this year). Each report has more than 100 facility-specific statistics of patient outcomes including mortality, hospitalization, and transplantation and of clinical practice measures including dose of dialysis, vascular access, serum albumin, and hematocrit measures with comparisons to the facility's state, Network, and nation (see the attached sample report). The research team at the UM-KECC built and housed the Coordinating Center for the Congressionally mandated National ESRD Data System (USRDS) for 11 years and produced these reports for 4 years with HCFA funding through the USRDS. The UM-KECC produced the reports for HCFA last year and expects to contract to produce them again next year.

The unit-specific reports produced by the UM-KECC have already proven to be an extremely valuable tool for improving the care of ESRD patients. Many facilities rely on them for use in their continuous quality improvement (CQI) efforts. We included dose of dialysis measures in these reports this year, the first year that such data were nationally available. In a pilot study, state surveyors are using statistics from these reports as one tool to help focus quality assurance (QA) inspections on those facilities with high patient mortality, inadequate dose of dialysis, and inadequate anemia management. We found that these factors were strongly predictive of state surveyor findings of non-compliance in a recent study with the Texas surveyors and ESRD Network. Later this year, statistics from these reports will be disseminated to consumers on a HCFA-sponsored internet site. We hope to be able to further improve these reports when other clinical performance measures are collected electronically with the VISION data system. These CQI / QA efforts are recognized as a HCFA responsibility, as reflected by the NIH decision to remove them from the USRDS tasks in the most recent USRDS contract. Although we are primarily a research unit, we also interact directly with the Networks and with individual dialysis facilities by responding to many questions about clinical practices and the statistics in the unit-specific reports.

[B] Reuse Studies: "To reuse or not to reuse?", that is not a simple question. Reuse practices have some potential benefits (better membranes can be used and bio-compatibility might be improved) and some potential disadvantages (infection, clotting of dialyzers, or toxicity). Only empirical research can resolve the relative importance of each. We have published several studies about reuse and in a 1994 study, we identified concerns about the use of some sterilants (Held PJ, Wolfe RA, Gaylin DS, Port FK, Levin NW, Turenne MN. American Journal of Kidney Disease 1994; 23: 692-708). Based on preliminary findings from that research, the FDA/CDC/HCFA issued a warning to assure and improve standards of reuse in 1993. HCFA started an intensive program with State Surveyors to improve reuse practices at dialysis facilities in 1994. Since then, we have monitored patient mortality nationally and have seen survival at reuse facilities improve substantially. Our current research suggests that patient mortality varies with

very specific combinations of reuse practices and that some combinations can be beneficial, so long as appropriate reuse practices are assured. We can supply more detailed information about reuse, upon request.

Other: Research has provided outcomes-based evidence regarding many other important issues in the care of ESRD patients including determination of the "optimal" dose of dialysis, dialyzer membranes, anemia management, blood pressure management, nutritional factors, peritoneal versus hemodialysis comparisons and transplantation outcomes. The UM-KECC research team has published hundreds of studies (see www.med.umich.edu/kidney/publications.html) related to ESRD patient outcomes. We have also monitored relative mortality at different dialysis chains and could provide you with this unpublished information if you would like to see it.

Historically, the ESRD community has worked closely with independent researchers and this collaboration has been very beneficial to patients. Independence is important to prevent bias and assure external review. All systems should undergo continual review and improvement. Our scientific and clinical knowledge about ESRD is growing rapidly and this increasing knowledge base can be used to target and to define standards for both CQI and QA efforts. The development of evidence-based standards of care is a process, not an end product. By contracting with independent researchers, the HCFA can continue to find ways to improve and assure care for ESRD patients.

The release of relevant data to researchers can be an important step in improving care. The perspective of specific groups is limited and often obscures their ability to see the big picture. For example, until recently, the evaluation of transplant mortality outcomes was hampered by consideration of only transplanted patients, or by inappropriate comparisons to dialysis patients. A recent study published in the New England Journal of Medicine (Wolfe, 1999) for both transplant and dialysis patients has clarified the benefits of transplantation relative to dialysis for many subgroups of patients.

In conclusion, I believe that the 4 items listed above are cost-effective steps that can help to assure and advance the welfare of ESRD patients. We have recently begun to work more directly with the HCFA to improve patient well being and hope that these efforts will be supported. Please contact me if you have questions or if I can provide you with further information.

Sincerely,

Robert A. Wolfe

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2000 Unit-Specific Report for Dialysis Patients
HCFA Provider # 000000 State: N/A Network: N/A

Dear Dialysis Unit Director:

This report has been prepared for your facility by the Kidney Epidemiology and Cost Center (KECC) at the University of Michigan with funding from the Health Care Financing Administration (HCFA). This is one of 3029 reports that have been sent to the ESRD Networks for distribution to ESRD providers in the U.S. Selected highlights from this report are given here.

Mortality: There was a 23% annual observed death rate among the patients treated at this facility between 1996-98, while a rate of 14% would be expected, based on the age, diabetes status, race, and sex of those patients. The standardized mortality ratio (SMR) of observed to expected deaths is 1.57, which is 57% more deaths than expected at your facility. Among all US facilities, 96% of facilities had an SMR lower than 1.57. This difference is statistically significant ($p<0.05$), so this higher mortality is unlikely due to random chance and probably represents a real difference from the expected mortality in the U.S. See Table 1 and Figure 1 for more detailed mortality statistics.

Hospitalization: Based on analogous methods, 77% of the Medicare primary payor hemodialysis patients treated at your facility between 1996-98, were hospitalized annually, while a rate of 42% would be expected. The standardized hospitalization ratio (SHR) for this facility is 1.84, which is 84% higher than expected. This difference is statistically significant ($p < 0.05$) and is unlikely to be due to random chance. See Table 2 and Figure 2 for additional hospitalization statistics.

Transplantation: Based on analogous methods, 3.6% of the patients under age 65 treated at this facility between 1996-98 who had not previously been transplanted, were transplanted annually, while a rate of 6.1% would be expected for these patients. The standardized transplantation ratio for your facility is 0.60, which is 40% lower than expected for your facility. This difference is not statistically significant ($p > 0.05$) and is plausibly due to random chance. See Table 3 and Figure 3 for additional transplantation statistics.

Practice Patterns: Among 67 hemodialysis patients in your facility with URR recorded in Medicare claims data, 7% have URR below DOQI guidelines (URR < 65%), compared to 17% nationally. Your facility reported that 16.0% of patients have central (temporary or cuffed) catheter accesses. The average percent of patients with central catheters is 21.3% nationally. Among 81 Medicare dialysis patients receiving EPO treatments in 1998 at your facility, 69% have hematocrit below DOQI guidelines (HCT < 33), compared to 46% nationally. See Table 4 for more information about practice patterns.

Patient Characteristics: See Table 5 for detailed summaries of 136 patients treated during 1998 at your facility. On average, there were 2.7 comorbidities reported on the HCFA 2728 for the 34 patients starting treatment at your facility between July 1998 and June 1999, which is higher than the average of 2.6 reported for the entire United States for patients starting treatment during this time. The average residual renal function (GFR) calculated for these patients from serum creatinine (before first dialysis) and other parameters was 8.9 ml/min, which is higher than the average of 8.1 reported for the entire United States. See Table 6 for additional information about these patients.

These are just a few highlights of the statistics you will find in this report based on the data for your facility. For comparison, the tables also report data for all patients or facilities in the United States, in your ESRD Network, and generally in your state. We hope that this report is of interest to you and that you will discuss it with your staff. We would appreciate your feedback on ways to improve future reports.

This report is based primarily on Medicare claims and data collected for HCFA by the ESRD Networks. Patients were assigned to your facility based on Medical Evidence forms (HCFA form #2728) submitted by your facility and on Medicare claims for your facility (See Table 7). Network N/A has a list of the patients included in the analyses for your facility. The Annual Facility Survey submitted by your facility indicates that 150 patients were being treated at your facility during 1998. Thus, the count of 136 patients included in this report for 1998 represents a large fraction of the patients treated at your facility. Differences in counts of patients can result from many causes, including changes in ownership or inaccuracies and incompleteness of data submitted to the HCFA for the patients in this facility. For a complete description of the data reported here please see the *Guide to the 2000 Unit-Specific Reports*. The Guide is available from ESRD Network N/A and is also on the KECC web site at *www.med.umich.edu/kidney*.

Sincerely,
The Kidney Epidemiology and Cost Center at the University of Michigan

2000 Unit-Specific Report for Dialysis Patients
HCFA Provider # 000000 State: N/A Network: N/A

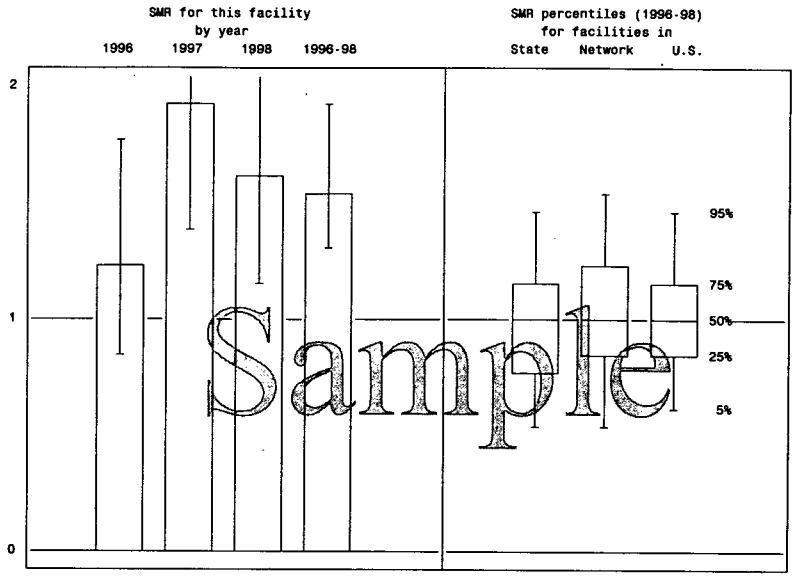
TABLE 1: Mortality Summary for All Dialysis Patients[1], 1996-98

	This Facility				Regional averages[2], 1996-98 per year		
	1996	1997	1998	1996-98	State	Network	U.S.
Death Rates							
1a Patients (n=number)	118	128	127	373[7]	62	61	69
1b Actual deaths (n)	25	33	26	84[7]	10	10	12
1c Expected deaths (n)	20.1	17.2	16.1	53.4[7]	10.1	9.7	12.1
1d Death rate (% of 1a)	21.2	25.8	20.5	22.5	16.5	16.7	17.5
1e Expected death rate (% of 1a)	17.0	13.4	12.7	14.3	16.3	16.0	17.6
Categories of Death							
1f Withdrawal from dialysis prior to death (% of 1b)	12.0	15.2	11.5	13.1	18.7	17.4	18.5
1g Due to infections, not including AIDS (% of 1b)	28.0	30.3	15.4	25.0	17.2	18.1	21.5
1h Dialysis unrelated deaths[3] (n) (excluded from SMR)	0	2	0	2[7]	0.2	0.2	0.2
Standardized Mortality Ratio							
1i SMR[4] (see Figure 1)	1.25	1.92	1.61	1.57	1.02	1.04	1.00
1j P-value[5]	0.16	0.01	0.01	0.01	n/a	n/a	n/a
1k C.I. for SMR[6]							
High (95% limit)	1.74	2.57	2.24	1.89	n/a	n/a	n/a
Low (5% limit)	0.87	1.41	1.13	1.30	n/a	n/a	n/a
SMR Percentiles for this Facility							
1l State	77	95	90	98			
1m Network	74	95	90	96			
1n U.S.	76	97	93	96			

n/a= not applicable.
[1] See Guide, Section IV.
[2] Values are shown for the average facility.
[3] Defined as deaths due to AIDS, street drugs, and accidents unrelated to treatment.
[4] Calculated as a ratio of actual (1b) to expected (1c). Not shown if (1c) is too small.
[5] A p-value less than or equal to 0.05 indicates that the difference between the actual and expected mortality is probably real and is not due to random chance, while a p-value greater than 0.05 indicates that the difference could possibly be due to random chance.
[6] The confidence interval (C.I.) range represents uncertainty in the value of the SMR due to random variation.
[7] Sum of 3 years used for calculations; should not be compared to regional averages.

2000 Unit-Specific Report for Dialysis Patients
HCFA Provider # 000000 State: N/A Network: N/A

FIGURE 1: Standardized Mortality Ratio (SMR) for Dialysis Patients



The vertical bar shows the value of the SMR (actual / expected mortality) for this facility. The vertical lines show the range of uncertainty due to random variation (90% confidence interval; significant if the vertical line does not cross at 1)

The horizontal line in the middle of each box is the median SMR for facilities in a region. The lower and upper boundaries of the box are the 25th and 75th percentiles for facilities in the region. The vertical lines extend to the 5th and 95th percentiles

Relative to other facilities for the years 1996-98,
the mortality (SMR = 1.57) at this facility was at the
96th percentile in the nation
96th percentile in the network
98th percentile in the state

2000 Unit-Specific Report for Dialysis Patients
HCFA Provider # 000000 State: N/A Network: N/A

TABLE 2: Hospitalization Summary for Medicare Hemodialysis Patients[1], 1996-98

		This Facility				Regional averages[2], 1996-98 per year		
		1996	1997	1998	1996-98	State	Network	U.S.
2a	Medicare Hemodialysis Patients (n)	80	82	77	239[7]	42	42	43
Patients Hospitalized								
2b	Patients hospitalized (once or more)	66	61	57	184[7]	26	26	26
2c	Expected number hospitalized (n)	32.1	35.5	32.2	99.9[7]	23.9	24.7	25.2
2d	Hosp. rate (% of 2a)	82.5	74.4	74.0	77.0	63.3	61.3	60.6
2e	Expected hosp. rate (% of 2a)	40.2	43.3	41.9	41.8	57.4	58.9	59.3
Total Admission Count								
2f	Observed total admissions (n)	204	179	169	552[7]	66	63	62
2g	Expected total admissions (n)	113.2	112.1	110.9	336.3[7]	61.8	62.1	62.1
2h	Stand. Total Adm. Ratio[3]	1.80	1.60	1.52	1.64	1.06	1.01	1.00
Diagnoses Present (% of 2a)								
2i	Septicemia	13.8	16.3	15.6	15.9	10.5	10.5	11.5
2j	Acute Myocardial Infarction	1.3	2.4	3.9	2.5	2.8	2.8	3.5
Length of Stay								
2k	Unadj. avg. length of admiss. (days)	5.3	6.1	5.5	5.6	6.4	6.9	7.4
2l	One day admissions (% of 2f)	28.4	23.5	21.3	24.6	22.0	18.0	16.5
2m	Unadjusted average days in the hospital per dialysis patient year	16.8	17.2	14.8	16.3	12.5	12.7	13.6
Standardized Hospitalization Ratio								
2n	SHR[4] (also shown in Figure 2)	2.05	1.72	1.77	1.84	1.10	1.04	1.02
2o	P-value[5]	0.00	0.00	0.00	0.00	n/a	n/a	n/a
2p	C.I. for SHR[6]							
	High (95% limit)	2.52	2.13	2.20	2.08	n/a	n/a	n/a
	Low (5% limit)	1.66	1.37	1.40	1.62	n/a	n/a	n/a
SHR Percentiles for This Facility								
2q	State	95	89	89	94			
2r	Network	96	91	93	96			
2s	U.S.	96	92	95	97			

n/a= not applicable.

[1] Based on patients with Medicare as primary insurer; See Guide, Section V.

[2] Values are shown for the average facility.

[3] Stand. Total Admission Ratio calculated as ratio of actual (2f) to expected (2g) total admissions.

[4] Standardized Hospitalization Ratio calculated as ratio of actual (2b) to expected (2c). Not shown if (2c) is too small.

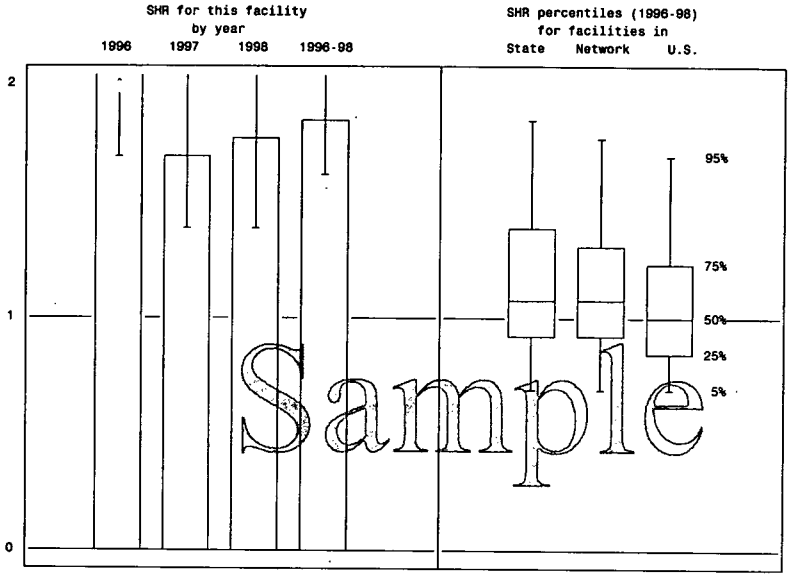
[5] A p-value less than or equal to 0.05 indicates that the difference between the observed and expected hospitalization is probably real and is not due to random chance, while a p-value greater than 0.05 indicates that the difference could possibly be due to random chance.

[6] The confidence interval (C.I.) range represents uncertainty in the value of the SHR due to random variation.

[7] Sum of 3 years used for calculations; should not be compared to regional averages.

2000 Unit-Specific Report for Dialysis Patients
HCFA Provider # 000000 State: N/A Network: N/A

FIGURE 2: Standardized Hospitalization Ratio (SHR) for Medicare Hemodialysis Patients



The vertical bar shows the value of the SHR (actual / expected hospitalization) for this facility. The vertical lines show the range of uncertainty due to random variation (90% confidence interval; significant if the vertical line does not cross at 1)
^ indicates SHR > 2

The horizontal line in the middle of each box is the median SHR for facilities in a region. The lower and upper boundaries of the box are the 25th and 75th percentiles for facilities in the region. The vertical lines extend to the 5th and 95th percentiles

Relative to other facilities for the years 1996-98,
the hospitalization (SHR = 1.84) at this facility was at the
97th percentile in the nation
96th percentile in the network
94th percentile in the state

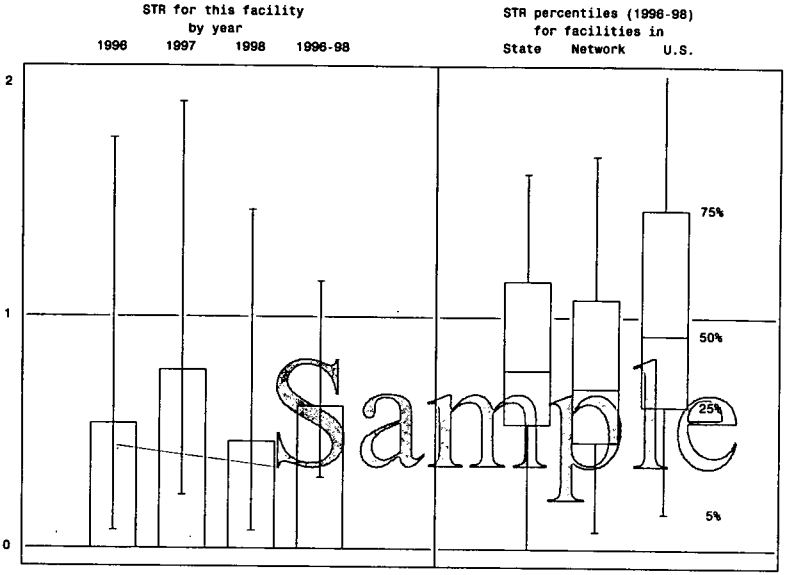
2000 Unit-Specific Report for Dialysis Patients
HCFA Provider # 000000 State: N/A Network: N/A

TABLE 3: Transplantation Summary for Previously Untransplanted Dialysis Patients Under age 65[1], 1996-98

		This Facility				Regional averages[2], 1996-98 per year		
		1996	1997	1998	1996-98	State	Network	U.S.
Transplantation Rates								
3a	Eligible patients (n)[3]	53	66	73	192[7]	32	33	35
3b	Actual 1st transplants (n)	2	3	2	7[7]	2	2	2
3c	Expected 1st transplants (n)	3.5	4.0	4.3	11.8[7]	1.9	2.1	2.1
3d	1st transplant rate (% of 3a)	3.8	4.5	2.7	3.6	5.1	5.0	6.4
3e	Exp. transp. rate (% of 3a)	6.7	6.0	5.9	6.1	5.9	6.2	6.2
3f	Number of Cadaveric transplants	1.0	3.0	2.0	6.0[7]	1.3	1.3	1.6
Standardized Transplantation Ratio								
3g	STR[4] (also shown in Figure 3)	0.57	0.76	0.47	0.60	0.86	0.80	1.04
3h	P-value[5]	0.32	0.44	0.20	0.10	n/a	n/a	n/a
3i	C.I. for STR[6]							
	High (95% limit)	1.78	1.96	1.47	1.12	n/a	n/a	n/a
	Low (5% limit)	0.10	0.20	0.08	0.28	n/a	n/a	n/a
STR Percentiles for This Facility								
3j	State	33	54	39	35			
3k	Network	38	57	56	35			
3l	U.S.	30	42	28	25			

n/a = not applicable.
[1] See Guide, Section VI.
[2] Values are shown for the average facility.
[3] See Guide, Section VI.
[4] Calculated as ratio of actual (3b) to expected (3c). Not shown if (3c) is too small.
[5] A p-value less than or equal to 0.05 indicates that the difference between the observed and expected transplantation is probably real and is not due to random chance, while a p-value greater than 0.05 indicates that the difference could possibly be due to random chance.
[6] The confidence interval (C.I.) range represents uncertainty in the value of the STR due to random variation.
[7] Sum of 3 years used for calculations; should not be compared to regional averages.

FIGURE 3: Standardized Transplantation Ratio (STR) for Previously Untransplanted Dialysis Patients under Age 65



The vertical bar shows the value of the STR (actual / expected transplantation) for this facility. The vertical lines show the range of uncertainty due to random variation (90% confidence interval; significant if the vertical line does not cross at 1)

The horizontal line in the middle of each box is the median STR for facilities in a region. The lower and upper boundaries of the box are the 25th and 75th percentiles for facilities in the region. The vertical lines extend to the 5th and 95th percentiles

Relative to other facilities for the years 1996-98,
the transplantation (STR = 0.60) at this facility was at the
25th percentile in the nation
35th percentile in the network
35th percentile in the state

2000 Unit-Specific Report for Dialysis Patients
HCFA Provider # 000000 State: N/A Network: N/A

TABLE 4: Facility Practice Patterns, 1998[1]

		This Facility	Regional Averages[2], 1998 State	Network	U.S.
4a Modality (%)	Hemodialysis	73.5	87.0	88.6	87.1
	CAPD/CCPD	20.6	11.4	9.7	11.1
	Other Dialysis (recent switch)	5.9	1.6	1.6	1.8
		100%	100%	100%	100%
Medicare dialysis patients treated as of 1/1/98					
4b Percent receiving EPO	Hemodialysis	97.1	97.3	97.1	97.0
	CAPD/CCPD	68.8	72.7	66.1	66.8
4c Average hematocrit (%)	Hemodialysis	32.1	32.6	32.7	32.9
of EPO treated patients	CAPD/CCPD	28.2	31.4	31.5	32.0
4d Hematocrit<33 (% EPO treated dialysis pts.)		69.1	52.3	50.7	46.0
4e Urea Reduction Ratio(URR) (% of pts.)					
	< 60.0 %	4.5	6.8	6.8	8.7
	60.0-64.9 %	3.0	6.9	7.8	8.7
	65.0-69.9 %	16.4	23.9	23.9	24.7
	70.0-74.9 %	35.8	36.2	34.0	31.3
	> 75.0 %	40.3	26.2	27.5	26.6
		100%	100%	100%	100%
4f URR<65% (% of pts.) (DOQI recommends URR>65%)		7.5	13.7	14.6	17.4
4g Missing URR (% of pts.)		11.6	11.5	11.7	21.9
4h Membrane Usage (% of all pts.)[3]					
	High Flux Polysulfone	0.0	28.8	37.2	46.0
	Low Flux Polysulfone	0.0	36.8	36.1	25.4
	Regenerated Cellulose	0.0	11.7	6.5	7.0
	Cellulose Acetate	0.0	14.1	15.7	11.9
	Cellulose Triacetate	0.0	0.4	0.2	6.0
	Hemophan	0.0	0.2	0.2	1.3
	PMMA	0.0	1.0	0.4	0.2
	Other	100.0	6.8	3.7	2.2
4i Vascular Access (% of all pts.)[3]					
	AV Graft	69.0	70.3	68.0	55.1
	AV Fistula	15.0	16.0	17.3	23.5
	Cuffed Central Catheter	0.0	8.7	10.0	16.0
	Temp. Central Catheter	16.0	5.0	4.6	5.3
4j Number of Patients with Vascular Access Infections[3]		10.0	5.9	4.7	6.9

n/a= not applicable
[1] See Guide, Section VII
[2] Values are shown for the average facility.
[3] These data are self reported and were collected by facilities in 17 of the 18 ESRD Networks.

2000 Unit-Specific Report for Dialysis Patients
HCFA Provider # 000000 State: N/A Network: N/A

TABLE 5: Summaries for All Dialysis Patients Treated During 1998[1]

		This Facility	Regional Averages[2], 1998 State	Network	U.S.
5a Number (n) (1/1/98 - 12/31/98)		136	69	67	78
5b Average age (yrs)		57.0	60.0	59.2	60.4
5c Age (% by group)	< 20	0.0	0.6	0.8	0.8
	20-64	67.6	56.1	58.0	54.2
	65+	32.4	43.4	41.2	45.0
		100%	100%	100%	100%
5d Cause of ESRD (%)	Diabetes	35.3	36.4	36.3	39.0
	Hypertension	32.4	33.4	33.7	27.1
	Glomerulonephritis	11.0	10.6	10.9	12.3
	Other/Unknown	16.2	15.9	15.2	18.4
	Missing	5.1	3.6	3.8	3.2
		100%	100%	100%	100%
5e Race (%)	Asian/Pacific Islander	0.7	0.6	0.5	3.6
	Black	78.7	62.8	59.3	36.1
	Native American	0.0	0.3	0.4	1.6
	White	19.6	36.4	39.6	56.9
	Other/Unk/Missing	0.7	0.2	0.2	1.8
		100%	100%	100%	100%
5f Sex (%)	Female	50.7	51.8	51.1	47.9
5g Incident during 1998 (as % of row 5a)		27.2	23.5	23.8	26.2
5h Average duration of ESRD (yrs) for Medicare dialysis patients treated as of 1/1/98		3.8	3.7	3.7	3.5

[1] See Guide, Section VIII
[2] Values are shown for the average facility.

TABLE 6: Patient Characteristics as Reported on the Medical Evidence Form (HCFA 2728) for Patients starting dialysis 7/1/98 to 6/30/99)[1]

Patient Characteristics [range][2]	This Facility (n)	Regional Summaries Network	U.S.
6a Total Number of Patients with Forms	34		
6b Age (average Years [0-95])	63.2	61.2	62.4
6c Sex (% Female)	52.9	49.8	46.9
6d Ethnicity (% Hispanic)	0.0	0.2	10.9
6e Race (%)	100% (34)		
White	26.5	49.3	63.8
Black	73.5	49.8	28.4
Asian	0.0	0.3	2.2
Native American	0.0	0.3	1.2
Pacific Islander	0.0	0.1	0.8
Arabian/Middle East	0.0	0.0	0.3
Indian Subcontinent	0.0	0.1	0.3
Other	0.0	0.1	2.5
Unknown	0.0	0.0	0.4
6f Body Mass Index[3] (Weight/Height^2)			
Male	23.9 (16)	25.1	25.5
Female	24.9 (14)	26.8	26.8
6g Primary Cause of ESRD (%)	100% (34)		
Diabetes	50.0	42.6	44.1
Hypertension	26.5	32.4	26.2
Primary Glomerulonephritis	5.9	8.0	9.8
Other	17.6	17.0	19.9
6h Employment[4]			
Six months prior to ESRD treatment	16.7 (6)	31.5	34.7
At first ESRD treatment	15.4 (13)	16.0	22.5
Lab Values Prior to Dialysis (average)			
6i Hematocrit (% [9-54])	27.9 (30)	28.5	29.0
6j Hemoglobin (g/dl [3-18])	9.1 (29)	9.4	9.6
6k Serum Albumin (g/dl [0.8-6.0])	3.2 (24)	3.2	3.2
6l Serum Creatinine (mg/dl [2-33])	7.2 (34)	8.2	7.7
6m BUN (mg/dl [24-250])	87.8 (30)	85.7	89.4
6n GFR (ml/min [0-25])	8.9 (21)	7.9	8.1

n/a = not applicable
[1] See Guide, Section IX
[2] For continuous variables, all summaries are computed based only on responses in range indicated in brackets for the variable.
[3] The average is computed for adult patients at least 20 years old.
[4] Full-time, Part-time, or Student (% of 18-60 year olds)

TABLE 6 (CONTINUED): Patient Characteristics as Reported on the Medical Evidence Form (HCFA 2728) for Patients starting dialysis 7/1/98 to 6/30/99)[1]

The following percentages are based on the 34 total form(s) from this facility.

Patient Characteristics	This Facility	Regional Summaries Network	U.S.
6o Pre-existing Co-morbidity (% yes)			
Congestive Heart Failure	64.7	30.4	32.3
Ischemic Heart Disease, CAD	17.6	21.1	24.4
Myocardial Infarction	0.0	7.8	9.2
Cardiac Arrest	0.0	0.8	0.8
Cardiac Dysrhythmia	2.9	5.1	5.9
Pericarditis	2.9	0.8	0.9
CVD, CVA, TIA	5.9	9.8	9.3
Peripheral Vascular Disease	23.5	13.1	14.8
History of Hypertension	64.7	78.8	74.4
Diabetes	41.2	42.7	40.9
Diabetes/on insulin (% of total)	17.6	25.6	23.4
Chronic Obstructive Pulmonary Disease	11.8	8.6	7.2
Current Smoker	2.9	7.1	6.1
Cancer	2.9	6.0	5.2
Alcohol Dependence	0.0	1.4	1.4
Drug Dependence	0.0	0.8	0.9
Inability to Ambulate	5.9	4.7	4.1
Inability to Transfer	0.0	1.7	1.4
6p HIV Status (%)			
Positive	5.9	0.6	0.6
Negative	94.1	97.3	28.1
Unknown/Cannot Disclose/Missing	0.0	2.1	71.2
6q AIDS Status (%)			
Positive	2.9	0.3	0.4
Negative	97.1	97.7	28.3
Unknown/Cannot Disclose/Missing	0.0	2.0	71.3
6r Average Number of Co-morbid Conditions	2.7	2.6	2.6

[1] See Guide, Section IX

2000 Unit-Specific Report for Dialysis Patients
HCFA Provider # 000000 State: N/A Network: N/A

TABLE 7: How Patients were Assigned to this Facility and Patient Status[1]

	This Facility					
	1996		1997		1998	
	n	%	n	%	n	%
7a Total number of patients placed in facility (equal to 1a)[2]	118	100%	128	100%	127	100%
Patient Placement in this Facility (7b-7g sum to 7a)						
Patients placed by:						
Medicare paid dialysis claim dated						
7b 0-6 months prior	96	81.4	107	83.6	101	79.5
7c 6-12 months prior	1	0.8	1	0.8	1	0.8
7d 12-24 months prior	0	0.0	1	0.8	0	0.0
HCFA Medical Evidence form dated						
7e 0-6 months prior	8	6.8	9	7.0	20	15.7
7f 6-12 months prior	10	8.5	1	0.8	3	2.4
7g 12-24 months prior	3	2.5	9	7.0	2	1.6
7h Patient exclusions due to AIDS death These patients were excluded from lines 7a-7g	0		2		2	
Patient Status During Year for Patients Placed in this Facility (7i-7p sum to 7a)						
Patients still in unit on 12/31 of the year						
7i Patients incident (new) during the year	15	12.7	30	23.4	28	22.0
7j Prevalent patients with > 100 days of dialysis claims paid to this facility	58	49.2	48	37.5	50	39.4
7k Prevalent patients with 1-99 days of dialysis claims paid to this facility	2	1.7	0	0.0	5	3.9
7l Prevalent patients with no paid dialysis claims paid to this facility	7	5.9	1	0.8	3	2.4
Patients no longer in unit on 12/31 of the year						
7m Patients alive and being treated in another unit on 12/31	9	7.6	12	9.4	13	10.2
7n Patients transplanted	2	1.7	3	2.3	2	1.6
7o Patients who died at this facility	24	20.3	29	22.7	21	16.5
7p Patients who died at another faciity	1	0.8	5	3.9	5	3.9

[1] See Guide, Section X
[2] Patients are placed on 1/1 of the year or on day 90 of ESRD during the year, by either their last dialysis bill or Medical Evidence Form.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

The Honorable Charles Grassley, Chairman
Special Committee on Aging
United States Senate
Washington, DC 20510

SEP 27 2000

Dear Chairman Grassley:

Thank you for the opportunity to testify before the Senate Special Committee on Aging regarding our End Stage Renal Disease Program on June 26, 2000.

Enclosed please find answers to your questions for the record regarding our current and future activities to address the concerns raised at the hearing by the HHS Office of the Inspector General and the General Accounting Office. Your continued interest and support are essential for the Medicare program's success. A similar letter has been sent to Senator Breaux.

Sincerely,

Nancy-Ann Min DeParle

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Enclosures

Answers to questions from the
Senate Special Aging Committee
to follow up on the
June 26, 2000 Hearing Regarding
ESRD Facilities

1. **What steps has HCFA taken to address the findings of the GAO (*Medicare Quality of Care, Oversight of Kidney Dialysis Facilities Needs Improvement)* and the HHS OIG (*1. External Review of Dialysis Facilities, A Call for Greater Accountability; and 2. External Quality Review of Dialysis Facilities, Two Promising Approaches)*, as released at the June 26, 2000 hearing?**

Office of Inspector General Report: External Quality Review of Dialysis Facilities, A Call For Greater Accountability (OEI-01-99-00050)

Recommendation: HCFA should hold individual dialysis facilities more fully accountable for the quality of care they provide and revise the Medicare Conditions for Coverage for dialysis facilities so the conditions serve as an effective foundation for accountability.
Current Status: We will address this recommendation in our proposed Conditions for Coverage. In our response to the IG report, we initially targeted early 2001for the Conditions for Coverage NPRM publication date. However, given the complexity and volume of work before our regulations team, we believe that summer 2001 is a more realistic target date for the NPRM. In drafting the NPRM, we are considering ways to strengthen the accountability of the dialysis facility governing body and to reinforce the accountability of the dialysis facility medical director for patient care. We are considering whether to require facilities to electronically report standardized performance measures, conduct their own Quality Assessment and Performance Improvement (QAPI) program, and establish internal systems for identifying, analyzing, and addressing the causes of medical injuries and medical errors. The Forum of ESRD Networks and the Renal Physicians Association are scheduled to meet October 30-31, 2000 in an ESRD Patient Safety Consensus Workshop to discuss and potentially develop a list of data elements on patient safety that should be collected. We are examining options to allow separate funding for the collection of this data through the ESRD Networks, as well as the best way to report the information to the public. In addition, we are considering whether to require dialysis facilities to monitor patient satisfaction using a common instrument approved by the Secretary. On August 8, 2000, the Forum of ESRD Networks Quality Improvement Committee met to discuss plans for developing such an instrument.

Recommendation: HCFA should use facility-specific performance measures to encourage facilities to improve the quality of care and to help ensure facilities meet minimum standards.
Current Status: We are identifying a core set of performance indicators to be collected regularly on all patients from facilities. We are establishing an electronic system that will allow us to collect information from each individual dialysis center to determine if the

center is providing appropriate care. This system will enable us to share these findings with the public electronically. We expect to begin testing this electronic system later this year. We also are collecting information on 16 additional clinical performance measures, developed pursuant to Section 4558(b) of the Balanced Budget Act (BBA) of 1997. These measures were pilot tested last year by ESRD Networks using a national sample of dialysis patients. They will be collected this year, both on a national sample of patients for quality improvement purposes and on all patients from a sample of dialysis facilities, through the electronic reporting system. Additionally, in another quality improvement initiative, the National Anemia Cooperative Project, our ESRD Networks have worked with dialysis providers to improve the management of anemia in dialysis patients.

Recommendation: HCFA should disseminate comparative facility-specific reports to facilities, Network, State survey agencies, and the public containing all of the performance indicators in the core set.
Current Status: We have developed fourteen facility-specific measures for the assessment of over 3,000 dialysis facilities. These measures are based on existing HCFA data and include descriptive information (e.g., name, address, phone number, type of services offered) staffing information, and three quality measures (adequacy of dialysis, anemia management, patient survival). From September 15 to October 13, 2000, dialysis facilities will have the opportunity to preview their respective data before it becomes available publicly. We will review any comments received from the facilities for consideration into the final design of our new "Dialysis Facility Compare" website on www.medicare.gov. This website is scheduled for public release in early 2001. Information on the website will be supplemented with other performance measures as they are collected on a facility-specific level. Additionally, in a seven-State pilot study, State survey agencies have used a composite score-ranking list to help them identify potential facilities to survey.

Recommendation: HCFA should strengthen the complaint system for patients and staff.
Current Status: A workgroup composed of our central and regional office staff met to review and revise the current ESRD Network instructions regarding the complaint process. Currently, this group is reviewing revised draft network manual instructions that include a mediation component. We also plan to conduct pilot projects to test ways in which the Networks and the State survey agencies can work together to create an integrated complaint system. However, prior to conducting such pilot projects, we will need to determine if funding is available for this purpose; and we will need to identify and work within the laws governing the sharing of patient-specific data.

Recommendation: HCFA should enhance the role of Medicare on-site certification surveys.
Current Status: We are working to determine an appropriate minimum cycle for conducting Medicare certification surveys of dialysis facilities. For FY 2001, the President has proposed increasing funding for the State survey process to decrease the time between surveys of dialysis facilities, from every six years to every three years, so we can better monitor the quality of care. We also are examining options to establish a minimum survey cycle.

Additionally, the IG recommended that we require joint Network-State agency surveys for initial certification visits to dialysis facilities. We did not concur with this recommendation. As we noted in our response to the IG report, the role of the Networks is to focus on educating and improving facility performance, while the role of the State survey agencies focuses on investigating and enforcing minimum requirements. We believe it is important to distinguish these roles during the initial survey process.

Recommendation: HCFA should hold the Networks and State survey agencies fully accountable for their performance in overseeing the quality of care provided by dialysis facilities and delineate the distinctive roles of the Networks and State survey agencies in quality oversight and to provide direction on how they should collaborate.
Current status: We are working to identify and overcome any barriers that prevent the sharing of information between Networks and State survey agencies. We will begin further work on this part of the recommendation once we are satisfied that this information can be shared legally.

Recommendation: HCFA should foster greater accountability of the Networks.
Current Status: We believe that Network accountability efforts should focus, in part, on how the Networks are using standardized performance data to improve the overall clinical performance of facilities in their region and to ensure that poor performers meet minimum standards of care. The Networks began a new contract cycle on July 1, 2000. Their quality improvement project efforts for the first year will focus on adequacy of dialysis. The Networks also have performance indicators that show which facilities need to improve in this area.

In addition to clinical performance, we believe our network accountability efforts should focus on how effectively the Networks are using a complaint system as a quality-of-care safeguard. The Networks began using their new Standardized Information Management System (SIMS) in January 2000. Through SIMS the Networks can categorize and log complaints in a systematic way that will allow us to report on how effective the Networks are in this area.

Recommendation: HCFA should increase public disclosure of information on Networks activities.
Current Status: On September 1, 2000, we verified with the Forum of ESRD Networks that the Compilation of Network Annual Reports, which reports on Networks' activities, will be available electronically. This will allow us to put the report on our website to increase public disclosure. To further promote the Networks to patients we operated a booth at the September 14, 2000 American Association of Kidney Patients Meeting. We also participated in the National Kidney Foundation Meeting on September 22 and 23, 2000, to discuss what we are doing for patients and how the Networks can help them. For example, we promoted our upcoming "Dialysis Compare" website, as well as our "New Patient" information package, which contains several resources to benefit new ESRD patients, including information on the Medicare benefit, as well as a booklet entitled "Preparing for Emergencies," to orient the beneficiary to ESRD. It also contains

a letter of introduction from the appropriate ESRD Network, information on the state agency, contact information for patient complaints, and a list of other ESRD information resources.

Recommendation: HCFA should foster greater accountability of the State survey agencies.
Current Status: We are working to improve the performance and accountability of State survey agencies. In FY 2001, we will conduct training sessions for States on basic survey skills, clinical issues, and the use of data. We also want to increase public disclosure of information on the State survey agencies' activities. To this end, we are developing educational materials regarding the existence and role of State Agencies for public distribution. Additionally, similar material was distributed at the September 14, 2000 American Association of Kidney Patients meeting.

General Accounting Office Reports (GAO)
Recommendation: Develop procedures on how and when to use its existing authority to impose partial or complete payment reductions for ESRD facilities that do not meet Medicare quality standards for dialyzer re-use.
Current Status: We intend to consolidate and clarify current alternative or intermediate sanctions, and establish new authorities across all provider types. We also are exploring procedures to implement these sanctions, as well as additional sanctions.

Recommendation: Establish procedures to facilitate better and more routine cooperation and information sharing between ESRD Networks and State survey agencies, particularly in targeting facilities for on-site surveys
Current Status: We are working to delineate more clearly the operational roles of the State survey agencies and the ESRD Networks, and to encourage more active cooperation between the State survey agencies and the ESRD Networks. In addition, we are researching section 1160 of the Social Security Act ("Prohibition Against Disclosure of Information") in order to clarify the legal issues regarding the release of Network data. The release of such data will facilitate the public identification of poor performing facilities.

Recommendation: Evaluate its project for using clinical outcome data to select facilities for on-site review before it uses such data as a key factor in the selection process. A trial component of the evaluation should be a determination of the extent to which the data are sufficient to predict which facilities have a higher likelihood of being out of compliance with Medicare's conditions for coverage.
Current Status: We have undertaken a facility-specific data initiative using outcomes data on standardized mortality ratios, hematocrit levels, dialysis adequacy levels to develop facility profiles to identify potential poor performing facilities. We are interested in the relationships and predicative value of facility-based data. Of particular interest is the relationship of surveyor results with mortality rates and practice patterns at the facility levels. As recommended, we will evaluate the efficacy of the facility-specific data. We also will use other tools to determine which facilities to survey. These will

include complaints, past inspection behavior, change of ownership, and Network information.

2. Please provide the committee with a long-term plan of action, which will ensure that the issues raised at the hearing regarding the ESRD program will be addressed.

We have made substantial improvements in the care provided to Medicare ESRD beneficiaries. For example, between 1994 and 1998, the percentage of ESRD patients with adequate hematocrit (red blood cell) levels increased from 55 to 83 percent. Additionally, in the same time period, the percentage of patients receiving adequate dialysis increased from 49 to 74 percent. We also know from the U.S. Renal Data System, a joint HCFA and National Institutes of Health project, the overall one year mortality rates for dialysis patients decreased form 24.9 deaths per 100 patient years in 1990 to 22.8 in 1997.

Despite this progress, improvements in the ESRD program are still needed, and we are committed to making further strides. We believe we can do so by focusing on the patient's entire experience with dialysis and creating a culture of continuous quality improvement throughout the dialysis community. This includes our work on the IG and GAO recommendations as discussed above. For example, expanding and improving the information available to consumers on the quality of care in dialysis centers should help foster renewed attention to providing high quality service that meets beneficiary needs. Strengthening the role of ESRD Networks and State survey agencies, especially by securing funds for more frequent surveys as proposed in the President's budget, is critical. And increasing payments to reflect rising costs and the severity of patients' conditions, as the President is proposing, is also essential to ensure high quality.

Ensuring high quality care was a primary reason behind the June OIG and GAO recommendations to improve the oversight of the ESRD Program in general. The Balanced Budget Act of 1997 also included initiatives toward this end. From these recommendations we have developed ideas that together constitute our general long-term plan to ensure beneficiaries receive the quality ESRD care that they deserve. The following action plan describes steps we have already taken and other steps we are considering.

We have organized our action plans into the following categories:
1. **Clinical Performance Measures**
2. **Conditions for Coverage**
3. **Data**
4. **State Agency**
5. **ESRD Network**

1. ESRD Clinical Performance Measures Plan
In addition to the above actions, we have developed Clinical Performance Measures (CPMs) based on the National Kidney Foundation Dialysis Outcomes Quality Initiative

Clinical Practice Guidelines for the areas of adequacy of hemodialysis and peritoneal dialysis, anemia management, and vascular access. We pilot tested the collection of these CPMs on a national sample of dialysis patients in 1999. Also in 1999, we merged the ESRD Core Indicators Project with the CPM Project, and the resulting combination is now known as the ESRD CPM project. In 2000, we have continued to collect the CPMs on a national sample of dialysis patients, and a report describing the results of this data collection should be available in early 2001.

When VISION is operational, which we have targeted for the summer of 2001, we plan to pilot test the collection of the CPMs on all dialysis patients, phasing in the system. Once national implementation is achieved and we receive CPM data on all dialysis patients from all dialysis facilities, we plan to disseminate facility-specific reports to the Networks and the dialysis providers. At that time we also will determine which CPMs to release to the public. We further intend to develop additional performance measures; however, this will be dependent upon the publication of new dialysis facility conditions for coverage, the successful implementation of VISION, and the publication of additional clinical practice guidelines.

We have developed a limited number of dialysis facility-specific measures to report to the public using existing HCFA data. These measures have been tested by consumers. As mentioned earlier, we also have developed a prototype design for our Dialysis Facility Compare website, which is similar to our very popular Nursing Home Compare website. This new website will be a primary mechanism for distributing this information to the public. Currently, dialysis facilities are in the process of previewing their data before it becomes available publicly. We expect to have the site go live with reports for over 3,000 dialysis facilities early next year.

2. ESRD Conditions for Coverage Plan

We intend to shift from the outdated, process-oriented requirements to patient-focused, outcome-oriented requirements. This includes establishing a framework to use patient information to define and measure outcomes of care for dialysis patients. Further, we plan to increase emphasis on specific health and safety standards such as water quality and infection control, physical environment, patient assessment and monitoring, and care at home. We expect that accomplishing these ends will call for requiring electronic reporting of data to HCFA by all dialysis facilities through our Vital Information System for Improvement of Outcomes in Nephrology (VISION). VISION contains facility-based data and is used by facilities to report information. We also are exploring mandating that each dialysis facility develop and monitor a Quality Assessment and Performance Improvement (QAPI) program encompassing such things as adequacy of dialysis, nutritional status, anemia management, standard mortality data, emotional and social well-being, and rehabilitative status. The QAPI would include the collection of patient satisfaction information.

We also are planning a facility QAPI program including certain performance measures (e.g., adequacy, nutrition, anemia management, quality of life and rehabilitative status) to be reported electronically to us. We would require minimum performance levels for each

performance measure, enabling us to hold facilities accountable to develop internal performance improvement plans to meet minimum performance levels.

3. ESRD Data Plan

We have a number of data systems that we plan to update in order to achieve improvements in ESRD care. These include:

Renal Management Information System (REMIS)

Our plans include making a complete transition to, and ongoing improvements in, the REMIS system, which is a federal system containing patient-specific data. This system will incorporate new features and be more user-friendly than our previous system. We intend to:

- Purchase development software,
- Create an analytical database,
- Institute online transaction processing, including a Web-based application to facilitate the use of this system,
- Create a process for calculating facility-specific measures for dialysis,
- Continue work on our Dialysis Facility Compare website, and
- Include VISION data processing in REMIS.

Standard Information Management System (SIMS)

SIMS standardized the Network databases and allowed them to conduct business in a more uniform fashion. Our plans to improve this system include:

- Implementing standardized reporting features,
- Enabling SIMS to accept and maintain VISION data,
- Enabling SIMS to accept and maintain Clinical Performance Measure (CPM) data, and
- Connecting HCFA Regional and Central offices to the system.

Vital Information System for Improvement of Outcomes in Nephrology (VISION)

As mentioned above, VISION contains facility-based data and is used by facilities to report information. After gathering input from a variety of sources within HCFA and the Networks, we intend to pilot test the VISION system with willing ESRD facility chains to gain their hands-on input and take advantage of their suggestions. In order to incorporate the VISION system we plan to:

- Deliver software to facilities,
- Train Networks, Facilities, and State Agencies,
- Begin VISION transmissions to a Central Repository,
- Incorporate QAPI requirements,
- Potentially incorporate medical errors/patient safety requirements, and
- Potentially incorporate patient satisfaction requirements.

In addition to these systems activities, we will be reviewing the forms we use to collect data. The Office of Management and Budget requires that we review these forms to ensure the utility of the data elements they include. Additionally, a review of these forms

moves toward compliance with the Government Paperwork Elimination Act, which we must implement by October 2003. The review of data elements on the forms also is a preliminary step to putting the forms on the Web and allowing electronic submission of data. We intend to establish a committee that will include representatives from the renal community to review all existing data elements and make appropriate revisions. To complete this process we will need to revise the Renal Facility Forms Manual, distribute the Forms Manual to facilities, and revise all systems and programs to incorporate changes to forms, including developing and implementing a training plan for facilities using the new forms.

Another project we have begun is an ESRD Data Dictionary to standardize the definitions of elements in the Core Data Set. Standardized definitions are important for sharing information across industry organizations, including outcomes information and quality indicators. For example, currently some organizations use the day the patient enters the operating room as the "date of transplant," while others use the day the patient leaves the operating room. The Data Dictionary will standardize the date organizations use, making sure that all parties can understand each other's data and communicate accurately. Once we have developed definitions for each element of the Core Data Set, we will seek input on the Data Dictionary from the renal community prior to its publication.

4. ESRD State Agency Plan

We are working to increase the resources available for surveying dialysis facilities, to improve the surveying process, and to communicate more information to the public about the role of States in the inspection process. The President has proposed that the State survey agencies be funded to provide more survey coverage in 2001, increasing Survey frequency from once every six years to once every three years. We plan to further increase that frequency level to once every two years.

Additionally, we plan to improve the survey process by providing the surveyors with more data. The data is intended to help surveyors select facilities to inspect and to help them structure the survey process. We also are improving the survey process by providing and evaluating training programs for surveyors on basic surveying skills, clinical issues, and the use of data in the survey process. Four new training sessions have been scheduled for 2001.

5. ESRD Network Plan

We are working with Networks, States, and Regional Office staff to develop a way to make the complaint process easier and more responsive for beneficiaries. We also intend to work with Networks, States, and our staff to develop the OIG-suggested template elements for an effective complaint system, and to develop pilot projects to further establish a complaint process that will be coordinated with State survey agencies. We will work with Networks and State survey agencies to develop a plan for collecting patient satisfaction information, including:

- Assessing current instruments and measures available,
- Developing instrument measures through a proposed rule, and
- Developing a collection mechanism.

In addition to the above activities, we intend to promote the role of Networks and States using the Internet and informational brochures. Along with this we plan to develop policy to delineate the roles of Networks and State survey agencies in improving quality of care. We also have developed a "New Patient" information package that, as mentioned above, contains several orientation resources to benefit new ESRD patients. These include:

- information on the Medicare benefit,
- a "Preparing for Emergencies" booklet,
- a letter of introduction from the appropriate ESRD Network,
- information on the state agency,
- contact information for patient complaints, and
- a list of other ESRD information resources.

We will distribute these materials beginning in October 2000.

Ensuring that all of Medicare's beneficiaries receive the high quality care they deserve is our top priority. The five plan categories discussed above represent ways we are working to improve the quality of care our ESRD beneficiaries receive. We are making strides in improving ESRD care, and we are committed to continuing this progress.