

October 2003

DIALYSIS FACILITIES

Problems Remain in Ensuring Compliance with Medicare Quality Standards





Highlights of [GAO-04-63](#), a report to the Chairman, Committee on Finance, U.S. Senate

Why GAO Did This Study

Most patients with end-stage renal disease (ESRD) must rely on dialysis treatments to compensate for kidney failure. Currently, over 222,000 ESRD patients visit dialysis centers several times a week to have toxins removed from their bloodstreams. While dialysis care has improved overall, questions remain regarding the quality of care provided by some of the nation's roughly 4,000 ESRD facilities. We examined (1) the extent and nature of quality of care problems identified at dialysis facilities, (2) the effectiveness of state survey agencies in ensuring that quality issues are uncovered, corrected, and stay corrected, and (3) the extent to which the Centers for Medicare & Medicaid Services (CMS) funds, monitors, and assists state survey activities related to dialysis care.

What GAO Recommends

GAO suggests that Congress consider authorizing CMS to impose immediate sanctions, such as monetary penalties or denying payment for new Medicare patients, on dialysis facilities cited with serious deficiencies in consecutive surveys. GAO recommends that the CMS Administrator create incentives for facilities to maintain compliance with quality standards, increase use of expert staff in conducting ESRD facility surveys, and enhance the support and monitoring of state survey agencies. CMS did not indicate an intention to implement five of our six recommendations.

www.gao.gov/cgi-bin/getrpt?GAO-04-63.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Leslie G. Aronovitz at (312) 220-7600.

DIALYSIS FACILITIES

Problems Remain in Ensuring Compliance with Medicare Quality Standards

What GAO Found

A substantial number of ESRD facilities do not achieve minimum patient outcomes specified in clinical practice guidelines, with significant proportions of their patients receiving inadequate dialysis or treatment for anemia. Similarly, inspections of dialysis facilities by state survey agencies have uncovered numerous problems that put patient health at risk. Between fiscal years 1998 and 2002, these inspections, commonly called surveys, revealed that 15 percent of facilities surveyed had serious quality problems that, if left uncorrected, would warrant termination from the Medicare program. Serious deficiencies commonly found during surveys included medication errors, contamination of water used for dialysis, and insufficient physician involvement in patient care.

Infrequent, poorly targeted, and inadequate inspections allow facilities' quality of care problems to go undetected or remain uncorrected. Specifically:

- Although ESRD survey activity has increased in recent years, only nine state survey agencies consistently met CMS's goal to inspect 33 percent of ESRD facilities annually.
- A substantial number of facilities go many years between inspections. In fiscal year 2002, 216 facilities nationwide went 9 or more years without an inspection.
- Deficiencies may not have been detected during an inspection if the surveyors had little experience in assessing dialysis quality.

Even when deficiencies are identified and facilities take corrective action, little incentive exists for these facilities to remain in compliance. Data show a pattern of repeated serious deficiencies in successive inspections of an individual facility. No effective sanctions are available to enforce compliance, short of terminating the facility from the Medicare program, which is rarely done.

Federal monitoring of state agencies' performance of surveys and technical assistance provided is uneven across CMS regions. CMS substantially increased its funding for ESRD surveys from an estimated \$3.1 million in fiscal year 1998 to \$8.2 million in fiscal year 2002. At the same time, several CMS regional offices in our study did not actively oversee how the state agencies used these funds to improve survey activities. CMS has not taken steps needed to facilitate information sharing between federally funded ESRD networks and state agencies on the performance of individual dialysis facilities—information that could help states to target their inspection resources. In addition, CMS has not offered adequate training opportunities for surveyors inspecting ESRD facilities.

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Abbreviations

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| CMS | Centers for Medicare & Medicaid Services |
| DFC | Dialysis Facility Compare Web site |
| EPO | erythropoietin |
| ESRD | end-stage renal disease |
| ICF/MR | intermediate care facilities for the mentally retarded |
| LTC | long-term care |
| OSCAR | Online Survey Certification and Reporting system |

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G A O

Accountability * Integrity * Reliability

United States General Accounting Office
Washington, DC 20548

October 8, 2003

The Honorable Charles E. Grassley
Chairman
Committee on Finance
United States Senate

Dear Mr. Chairman:

Most patients with end-stage renal disease (ESRD)—a life-shortening, chronic illness—must rely on dialysis treatments to compensate for kidney failure. Currently, over 222,000 ESRD patients spend 3 to 5 hours at dialysis centers three times a week, where dialysis machines remove toxins from their bloodstreams. In addition to having permanent kidney failure, ESRD patients are likely to suffer from diabetes or heart disease and are at risk for developing illnesses during their course on dialysis. Therefore, the care of ESRD patients requires expertise in both the medical and technical aspects of maintaining patients on dialysis.

While dialysis care has improved overall, according to a 2002 Department of Health and Human Services report, questions remain regarding the quality of care provided to Medicare beneficiaries by some of the nation's roughly 4,000 dialysis facilities. The HHS report noted that many ESRD patients do not receive treatment meeting the minimum standards established in the National Kidney Foundation's clinical practice guidelines, which, when not met, have documented adverse effects on patient outcomes. In 2001, 16 percent of dialysis patients did not have an adequate amount of toxins removed from their blood, 24 percent had anemia that was not brought under control, and 19 percent of patients were dialyzed for extended periods using catheters, the least effective and most risky method for connecting patients to dialysis machines.¹

ESRD is the one medical condition that confers eligibility regardless of age to the Medicare program, which otherwise pays for health care provided

¹Department of Health and Human Services, Centers for Medicare & Medicaid Services, *2002 Annual Report: End Stage Renal Disease Clinical Performance Measures Project* (Baltimore, Md.: December 2002). These assessments are based on the clinical performance measures developed by CMS, building on the National Kidney Foundation's 1997 *Dialysis Outcome Quality Initiative Clinical Practice Guidelines*.

to people who are over 65 years of age or to those with disabilities. The Centers for Medicare & Medicaid Services (CMS), which oversees the Medicare program, has responsibility for ensuring that dialysis patients receive quality care. For this purpose, CMS contracts with state survey agencies that conduct onsite inspections. Following up on a report we issued in June 2000,² you asked us to review CMS's system for enforcing Medicare's minimum quality and safety standards for ESRD facilities and to assess whether and how it might be strengthened. Specifically, we examined (1) the extent and nature of quality of care problems identified at dialysis facilities, (2) the effectiveness of state survey agencies in ensuring that quality issues are uncovered, corrected, and stay corrected, and (3) the extent to which CMS funds, monitors, and assists state survey activities related to dialysis care.

To address these issues, we obtained data from existing national databases and original data from 10 states. We analyzed facility-specific information about quality measures reported on CMS's Dialysis Facility Compare, a consumer guide available on the Internet. For the nation as a whole and each of the states,³ we also analyzed data from CMS's Online Survey Certification and Reporting (OSCAR) system for the last 5 fiscal years, 1998 through 2002. This database provides information on the dates when surveys took place, the deficiencies cited, and the time spent conducting various survey activities. In addition, we interviewed cognizant officials at CMS's central office and reviewed changes in the CMS budget devoted to survey activities from fiscal years 1998 to 2002.

To supplement available national data, we obtained additional information from 10 states—Alabama, California, Florida, Kansas, Maryland, Mississippi, Missouri, Nevada, New York, and Pennsylvania—which together accounted for more than one-third of all facilities in fiscal year 2001. They were selected to provide variation across a range of dimensions, including the proportion of ESRD facilities surveyed and deficiencies cited, number of ESRD facilities, and geographic diversity. We interviewed state surveyors and administrators, representatives from

²U.S. General Accounting Office, *Medicare Quality of Care: Oversight of Kidney Dialysis Facilities Needs Improvement*, GAO/HEHS-00-114 (Washington, D.C.: June 23, 2000). This report highlighted the need for additional enforcement tools to ensure that corrections of quality problems identified in surveys of ESRD facilities would be sustained over time. It also urged improved cooperation and data sharing between state survey agencies and ESRD networks to improve targeting of facilities selected for inspection.

³In this report, "states" refers to the 50 states and the District of Columbia.

ESRD networks (organizations that promote quality improvement in ESRD services), and federal regional office officials responsible for monitoring ESRD facility surveys. In addition, we collected detailed information on several states' corps of ESRD surveyors, including their background, training, and experience. We also examined the written reports from numerous facility surveys conducted within the last 2 years. (App. I contains more detail on our scope and methodology.) Our work was conducted from August 2002 to September 2003 in accordance with generally accepted government auditing standards.

Results in Brief

A substantial number of dialysis facilities do not achieve the minimum patient outcomes specified in clinical practice guidelines for a significant proportion of their patients. Data reported on Dialysis Facility Compare show that, in 2000, 512 facilities had 20 percent or more of their patients receiving inadequate dialysis treatment, and nearly 1,700 facilities had 20 percent or more of their patients receiving inadequate care for anemia. In addition, the CMS-funded system of on-site inspections of facility conditions, equipment, and staffing has uncovered numerous problems that put patient health at risk. From fiscal year 1998 through 2002, these inspections, generally called surveys, revealed that 15 percent of facility surveys identified serious quality problems that, if left uncorrected, would warrant termination from the Medicare program. Serious deficiencies commonly found during surveys included medication errors, contamination of water used for dialysis, and insufficient physician involvement in patient care.

Infrequent, poorly targeted, and inadequate inspections by state survey agencies allow facilities' quality of care problems to go undetected or remain uncorrected. Specifically:

- Although ESRD survey activity has increased in recent years, state compliance with CMS's goal to resurvey 33 percent of ESRD facilities annually has been inconsistent. While 33 states met the goal in at least 1 of the last 2 fiscal years, only 9 of the 33 states surveyed a third or more of their facilities in both years. Eighteen states failed to meet the goal in either fiscal year 2001 or 2002.
- A substantial number of facilities go many years between inspections. In fiscal year 2002, 216 facilities nationwide (5.4 percent) went 9 or more years without an inspection, up from 53 facilities (1.6 percent) in fiscal year 1998.
- Deficiencies may not have been detected during a survey if the surveyors who inspected the facilities had little experience in assessing dialysis

quality. Data from several states showed that survey agencies where designated staff specialized in performing ESRD surveys uncovered a substantially larger number of deficiencies than agencies without such staff expertise.

Even when deficiencies are identified and facilities take corrective action, little incentive exists for these facilities to remain in compliance with Medicare's minimum quality standards on a continuing basis. As shown in nationwide data, when quality problems were cited, the problems were corrected but often did not stay corrected. For example, from fiscal years 1998 through 2002, 18 percent of facilities found to have serious deficiencies were cited again for the same deficiencies in successive inspections. At present, there is no effective sanction to encourage a facility to avoid repeating prior deficiencies, short of terminating the facility from the Medicare program, which is rarely done.

CMS has expanded funding to support state ESRD survey activities, but its monitoring of state agencies' performance of surveys and providing technical assistance is uneven across CMS regions. CMS substantially increased its aggregate funding for ESRD surveys from an estimated \$3.1 million in fiscal year 1998 to \$8.2 million in fiscal year 2002. At the same time, several regional offices in our study did not actively oversee or assist in improving ESRD survey activities. In addition, CMS has not removed barriers between federally funded ESRD networks and state agencies that inhibit the sharing of information on the performance of individual dialysis facilities—information that could assist states in targeting their inspection resources. Furthermore, surveyors in several states reported that CMS has not offered adequate training opportunities for surveyors inspecting ESRD facilities.

To encourage ESRD facilities to adhere to Medicare quality standards, we suggest that Congress consider authorizing CMS to impose immediate sanctions, such as monetary penalties or denying payment for new Medicare patients, on dialysis facilities cited with serious deficiencies in consecutive surveys. We are also recommending that CMS: conduct more frequent surveys of facilities with serious deficiencies; publicize facilities' survey results; encourage state agencies to use ESRD-specialized surveyors; expand ESRD surveyor training opportunities; require periodic, routine sharing of information between ESRD networks and state survey agencies; and enhance oversight of state agency performance.

In its comments on a draft of this report, CMS affirmed its commitment to strengthening oversight of dialysis facilities and state survey agencies, but did not indicate an intention to implement five of our six recommendations. Instead, the agency highlighted its efforts to develop tools to assist states in selecting facilities for inspection and to make the survey process more uniform. We continue to believe that more focused efforts to evaluate compliance with Medicare requirements and stronger actions against poor performers are needed to ensure an effective, consistent, and timely ESRD survey and certification program.

Background

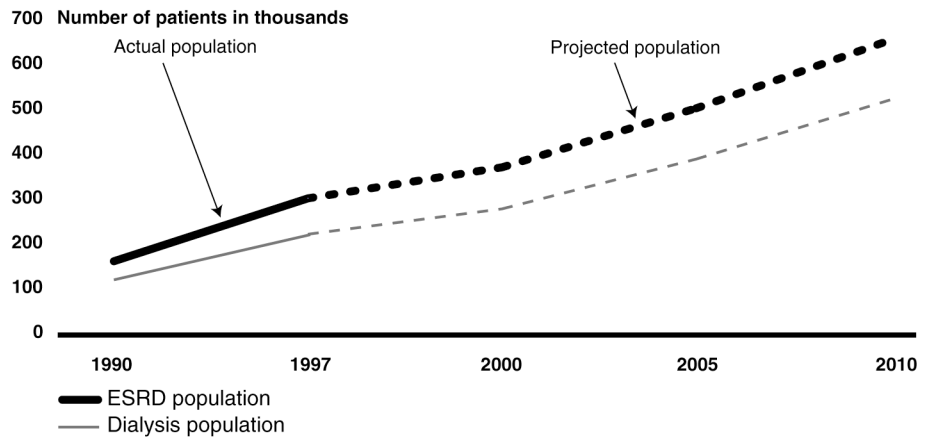
Individuals with ESRD, characterized by permanent kidney failure, must undergo either regular dialysis treatment or a kidney transplant to stay alive. In 2000, about 248,000 individuals received one of two modes of dialysis treatment—hemodialysis or peritoneal dialysis—both of which can be performed at a facility or at home.⁴ Most ESRD patients undergo hemodialysis.⁵ The number of hemodialysis patients enrolled in Medicare has risen sharply, from about 118,000 in 1991 to over 222,000 in 2000. With anticipated annual growth of over 7 percent, the dialysis population is projected to reach more than 520,000 by 2010.⁶ (See fig. 1.) This growth in enrollment has been attributed largely to improvements in the survival rate for people with ESRD and an increase in the number of Americans with conditions, such as diabetes or high blood pressure, that often lead to kidney failure.

⁴In hemodialysis, a patient's blood is filtered through an external machine that acts as an artificial kidney to withdraw excess fluids and toxic materials before returning cleansed blood to the patient. The machine uses a semipermeable membrane, called a hemodialyzer, to filter out the toxins. In peritoneal dialysis, the patient's peritoneal membrane, located within the abdominal cavity, is used to remove excess fluids and toxins.

⁵In 2000, about 222,300 patients received hemodialysis, 21,400 underwent peritoneal dialysis, and 4,400 underwent dialysis of an unspecified mode. In addition, approximately 74,700 beneficiaries were recipients of kidney transplants, for a total of approximately 322,800 individuals that received Medicare benefits as of December 31, 2000.

⁶Projections are based on data for 1982 to 1997. See J.L. Xue, J.Z. Ma, T.A. Louis, and A.J. Collins, "Forecast of the Number of Patients With End-Stage Renal Disease in the United States to the Year 2010," *Journal of the American Society of Nephrology*, vol. 12 (2001): 2753-2758.

Figure 1: Projected Growth in the ESRD Population and Medicare Costs



Source: Xue, J. L., et. al.

Growth in the ESRD population has been matched by growth in the number of dialysis facilities. In the decade between 1991 and 2001, the number of outpatient dialysis facilities doubled from about 2,000 to more than 4,000 facilities. In 2001, 83 percent of all facilities were freestanding (nonhospital-based) and 79 percent of all facilities were for-profit. In 2001, the four largest for-profit dialysis chains accounted for about two-thirds of all freestanding facilities.

The rise in the ESRD population has been accompanied by an even more rapid increase in program spending. Medicare not only provides coverage

to most beneficiaries with ESRD for all ESRD-related services but for their other health care needs as well.⁷ From 1990 to 2001, Medicare expenditures for beneficiaries with ESRD rose from about \$5 billion to over \$15 billion, and are forecast to grow to \$28 billion in 2010. Spending growth has been fueled by an expansion of enrollees with greater medical needs—older beneficiaries and those with chronic comorbidities⁸—and the program’s inclusion of new treatments, particularly erythropoietin (EPO)—a synthetic hormone widely used to manage anemia—and other injectable medications. While Medicare pays ESRD providers a set amount—a composite rate—including the nursing services provided and supplies used in each dialysis treatment, it pays separately for injectable drugs.⁹ The composite rate for dialysis services has remained virtually unchanged since the program’s inception. However, payments to freestanding dialysis facilities for injectable drugs have grown considerably in recent years, increasing from 33 percent of total payments in 1997 to 40 percent in 2001.

In 1976, CMS established minimum requirements that dialysis facilities must meet in order to receive Medicare payments. The regulations, referred to as “conditions for coverage,” address 11 general areas, including the facility’s physical environment and overall management by a governing body, as well as the adequacy of patient treatment plans.¹⁰ (See app. II.) One condition covers the detailed procedures that facilities must follow if they choose to reuse certain supplies, such as dialyzers, rather than replace them for each treatment.¹¹ Under each condition are related “standards.” For example, under the condition “physical environment,”

⁷For individuals eligible for Medicare only because of permanent kidney failure, Medicare coverage starts on the fourth month of dialysis. Medicare will not pay for services during the first 3 months of dialysis unless the patient already has Medicare because of age or disability. After that, Medicare is the secondary payer for 30 months. During this period, private insurance or Medicaid pays first on health care bills and Medicare pays second. Full Medicare coverage begins with the 34th month of dialysis and any private insurer becomes the secondary payer. For those who are uninsured, Medicare is the primary payer.

⁸The proportion of new ESRD patients 75 or older grew from 18 percent in 1991 to about 25 percent in 2001, while the proportion of new ESRD patients with diabetes grew from 36 percent of all new patients to 46 percent during the same period.

⁹In 2002, the average composite rate was approximately \$130 for freestanding dialysis facilities. Payments for injectable drugs averaged about \$80 per treatment in 2001.

¹⁰See 42 C.F.R. Part 405 Subpart U (2002).

¹¹These requirements include appropriate methods for disinfection and steps to ensure that such supplies are only reused by the same patient.

there are specific standards to maintain the purity of water used for dialysis. Even deficiencies found solely at the standard level indicate potential harm to patients. But, deficiencies cited at the condition level are the most egregious, as they indicate a problem that is widespread at a facility or serious in terms of its harm, or potential to harm patients. Typically, they are accompanied by multiple standard-level deficiencies under that condition.

To ensure provider compliance with dialysis quality standards, Medicare contracts with state survey agencies.¹² These agencies conduct initial on-site surveys of dialysis facilities when providers seek enrollment in the Medicare program. Subsequently, state agencies periodically conduct unannounced inspections, referred to as recertification surveys, to ensure that facilities are maintaining compliance with Medicare standards. Although no statutory or regulatory requirements exist regarding the frequency of recertification surveys, CMS has established goals for state survey agencies to ensure that facilities are surveyed within certain intervals. States are expected to survey 33 percent of their dialysis facilities annually, and each facility every 3 years. In addition, state survey agencies must respond to complaints that they receive concerning dialysis facilities and, when warranted, conduct on-site investigations.

If the state agency determines that a facility is out of compliance with any condition or standard, CMS requires that the facility develop a plan to correct the deficiency. The state agency is then responsible for determining if the plan of correction is adequate to address the quality problems identified. Facilities that do not correct condition-level deficiencies within a reasonable amount of time, generally within 90 days, are subject to termination from the program. A much shorter time frame for termination applies in situations where a facility's noncompliance poses an immediate and serious threat to patient health or safety.

CMS also contracts with 18 ESRD network organizations that are responsible for helping providers improve the quality of care patients receive in dialysis facilities. Rather than enforcing compliance with federal quality regulations, the networks recruit facility participation in national and regional quality improvement projects that focus on enhancing

¹²These agencies are typically part of state health departments and are responsible for monitoring compliance with quality standards associated with several types of facilities, including nursing homes and home health agencies.

specific clinical outcomes of dialysis patients. Networks collect data from individual facilities on numerous clinical indicators and provide them feedback on their performance. The networks also provide technical assistance to facilities and handle grievances concerning patient care. Each network has a medical review board composed of dialysis facility representatives, physicians, and dialysis patients, that oversees network operations.

To assist beneficiaries with ESRD in deciding where to get dialysis services, CMS reports certain information on Dialysis Facility Compare, an Internet Web site. Initiated in 2001, the site provides information on specific characteristics—such as the location, operating hours, and size—of all Medicare-certified facilities. It also provides data on clinical outcomes related to several quality measures, but does not contain the results of state agency surveys. In contrast, CMS routinely posts survey results for nursing homes on a similar but separate Internet Web site called Nursing Home Compare.

Quality Problems Prevalent among Dialysis Facilities and Put Patient Health at Risk

Data made public by CMS reveals that poor care is a problem at many facilities, with large numbers of patients receiving inadequate hemodialysis or treatment for anemia. Similarly, inspections of ESRD facilities continue to find evidence that serious health and safety problems exist for dialysis patients. From fiscal year 1998 through 2002, as many as one out of seven surveys identified problems sufficiently severe to initiate the process of terminating the facility from the Medicare program. These deficiencies, such as medication errors and contamination of water used for dialysis, put the health of patients at risk.

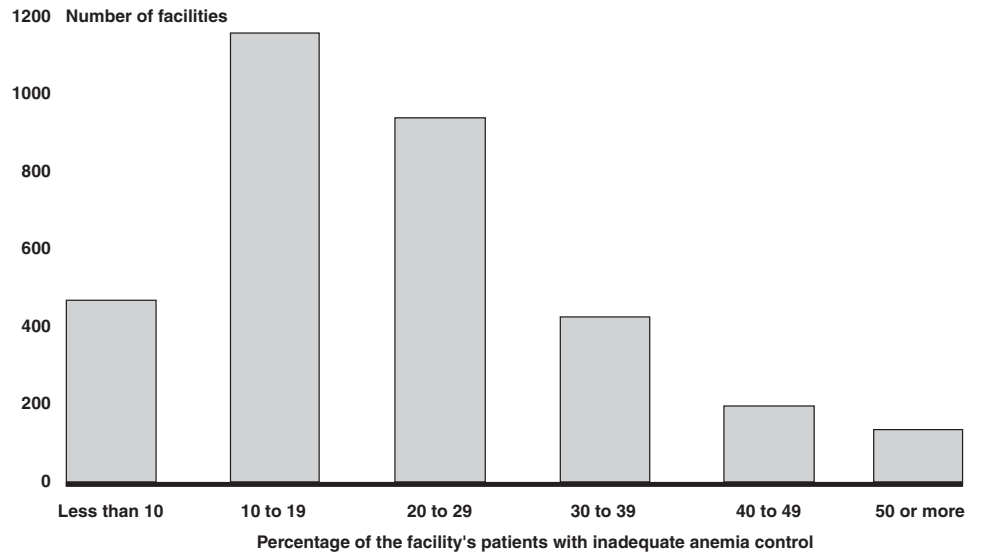
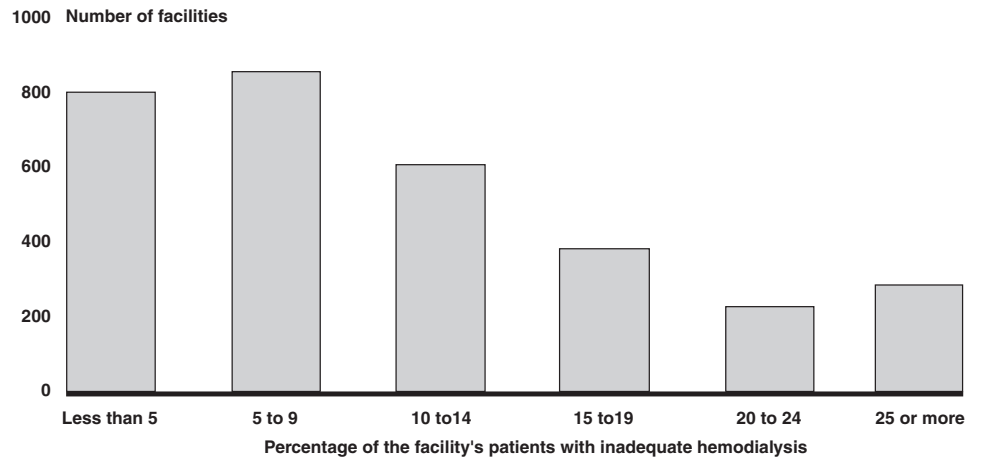
Many Facilities Do Not Provide Adequate Care to Their Hemodialysis Patients

Data reported on the Dialysis Facility Compare Web site provides evidence that the care delivered at many facilities is substandard. The most recent information available indicates that, in 2000, a substantial number of facilities did not provide all of their Medicare patients with a level of care that meets minimum clinical practice guidelines. Figure 2 shows the extent to which facilities did not achieve two commonly accepted quality benchmarks based on the National Kidney Foundation guidelines: (1) the percent of the facility's patients not receiving adequate hemodialysis and (2) the percent of the facility's patients receiving EPO whose anemia was not adequately managed.¹³ Despite some measurement limitations, both of

¹³EPO is used for the treatment of anemia for nearly all dialysis patients.

these indicators are considered characteristics of patient care that reflect dialysis facility quality.

Figure 2: Number of Facilities Where Some Patients Receive Inadequate Dialysis Treatment and Anemia Management, 2000



Source: CMS, Dialysis Facility Compare Web site.

Notes: Adequacy of dialysis is measured as the percentage of the facility's hemodialysis patients that had the minimum recommended urea reduction ratio—a measure of the waste products removed from the blood—of 65 or more. Data were reported for 3,158 facilities.

Anemia management is measured as the percentage of the facility's patients who received EPO that had a hematocrit level—a measure of low red blood count—of 33 or greater. Data were reported for 3,325 facilities.

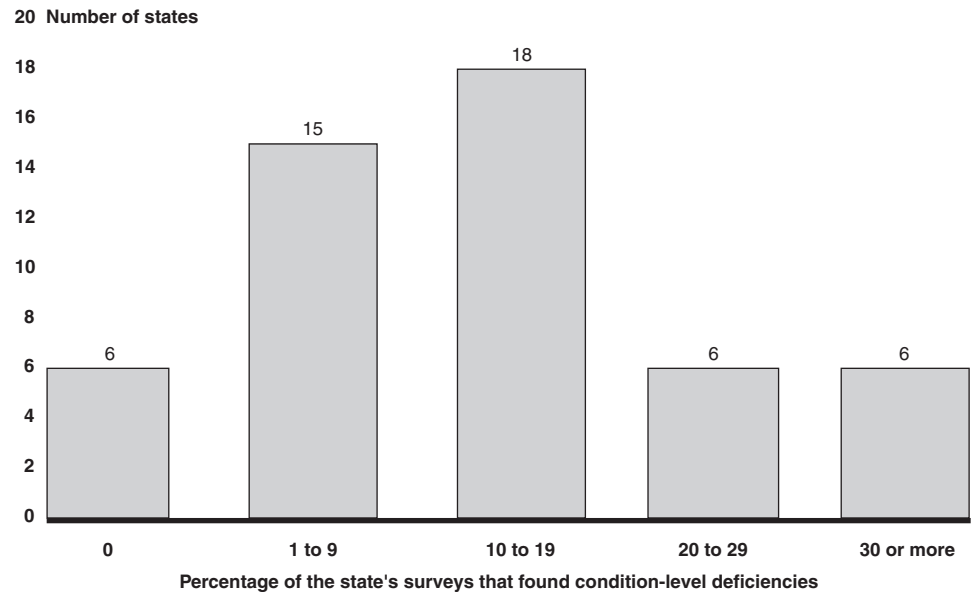
Relatively few dialysis facilities reported meeting these two national guidelines for 100 percent of their patients. At about half of the facilities, fewer than 10 percent of their patients fell short of the hemodialysis guideline, but at 512 facilities, 20 percent or more of their patients received inadequate hemodialysis. Results for anemia treatment were less favorable overall. Nearly 1,700 facilities fell short of meeting the guideline for anemia management for 20 percent or more of the patients in their care; at 135 facilities, more than 50 percent of patients received inadequate treatment for anemia. Research has shown that variation in such patient outcomes as dialysis adequacy is largely attributable to factors at the facility—its policies governing dialysis care, associated practice patterns, and attention to individual patient problems—as opposed to patient-specific causes.¹⁴

Facility Inspections Identify an Unacceptable Level of Serious Quality Problems

The cumulative results of surveys conducted from fiscal years 1998 through 2002 suggest that condition-level deficiencies—quality problems severe enough to warrant termination from the Medicare program unless corrected within 90 days—are still far from rare. Fifteen percent of recertification surveys conducted nationwide from fiscal year 1998 through 2002 reported one or more condition-level deficiencies. The distribution across states of condition-level deficiencies cited was substantially uneven. Several states reported no condition-level deficiencies during that 5-year period, whereas other states found such deficiencies in roughly 60 percent of their surveys. As shown in figure 3, most states were at the lower end of the range, with 39 states citing condition-level deficiencies in fewer than 20 percent of their surveys, and 21 states, in fewer than 10 percent of their surveys.

¹⁴J.C. Fink, S.A. Blahut, A.E. Briglia, and others, “Effect of Center- Versus Patient-Specific Factors on Variation in Dialysis Adequacy,” *Journal of the American Society of Nephrology*, vol. 12 (2001): 164-169.

Figure 3: State Variation in the Rate of Condition-Level Deficiencies Cited in Recertification Surveys Conducted from Fiscal Year 1998 through 2002



Source: GAO analysis of CMS OSCAR data.

Problems Cited at ESRD Facilities Create the Potential for Harm to Patients

Our review of recertification survey reports from fiscal years 2001 and 2002, collected from the 10 states in our study, identified condition-level deficiencies that were commonly cited among noncompliant facilities. Multiple instances were found of inadequate clinical management, medication errors, improper use of reusable dialysis equipment, contamination of water used for dialysis, and insufficient professional medical involvement in the dialysis patients' care. State surveyors documented these problems after reviewing facility personnel files, policies, procedures, and the facility's overall environment. In addition, surveyors reviewed a random sample of medical records from 10 percent of the facility's patients.¹⁵ The vignettes presented below—which illustrate the types of problems found in 35 percent of all surveys conducted from fiscal year 1998 through 2002—were extracted from surveyors' findings

¹⁵ A patient's medical record contains required information on identified problems, a plan of care, and documentation tracking the treatments actually provided. The record must show ongoing assessments of patient needs as well as evidence that patients participate in developing their treatment plans and are informed of outcomes.

reports. Registered nurses with substantial ESRD survey experience, who we asked to comment on the clinical implications of these findings, indicated that the deficiencies could lead in some cases to severely adverse patient outcomes.

- *Failure to monitor laboratory values and medication supply.* A Maryland surveyor found that for 31 days, one facility did not provide any of its patients with EPO, a medication routinely used to stimulate the production of red blood cells that are compromised by chronic kidney disease. Upon reviewing patients' medical records, 8 out of 10 sampled records indicated that the patient's red blood cell count was below normal, thus requiring EPO. In addition, 5 of these records showed that the patient's red blood cell level decreased over a 4-month period. The facility's head nurse did not monitor and report the patients' abnormal laboratory values to the physicians and did not respond to the patients' complaints of feeling tired and lacking energy.

According to our nurse reviewers, patients who have a diminished red blood cell count for an extended period of time can develop health-related complications, including heart irregularities and a decrease in brain function.

- *Failure to administer medication as prescribed.* A California surveyor cited a condition-level deficiency when she found that physician orders were not being followed. One patient's medical record documented that 6,000 units of EPO were prescribed for each dialysis treatment but that the patient received only 600 units at each treatment for 20 treatments. Staff confirmed that the patient was receiving the wrong dose, and when questioned by the surveyors, could not provide an explanation. Another patient's medical record revealed that, despite a physician-ordered increase in EPO, the patient received an incorrect dosage of the medication for almost 2 months. Again, staff acknowledged that the order to increase the dosage was not carried out. A review of two more patients' medical records showed written orders for Venofer, a medication to treat iron deficiency. The records documented that both patients failed to receive this medication for a week or more. Staff acknowledged that there was a period of time during which the facility ran out of the medication.

Our nurse reviewers reported that a reduction of Venofer or EPO could increase the dialysis patients' risk for anemia, a condition that, as noted above, can cause a patient to experience extreme fatigue and eventually clinical impairments to the heart and brain.

-
- *Failure to administer dialysis treatments as prescribed.* A recertification survey in Pennsylvania discovered that, for over half of the medical records reviewed, the facility did not ensure that diagnostic and therapeutic orders were followed. Specifically, documentation in patients' medical records revealed that the duration of dialysis treatments deviated from the amount of time prescribed by a physician. One patient's medical record indicated that dialysis treatments were ordered for 3.5 hours in duration. However, actual treatment periods were all less than the prescribed amount—by 20 to 90 minutes. Similarly, another patient's record indicated that dialysis treatments were ordered for a duration of 3 hours and 45 minutes but most treatments were for shorter duration—as much as an hour less.

Nurse reviewers indicated that when the dialysis treatment period is reduced, the patient retains toxins and other fluids that have not been removed adequately from the blood stream. This condition can adversely affect the patient's overall general health and lead to loss of appetite, swelling, fatigue, shortness of breath, and possibly heart failure.

- *Failure to monitor concentration of chemicals in the water system.* A New York surveyor found that a facility did not monitor the purity of water used for dialysis. The water used to prepare dialysate, a solution that removes wastes from the blood during dialysis, contained chemical contaminants in excess of allowed concentrations. For at least 8 months, fluoride levels were 1.0—five times greater than the maximum allowable limit of 0.2. In addition, two water tests showed that calcium levels were above 5.25, well above the maximum allowable limit for calcium of 2.0. The facility medical director did not monitor the results of water tests conducted and did not ensure that the facility's staff took appropriate action, such as reporting abnormal values or resampling the water.

Nurse reviewers told us that excessive amounts of fluoride could cause a dialysis patient's red blood cells to rupture and clot and that excessive amounts of calcium in the blood could increase the incidence of bone disease.

- *Failure to involve a transplant surgeon in the review of patients' long-term care plans.* A recertification survey in Mississippi revealed that the facility did not involve a transplant surgeon, as required, in the review of patients' long-term care plans. All of the medical records reviewed in that facility had long-term care plans that were not updated within the required 6-month time frame. The surveyor interview with the facility's medical director confirmed that a transplant surgeon or his designee had not examined patients' long-term care plans.

Nurse reviewers commented that, until screened by a transplant surgeon, the dialysis patient's potential for kidney transplantation cannot be properly assessed.

Limitations in the ESRD Survey Process Leave Quality Problems Undetected or Inadequately Addressed

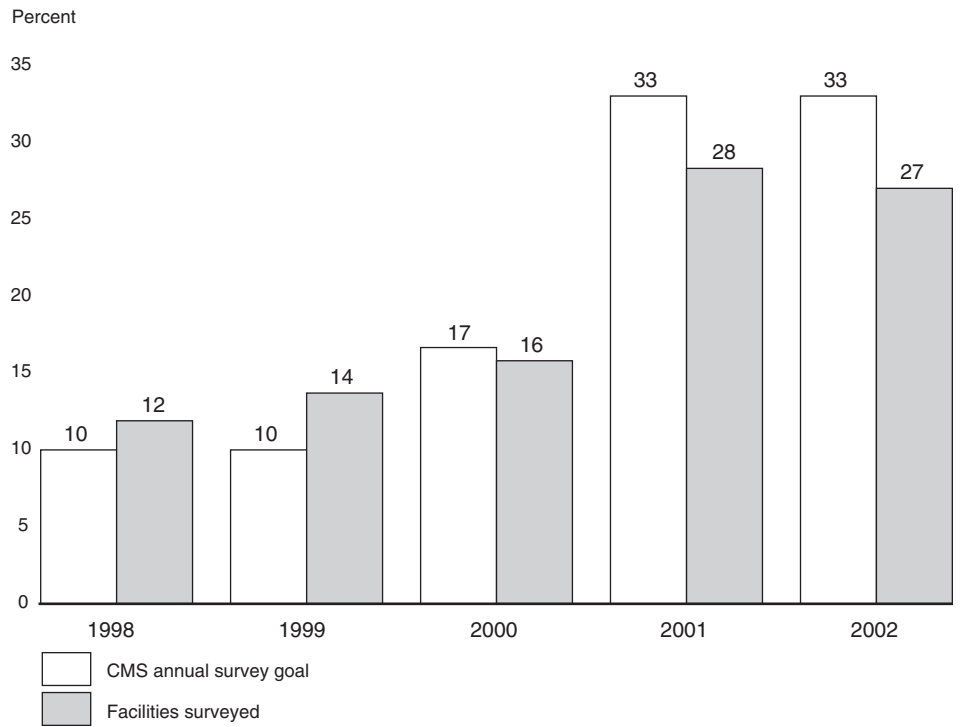
Infrequent or poorly targeted inspections allow facilities' quality of care problems to go undetected or remain uncorrected. Although state survey activity increased from fiscal year 1998 to 2002, numerous state agencies did not meet the goal currently set by CMS to survey 33 percent of all ESRD facilities annually. An increasing number of facilities continued to operate 9 or more years between inspections. In addition, states that relied primarily on surveyors with limited experience in conducting inspections of ESRD facilities tended to report substantially fewer deficiencies than states using more experienced surveyors, suggesting that surveyors in the first group of states may have missed some quality problems. We also found patterns of repeated condition-level deficiencies, and particularly, citations for the same problem in successive inspections of an individual facility. Finally, facilities had little incentive to ensure continued adherence to Medicare's minimum quality standards in the absence of sanctions for noncompliance other than termination from the Medicare program—which, historically, has been rarely used.

Increased CMS Goals Have Led to Greater Survey Activity, but Many States Fall Short

In recent years, CMS has underscored the importance of conducting recertification surveys of ESRD facilities by raising its expectations for the state agencies regarding the frequency with which such surveys should take place. In fiscal year 2001, CMS increased the recertification goal for states to 33 percent of facilities each year, up from 10 percent in fiscal year 1999 and 17 percent in fiscal year 2000. Moreover, since fiscal year 2001, there has been a parallel goal for states to survey every dialysis facility within a 3-year period. Thus, by the end of fiscal year 2003, no dialysis facility should have gone more than 3 years since its last recertification survey.

In response to CMS's heightened expectations, state agencies surveyed more ESRD facilities, but not enough to fully meet CMS's current goals. As shown in figure 4, the percentage of ESRD facilities undergoing recertification surveys annually grew substantially from fiscal year 1998 to 2001. However, collectively, state agencies did not achieve the current goal, effective in 2001, of surveying 33 percent of all ESRD facilities each year. In fact, after increasing to over 28 percent in fiscal year 2001, the survey frequency rate declined to about 27 percent in fiscal year 2002.

Figure 4: ESRD Facility Survey Rate Compared to CMS Goal, Fiscal Years 1998 to 2002

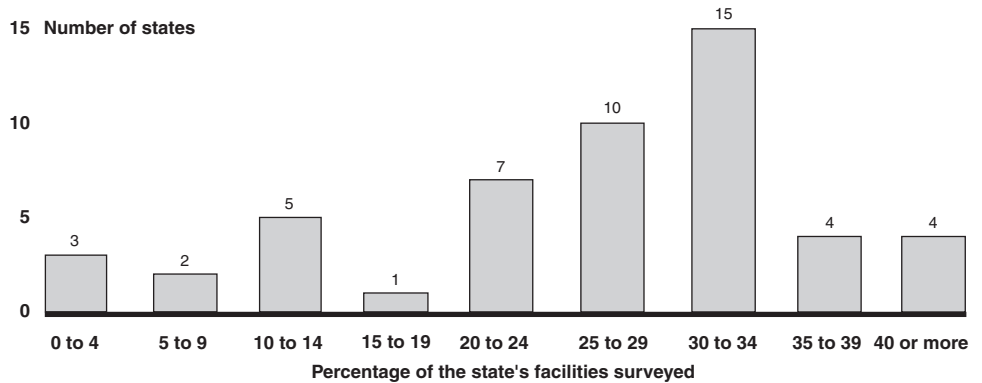


Source: GAO analysis of CMS OSCAR data.

Underlying this aggregate trend are wide disparities in survey frequency rates across the individual state agencies, as shown in figure 5. State recertification survey rates ranged from zero to 89 percent in fiscal year 2002. Even among the 13 states with the largest number of ESRD facilities,¹⁶ recertification survey rates varied widely—from 10 percent to 40 percent.

¹⁶This top quartile of states represents 60 percent of all ESRD facilities and 64 percent of all dialysis patients.

Figure 5: State Variation in the Proportion of Dialysis Facilities Surveyed for Recertification, Fiscal Year 2002



Source: GAO analysis of CMS OSCAR data.

While 33 state survey agencies met the expanded CMS survey frequency goal in at least 1 of the last 2 fiscal years—sometimes by substantial margins—only 9 of those states met the 33 percent goal in both years. (See table 5 in app. III.) By contrast, 18 state agencies failed to reach 33 percent in either of the two most recent fiscal years, including some of the largest ESRD states, such as California, Michigan, Pennsylvania, and Virginia.

As a result, many states may have difficulty meeting CMS's second goal for state recertification activity, to survey all their ESRD facilities within a 3-year period. Because this goal was established in fiscal year 2001, the first test of state compliance will come at the end of fiscal year 2003. Based on the facilities surveyed in fiscal year 2001 and 2002, 35 states will have to inspect more than a third of their ESRD facilities in fiscal year 2003 if they are to meet the 3-year goal. (See table 6 in app. III.) About one in five states has more than 60 percent of facilities left to survey. Alabama has the most facilities—89 percent—that need to be surveyed in the current fiscal year. Among the largest states, California and Virginia have the largest backlogs to overcome—around 76 percent.

Despite improvement in the overall rate of ESRD facility surveys, a significant proportion of dialysis facilities continue to operate for long periods without inspections. For example, as of September 30, 2002, 466 facilities had not been surveyed for 6 or more years, of which 216 had not been inspected for recertification in 9 or more years. Most of the effort to shorten the interval between recertification surveys has focused on

reducing the number of facilities surveyed within 3 to 6 years. (See table 1.) From fiscal year 1998 to 2000, the proportion of facilities not surveyed for more than 6 years rose sharply (from 9.8 to 17.4 percent) and then declined (to 11.6 percent). Those that operated 9 or more years without a recertification survey steadily increased from 1.6 percent (53 facilities) in fiscal year 1998 to 5.4 percent (216 facilities) in fiscal year 2002. This aggregate result reflected highly variable survey rates across states. Four states—California, Texas, New York, and Missouri—accounted for 174 facilities that had not been surveyed within 9 years by the end of fiscal year 2002.

Table 1: Proportion of ESRD Facilities Recertified Within 3, 6, 9, or More Years, Fiscal Years 1998 to 2002

| Length of time since last recertification survey | Percentage of facilities subject to a recertification survey | | | | |
|--|--|-------------------|-------------------|-------------------|-------------------|
| | 1998 (n=3,250) | 1999 (n=3,462) | 2000 (n=3,679) | 2001 (n=3,882) | 2002 (n=4,011) |
| Less than 3 years | 51.6 | 51.2 | 49.8 | 62.5 | 72.4 |
| 3 to <6 years | 38.6 | 32.8 | 32.8 | 22.9 | 16.0 |
| 6 to <9 years | 8.2 | 13.9 | 14.2 | 10.1 | 6.2 |
| 9 or more years | 1.6 | 2.1 | 3.2 | 4.4 | 5.4 |

Source: GAO analysis of CMS OSCAR data.

State agencies have to balance their efforts to meet survey workload goals for ESRD facilities against the demands on inspection staff to meet other CMS survey requirements. In particular, state agencies are required to inspect nursing homes every 15 months,¹⁷ intermediate care facilities for the mentally retarded (ICF/MR) at least annually, and home health agencies at least once every 3 years. In its letter to state agencies on fiscal year 2003 program requirements and budget guidelines for survey activities, CMS made inspections of dialysis facilities and nine other types of providers lower in inspection priority, behind nursing homes, ICF/MRs, and home health agencies.¹⁸ ESRD recertifications also received lower

¹⁷The statewide average interval between standard surveys must be 12 months or less. See 42 C.F.R. § 488.308(b).

¹⁸Department of Health and Human Services, CMS, memorandum from the Director, Survey and Certification Group, "Fiscal Year (FY) 2003 State Survey and Certification Budget Call Letter — ACTION," July 2, 2002.

priority than investigation of complaints filed against all types of providers.¹⁹ CMS officials asserted that they provide the state survey agencies with sufficient resources to fulfill expectations across all provider types. Nonetheless, several state officials we spoke with reported difficulty in meeting all of these expectations, especially those experiencing substantial growth in ESRD facilities in their states. They indicated that, given the relatively low priority assigned to ESRD recertifications, they would most likely cope by adjusting the number of dialysis facilities inspected.

Lack of Surveyor Specialization May Contribute to Less Effective Surveys

Even when facilities are inspected, some surveyors may be more adept than others at identifying quality problems. Because dialysis treatment is technically complex, surveyors who focus on ESRD surveys say that they become more proficient in detecting and properly documenting quality of care problems as a result. However, state agencies may be reluctant to designate a subset of surveyors who specialize in performing ESRD inspections as it limits their flexibility in scheduling inspections of nursing homes, home health agencies, and other provider types. Moreover, such specialization is less feasible for states with few ESRD facilities overall. In states without a specialist approach to facility inspections, many surveyors are likely to conduct no more than a few ESRD surveys each year. Among the nine state survey agencies from which we collected workload data, six typically assigned ESRD inspections to surveyors who spent most of their time surveying other provider types.²⁰ The other three assigned most ESRD inspections to surveyors who often performed surveys of dialysis facilities.

¹⁹CMS requires every state to establish a screening mechanism to evaluate complaints as they come in, and to apply explicit criteria to determine which ones need to be followed up with a survey as well as the time frame within which that survey must take place. Surveys prompted by complaints are intended to address a particular issue raised in the complaint, which often does not involve clinical issues. If during the course of the complaint investigation the surveyor discovers systemic quality problems, the inspection is usually converted into a recertification survey.

²⁰For each state, we calculated a specialization ratio that indicated the likelihood that any given ESRD survey would be conducted by a surveyor who frequently conducted surveys of dialysis facilities. (See app. I.) On a scale of zero to one, the values of the specialization ratio clustered into two groupings: the states with specialized ESRD staff included New York (0.68), California (0.63), and Maryland (0.57); the states without ESRD specialized staff included Pennsylvania (0.36), Missouri (0.27), Alabama (0.21), Florida (0.17), Kansas (0.14), and Nevada (0.11).

A comparison of survey results between states that had a designated corps of ESRD surveyors and those that did not suggested that surveyors who frequently conduct ESRD inspections may be more effective in detecting and reporting deficiencies. Table 2 shows that the more specialized group of states was almost three times as likely to find a condition-level deficiency. Surveyors from these states cited a substantially larger number of deficiencies at the less serious “standard-level” as well. While other factors could have also influenced the number of deficiencies reported by surveyors in various states, the magnitude of the difference observed between states that did and did not specialize suggests that specialization has a major impact.²¹

Table 2: Association between Surveyor Specialization and Rate of Condition- and Standard-Level Deficiencies Cited in Fiscal Years 2001 and 2002

| | State surveyor specialization in ESRD ^a | |
|---|--|---|
| | Percentage of surveys in nonspecialized states (n=367) | Percentage of surveys in specialized states (n=261) |
| Surveys with condition-level deficiencies | 8.4 | 24.1 |
| Surveys with standard-level deficiencies numbering | | |
| 0 | 26.4 | 6.9 |
| 1 to 5 | 45.8 | 21.1 |
| 6 to 10 | 14.2 | 31.0 |
| 11 to 20 | 11.4 | 28.4 |
| 21 or more | 2.2 | 12.6 |

Source: GAO analysis of state-provided workload data and CMS OSCAR data.

^aNonspecialized states include Pennsylvania, Missouri, Alabama, Florida, Kansas, and Nevada. Specialized states include, California, Maryland, and New York.

The importance of surveyor specialization for inspection results may be stronger for ESRD facilities than other types of providers. Although some general surveying skills apply across provider types, much of the content of ESRD standards is highly specialized, reflecting both the technological

²¹Statistical tests (chi square) indicate that the difference in outcomes between these two groupings of states is highly significant (p=0.000). Thus, it is very unlikely that these differences could have occurred simply by chance.

complexity of the dialysis process and the clinical complexity and vulnerability of the ESRD patient population. In a 184-page appendix devoted to ESRD surveys, CMS's State Operations Manual lays out the specific steps that surveyors are expected to follow. Presumably, surveyors who have the opportunity to focus on mastering this material develop greater proficiency in identifying quality of care problems, including proficiency in identifying indications of adverse patient outcomes and appropriate facility responses.

Facilities with Prior Deficiencies Are Likely to Be Cited for Problems in Subsequent Surveys

Our June 2000 ESRD report described the inability of Medicare's survey and certification system to ensure that problems identified in surveys and addressed by a facility's plan of correction will stay corrected for the long term. Once a facility has been recertified, it faces no adverse consequences should it fail to remain in compliance in the future. When the next survey takes place—usually several years later—the process will start over with deficiencies identified and a new opportunity for the facility to correct them. This allows facilities to cycle in and out of compliance with Medicare's quality standards.

The results of surveys conducted from fiscal year 1998 through 2002 showed that a pattern of persistent noncompliance with quality standards was not uncommon. First, facilities cited for deficiencies in previous surveys were substantially more likely than other facilities to have deficiencies when surveyed again. Of surveys involving facilities that had a condition-level deficiency in their most recent prior survey, 29 percent had a condition-level deficiency in the subsequent survey as well, compared with 16 percent for those with only standard-level deficiencies in the prior survey and 12 percent for those with no prior deficiencies.

Similarly, we found that repeated citations for the same deficiency occurred frequently. From fiscal year 1998 through 2002, 2,073 recertification surveys (57 percent of the total) involved facilities that had received deficiencies in their most recent prior survey. Of those, a third found deficiencies that repeated one or more specific condition- or standard-level deficiency codes cited in that prior survey. Moreover, 18 percent of the facilities with a condition-level deficiency on the prior survey were cited again for the same condition-level deficiency. (See table 3.) Another 44 percent repeated one or more standard-level deficiencies.

Table 3: Rates of Repeated Deficiencies in Consecutive Surveys Conducted from Fiscal Years 1998 through 2002

| | Percentage of subsequent surveys identifying the same deficiencies | | Percentage of subsequent surveys not identifying the same deficiencies |
|---|--|---------------------|--|
| | Condition-level | Standard-level only | |
| Prior survey with both condition- and standard-level deficiencies (n=271) | 18.1 | 43.9 | 38.0 |
| Prior survey with only standard-level deficiencies (n=1,802) | n/a | 28.6 | 71.4 |

n/a = not applicable

Source: GAO analysis of CMS OSCAR data.

ESRD surveyors in 6 of the 10 states in our study stated that they try to reduce the occurrence of persistent noncompliance by taking a facility's previous survey results into account when deciding which facilities to survey. Following this policy, facilities doing poorly on one survey should undergo a recertification survey more frequently. However, CMS's current goals for ESRD surveys, because they focus solely on the frequency of survey performance and not on the effectiveness of survey targeting, create a disincentive for states to give greater attention to previously noncompliant facilities. In particular, CMS's mandate to survey every facility within a 3-year period tends to discourage survey agencies from revisiting poorly performing facilities until all other facilities have been inspected.

An analysis of survey activity from fiscal year 1998 through 2002 indicates that targeting of facilities based on their past survey results occurred to only a limited extent in recent years. Only 5.9 percent of facilities surveyed from fiscal year 1998 through 2001 with condition-level deficiencies were resurveyed within a year, compared to 3.9 percent of facilities that had no condition-level deficiencies that also were resurveyed within a year. The difference was somewhat greater over a 2-year period, with 20.8 percent of facilities having condition-level deficiencies in fiscal year 1998 through 2000 being resurveyed compared to 12.6 percent of facilities that had no condition-level deficiencies. Nonetheless, the large majority of facilities with condition-level deficiencies were not resurveyed on an accelerated 1- or 2-year schedule.

CMS Has Few Options to Sanction Noncompliant Facilities

State agencies are hampered in their ability to induce facilities to comply fully and consistently with Medicare quality standards by the paucity of sanctions available for cases of noncompliance. At present, the only penalty that CMS can impose on ESRD facilities that do not comply with these requirements is revoking their eligibility to participate in the Medicare program. However, facilities typically are given a grace period—usually 3 months—in which to correct any problems identified in a survey. As long as these deficiencies have been addressed when surveyors revisit the facility, the provider suffers no adverse consequences from having failed to maintain compliance with Medicare quality standards.²² Consequently, very few ESRD facilities are terminated from Medicare, and those that are can apply for readmission to the program. From fiscal years 1998 through 2002, only one dialysis facility was terminated from the Medicare program and stayed out of business.²³

Moreover, state survey agencies are often reluctant to press for the termination of dialysis facilities because such closures would force patients to find another provider and, in general, reduce patient access to care. Many surveyors expressed a need to have additional sanctions available to deal with poorly performing ESRD facilities. A number of such alternatives already exist for nursing homes, including a denial of payment sanction for new patients and civil monetary penalties. Denying Medicare payments for new patients would curb the facility's major source of revenue without eliminating, as a termination does, its ability to serve existing patients. However, the lost revenue from potential new patients, while the sanction is in effect, creates a concrete incentive for the facility to resolve its quality problems quickly and to stay in compliance thereafter. In addition, CMS requires states to refer for immediate sanctions nursing homes found to have actually harmed one or more residents or exposed them to potential serious injury on successive surveys. In this situation, no grace period is granted to the facility. Having

²²If surveyors find that the facility is still out of compliance at the first revisit, additional revisits are usually scheduled. Some facilities get as many as four or five separate opportunities to demonstrate that they have achieved compliance with Medicare's minimum quality requirements.

²³Adverse results on surveys could contribute to a provider's decision to close a facility, even without a termination from Medicare. An examination of OSCAR data for fiscal years 1998 through 2002 revealed six instances where facilities closed voluntarily within 6 months of a survey that had condition-level deficiencies. Five different facilities were recorded as voluntary terminations, but remained open at the same addresses, sometimes under new names and sometimes not.

multiple sanctions available means that surveyors can recommend the one that best fits a given set of circumstances, taking into account the likely impact on both the facility and the patients it serves.

In our June 2000 ESRD report, we noted that CMS had the authority to expand the enforcement tools available for addressing quality problems with ESRD facilities, but had not issued regulations and procedures to implement alternative sanctions. Other sanctions, notably civil monetary penalties, would require legislative changes by Congress. At that time, we recommended that CMS act to expand available penalties where permitted under its existing authority and that Congress consider authorizing civil monetary penalties for dialysis facilities comparable to those already in place for nursing homes. Since then, there have been no regulatory or legislative actions to expand available enforcement tools for ESRD facilities.

The publication of survey results could provide another incentive for facilities to maintain compliance with Medicare quality standards. If ESRD patients were able to readily compare the outcomes of surveys for facilities in their area, they could choose to seek care from facilities with more favorable inspection results. CMS has not taken any steps to make survey results publicly available. By contrast, CMS routinely posts survey results for nursing homes on an Internet Web site called Nursing Home Compare. In 2001, when CMS created a comparable Web site covering ESRD facilities, Dialysis Facility Compare, it chose not to make survey results accessible.

CMS Has Increased Funding for State Surveys, but Monitoring and Technical Support Are Uneven

The limitations inherent in state survey processes have been compounded by inconsistent CMS oversight. On the one hand, CMS has substantially increased funding for ESRD surveys in line with its expectation that states survey a higher proportion of facilities each year. On the other hand, survey agencies do not always receive the monitoring and technical support that could enhance ESRD survey effectiveness. CMS regional offices vary widely in the extent to which they examine states' ESRD survey activities and provide related assistance. In addition, many state agencies do not routinely have access to information from ESRD networks that could assist them in selecting facilities to survey. Finally, the limited number of CMS courses has made it difficult for many state surveyors to obtain the training considered necessary to conduct ESRD surveys.

Funding Has Increased to Support CMS's ESRD Survey Goals

In recent years, financial support for state survey activities overall has grown substantially. According to the Director of CMS's Survey and Certification Group, the increases responded to concerns that financial support for survey activities was not keeping pace with the growth in facilities and was putting Medicare beneficiaries at risk. From fiscal year 1998 to 2002, total federal expenditures for state surveys increased about 60 percent, with spending for long-term care (LTC) and non-LTC facility survey activities growing 61 and 56 percent, respectively.²⁴ Non-LTC facility survey activities are supported almost entirely by federal funds, which must be allocated by states among home health agencies, hospices, ambulatory surgical centers, rehabilitation facilities, and other types of providers, as well as ESRD facilities—within a set of guidelines established by CMS. ESRD survey activities, therefore, must compete for funding with other non-LTC survey activities, including statutorily-required surveys for home health agencies that receive a higher priority. However, survey goals for ESRD facilities are more ambitious than those for hospices, ambulatory surgical centers, and many other non-LTC providers as CMS expects the agencies to survey ESRD facilities more frequently.

Notwithstanding the competing survey priorities, the expansion in financial support allowed state survey agencies to increase funding for ESRD surveys to help meet higher survey goals. We estimated that federal expenditures for ESRD survey activities nearly tripled from fiscal year 1998 to 2002, from \$3.1 million to \$8.2 million.²⁵ Most of the increase occurred between fiscal years 2000 and 2001, when the ESRD survey goal almost doubled from 17 to 33 percent of a state's facilities each year. (See table 4.) Increased spending for ESRD survey activities was evident across nearly all states. From fiscal year 1998 to 2002, 42 states had an increase in spending for ESRD survey activities, and the median state experienced a 144 percent increase.

²⁴CMS allocates most funding for state survey activities by LTC and non-LTC categories. LTC funding covers surveys of nursing homes and ICF/MRs. Non-LTC funding supports surveys of dialysis facilities, home health agencies, accredited and nonaccredited hospitals, hospices, ambulatory surgical centers, outpatient physical therapy providers, rural health clinics, comprehensive outpatient rehabilitation facilities, portable x-ray suppliers, psychiatric residential treatment facilities, and psychiatric hospitals.

²⁵These estimates are based on workload and expenditure reports provided annually to CMS by state survey agencies, which combine all non-LTC survey activities. Several state governments also fund provider survey and certification activities for non-LTC providers. In fiscal year 2001, state support accounted for approximately 6 percent of total spending on non-LTC activities.

Table 4: Federal Support for Provider Surveys, Fiscal Years 1998 to 2001

Dollars in millions

| | Total | Long-term care provider surveys | Non-long-term care provider surveys | |
|------|----------|---------------------------------|-------------------------------------|--------------------------|
| | | | Non-ESRD surveys (estimated) | ESRD surveys (estimated) |
| 1998 | \$ 253.2 | \$ 209.2 ^a | \$ 41.0 ^a | \$ 3.1 ^a |
| 1999 | 265.1 | 217.2 ^b | 44.5 ^{b,c} | 3.3 ^{b,c} |
| 2000 | 312.1 | 260.3 | 47.3 ^d | 4.6 ^d |
| 2001 | 350.6 | 288.9 ^e | 53.7 ^e | 8.1 ^e |
| 2002 | 405.2 | 336.6 | 60.5 | 8.2 |

Source: CMS aggregate budget data for Medicare and Medicaid survey activities.

Note: GAO estimates are based on the ESRD share of non-LTC survey hours reported to CMS. The three budgetary subcomponents do not sum to totals because of rounding.

^aExcludes Nebraska.

^bExcludes Tennessee.

^cExcludes Washington.

^dExcludes Arkansas.

^eExcludes Vermont and Virginia.

In most states, the increase in ESRD spending outpaced the growth in spending for all non-LTC survey activities. As a result, the ESRD share of non-LTC expenditures also increased, from about 7 percent of non-LTC survey expenditures in fiscal year 1998 to about 12 percent in fiscal year 2002. For fiscal year 2002, we estimated that the ESRD share of non-LTC survey expenditures across states ranged from about 0 to 35 percent. For the states with the largest number of dialysis facilities, the ESRD share ranged from 6 percent in Virginia to 25 percent in Georgia.

Regional Office Monitoring and Assistance to State Agencies Are Highly Inconsistent

Regional offices' review of agency surveys, referred to as federal monitoring surveys, are conducted by CMS to monitor state agency performance in interpreting and applying federal standards as well as to identify training or technical assistance needs of surveyors. Although CMS is required to conduct monitoring surveys that assess the adequacy of the state's survey for nursing homes, no similar legislative requirements apply

to ESRD facilities.²⁶ As such, CMS has used monitoring surveys for dialysis facilities that are observational in nature—regional office staff accompany state surveyors on inspections of dialysis facilities, observe them as the surveyors identify and document facility deficiencies, and provide feedback on the surveyors’ performance. CMS has not specified the number of ESRD monitoring surveys that regional offices should conduct. Perhaps as a consequence, representatives for six regional offices that we contacted—responsible for 29 states—told us they have conducted very few such surveys over the last 2 fiscal years. In fiscal year 2001, the number of monitoring surveys each regional office performed ranged from 3 to 11; in fiscal year 2002, they ranged from 2 to 6. None of the regional offices in either year conducted a monitoring survey for every state in its jurisdiction.

Even for the few monitoring surveys conducted, most CMS regional offices in our study provided little feedback to the states. At 3 of the 10 state survey agencies we contacted, representatives reported receiving only one monitoring survey in 5 years and were provided no feedback. Other survey agency representatives stated that regional offices provided verbal feedback on their monitoring surveys. In contrast, two CMS regional offices also provided written feedback that included evaluations of surveyors’ decisions regarding specific conditions and standards.

The regional offices in our study also have not taken full advantage of available data to monitor state agencies’ survey performance for ESRD activities. CMS has instructed regional offices to use data from its OSCAR system as an integral tool to assess and compare state agency performance, particularly differences in the time required to conduct surveys and the types of deficiencies cited. According to CMS, such analyses can provide the information necessary to help state agencies improve their efficiency in conducting ESRD surveys and achieve consistency in their quality. For example, because OSCAR contains data on the number of hours spent on each ESRD survey, regional offices could use a benchmark to compare and assess survey times across their state agencies. CMS has indicated that similar analyses could be performed for the types of deficiencies cited by surveyors to determine whether there

²⁶For each state, CMS is required to perform validation surveys—on-site inspections of facilities, separate from those conducted by the state agency—for at least 5 percent of the nursing home surveys conducted annually, but no fewer than five homes in each state. *See* 42 U.S.C. § 1395i-3 (g) (3) (B) (2000).

were any differences in state agencies' application of quality standards.²⁷ Despite such potential uses of data to monitor state agency performance, most of the regional offices analyzed their available data on a more limited basis. They checked on past survey results for certain ESRD facilities and relied extensively on quarterly workload reports from each state agency to determine the number of recertification surveys conducted.

In addition to monitoring and tracking ESRD survey activities, CMS requires regional offices to assist state agencies in fulfilling their survey responsibilities. Such assistance includes alerting the agencies to CMS policies and goals, coordinating communications with the CMS central office, helping surveyors obtain ESRD training, and consulting on a regular basis on program activities and achievement of survey goals. The performance of regional offices in our study varied from little contact with their state agencies to extensive collaboration. One CMS regional office had almost no contact with its state survey agencies or network and was not sure of the state agencies' performance in meeting ESRD survey goals. A survey agency representative in that region stated that contact with the regional office consisted primarily of a few calls the agency made to obtain clarification on a policy or procedure. In contrast, most of the regional offices included in our study, at a minimum, contacted state survey agencies to discuss CMS policies and goals, provided technical information or training on ESRD issues, and offered assistance in conducting select surveys.

Among the most active regional offices in providing support on ESRD surveys was Region 9.²⁸ Its efforts to improve state agency survey performance included a range of activities:

- The office collaborated with state agencies and networks to provide ESRD training to state surveyors in addition to that provided by the CMS central office.
- Through conference calls, the office contacted its state agencies monthly (including their district offices) to discuss current ESRD survey issues, relevant federal bulletins or alerts, instructions for more consistent coding of deficiencies, updates on training needs and slots available, and surveyor

²⁷Regional offices have used OSCAR data to prepare tracking reports on areas related to state and regional office performance for nursing home surveys, including facility terminations, number of surveys without deficiencies, and analyses of most-frequently cited deficiencies across states.

²⁸Region 9 includes state survey agencies for Arizona, California, Hawaii, and Nevada.

decisions related to inspection findings. The conference calls provided a mechanism for surveyors to pose questions directly to CMS officials and often receive an immediate response.

- The office conducted quarterly conferences that included representatives from the networks and state survey agencies to provide updates on quality improvement programs underway by the networks, general issues related to ESRD, and issues specific to certain facilities.
- The office joined state agencies and networks in a campaign to educate facility managers about ESRD regulations and the survey process.

Disparities in regional office performance—not unlike the disparities in state survey agency performance—may reflect their ability to cope with CMS’s survey priorities. Officials representing several regional offices noted that CMS’s focus has been on nursing homes and other types of facilities that are a higher survey priority than ESRD facilities. Some of these officials indicated that, as a consequence, needed attention in monitoring state agencies and providing technical assistance for ESRD survey activities has lagged.

Networks Do Not Routinely Share Facility Data with State Agencies

State survey agencies are not routinely receiving information from ESRD networks—organizations authorized by statute to collect information on patient complaints, quality improvement projects, and clinical performance. The networks operate under contracts with CMS which, in fiscal year 2002, totaled \$24.7 million, approximately three times the amount of federal funds we estimate were spent on state survey and certification activities for dialysis facilities.²⁹ Networks use the information they collect to perform a wide range of quality improvement activities and to identify and address any quality issues that may arise with individual facilities. Under the terms of their CMS contract, they are to cooperate with state survey agencies by providing them facility-specific information upon request. However, our June 2000 study found that most CMS regional offices had restricted networks from sharing facility-specific information, contending that federal confidentiality regulations prohibited such exchanges. In response, we recommended that CMS establish procedures

²⁹Network responsibilities are established by the Social Security Act, which also authorizes the Secretary to prescribe other network duties and functions. *See* § 1320c-9(b)(1) and § 1395rr(c)(2). Current network responsibilities are set forth in contract: ESRD Network Organizations, Statement of Work, FY 1999-2003, Section C.4.F, Cooperative Activities With State Survey Agencies and Quality Improvement Organizations, CMS. The networks are funded through a fifty-cent charge on each Medicare dialysis treatment.

to facilitate routine cooperation and information sharing between networks and state agencies. The HHS Inspector General made similar recommendations in June 2002.³⁰ However, most of the states in our current review reported that they have seen little evidence of increased information sharing by ESRD networks.

Most of the state agencies included in our study did not receive facility-specific information from networks on a regular basis. State agency officials indicated that the networks typically provided summary data for facilities, and that access to facility-specific information occurred on a case-by-case basis. Much of the information that was shared by networks came in response to inquiries from state agencies regarding specific providers. In addition, networks rarely identified facilities as candidates for inspection. For example, one state agency official noted that the area ESRD network rarely shared information on complaints and made only one recommendation over the last 5 years that identified a facility for inspection.

Several state agency officials attributed the limited disclosure of facility-specific information to confusion in the ESRD community about requirements pertaining to safeguarding this information. The Social Security Act prohibits the disclosure of facility-specific information to any person subject to several exceptions, for example, where federal regulation authorizes the disclosure in order to protect the rights and interests of patients.³¹ Although their contracts with CMS indicated that the agency wanted them to share facility-specific information with state survey agencies, the networks are hesitant to follow this directive because the agency regulations do not identify such disclosure as a specific exemption from the general statutory prohibition. Reportedly, network officials are concerned that the release of such information could undermine their quality improvement efforts and collaborative relationships with facilities.³² CMS acknowledged that confusion exists in this area and convened a workshop to promote more understanding and

³⁰Department of Health and Human Services, Office of Inspector General, *External Quality Review of Dialysis Facilities: A Call for Greater Accountability*, OEI-01-00050 (Washington, D.C.: June 2000).

³¹See 42 U.S.C. §§ 1320c-9(a) and (b).

³²CMS policy stipulates that state agencies may not release confidential information that they receive from ESRD networks to third parties, even under subpoena.

cooperation between the networks and the state agencies.³³ However, CMS has not required networks to routinely share facility-specific information.

The potential benefits that can be achieved from increased sharing of network information are well illustrated by the recent experience of the California state survey agency. The state agency routinely receives facility-specific information from its two corresponding networks verbally—no facility-specific data are sent to the state agency in written form. Regardless of the method, the networks and the state agency agreed that they need to be able to share such information, considering its potential benefits in improving facilities' quality of care, and have conveyed this to the ESRD facilities' managers. Consequently, the networks regularly contact the state agency to share different types of quality of care information on individual facilities, including complaints the network received and the results of related investigations. The networks now routinely make suggestions regarding potential facilities for the state agency's attention. This relationship improved markedly after years of little communication between the state agency and the networks, largely as the result of increased trust derived from working together on a series of joint projects.³⁴

States Report Insufficient ESRD Training Opportunities

According to state officials, scarcity of ESRD training opportunities has impeded state agencies' efforts to improve surveyor performance. Because most surveyors do not have prior training or experience in dialysis, state survey agencies have for years relied on the courses that CMS has organized to train ESRD surveyors in the technical aspects of dialysis and the application of ESRD quality standards. The need for specialized training is consistent with the highly technical nature of ESRD surveys relative to surveys of other provider types. CMS offers basic ESRD training for surveyors who are not experienced with ESRD surveys and advanced training for others. Officials at the state agencies in our study generally

³³To encourage data sharing, CMS has begun work on a draft Memorandum of Understanding that the state agencies and ESRD networks could adopt.

³⁴In 2000, the state agency and the network participated in a special project intended to increase the number and quality of ESRD surveys. The networks, along with the state agency and the CMS regional office, jointly provided ESRD training to surveyors who had limited experience with ESRD surveys. All three then worked together to help facilities correct deficiencies and have since collaborated on educating facility managers about ESRD standards and the survey process.

commended these courses, noting that they provided surveyors with the knowledge and skills needed to conduct ESRD surveys effectively.

Three of the state agencies we reviewed require that surveyors complete CMS's basic ESRD training before they are allowed to perform surveys unassisted. State agency officials emphasized that they try to get surveyors trained as quickly as possible after they have been assigned ESRD survey responsibilities. This not only permits the surveyors to gain expertise in conducting ESRD surveys at the appropriate time, but it also allows them to begin conducting surveys unassisted in a timely fashion. Delays in getting surveyors scheduled for basic training delays their readiness to conduct surveys unassisted, which in turn has an impact on a state agency's performance in the number of surveys it conducts during the year.

For most of the state agencies in our study, the limited number of CMS training classes offered has been problematic. In particular, the infrequency of classes at the introductory level for ESRD training has had the greatest impact on state agency operations. From fiscal year 1999 to 2002, CMS offered only one course each year for basic training, always given at the same time of year, and since fiscal year 2000, always in Denver. In light of this schedule, state agencies were particularly concerned about the delay in training surveyors who were new to ESRD. At times, state agencies sent these surveyors to take advanced courses when openings in the basic course were unavailable. However, these courses dealt largely with selected topics and did not explain the core technical and regulatory concepts covered in the basic course. As a result, surveyors who had previously taken basic training and had some experience in conducting ESRD surveys found the advanced courses most informative and useful. Officials of several state agencies also indicated that CMS could help accommodate surveyors by offering basic ESRD training at multiple sites, taking into consideration the location of class enrollees. Some officials added that this would provide the additional benefit of helping their agencies save funds used for travel.

CMS has highlighted the value to surveyors of attending its basic ESRD training course by instituting a new policy that requires all newly appointed ESRD surveyors to complete it. Effective fiscal year 2003, all newly hired ESRD surveyors, or surveyors who have not previously performed ESRD surveys, must complete the course before they can serve in a capacity other than a trainee. However, CMS has chosen not to fill this gap for surveyors who took advanced courses as a substitute for the basic course in years past. For surveyors who performed ESRD surveys prior to

fiscal year 2003, other CMS ESRD training courses are considered equivalent. Experienced ESRD surveyors who have not received any ESRD training from CMS have until fiscal year 2004 to complete either ESRD basic or advanced training.

CMS fielded a questionnaire to state agencies to determine current training needs in light of the new training requirement. Although the results of this survey are still being reviewed and analyzed by CMS, preliminary tabulations indicate that at least 21 percent of experienced ESRD surveyors met the training requirement through one of the presumed equivalent courses and had never taken the CMS basic course. In at least six states fewer than half the surveyors had taken the basic ESRD training. The extent to which experience in conducting ESRD surveys compensates for a lack of formal training is an open question. Until that process is complete, the scarcity of training opportunities in the past could continue to constrain the effectiveness of many ESRD surveyors.

Conclusions

As a result of critical weaknesses in the system established to monitor and enforce compliance with Medicare's quality standards for ESRD facilities, full and consistent compliance with these standards has become more the exception than the rule. Despite increased surveying goals recently set by CMS, many facilities continue to escape the attention of state surveyors for long periods of time. This is especially problematic for facilities that have performed poorly in the past and are therefore relatively more likely to reveal deficiencies when surveyed again. In addition, there are few if any negative consequences for facilities if they are surveyed and found out of compliance with Medicare's quality standards. Currently, facilities can escape negative publicity from having multiple deficiencies, despite the fact that the statement of deficiencies prepared by state surveyors is a public document.

The wide variation across states in the number of condition-level deficiencies found indicates in part that some surveyors are more proficient than others in detecting quality problems. ESRD survey expertise can be enhanced through training and experience. Promoting surveyor specialization should lead to more thorough ESRD inspections and more accurate documentation of deficiencies. Similarly, were CMS to offer more basic level ESRD courses, at different locations and times, surveyors newly assigned to ESRD facilities could more quickly obtain the training they need to conduct effective inspections. In addition, a comparable expansion in advanced course offerings would enable a larger

proportion of experienced surveyors to catch up with technical developments in dialysis treatments.

State survey agencies could better target their survey activities if they had access to information from ESRD networks on the extent of serious quality problems at individual facilities. However, CMS regulations that require networks to safeguard the confidentiality of data that they obtain from dialysis facilities has generated confusion among the networks as to what facility-specific information they legitimately can and should share with state survey agencies. CMS could remove this long-standing impediment by revising those regulations to clearly make such data sharing with state agencies mandatory.

Moreover, the magnitude of variation across states in the level of survey activity and survey results underlines the need for more intensive monitoring of, and support to, the individual state agencies. However, CMS has not addressed the enormous variation among its own regional offices in the extent to which they undertake these activities. The highly inconsistent performance in the number of ESRD surveys conducted by state agencies and surveyors' detection of deficiencies may reflect uneven monitoring and support provided to them by CMS regional offices—some of which devoted considerable attention to ESRD survey activities, and others, virtually none.

Ultimately, no quality assurance system can be effective unless providers face real consequences when they are cited repeatedly for deficiencies. Because they are routinely given multiple opportunities to demonstrate that they have corrected any problems found, ESRD facilities have no strong incentive to adhere to those standards until a survey takes place. Facilities are likely to continue cycling in and out of compliance until state agencies have a broader range of enforcement tools, especially ones that take effect even if deficiencies are subsequently corrected. CMS could implement some additional sanctions by regulation. However, as we noted in our June 2000 report, CMS did not have the authority to expand to ESRD facilities the range of alternative sanctions available for use against noncompliant nursing homes. We therefore suggested at that time that Congress consider authorizing CMS to impose civil monetary penalties on dialysis facilities. Our current work supports consideration of this suggestion.

Moreover, the effectiveness of alternative sanctions would be greatly strengthened if they could also be imposed promptly, without allowing facilities a grace period to correct identified deficiencies. Such immediate

sanctions could be applied when facilities are found to have condition-level deficiencies in successive surveys. For instance, immediate denial of payments for new patients could create a strong incentive to maintain compliance because the facility loses income from Medicare, which usually represents a substantial part of operating revenues.

Matter for Congressional Consideration

To encourage ESRD facilities to sustain their compliance with Medicare quality standards, Congress should consider authorizing CMS to immediately impose a sanction when a dialysis facility has condition-level deficiencies in successive surveys without providing the facility a grace period before the sanction takes effect. The immediate sanction options available to CMS should include denial of Medicare payments for new patients and civil monetary penalties.

Recommendations for Executive Action

We recommend that:

To create incentives for facilities to maintain compliance with Medicare quality standards, the Administrator of CMS should

- establish a goal for state agencies to reduce the time between surveys for facilities with condition-level deficiencies and
- publish facilities' survey results on its Dialysis Facility Compare Web site.

To help surveyors identify and systematically document deficiencies, the Administrator of CMS should

- strongly encourage states to assign ESRD inspections to a designated subset of surveyors who specialize in conducting ESRD surveys and
- make ESRD training courses more available to state surveyors, which may include increasing the number of classes and slots available as well as varying class location.

To enhance the support and monitoring of state survey agencies, the Administrator of CMS should

- amend its regulations to require that networks share facility-specific data with state agencies on a routine basis and
- ensure that regional offices both adequately monitor state performance and provide state agencies ongoing assistance on policy and technical issues through regularly scheduled contacts with state surveyors.

Agency Comments and Our Evaluation

In its written comments, CMS did not indicate an intention to implement five of our six recommendations. Nevertheless, it affirmed its commitment to ensuring adequate oversight of dialysis facilities and state survey agencies, and described a number of measures that it has initiated to strengthen this process. (CMS's comments are reprinted in app. IV.) However, two of these initiatives—a proposed survey of ESRD beneficiaries and the automation of data reporting by facilities to CMS—will only indirectly affect the survey and certification program that was the focus of our report. In our report, we identified several key limitations in the structure and implementation of this program that constrain its effectiveness in enforcing Medicare's quality standards for ESRD facilities. In addition to comments on each of our recommendations, CMS also provided technical comments that we incorporated where appropriate.

With respect to our matter for congressional consideration, CMS affirmed its commitment to take action against ESRD facilities with serious quality problems. It also acknowledged that the agency needed to create strong incentives for facilities to provide quality care. The agency proposed to address this issue by initiating an evaluation of the effectiveness of sanctions on improving nursing home care. Although such an evaluation may produce useful information about nursing homes, it will have limited relevance for the quality of care provided to ESRD patients. We continue to believe that Federal oversight of dialysis facilities could be improved by strengthening the enforcement process. Therefore, Congress should consider authorizing CMS to impose immediate sanctions on dialysis facilities cited with serious deficiencies in consecutive surveys.

CMS's response to the first of our recommendations for executive action—that it set a goal for more frequent surveys of facilities with a history of condition-level deficiencies—acknowledged the value of targeting surveys on poorly performing providers. Though it expressed a strong commitment to increased oversight of such facilities, CMS did not indicate a willingness to set this additional goal. Instead, CMS relies on the states to use the flexibility that it has built into its budget call letter to target their surveys on ESRD providers most likely to have quality problems. However, we found that the budget call letter placed ESRD facilities in a lower priority category, behind both nursing homes and home health agencies. Without a change in the priorities that CMS has communicated to the state agencies, it is unrealistic to expect most states to go beyond the goals currently set by CMS for ESRD survey activity.

In its comment, CMS also highlighted its efforts to develop tools to help state agencies identify facilities that are most likely to exhibit quality

problems. These include reports on individual facilities—produced from claims data and other administrative data files by CMS contractors—that describe their practice patterns and outcomes. CMS also stated that it distributes to the states an Outcomes List that ranks facilities for surveying priority based on their performance on dialysis adequacy, anemia management, and adjusted mortality rates. However, CMS’s surveying goals for the states, as they are currently structured, do not focus on targeting of any sort. Our analysis of state survey activity found scant evidence that state agencies were conducting more frequent surveys of even the most obvious candidates—facilities that had condition-level deficiencies in their most recent prior survey. Our evidence and CMS’s response indicates a need for CMS to go beyond its current efforts to developing inspection goals on poorly performing facilities.

CMS did not directly respond to our second recommendation, that CMS publish survey results on its Dialysis Facility Compare Web site. Instead, the agency described various studies it has underway to develop better information for consumers, including efforts to make survey results more uniform across the country. While greater uniformity in survey results is a laudable objective, we would note that the results of surveys currently conducted are the basis for the agency’s decisions to either recertify or (potentially) terminate ESRD facilities as Medicare providers. Therefore, the information we have recommended that CMS share with the public does not represent an abstract quality indicator of unknown validity. Rather, it conveys the actual status of the facility in terms of fulfilling its basic obligation to meet Medicare’s conditions for coverage. In our opinion, these nominally public, but heretofore undisseminated, survey outcomes would convey useful information to interested ESRD patients trying to decide among alternative facilities.

Our third recommendation was that CMS encourage state agencies to identify a subset of surveyors who would specialize in conducting ESRD facility inspections. In its comment CMS did not address our recommendation but responded that, in general, it encouraged states to have specialized surveyors when possible. However, the agency did not describe what specifically it had done to promote this practice. CMS did highlight other initiatives it has taken to enhance surveyor skills and improve the survey process more generally. These include its development of a new software system to help guide surveyors as they conduct surveys, the reports on practice patterns and outcomes of individual facilities, and increases in the surveyor training that CMS provides. CMS concluded that these steps were the most appropriate use of limited resources. We would note, however, that to the extent that states do not concentrate their ESRD

surveys on a subset of specialist surveyors, more surveyors will need to receive CMS training in conducting ESRD surveys. That represents a less efficient use of CMS training resources. We continue to believe that surveyor specialization contributes to more thorough and effective inspections, in addition to whatever benefits accrue from other improvements such as expanded training and customized software.

Our fourth recommendation was that CMS expand the number and slots available in training courses for ESRD inspections, as well as vary their locations. CMS responded that it has arranged to increase its offerings to a minimum of two basic ESRD training classes annually, with one course conducted in Denver and one in Minneapolis. According to CMS, more advanced ESRD training may also be increased, depending on demand. This expansion should lessen considerably the difficulty that state survey agencies have experienced obtaining the necessary training for their ESRD surveyors on a timely basis.

In our fifth recommendation, we urged CMS to amend its regulations to require that ESRD networks share facility-specific data with state agencies on a routine basis. CMS responded that networks are currently required to share data with CMS, which can then provide appropriate information, such as the previously mentioned Outcomes List, to state agencies. CMS also stated that information that networks obtain through their quality improvement efforts has limited utility for quality assurance because it is not standardized (that is, the specific information collected will vary across networks and projects). On the contrary, we found that the networks' quality improvement projects collect new information directly from dialysis facilities which helps identify those facilities that perform poorly on one or more quality dimensions. As the experience of California has shown, such data can provide valuable guidance to state surveyors in their selection of facilities to inspect, regardless of whether identical information is collected by every network across the country.

Our last recommendation stated that CMS should ensure that its regional offices provide adequate oversight of, and assistance to, state agency monitoring of ESRD facilities. As with several previous recommendations, the agency reaffirmed its commitment to the overall goal, but did not address the weaknesses that we found in its implementation. CMS's comment describes the resources available to the regional offices, including assigned ESRD specialists, regional data reports, and monthly conference calls with state agency officials. However, CMS did not address the large variation across regions in the extent to which they use these tools, and refers to no specific measures intended to stimulate greater

effort in regions that have been less active to date. CMS stated that it is working hard to clarify its expectations for both state agencies and its own regional offices, but in its comment provides no explanation or examples of what this might entail.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days from its date. At that time, we will send copies of this report to the Administrator of CMS and to other interested parties. In addition, this report will be available at no charge on GAO's Web site at <http://www.gao.gov>. We will also make copies available to others upon request.

If you or your staff have any questions about this report, please call me at (312) 220-7600. An additional GAO contact and other staff members who prepared this report are listed in appendix V.

Sincerely yours,



Leslie G. Aronovitz
Director, Health Care—Program
Administration and Integrity Issues

Appendix I: Scope and Methodology

Quality of Care

To analyze variation in the clinical performance of individual facilities, we downloaded information available from CMS's Web site, Dialysis Facility Compare (DFC)—<http://www.medicare.gov/Dialysis/Home.asp>.¹ DFC provides information on two clinical performance measures: the proportion of patients with adequate hemodialysis—defined as a Urea Reduction Ratio of at least 65—and the proportion of patients with adequate anemia control—defined as a hematocrit of 33 or better. DFC has data on the latter measure for patients taking the drug erythropoietin (EPO)—the therapy generally used to treat anemia among ESRD patients. The most currently available data for both measures came from information provided on Medicare claims submitted for treatment furnished in 2000. DFC reports the proportion of patients at each ESRD facility who achieved the designated threshold for these two measures.

To provide a more concrete sense of the types of quality problems encountered by state surveyors, we selected five survey reports, known formally as a “statement of deficiencies” (Form 2567), that described in detail the deficiencies cited in inspections of individual facilities in five states. We abstracted from each survey report the justification written by the surveyor for one deficiency citation. The episodes we chose involved deficiency codes that are widely cited among survey reports nationwide. In the data we assembled from CMS's Online Survey Certification and Reporting (OSCAR) system, at least one of these six specific deficiency codes—111, 112, 118, 240, 264, and 423—was cited in 35 percent of all recertification surveys conducted in fiscal years 1998 through 2002.

To more fully appreciate the clinical consequences of these deficiencies for patients, we shared our abstracted citations with three ESRD surveyors, each with at least 5 years of ESRD survey experience, whom we had previously interviewed in conjunction with our site visits to three different states. All were registered nurses. The three surveyors commented on each of the six vignettes that we sent them by describing the potential impact of these situations on patient health and well-being. Their analyses encompassed expected symptoms, such as fatigue, swelling, and shortness of breath, medical conditions that could result, such as heart failure and ruptured red blood cells, and related outcomes, such as shortened life expectancy.

¹Other clinical performance measures have only been reported from samples of patients, providing data on national and regional trends but without the ability to compare results across individual dialysis facilities.

Survey Frequency and Results

To analyze the frequency and results of surveys conducted in the 50 states plus the District of Columbia, we obtained all the data stored on CMS's OSCAR system relating to standard surveys of ESRD facilities. Standard surveys include initial surveys—conducted when a facility first applies for Medicare certification—and recertification surveys—conducted at intervals subsequent to the initial survey for that facility.² The OSCAR database is continuously updated and retains data for the four most recent surveys for each facility. Our analysis was not adversely affected by the potential loss of data if a given facility had more than four standard surveys conducted, because less than 1 percent of ESRD facilities had as many as four surveys from fiscal year 1998 through 2002, the period of our review.

When state survey agencies complete their work on these surveys, CMS requires them to record in OSCAR information about the inspection including the dates that the surveys took place and the specific deficiency codes for each standard-level and condition-level deficiency cited. OSCAR also contains Provider of Service file information on ESRD facilities, including their name, address, chain ownership, date of Medicare enrollment, and the date of, and reason for, termination (if any).

The data used in our OSCAR analyses was downloaded on April 2, 2003, providing a 6-month period following the end of fiscal year 2002 for state agencies to complete the process of data entry. To assess the completeness of the data, we compared the number of surveys we found in OSCAR for fiscal years 1998 through 2002 with the number of surveys that state agencies indicated that they completed in annual workload reports submitted to CMS. Although complete workload data were not always available, where they were, the numbers of ESRD surveys reported for most states matched the number recorded in OSCAR either exactly or nearly (plus or minus 3) in each of the 5 fiscal years.

In analyzing the proportion of ESRD facilities resurveyed in fiscal years 1998 through 2002, we determined the facilities that were available for recertification in each year. We excluded those facilities that were subject to an initial survey, and any that had either dropped out of Medicare prior to that year or that did not begin participating in the program until later.

²Similar information is collected on complaint surveys but stored in separate data files.

Surveyor Specialization

To assess the effect of surveyor specialization, we analyzed the relationship of survey results statewide with the degree of surveyor specialization in that state. We defined specialization as assigning ESRD facility inspections to a subset of surveyors who spend much of their time focused on ESRD quality issues. We knew from our state site visits and interviews that some states promoted specialization while other states distributed ESRD assignments roughly equally among surveyors who spent most of their time inspecting nursing homes and home health agencies. From 9 of the 10 states that we examined most closely, we obtained data on the number of ESRD and non-ESRD surveys conducted by each surveyor during fiscal year 2002. (We were not able to obtain this information from Mississippi.) From those data we calculated the proportion of total surveys that were of ESRD facilities, first for each individual surveyor, and then for the state as a whole. The statewide ratio combined the individual surveyor ratios, with each individual's ratio weighted by the proportion of ESRD surveys in fiscal year 2002 accounted for by that individual. The result was a state specialization score that had a possible range from almost 0 to 1. (A state would get a score of 1.0 if all of its ESRD surveys were done by surveyors who never inspected any other provider types.) This approach was designed to gauge the relative likelihood that any given ESRD survey in the state would be conducted by a surveyor whose survey activities focused on ESRD facilities.

We assessed the strength of the relationship of surveyor specialization to survey results by comparing the aggregate results of states with low specialization scores with states that had relatively high scores. Specifically, we compared the proportion of surveys with condition-level deficiencies and the number of standard-level deficiencies cited in surveys. We applied chi-square tests to determine if observed differences between the two groups were likely to have occurred by chance, using the conventional 95 percent confidence interval. We were not able to link the results of individual surveys to the experience level of the surveyors who conducted them. Therefore, our analysis compared aggregate survey outcomes across two groups of states, distinguished by their overall level of surveyor specialization.

Surveyor Training

To assess the extent of state surveyor training to perform ESRD facility inspections, we drew on the results of a survey conducted by CMS of the state survey agencies. CMS solicited data on the titles and dates of all CMS-sponsored training on ESRD completed by each of the states' individual surveyors who had performed ESRD inspections prior to fiscal year 2003. It initially collected these data in January and February of 2003

and continued obtaining updated and corrected information through May 2003. We analyzed the most recent data supplied to us by CMS at that time.

Federal Funding for ESRD Surveys

To assess federal funding for ESRD and other survey activities, we reviewed quarterly and annual expenditure reports submitted to CMS by state survey agencies for fiscal years 1998 to 2002. These reports specify the funds spent by state agencies for both long-term care (LTC) and non-LTC survey activities under the Medicare and Medicaid programs. However, because the reports aggregate expenditures for all non-LTC survey activities, we had to estimate the expenditures related to ESRD surveys. We developed our estimates based on additional CMS data that indicated the number of hours each state agency reported was spent on activities related to ESRD surveys, as well as activities related to non-LTC surveys overall. We then calculated the ESRD-related share of non-LTC survey hours and applied that percentage to the total non-LTC survey expenditures each state agency indicated on its annual expenditure report.

Appendix II: Medicare Conditions for Coverage for Dialysis Facilities

| Condition for coverage | Description |
|--|---|
| Compliance with federal, state, and local laws and regulations | 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 | 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 | 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 | 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 | Patient medical records must be maintained to document patient assessments, diagnosis, and treatment, and medical and nursing histories. |
| Physical environment | 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 | Facilities that reuse hemodialyzers and other dialysis supplies must follow established protocols and standards to ensure patient and staff safety. |
| Affiliation agreement or arrangement | 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 | 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 | 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 | Dialysis facilities must provide dialysis services as well as laboratory, social, and dietetic services needed to address ESRD patient needs. |

Source: 42 C.F.R. Part 405 Subpart U (2002).

Appendix III: State Agencies' Progress toward Meeting CMS Survey Goals

The table below shows the percentage of facilities surveyed, by state, in fiscal years 1998 to 2002. It indicates how the individual states responded to the increases in the goal for annual ESRD recertification rates set by CMS, from 10 to 17 percent per year in fiscal year 2000 and then to 33 percent each year starting in fiscal year 2001.

Table 5: ESRD Facilities Recertified Annually by State, Fiscal Years 1998 to 2002

| | Percentage | | | | |
|---|------------|------|------|------|------|
| | 1998 | 1999 | 2000 | 2001 | 2002 |
| CMS goal | 10 | 10 | 17 | 33 | 33 |
| State recertification survey rates | | | | | |
| Alabama | 12 | 15 | 17 | 9 | 2 |
| Alaska | 50 | 0 | 100 | 100 | 0 |
| Arizona | 8 | 13 | 11 | 28 | 23 |
| Arkansas | 11 | 50 | 16 | 32 | 37 |
| California ^a | 2 | 4 | 12 | 12 | 11 |
| Colorado | 7 | 6 | 24 | 6 | 27 |
| Connecticut | 17 | 28 | 27 | 39 | 39 |
| Delaware | 0 | 9 | 0 | 15 | 36 |
| District of Columbia | 8 | 4 | 28 | 22 | 28 |
| Florida ^a | 10 | 14 | 22 | 37 | 40 |
| Georgia ^a | 12 | 12 | 17 | 37 | 36 |
| Hawaii | 21 | 13 | 6 | 25 | 22 |
| Idaho | 17 | 13 | 14 | 14 | 14 |
| Illinois ^a | 29 | 21 | 22 | 41 | 32 |
| Indiana | 5 | 19 | 16 | 33 | 31 |
| Iowa | 9 | 11 | 17 | 26 | 27 |
| Kansas | 14 | 24 | 21 | 44 | 33 |
| Kentucky | 63 | 54 | 70 | 83 | 89 |
| Louisiana ^a | 10 | 18 | 17 | 32 | 31 |
| Maine | 38 | 38 | 8 | 33 | 25 |
| Maryland | 17 | 16 | 5 | 26 | 28 |
| Massachusetts | 8 | 13 | 14 | 37 | 31 |
| Michigan ^a | 31 | 28 | 11 | 18 | 10 |
| Minnesota | 21 | 4 | 5 | 27 | 33 |
| Mississippi | 8 | 9 | 36 | 69 | 9 |
| Missouri | 5 | 7 | 12 | 19 | 22 |
| Montana | 64 | 36 | 21 | 36 | 33 |

Appendix III: State Agencies' Progress toward Meeting CMS Survey Goals

| | Percentage | | | | |
|-----------------------------|------------|------|------|------|------|
| | 1998 | 1999 | 2000 | 2001 | 2002 |
| Nebraska | 10 | 11 | 25 | 36 | 33 |
| Nevada | 20 | 0 | 8 | 38 | 16 |
| New Hampshire | 11 | 22 | 0 | 40 | 50 |
| New Jersey | 8 | 12 | 15 | 34 | 22 |
| New Mexico | 16 | 0 | 29 | 14 | 10 |
| New York ^a | 4 | 6 | 10 | 33 | 29 |
| North Carolina ^a | 16 | 15 | 21 | 23 | 31 |
| North Dakota | 21 | 31 | 31 | 46 | 42 |
| Ohio ^a | 13 | 11 | 17 | 38 | 26 |
| Oklahoma | 13 | 22 | 16 | 41 | 21 |
| Oregon | 22 | 65 | 19 | 33 | 31 |
| Pennsylvania ^a | 5 | 10 | 10 | 11 | 28 |
| Rhode Island | 10 | 0 | 0 | 15 | 8 |
| South Carolina | 18 | 16 | 17 | 32 | 34 |
| South Dakota | 13 | 19 | 18 | 42 | 22 |
| Tennessee ^a | 11 | 9 | 23 | 47 | 29 |
| Texas ^a | 2 | 7 | 3 | 21 | 34 |
| Utah | 35 | 30 | 30 | 19 | 33 |
| Vermont | 00 | 25 | 0 | 33 | 0 |
| Virginia ^a | 31 | 13 | 12 | 12 | 13 |
| Washington | 26 | 18 | 42 | 33 | 32 |
| West Virginia | 14 | 17 | 13 | 33 | 26 |
| Wisconsin | 10 | 16 | 21 | 28 | 30 |
| Wyoming | 14 | 0 | 0 | 33 | 22 |

Source: GAO analysis of CMS OSCAR data.

^aIndicates the 13 states with the greatest number of dialysis facilities in 2002.

Starting in fiscal year 2001, CMS also set a goal for states to survey all ESRD facilities every 3 fiscal years. The initial 3-year cycle will be completed at the end of fiscal year 2003. Table 6 shows the number of facilities available for recertification in each state at the start of fiscal year 2001 (and not terminated since then) and the percentage that remained to be surveyed in fiscal year 2003. In fiscal year 2003, 35 out of 50 states, plus the District of Columbia, need to survey over a third of their ESRD facilities to meet the cycle goal.

Appendix III: State Agencies' Progress toward Meeting CMS Survey Goals

Table 6: Facilities to Be Recertified to Meet CMS 3-Year Goal, by State

| | State | ESRD facilities needing recertification in fiscal years 2001 through 2003 (number) | Share of facilities that need to be surveyed in fiscal year 2003 to meet CMS goal (percentage) |
|----|----------------------|---|---|
| 1 | Alabama | 92 | 89 |
| 2 | Rhode Island | 13 | 77 |
| 3 | California | 347 | 76 |
| 4 | New Mexico | 29 | 76 |
| 5 | Virginia | 119 | 76 |
| 6 | Idaho | 7 | 71 |
| 7 | Michigan | 104 | 71 |
| 8 | Vermont | 6 | 67 |
| 9 | Colorado | 35 | 66 |
| 10 | Missouri | 102 | 64 |
| 11 | Pennsylvania | 216 | 62 |
| 12 | District of Columbia | 23 | 52 |
| 13 | Hawaii | 16 | 50 |
| 14 | Utah | 20 | 50 |
| 15 | Arizona | 78 | 49 |
| 16 | North Carolina | 111 | 49 |
| 17 | Maryland | 95 | 47 |
| 18 | Iowa | 47 | 47 |
| 19 | Delaware | 13 | 46 |
| 20 | Texas | 285 | 45 |
| 21 | Wyoming | 9 | 44 |
| 22 | Nevada | 16 | 44 |
| 23 | Wisconsin | 76 | 43 |
| 24 | New Jersey | 87 | 43 |
| 25 | Maine | 12 | 42 |
| 26 | Oklahoma | 57 | 40 |
| 27 | New York | 205 | 40 |
| 28 | West Virginia | 23 | 39 |
| 29 | Washington | 43 | 37 |
| 30 | Indiana | 78 | 37 |
| 31 | Minnesota | 61 | 36 |
| 32 | Louisiana | 115 | 36 |
| 33 | South Dakota | 17 | 35 |

Appendix III: State Agencies' Progress toward Meeting CMS Survey Goals

| | State | ESRD facilities needing recertification in fiscal years 2001 through 2003 (number) | Share of facilities that need to be surveyed in fiscal year 2003 to meet CMS goal (percentage) |
|----|----------------|---|---|
| 34 | Oregon | 40 | 35 |
| 35 | Ohio | 149 | 35 |
| 36 | South Carolina | 75 | 33 |
| 37 | Massachusetts | 61 | 33 |
| 38 | Arkansas | 52 | 29 |
| 39 | Montana | 14 | 29 |
| 40 | Nebraska | 21 | 29 |
| 41 | Illinois | 126 | 26 |
| 42 | Mississippi | 62 | 26 |
| 43 | Kansas | 39 | 26 |
| 44 | Georgia | 168 | 24 |
| 45 | Tennessee | 106 | 23 |
| 46 | New Hampshire | 9 | 22 |
| 47 | Florida | 237 | 22 |
| 48 | Connecticut | 26 | 19 |
| 49 | North Dakota | 12 | 17 |
| 50 | Alaska | 2 | 0 |
| 51 | Kentucky | 45 | 0 |

Source: GAO analysis of CMS OSCAR data.

Appendix IV: Comments from the Centers for Medicare & Medicaid Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: SEP 24 2003

TO: Leslie G. Aronovitz
Director, Health Care - Program
Administration & Integrity Issues

FROM: Thomas A. Scully
Administrator

SUBJECT: General Accounting Office (GAO) Draft Report: *DIALYSIS FACILITIES: Problems Remain in Ensuring Compliance with Medicare Quality Standards*, (GAO-03-882)

Thank you for the opportunity to review and comment on the above referenced draft report.

In the last year, the Centers for Medicare & Medicaid Services (CMS) has worked diligently to strengthen cooperation, coordination, and information sharing between:

- the end-stage renal disease (ESRD) Networks and the state survey agencies;
- the Agency and our ESRD beneficiaries; and,
- the different parts of the Agency that administer the ESRD Program.

In October 2002, CMS brought together 154 representatives from the state survey agencies and the ESRD Networks in order to help them understand each other's roles and responsibilities and to either continue, or begin, discussions on collaboration and information sharing. As a result of these discussions, state survey agencies and ESRD Networks have reached a variety of agreements which are mutually supportive of each other, in order to increase the effectiveness of each organization in both improving the care provided and responsiveness to beneficiary concerns.

Through an interagency agreement, CMS and the Agency for Healthcare Research and Quality (AHRQ) have jointly set a priority of developing a standardized survey that may be used to solicit feedback from ESRD beneficiaries, as well as make widely available comparable measurements of their experiences with care. On August 25, 2003, a Federal Register Notice was published asking for potential measurement instruments and protocols. The finalized instrument will bear the CAHPS trademark and the goal of

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developing the standardized survey and reporting quality data on hemodialysis facilities could be reached within the next few years.

Currently, the only facility-specific outcomes data for ESRD that are widely available to state survey agencies come from administrative data. The CMS also collects standardized Clinical Performance Measures (CPM) on a 5 percent sample of ESRD patients annually and Networks capture additional information in their quality improvement efforts, but because the CPM sample is small and the Network data is not standardized, their use in quality assurance is limited. To coordinate these efforts and provide one patient-centered data set that can be used for program oversight, CMS is working with the ESRD community to develop and implement the ESRD Core Data Set and the VISION software system, both of which will include the CPMs. These efforts will improve the quality, quantity, and timeliness of data and reduce facility burden through electronic transmission and elimination of redundant data collection.

Attached are our specific comments to the report. We look forward to working with GAO on this and other issues in the future.

Attachments

The Centers for Medicare & Medicaid Services' Comments to GAO's Draft Report, *DIALYSIS FACILITIES: Problems Remain in Ensuring Compliance with Medicare Quality Standards*, (GAO-03-882)

Recommendation

Establish a goal for state agencies to reduce the time between surveys for facilities with condition-level deficiencies.

Comment

The Centers for Medicare & Medicaid Services (CMS) is strongly committed to increased oversight of facilities which continue to experience quality problems, particularly at the condition level. As GAO noted, between 1998 and 2002, we more than doubled the aggregate funding for ESRD surveys, as well as reduced the goal for the maximum time required between surveys, from six years to three years. In addition, any facility that is found to have condition level non-compliance receives at least one revisit; and more if necessary. We believe that it is necessary for facilities to be surveyed at least once every three years.

In recognition of the limited state and Federal resources available to conduct all necessary survey activity, we have built some flexibility into our budget call letter in order to allow states to manage their resources and better target facilities with quality issues. The CMS has provided a series of tools to assist state agencies with this effort. Annually, in conjunction with the University of Michigan, CMS issues an outcomes report that includes key patient quality indicators for all ESRD providers in their State. The Outcomes List is ordered by facility performance on key patient outcomes based upon adherence to the National Kidney Foundation's Kidney Dialysis Outcomes Quality Initiative (DOQI) guidelines for adequacy of dialysis, hemoglobin/hematocrit levels, and adjusted mortality rates. The Outcomes List is positively correlated with survey deficiencies, making the list a supportive tool to be used in conjunction with key survey and certification information, such as past survey findings and reports of complaints. In conjunction with the University of Michigan and the Colorado Foundation for Medical Care, CMS issues facility-specific reports to providers, state agencies, and ESRD networks. These 17-page reports include comparative data on facility characteristics, practice patterns, and outcomes. The reports are used to inform each entity—provider, state agency, and network—so that each entity can better achieve its respective goal(s), whether it is improved care, improved monitoring, or improved technical assistance.

Recommendation

Publish facilities' survey results on its Dialysis Facility Compare Web site.

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Comment

The CMS is exploring a variety of options for providing better consumer information on the Dialysis Facility Compare Web site. The first step we are undertaking is a more thorough analysis of the survey and certification data for dialysis facilities. Under a contract with Lewin Associates, CMS is developing an automated survey tool, the Surveyor Technical Assistant for Renal Disease (STAR). We feel that once STAR is in use, the survey data will be more consistent nationally. In addition, we are also examining the experience of providing survey and certification data through Nursing Home Compare. The Dialysis Facility Compare workgroup will then explore user-friendly options available for sharing the data.

Recommendation

To help surveyors identify and systematically document deficiencies, the Administrator of CMS should strongly encourage states to assign ESRD inspections to a designated subset of surveyors who specialize in conducting ESRD surveys.

Comment

We encourage states to have specialized surveyors when possible. The CMS is taking several steps to enhance surveyor skills and improve the survey process. We expect to provide greater consistency and thoroughness in the survey process and findings with STAR. The STAR will use tablet computers loaded with survey software which guides surveyors through various investigative techniques based on the answers elicited during the survey progresses. As the STAR system guides the surveyors through the survey process, the system provides background information, clarifications, and a menu of possible citations for different observations. The program automatically converts the surveyors' findings into a formatted report. That software will be pilot tested in five states in the second half of Fiscal Year (FY) 2004. Through this automated system, CMS expects to collect data and information which will assist in CMS's oversight responsibilities, as well as each state's and facility's oversight responsibilities.

Under a contract with the University of Michigan, CMS produces Dialysis Facility Reports, which include information on patient and facility characteristics, directly actionable practice patterns (e.g., dose of dialysis, vascular access, and anemia management) as well as general outcomes (e.g., mortality, hospital admissions, and transplant) that can be used to educate providers about the efficacy of practice patterns. These data have consistently shown a strong relationship between patient outcomes and practice patterns. These data also show a relationship between patient outcomes and survey deficiencies. A guide that accompanies the data assists surveyors with the interpretation and use of the data. The CMS has also increased the number of basic ESRD training courses it holds each year, and now requires that surveyors attend basic training before conducting ESRD surveys. The CMS believes that these are the right steps to improve surveys generally, and ESRD surveys in particular. The CMS has also increased the number of basic ESRD training courses it holds each year, and now

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requires that surveyors attend basic training before conducting ESRD surveys. The CMS believes that these are the right steps to improve surveys generally, and ESRD surveys in particular. At this time we believe these steps to be the most appropriate use of limited state resources.

Recommendation

Make ESRD training courses more available to state surveyors, which may include increasing the number of classes and slots available as well as varying class location.

Comment

The CMS is committed to ensuring that all surveyors receive the necessary training, as feasible under our current budget and workload constraints. Until FY 2003, CMS had been limited in the number of classes it could hold, however, CMS has recently obtained additional access to a training site with dialysis equipment (e.g., a water treatment system, a dialyzer reprocessing system, and dialysis machines) and “mock” patients. CMS is partnering with two industry leaders to provide this training. We have onsite training with all the necessary equipment at Gambro in Denver, Colorado and with Minntech in Minneapolis, Minnesota. Because of this partnering effort, we will now be able to offer a minimum of two basic trainings a year (one at each location). We also plan to have an advanced technical training program at the Minntech facility in FY 2004. Based on responses to that, we will determine whether or not to hold advanced training annually or biannually. Another key training opportunity we continue to offer is an Annual Update in conjunction with a nephrology professional meeting. The FY 2004 Update is scheduled with the National Kidney Foundation Spring Clinical Meeting in Chicago in April 2004. We believe our partnership with the industry allows surveyors to hone their survey skills while also getting the latest industry information.

Recommendation

To enhance the support and monitoring of state survey agencies, the Administrator of CMS should amend its regulations to require that networks share facility-specific data with state agencies on a routine basis.

Comment

We believe the current regulations do not prohibit networks from sharing data collected under the aegis of CMS. Networks serve not only as the quality improvement association for ESRD, but also as the data collection vehicle for CMS. As such, we require networks to share data with CMS. The CMS can then share appropriate data with the state survey agency and the public. These data are useful for structuring the survey process and targeting facilities for survey. For example, facilities scoring poorest on the Outcomes Lists are more likely to have condition-level deficiencies. We will continue to encourage state agencies to use this information as well as compliance history in choosing and scheduling surveys.

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Currently, the only facility-specific outcomes data for ESRD that are widely available to state survey agencies come from administrative data. The CMS also collects standardized Clinical Performance Measures (CPM) on a 5 percent sample of ESRD patients annually and Networks capture additional information in their quality improvement efforts but because the CPM sample is small and the Network data are not standardized, their use in quality assurance is limited.

The ESRD facilities receive feedback on their performance through numerous reports that have different purposes and measurements and come from different datasets and time periods. For example, a clinic may receive the following feedback from CMS over the course of a year:

- reports from the Networks;
- a Facility-Specific Report developed by the University of Michigan;
- the Annual ESRD CPM Project Report if the facility was included in the 5 percent sample; and,
- public reporting on the Dialysis Facility Compare Web site.

To coordinate these efforts and provide one patient-centered data set that can be used for program oversight, CMS is working with the ESRD community to develop and implement the ESRD Core Data Set and the VISION software system, both of which will include the CPMs. These efforts will improve the quality, quantity, and timeliness of data and reduce facility burden through electronic transmission and elimination of redundant data collection.

Recommendation

Ensure that regional offices both adequately monitor state performance and provide state agencies ongoing assistance on policy and technical issues through regularly scheduled contacts with state surveyors.

Comment

The CMS is committed to providing adequate oversight of provider and state agency performance. We continue to work hard at clarifying these expectations for states and regions. By offering more basic and advanced training, we will increase opportunities for regional office and state staff to interact. Each of the 10 CMS regional offices (ROs) has an ESRD specialist who directly oversees the state survey agencies in that respective regional jurisdiction. Tools that the ROs use to assist in state oversight are the following: A Regional Data Report that summarizes and compares practice patterns and outcomes in the states in that specific region's jurisdiction; a monthly conference call where regions discuss and coordinate issues and programs; and an annual meeting of ESRD RO specialists, which serves as both a training and sharing event for these RO specialists. The ESRD surveyors in the ROs provide oversight and technical advice to state survey agencies. We will also continue exploring ways for ROs to perform more

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collaborative and comparative ESRD monitoring, keeping in mind the current budget and staffing constraints.

GAO Matter for Congressional Consideration

The Congress should consider authorizing CMS to immediately impose a sanction when a dialysis facility has condition-level deficiencies in successive surveys without providing the facility a grace period before the sanction takes effect.

Comment

The CMS is committed to taking appropriate actions against facilities that have condition-level problems, especially on an ongoing basis. The purpose of our actions must be to provide either a strong incentive for the provider to come back into compliance and furnish quality care to our beneficiaries, or provide a mechanism to remove the provider from the program. To ensure that we achieve the optimum outcome for both beneficiaries and providers, we are exploring various information and education sources both internally and externally. We are in the process of awarding a contract to evaluate the effectiveness of sanctions and remedies for improving nursing home resident care. We believe that this information will help us better understand what directions to take in working with the industry to improve quality outcomes for beneficiaries and sustained compliance for providers.

Appendix V: GAO Contact and Staff Acknowledgments

GAO Contact

Rosamond Katz, (202) 512-7148

Acknowledgments

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Related GAO Products

Nursing Home Quality: Prevalence of Serious Problems, While Declining, Reinforces Importance of Enhanced Oversight. [GAO-03-561](#). Washington, D.C.: July 15, 2003.

Major Management Challenges and Program Risks: Department of Health and Human Services. [GAO-03-101](#). Washington, D.C.: January 1, 2003.

Nursing Homes: Public Reporting of Quality Indicators Has Merit, but National Implementation Is Premature. [GAO-03-187](#). Washington, D.C.: October 31, 2002.

Medicare Home Health Agencies: Weaknesses in Federal and State Oversight Mask Potential Quality Issue. [GAO-02-382](#). Washington, D.C.: July 19, 2002.

Nursing Homes: Sustained Efforts Are Essential to Realize Potential of the Quality Initiatives. [GAO/HEHS-00-197](#). Washington, D.C.: September 28, 2000.

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

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