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MEDICARE QUALITY OF CARE

Oversight of Kidney Dialysis Facilities Needs Improvement

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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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Health, Education, and
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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

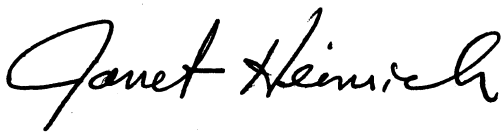
evaluation are needed before outcome measures are used as a significant factor in selecting ESRD facilities for survey. HCFA stated its intention to continue studying this issue.

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.



Janet Heinrich
Associate Director, Health Financing and
Public Health Issues

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.

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.

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.

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.

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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