

**Department of Health and Human Services**

**OFFICE OF  
INSPECTOR GENERAL**

**External Quality Review of Dialysis Facilities**

**Two Promising Approaches**



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# EXECUTIVE SUMMARY

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## PURPOSE

To describe two promising approaches to hold dialysis facilities more fully accountable for their quality of care.

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## 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.

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## 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.

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## **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.

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## 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).

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# INTRODUCTION

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## PURPOSE

To describe two promising approaches to hold dialysis facilities more fully accountable for their quality of care.

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## 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<sup>1</sup> 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.<sup>2</sup> 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<sub>urea</sub>.** Two measures used to measure adequacy in peritoneal patients. Creatinine clearance measures the removal of creatine and Kt/V<sub>urea</sub> 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<sup>2</sup>.

**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 100 ng/mL and a TSAT 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 substantive 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.<sup>3</sup> 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.<sup>4</sup>

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.<sup>5</sup>

## 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.)

<b>Occurrence</b>	<b>1996-1997</b>	<b>1997-1998</b>	<b>1998-1999*</b>
<b>Death</b>	32	28	6
<b>Hospitalization</b>	275	565	543
<b>Conversions to hepatitis B+</b>	10 patients	6 patients 1 staff**	14 patients
<b>Fire</b>	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.<sup>6</sup> 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.<sup>7</sup> 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 recommend 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.<sup>8</sup> 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.<sup>9</sup>

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## 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.<sup>10</sup>

### 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.<sup>11</sup> 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.<sup>12</sup> 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 4<sup>th</sup> quarter 1997 to 76 percent in 4<sup>th</sup> 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.<sup>13</sup> 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.<sup>14</sup>

**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.

**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 4<sup>th</sup> 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
<b>SEX</b>				
Men	62%	57%	53%	52%
Women	38%	43%	47%	47%
<b>RACE</b>				
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%
<b>AGE</b>				
< 18	0%	1%	0%	0%
18 - 44	22%	16%	17%	16%
45 - 64	43%	33%	36%	35%
65 +	35%	49%	46%	47%
<b>DIAGNOSIS</b>				
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	Net
# 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

  

	FAC	REG	STATE	NET
4Q1996	31%	51%	63%	66%
4Q1997	34%	53%	66%	71%
4Q1998	57%	65%	72%	76%

**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																														
<b>Treatment of Anemia:</b> Hematocrit (HCT) vol%  Your % pts meeting the criteria during July 1999 is 0.19 std dev below the Network rate	<b>Pt values this fac:</b> # values 22 Mean 32.07 Std Dev 3.91  <b>Pt values all facs:</b> # values 30 Mean 32.88 Std Dev 4.25	<table border="1"> <caption>% HCT &gt;= 31 vol%</caption> <thead> <tr> <th>Category</th> <th>Jul1998</th> <th>4Q1998</th> <th>Apr1999</th> <th>Jul1999</th> </tr> </thead> <tbody> <tr> <td>Network</td> <td>77%</td> <td>77%</td> <td>78%</td> <td>82%</td> </tr> <tr> <td>State</td> <td>77%</td> <td>78%</td> <td>80%</td> <td>84%</td> </tr> <tr> <td>Facility</td> <td>67%</td> <td>70%</td> <td>73%</td> <td>73%</td> </tr> <tr> <td>Phys (fac)</td> <td>71%</td> <td>59%</td> <td>74%</td> <td>73%</td> </tr> <tr> <td>Phys (all)</td> <td>77%</td> <td>58%</td> <td>69%</td> <td>77%</td> </tr> </tbody> </table>	Category	Jul1998	4Q1998	Apr1999	Jul1999	Network	77%	77%	78%	82%	State	77%	78%	80%	84%	Facility	67%	70%	73%	73%	Phys (fac)	71%	59%	74%	73%	Phys (all)	77%	58%	69%	77%
Category	Jul1998	4Q1998	Apr1999	Jul1999																												
Network	77%	77%	78%	82%																												
State	77%	78%	80%	84%																												
Facility	67%	70%	73%	73%																												
Phys (fac)	71%	59%	74%	73%																												
Phys (all)	77%	58%	69%	77%																												
<b>Treatment of Anemia</b> Ferritin Levels (ng/mL)  Your % pts meeting the criteria during July 1999 is 0.22 std dev above the Network rate	<b>Pt values this fac:</b> # values 21 Mean 712.71 Std Dev 723.33 % < 100 14%  <b>Pt values all facs:</b> # values 29 Mean 660.14 Std Dev 648.34 % < 100 14%	<table border="1"> <caption>% Ferritin &gt;= 100 ng/mL</caption> <thead> <tr> <th>Category</th> <th>Jul1998</th> <th>4Q1998</th> <th>Apr1999</th> <th>Jul1999</th> </tr> </thead> <tbody> <tr> <td>Network</td> <td>82%</td> <td>80%</td> <td>82%</td> <td>82%</td> </tr> <tr> <td>State</td> <td>90%</td> <td>84%</td> <td>90%</td> <td>90%</td> </tr> <tr> <td>Facility</td> <td>95%</td> <td>90%</td> <td>91%</td> <td>92%</td> </tr> <tr> <td>Phys (fac)</td> <td>88%</td> <td>86%</td> <td>91%</td> <td>88%</td> </tr> <tr> <td>Phys (all)</td> <td>92%</td> <td>88%</td> <td>91%</td> <td>88%</td> </tr> </tbody> </table>	Category	Jul1998	4Q1998	Apr1999	Jul1999	Network	82%	80%	82%	82%	State	90%	84%	90%	90%	Facility	95%	90%	91%	92%	Phys (fac)	88%	86%	91%	88%	Phys (all)	92%	88%	91%	88%
Category	Jul1998	4Q1998	Apr1999	Jul1999																												
Network	82%	80%	82%	82%																												
State	90%	84%	90%	90%																												
Facility	95%	90%	91%	92%																												
Phys (fac)	88%	86%	91%	88%																												
Phys (all)	92%	88%	91%	88%																												

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## ENDNOTES

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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.
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.