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# MEDICARE QUALITY OF CARE

# Oversight of Kidney Dialysis Facilities Needs Improvement

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# Medicare Quality of Care: Oversight of Kidney Dialysis Facilities Needs Improvement

Mr. Chairman and Members of the Special Committee:

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

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

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

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

has a clear picture of what the other is finding and is unable to take advantage of that information to target or otherwise modify its own activities. Our report recommends changes to address all three problems. HCFA has reviewed these recommendations and agrees with them.

## Background

To stay alive, a patient with ESRD must receive either a kidney transplant or regular kidney dialysis treatments. Such treatments use a machine to do the kidneys' job of removing impurities from the blood. If performed improperly, such treatments can contaminate patients' blood, causing serious complications and even death.

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

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

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

## Most Facilities Go Years Between Surveys for Compliance With HCFA Standards

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

While the number of surveys is going down, the proportion of surveys that find major problems is increasing. In 1993, 6 percent of facilities surveyed were cited for not meeting a condition of participation; that figure rose to 15 percent in 1999. A condition-of-participation deficiency means that the problems found are serious enough that, unless corrected, the facility's participation in Medicare will be terminated by HCFA. Because so few facilities actually receive a recertification survey in a given year and surveys are not performed on a random basis, it is not clear whether this increased percentage is indicative of all facilities. Nevertheless, it is cause for concern.

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

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

## Enforcement Process Gives Facilities Little Incentive to Sustain Compliance

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

We found that the problem was not getting facilities to comply, but assuring that they stay compliant. If a facility slips out of compliance again, it can avoid a penalty by once again coming into compliance during the next grace period. Because of the infrequency of recertification surveys, it is difficult to determine how quickly and how often facilities fall out of compliance. It also means that a facility that becomes deficient again could remain so for a very long time. Analysis of HCFA's survey database suggests that facilities do tend to have repeat deficiencies. Of those facilities with four or more surveys, 38 percent that had deficiencies on their most recent survey were also deficient in at least one of the same areas on their prior survey. More than half of them had two or more repeat deficiencies. For example, a Texas facility cycled in and out of compliance over a 9-year period while developing numerous plans of correction. On many occasions the deficiencies were so severe they put the health and safety of the facility's 227 patients in immediate jeopardy. In 1999, the deficiencies included not providing care necessary to address patients' medical needs, not complying with physician orders, and not following up on adverse incidents. It took more than 4 months and two revisits from the state before the facility came back into compliance. However, when the state conducted another survey 4 months later, the facility was again out of compliance. At the time of our review, state agency officials were exploring enforcement options under state licensing authority.

In the past, this Committee has examined a similar problem—nursing homes that cycled in and out of compliance with quality standards. The Congress has allowed HCFA a broad range of penalties to help encourage nursing homes to maintain compliance with standards. For example, for nursing homes HCFA has authority to levy monetary penalties and stop Medicare payments to deficient nursing homes, but neither of these

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

options can be applied to dialysis facilities. Effective options for dealing with chronically deficient dialysis facilities do not exist.

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

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

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

## Efforts and Opportunities to Improve On-Site Inspections

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

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

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

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

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

HCFA's current policy allows networks to share facility-specific information with state survey agencies to aid in the certification process. However, HCFA regional offices that oversee network and survey agency activities have not applied this policy consistently. As a result, the level of coordination and information sharing varies dramatically across regions, and in most cases little has taken place. Most HCFA regional offices restrict networks from sharing facility-specific information and support

ESRD networks when they deny requests by state survey agencies for such information, saying that federal confidentiality restrictions prohibit this sort of exchange. In contrast, with the knowledge of its HCFA regional office, the ESRD network in Texas began providing facility-specific information to the Texas Department of Health after the state passed a licensure law for dialysis facilities in 1996. More recently, early this year, some HCFA regional offices have begun efforts to facilitate the communication and exchange of information, including facility-specific performance information, between ESRD networks and state agencies. Because we see increased communication as a way to help identify which facilities are most likely to need attention, we recommended that HCFA encourage better and more consistent cooperation and information sharing between ESRD networks and state survey agencies.

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

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

## GAO Contacts and Acknowledgment

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

# Related GAO Products

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

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

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

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

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

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

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