

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

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

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

External Quality Review Is Important.

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

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

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

Variation in the quality of care. Performance data reveal that a substantial portion of patients nationwide do not achieve the clinical outcomes recommended by clinical practice guidelines. For example, 20 percent of hemodialysis patients did not meet clinical guidelines for the minimum dose of dialysis (as measured by a Kt/V1.2). And, 41 percent of hemodialysis patients did not meet the guidelines for the management of anemia (as measured by a hemoglobin level that met or exceeded 11-12 gm/dL). Similarly, scientific studies suggest widespread variation in the quality of care patients receive in facilities. One study in particular showed that facilities differ in mortality rates, and that higher mortality rates were correlated with facilities that provided less adequate doses of dialysis.

Marketplace pressures. The dialysis industry has grown significantly in recent years. Moreover, through a series of mergers and acquisitions, there has been increased consolidation in the ownership of

the facilities. Along with growth and consolidation, the dialysis treatment environment is characterized by at least three other increasingly prominent forces: increased competition for patients, heightened concerns to contain costs, and increased difficulty in finding and retaining experienced nurses and technicians in an increasingly competitive marketplace.

HCFA's External Review Bodies

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

Our Inquiry

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

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

FINDINGS

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

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

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

Performance measures are rarely used to hold individual facilities accountable. HCFA does not require Networks or States to collect a set of facility-specific performance data to monitor the performance of individual facilities. Without facility-specific data it is difficult for Networks and States to identify poorly performing facilities that require intervention. In some instances, Networks have access to facility-specific data either because they collect them on their own or through other research efforts. Even if a Network is able to identify a facility performing well below accepted standards,

Networks have little enforcement authority to ensure compliance and are reluctant to share such information with States who have more authority. Networks are reluctant to share data with the States because they fear that States will misinterpret the data and will be unable to protect the data from public disclosure. Networks believe eventual public disclosure will undermine their collegial relationships with the facilities. Currently, no data are readily available to the public on a facility-specific basis either by HCFA, Networks, or States.

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

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

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

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

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

Medicare certification surveys play a limited role in ensuring facilities meet minimum standards.

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

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

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

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

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

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

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

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

RECOMMENDATIONS

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

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

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

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

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

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

Medical Injuries. The Institute of Medicine recently called for a mandatory national system for reporting of such adverse events in hospitals and other health care facilities. Given that dialysis treatments are paid for primarily by Medicare funds, and that HCFA has the major responsibility for the external quality oversight of the facilities, dialysis facilities are an ideal candidate for testing this kind of reporting system. HCFA could facilitate the development of publicly accountable means for identifying serious medical injuries and analyzing their causes. The system should provide for the analysis of adverse events and for any necessary corrective actions at the facilities involved.

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

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

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

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

We presented our recommendations in the context of the current oversight system in which HCFA relies upon the Networks and State survey agencies. We believe that this system has the potential to provide

effective oversight if HCFA moves in the direction we call for. We want to stress that while HCFA has authority and leverage, it must approach the Networks and State agencies as partners who contribute to and share a commitment to high-quality dialysis care. We also want to stress that external oversight must be conducted in ways that minimize the regulatory burden on dialysis facilities and seek to complement the facilities' own internal quality review efforts.

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

This concludes my testimony, and I welcome your questions.