DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

Clinical Performance Measures for Dialysis Facilities

Lessons Learned by the Major Dialysis Corporations and Implications for Medicare

Supplemental Report # 2

JANET REHNQUIST
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OEI's Boston office prepared this report under the direction of Mark R. Yessian Ph.D., Regional Inspector General and Joyce M. Greenleaf, M.B.A., Assistant Regional Inspector General. Principal OEI staff included:

BOSTON

Aimee K. Golbitz, *Lead Analyst*
Norman J. Han, *Program Analyst*

HEADQUARTERS

Bambi D. Straw, *Program Specialist*

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EXECUTIVE SUMMARY

PURPOSE

To present lessons learned by the five largest dialysis corporations in using clinical performance measures to hold facilities accountable for the quality of care and to address the implications they have for the Centers for Medicare & Medicaid Services, formerly the Health Care Financing Administration.

BACKGROUND

In our June 2000 report, *External Quality Review of Dialysis: A Call for Greater Accountability*, we urged the Centers for Medicare & Medicaid Services (CMS) to use facility-specific clinical performance measures as a key part of its oversight of dialysis facilities. Clinical performance measures are quantitative indicators, typically expressed as a percentage, that reflect the quality of care patients received. CMS concurred with the directions we suggested and presented a detailed action plan to strengthen its use of clinical performance measures. Since then it has been active in carrying out this plan.

In this follow-up inquiry, we examine the practices of the five largest dialysis corporations in using clinical performance measures to hold their own facilities accountable for the quality of care. We regard such an inquiry as important because: (1) these corporations account for about 70 percent of all dialysis patients in the United States, the vast majority of whom are Medicare beneficiaries, and represent over 2,000 facilities, (2) they have a substantial body of experience in using performance measures, and (3) they have gained know-how that can be helpful to CMS and others.

This report is the second of two supplemental reports focusing on clinical performance measures for dialysis facilities. The main report is entitled, *Building on the Experiences of the Dialysis Corporations*. The first supplemental report, *Practices of the Major Dialysis Corporations*, describes the processes the corporations have to collect and use performance measures. All three reports are based on our review of corporate documents, interviews with corporate medical directors, and visits to a number of the corporations' dialysis facilities. We sought to describe their processes and we did not evaluate the overall effectiveness of their systems. We did not audit or validate the performance data the corporations collect from their facilities. The corporations voluntarily participated in this review and the data presented was self-reported by the corporations.

LESSONS LEARNED BY THE CORPORATIONS

In our first report in this series, we described how the corporations collect, review, analyze, and disseminate facility-specific clinical performance measures. We found that each collects over a dozen measures and generates timely, facility-specific performance

reports. In this report, we present the lessons that the five major dialysis corporations told us that they have learned over the years in using these measures. The first two lessons address the foundation for accountability that must be established in order for the measures to have impact. The remaining lessons address the particulars of establishing and using the measures.

Establishing a Foundation for Accountability

- ✓ Look to medical directors to exert sustained leadership.
- ✓ Secure the commitment of attending physicians.

Implementing Clinical Performance Measures

- ✓ Collect a broad set of measures.
- ✓ Revisit the relevance of the measures regularly.
- ✓ Establish minimum performance standards.
- ✓ Develop performance goals.
- ✓ Apply strict definitions to performance measures.
- ✓ Check the accuracy of performance data regularly.
- ✓ Minimize the data reporting burden.
- ✓ Present performance data in ways that facilitate comparative assessment.
- ✓ Provide timely feedback of performance data to facilities.
- ✓ Stress quality improvement projects at the facility level.
- ✓ Use performance data as a guide to possible performance problems, not as definitive indicators.
- ✓ Intervene with facilities having performance problems in ways likely to motivate change.

RECOMMENDATIONS

CMS has played an important leadership role in developing national clinical performance measures to assess the quality of care of dialysis patients and, like the corporations, has

its own system in place to collect facility-specific performance measures. The major dialysis corporations also have been proceeding on a similar track and have gained considerable know-how in how to make the most effective use of facility-specific performance measures. The lessons that the corporations have learned in collecting and using clinical performance measures reinforce the directions that CMS is taking to further develop its system to collect and use facility-specific performance measures.

Below we draw on the lessons the corporations have learned that we conclude have implications for CMS. Our intent is to help CMS further tap into the potential of performance measures as a means of improving health care outcomes for dialysis patients.

Conditions for Coverage. CMS should revise the Conditions for Coverage, Medicare's regulations for dialysis facilities, so that they:

- Require facility medical directors to exert leadership in quality improvement.
- Require dialysis facilities to conduct their own quality improvement projects.

Attending Physicians. CMS should examine ways to foster the commitment of attending physicians to performance measures.

- Conduct educational forums that address the value of measurements to patient care.
- Examine the possibility of physician-specific report cards.
- Focus greater attention on the responsibilities of attending physicians.

Intervention Strategies. CMS, with its oversight agents, the End-Stage Renal Disease Networks and the State Survey Agencies, should develop more effective intervention strategies for facilities experiencing performance problems. For this to happen, CMS should:

- Foster greater collaboration between the Networks and the States that incorporates the respective strengths of the two.
- Address the confidentiality and liability concerns that impede such integrated efforts.

Dialysis Corporations. CMS should work with the corporations to share experiences and minimize burdens on dialysis facilities. At the core, the two have similar concerns about improving care. More sharing of experiences could be helpful to both parties, and, most importantly, to patients.

COMMENTS

We received written comments on the draft report from the CMS, the Forum of End-Stage Renal Disease Networks, Renal Physicians Association, National Renal Administrators Association, and the five corporate dialysis providers that were the focus

of our inquiry. Their comments were strongly supportive of the lessons we presented and of the thrust of the recommendations we made to CMS. We include the full text of the comments in appendix C. On the basis of the comments, we made a number of clarifications and technical changes. Among the respondents, our recommendations addressing medical director leadership and the commitment of attending physicians generated the most attention. Below, we briefly summarize the comments and our responses to them.

Medical Director Leadership. CMS supported our recommendation that the Medicare Conditions for Coverage be revised to require medical directors to exert leadership in quality improvement. The dialysis corporations and the other commenters also underscored the importance of such leadership, but to varying degrees raised concerns about how it might be defined in the Medicare Conditions. They urged that leadership expectations be in accord with the real world in dialysis facilities. Their comments reinforce the importance of CMS clearly establishing the medical director's authority and responsibility to provide leadership if it expects performance measures to be instrumental in improving care in dialysis facilities. At the same time, the comments suggest the value of collaboration between the corporations and CMS in further defining the leadership role of medical directors.

CMS and other respondents supported our recommendation that medical directors be given authority to conduct or initiate peer review of attending physicians. But they were clearly wary of our recommendation that when patients are put at risk because of substandard medical care, the medical director should report the physician to an authoritative body, such as the facility's governing board, the End-Stage Renal Disease Network, or the State medical board. We suggest that this is a vital patient protection responsibility that must be part of the purview of the medical director and that CMS should address it as part of its efforts to foster quality dialysis care.

Securing the Commitment of Attending Physicians to Performance Measures. This is a vital matter having a significant bearing on the successful use of performance measures. CMS expressed its readiness to consider the measures we called for. Other respondents were supportive of convening educational forums. But some raised concerns with the use of physician-specific reports (which are already being used by at least one End-Stage Renal Disease Network and by two dialysis corporations) and with the establishment of more explicit Federal standards or requirements concerning the performance of attending physicians. We recognize that these are difficult issues, but suggest that they warrant careful examination as means of more fully engaging attending physicians in quality improvement efforts.

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INTRODUCTION

PURPOSE

To present lessons learned by the five largest dialysis corporations in using clinical performance measures to hold facilities accountable for the quality of care and to address the implications they have for the Centers for Medicare & Medicaid Services, formerly the Health Care Financing Administration.

BACKGROUND

In 1972, Medicare began covering individuals with end-stage renal disease, or permanent kidney failure, making it the only entitlement criteria for Medicare based solely on a disease category. Patients receiving hemodialysis, the most common method of treatment, typically receive treatment in outpatient dialysis facilities three times a week.[1] About 3,500 dialysis facilities provide ongoing, life-sustaining dialysis treatments to about 240,000 patients around the country.[2]

Our Prior Inquiry

In June 2000 we released a report examining the Centers for Medicare & Medicaid Services' (CMS), formerly the Health Care Financing Administration, oversight of dialysis facilities as carried out by the End-Stage Renal Disease Networks and the State Survey Agencies (*External Quality Review of Dialysis: A Call for Greater Accountability*, OEI-01-99-00050).[3,4] In that report we gave attention to the fact that performance measures can be an important tool to encourage facilities to improve the quality of care and to help ensure that they meet minimum standards. But we also found that CMS rarely uses such measures to hold individual facilities accountable.

In our recommendations, we urged CMS to collect and use facility-specific performance data as a key element of its external review system. Clinical performance measures are quantitative indicators, typically expressed as a percentage, that reflect the quality of care patients received. For example, the percentage of patients at a facility that achieved an adequate dose of dialysis as measured by a urea reduction ratio of $\geq$65 percent, is an indicator. (See appendix A for a glossary of terms.)

We urged CMS to identify a new core set of performance measures to collect regularly on all patients from all facilities. We recommended that it make these measures available to:

- **facilities** to support internal quality improvement activities,
- **Networks** to support regional quality improvement activities and to identify outliers for further review,

- **State survey agencies** to help guide and inform the Medicare survey process, and
- **the public** to foster public accountability.

CMS' Actions

CMS concurred with the directions we set forth and presented a detailed action plan that incorporated numerous efforts it had underway and would be initiating. It is drafting new Conditions for Coverage, Medicare regulations, for dialysis facilities, which it expects to release in draft in the coming months. In doing so, it plans to consider our recommendations to strengthen the role of the medical director, to require facilities to electronically report on a core set of performance measures, and to require facilities to conduct their own quality improvement activities.

CMS has also committed to strengthening its existing efforts to collect facility-specific data on all Medicare beneficiaries as soon as it is able to put into place its new information system, Vital Information System for Improvement of Outcomes in Nephrology.[5] This new information system will allow facilities to electronically report data directly to CMS. The system will also help ensure accurate reporting through computer software that will contain automatic data edits that will notify the user when data that is illogical is entered. CMS has already implemented the Standard Information Management System for the End-Stage Renal Disease Networks, which connects all the Networks together and directly with CMS. CMS is also revising three administrative data forms that it collects from facilities that contain data used to calculate performance measures. Eventually these forms will be submitted to CMS electronically by the facilities.

Since 1995, CMS, via the End-Stage Renal Disease Networks, has distributed Unit-Specific Reports that provide comparative, facility-specific data, which includes mortality and hospitalization rates. Facility-specific urea reduction ratio and hematocrit levels were added to the reports after 1998. In January 2001, CMS publicly released comparative facility-specific reports that contained three performance measures: urea reduction ratio, hematocrit, and mortality. The reports are available on the Internet.[6] In July 2001, CMS distributed to State survey agencies, facility-specific reports that also contain key performance measures. State survey agencies use these reports to assist in selecting facilities for review and to focus Medicare certification surveys. Currently the majority of the data in these reports comes from Medicare billing and administrative data and the data are over 2 years old. As the CMS implements its Vital Information System for Improvement of Outcomes in Nephrology it is expected that the data for these reports will be more timely (see appendix B for more detailed information about Federal sources of performance data).

Finally, CMS revised its process to review and approve each of the Networks annual quality improvement projects. The new process is intended to reduce variation in the quality of projects and help Networks design more sophisticated projects. The new

process also gives Networks more guidance on what topic areas they should focus on for their quality improvement projects.

Dialysis Corporations Use of Clinical Performance Measures

In this follow-up inquiry we focus on the experiences of large, corporate dialysis providers in using clinical performance measures as a way of holding their own facilities accountable for the quality of care provided. This is a significant domain of external quality oversight that we did not address in our June 2000 report and that has been largely ignored in the public sphere.

We regard it as important to learn more about the experiences of these providers for three major reasons. First, as the dialysis industry has consolidated in recent years, these corporations have become a major force in the dialysis field. The five largest corporations, which we focus on in this report, now account for about 70 percent of all dialysis patients in the United States, the vast majority of whom are Medicare beneficiaries.[7] They account for over 2,000 of the nation's 3,500 dialysis facilities.[8] Second, they have a substantial body of experience in using performance measures to monitor the quality of care at their own facilities. And, third, they have gained know-how that may be useful to Federal efforts.

Methodology

We limited our inquiry to the five largest providers: Fresenius Medical Care North America, Gambro Healthcare, Davita (formerly Total Renal Care), Renal Care Group, and Dialysis Clinic, Inc. In selecting the top five, we do not seek to imply that they are necessarily the best in using performance measures, nor to suggest that other corporations or independently owned facilities are not also experienced in using such measures. Each of the five corporations participated in our study voluntarily and made available to us information concerning its practices. The information we present is current as of June 2001. The information contained in this report was self-reported by the dialysis corporations.

At the outset, we considered including in our review measures that relate to clinical performance, patient satisfaction, and adverse events. Each is important to national policy and in each case the corporations have relevant experience. However, for this inquiry, we decided to limit our focus to clinical performance measures in order to allow for greater detail. Clinical performance measures are the measures that the corporations have the most experience with, receive most of their attention, and bear most immediately on CMS' oversight.

Our data-gathering methods included two focus groups with the medical directors of the five corporations, further interviews with each of the corporate medical directors and

other corporate officials, visits to several corporations' dialysis facilities, and reviews of pertinent documents of the corporations.

It is important to underscore that our inquiry is not an evaluation of the corporations' practices. They have been carrying out these practices at their own initiative, not in response to any Federal requirements. We did not seek to assess how well they are using performance measures, nor did we obtain sufficient information to make such an assessment. We did not audit or validate the performance data the corporations collect from their facilities. We did seek to gain a clear understanding of their current practices.

We also interviewed key stakeholders. The stakeholders included the Renal Physicians Association, the Forum of End-Stage Renal Disease Networks, and the National Renal Administrators Association.

This Report and its Companion Report

This report is the second of two supplemental reports that we are issuing based on the main report entitled, *Clinical Performance Measures for Dialysis Facilities: Building on the Experiences of the Dialysis Corporations* (OEI-01-99-00052). This supplemental report begins with two basic lessons associated with establishing a foundation for accountability within the dialysis facilities. It then to 12 lessons that concern the implementation of clinical performance measures. The report concludes with recommendations to CMS as it moves forward to strengthen its own facility-specific data collection.

The first supplemental report, *Clinical Performance Measures for Dialysis Facilities: Practices of the Major Dialysis Corporations* (OEI-01-99-00053), describes the corporate practices concerning the use of facility-specific performance measures. We address specifics concerning data collection, validation, analysis, dissemination, and corporate practices for fostering improvements and intervening with poor performers.

We conducted this study in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

LESSONS LEARNED BY THE CORPORATIONS

Below we present key lessons the dialysis corporations told us they have learned in using clinical performance measures to hold facilities accountable for the care they provide. The first two address the foundation for accountability that must be established in order for the measures to have impact. The remaining lessons are more operational and cover the particulars of establishing and using clinical performance measures.

Establishing a Foundation for Accountability

Performance measures do not automatically contribute to improved dialysis care. For their potential to be realized, it is essential that they be used at the local level by individual dialysis facilities. The facilities' governing boards, clinical and technical staff, and administrators must view the measures as helpful instruments to improve the overall processes of the facility.

While it is important to gain the commitment of all those who are associated with the dialysis facilities, it is especially important to ensure that the two parties that have the most influence over the processes of dialysis treatment—the facility medical directors and the attending physicians—integrate the measures into their decision-making process (see text box). In the sections that follow, we elaborate on what the corporations have learned in this regard.

The Role of the Facility Medical Directors and Attending Physicians

Medical Directors. The Medicare Conditions for Coverage require each facility to have a physician who serves as a medical director who is responsible for "planning, organizing, conducting, and directing the professional [end-stage renal disease] services." Corporations contract with local physicians to serve in this capacity. For facilities that are not part of a corporate chain, the facility owner and medical director can be the same person. In addition to their medical director duties, these physician directors have their own patients that can make up the majority of patients at a facility. It is not uncommon for a medical director to also be an attending physician at another facility regardless of the ownership.

Attending Physicians. Dialysis facilities allow local physicians to send their patients to them for treatment. Attending physicians may send patients to several facilities that may be owned by several different corporations or entities. The physicians are not contractors or employees of the facility or the corporation, and their privileges can be revoked if they do not adhere to the facility's policies.

Lesson 1. Look to medical directors to exert sustained leadership.

The dialysis corporations underscore that if performance measurements are, in fact, to stimulate improved care, it is essential that facility medical directors provide leadership. They look to their medical directors to exert this leadership in two key ways. One is to lead by example. The medical directors must show that they are willing to use performance data to improve their own practices, for their own patients. Since the medical directors can account for a majority of a facility's patients, such leadership by example is of no small consequence.

The other dimension of medical director leadership is that of ensuring sustained attention in the facility to the improvement opportunities that performance measures can offer. The corporations have come to expect the medical directors to serve as the primary on-site agents to implement the corporate initiatives concerning the collection and use of measures, to help nurses and attending physicians recognize the value of using the measures, to determine how measures can foster continuous quality improvement efforts, and, where necessary, to intervene with individual physicians or nurses whose performance may be adversely effecting the facility's overall performance.

The medical directors' contracts spell out their leadership responsibilities. These contracts include the responsibilities required by the Medicare regulations as well as any additional responsibilities required by the corporation.[9] Among the contracts that we reviewed, we saw specifications that medical directors review their facilities' performance measures monthly, attend regular training or meetings concerning quality improvement, and address attending physicians not performing adequately. Two of the corporations even include in their contracts a provision indicating that a portion of the medical director's salary is contingent on how well their facilities fared on various performance measures.

To further the leadership of their medical directors, the corporations also convene forums of various kinds at which medical directors receive training about the use of performance measures and the dynamics of quality improvement efforts. These sessions tend to focus on how such efforts can be instrumental in improving the processes of care. The corporations also conduct other kinds of outreach to help medical directors. For instance, one holds quarterly conference calls in which medical directors and other facility staff are encouraged to participate. The corporate leaders we met with believed that these efforts are helpful in engaging the medical directors.

The corporate officials disagreed about how fully they are able to hold facility medical directors accountable for exerting leadership. Some stated that they had all the authority they needed through their contracts with facility medical directors. For them, it was simply having the will to enforce their contracts. Others drew attention to the limited leverage that the medical directors themselves have over the attending physicians who, unlike medical directors, do not have contractual obligations to the facility or the corporation and who often have patients at various facilities.[10] The Medicare Conditions

for Coverage do not make explicit that medical directors have the authority to take action concerning patients attended to by other physicians.[11] However, in CMS' comments to this report it stated, "that medical director may take "independent action" (which can encompass a number of options) in the absence of explicit statutory or regulatory authority."[12] Moreover, in competitive marketplaces, medical directors and attending physicians, if unhappy with a facility, can encourage their patients to move with them to another dialysis facility.

Lesson 2. Secure the commitment of attending physicians.

For their own patients, the attending physicians determine the amount of dialysis, prescribe medications, and monitor the ongoing effects of dialysis treatment. In performing these roles, the attending physicians have a considerable influence on the quality of care provided at dialysis facilities and can influence how well particular facilities fare when performance measures are aggregated.

Yet, corporate representatives indicate that these attending physicians, when they are not the medical director, are not necessarily drawn to facility-based performance measures. With their patients in a number of different facilities, they may find any one facility's measurements to be of little consequence to their own clinical performance. And, finally, as busy professionals, they may find that they have little time to devote to improvement efforts, for which they receive no additional compensation.

Still the corporations have devised ways to encourage attending physicians to participate in facility efforts to improve the quality of care being provided. One approach they use is to establish clear standards that attending physicians must meet in order to send their patients to the facility. Typically these standards are set forth in the facility bylaws. At least one of the corporations has reinforced its standards by requiring all attending physicians to sign an agreement stipulating their roles and responsibilities. Another approach is to provide opportunities for physicians to attend seminars or conferences addressing performance measures and/or quality improvement. Finally, to foster a stronger sense of individual physician accountability, two corporations provide physician-specific performance reports so that physicians can see data that are more relevant to their own practice.

Implementing Clinical Performance Measures

The corporations have been collecting and using facility-specific performance measures for many years. They have gained a considerable appreciation for the complexities of the tasks involved. They have made and continue to make changes in their policies and procedures. We offer what they regard as major lessons learned.

Lesson 3. Collect a broad set of measures.

Even with all the research on dialysis treatment in the last 25 years, there still is a lack of complete understanding of what affects mortality on dialysis patients. Dialysis treatment is a complex process. Treatment is also complicated by the fact that many patients suffer from other serious chronic conditions, such as hypertension and diabetes. Therefore, it is critical that facilities monitor many different measures in order to obtain a better picture of the care patients receive.

Lesson 4. Revisit the relevance of the measures regularly.

The measures the corporations collect have changed over time in order to keep pace with scientific advances. The corporations stated that if the measures were outdated (i.e., not clinically relevant), then physicians, nurses, and other renal professionals would be unwilling to invest their time in collecting and reviewing them.

The vast majority of revisions have been adding new measures and refining definitions as opposed to eliminating measures. With new research coming out all the time and as researchers learn more about the process of dialysis treatment, new parameters are identified that influence mortality. In order to accomplish this task, the corporations rely on staff at the central level who monitor the latest research and can react quickly to revise the measures.

Lesson 5. Establish minimum performance standards.

Corporate officials emphasized that setting clear expectations for facility performance is key to ensuring a minimum level of care across all facilities. The corporations recognize that some variation will always exist in dialysis care. However, the corporate leaders agreed that there is a floor below which care is unacceptable.

Minimum standards are often expressed as a percentage of patients meeting a certain target value rather than the average value for all patients at the facility for a given measure. Percentages more clearly indicate the number of patients not receiving adequate treatment. If 80 percent of patients are meeting the target value, then 20 percent of patients are not. The facility is then able to focus on that 20 percent. With averages it can be unclear how many patients are above and below the target and what the variance is among patients.

Lesson 6. Develop performance goals.

Corporate leaders emphasized the need for all facilities, even the top performers, to continually improve their performance. In order to prevent facilities from striving just to meet the minimum standards, three of the corporations have established goals for each performance measure. The goals are intended to be challenging enough to motivate all

facilities to improve. One corporate official stated that without goals, the minimums become the goals and the race to the bottom begins.

Lesson 7. Apply strict definitions to performance measures.

Standard definitions and processes need to be in place prior to collecting the data. Many of the clinical performance measures are collected as part of regular treatment, but they are not necessarily standardized. In order for the data to be used as part of an aggregate analysis, all the data need to be collected and analyzed in the same manner. For example, to obtain the urea reduction ratio a blood sample needs to be drawn from the patient. Depending on when and how the blood is drawn, the result will differ. In order to bring attention to this issue, one corporation requires all its staff members to wear a clip-on badge similar to an identification badge. The badge spells out the process for collecting blood samples for the urea reduction ratio.

Other measures that corporate leaders have been especially careful to define the type of calculations to perform are hospitalization and mortality rates. For example, some corporations exclude patients with certain terminal diseases in calculating mortality rates and some do not. With hospitalization, some count the length of stay and some just count the number of times admitted. All the corporations indicated that it was important to make clear exactly what the measure represents so that all facilities can be collecting the same type of data.

Lesson 8. Check the accuracy of performance data regularly.

All the corporations indicated that this process is time consuming and often tedious. But without it, they were concerned that the integrity of the data could be compromised. Facilities first and foremost are in the business of providing patient care; they are not focused on statistics or data entry. Therefore, it is important to have a system in place to monitor the data.

The review process serves two main functions: it helps ensure the accuracy of the data and it helps to foster the integrity of the entire performance measure program among physicians and facility staff. If care givers perceive that the data lacks integrity, they will likely ignore any reports generated from the data.

Some of the corporations thought that, without review, some facilities might try to manipulate the data to make their performance appear to be better than it actually is. Other corporations disagreed. However, all the corporations agreed that a review process helps foster confidence in the data.

Lesson 9. Minimize the data reporting burden.

Staff time, as in any health care setting, is in short supply. Nurses and technicians are busy caring for patients and have little time left over for other activities, especially for

quality improvement activities that sometimes can be perceived as more paperwork. It is often the nurses and technicians who are left to deal with quality improvement tasks such as entering the data and submitting forms. To help reduce the workload, some of the corporations have integrated their electronic data systems for quality management with their data systems for patient management that nurses and doctors rely upon to provide day-to-day patient care. These types of integrated systems eliminate the need for double data entry.

Lesson 10. Present the performance data in ways that facilitate comparative assessment.

Corporate performance reports compare a facility to its own past performance and to its peers at the regional or national levels. Corporate officials told us that comparisons are a big motivator for improvement. They show at-a-glance where one facility stands among its peers. The facility can then begin to explore how the care they provide differs from their peers.

Lesson 11. Provide timely feedback of performance data to dialysis facilities.

If the data are 2 years old, or even a year old, physicians may tend to view them as something that shows a long-term trend that is irrelevant to the care they are providing today. According to corporate leaders, the more recent the data, the more likely physicians and staff will take them seriously as a reflection of the care they are providing now and if necessary make changes in their practices.

They also believed that the performance measures can have greater impact if physicians are looking at them as part of their care-giving process, not as a task that they save until the end of the day after they have seen all their patients. Thus, the data need to be readily accessible through patient charts or on computer terminals within the facilities.

Lesson 12. Stress quality improvement projects at the facility level.

The corporations expect individual dialysis facilities to take the lead in conducting quality improvement projects. They look to the facilities to identify problems and to develop and implement their own quality improvement projects. Facilities are in the best position to identify areas in need of improvement. Furthermore, improvements can only occur if the individuals providing the care make changes in their processes.

The corporations view themselves as assisting their facilities in improvement activities rather than conducting the projects themselves. Thus, they provide extensive training, technical assistance, and materials to help facilities conduct their own projects. On occasion, corporations will conduct corporate-wide projects, but most often the emphasis is placed on facility-based projects.

Lesson 13. Use performance data as a guide to possible performance problems, not as definitive indicators.

Corporations use performance measures cautiously, as signals of possible problems. It is important that measures are used with other types of information. Prior to intervening, the corporations seek to verify the concern. They may examine the results of recent patient satisfaction surveys, complaints, results of any State surveys, adverse event reports, and the current demographics of the patient population. Some corporations wait until a definite pattern appears over several months before they will intervene. Corporate representatives emphasized that performance measures used in isolation can lead to false conclusions on both sides. A facility that fails to meet performance minimums may in fact be providing high quality care. Similarly, a facility exceeding performance goals may be providing inadequate care.

One representative told us about a time that he called a facility medical director to express concern about the facility's high mortality rate. It quickly became apparent the high mortality rate was explained by a patient population that included a large number of patients suffering from AIDs. The corporation did not adjust its data for AIDs and other terminal illnesses. The issue of patient comorbidity can be particularly complex as many measures are not adequately risk-adjusted. Another corporate official told us that he was surprised when he received a State survey report from one of his facilities that outlined several serious deficiencies. The facility was performing well on each of its performance measures. From these events and others, the corporations have learned not to rush to judgement based on the measures alone.

Lesson 14. Intervene with facilities having performance problems in ways likely to motivate change.

When the corporations have determined that a cause for concern exists at a facility, they will intervene using graded approaches. The corporations tend to begin their interventions with targeted training for the facility. Often facilities struggle because they simply do not know how to interpret their data and develop a corrective action plan. Often the training occurs on site so that the corporate officials can also review first-hand the practices of the facility. Many of the corporate officials believed that training would not only help the facility fix its current problem, but also help the facility address any problems in the future. If training fails, the next level of response is peer review. Corporate officials indicated to us that physicians and nurses are more receptive to advice from their regional peers than from a person in an executive position. According to the corporate representatives, these approaches are highly successful. It was rare that they had to resort to punitive actions such as firing facility staff, terminating contracts with facility medical directors, or revoking attending physician privileges.

RECOMMENDATIONS

CMS has played an important leadership role in developing national clinical indicators to assess the quality of care of dialysis patients. Its efforts, through the Clinical Performance Measures Project, have drawn attention to the potential of clinical performance measures in the dialysis field. The data show that between 1994 and 1999 the percentage of patients with adequate dialysis treatment, defined as a urea reduction ratio $\geq$65 percent, has increased from 43 to 80 percent. The percentage of patients receiving adequate anemia management, defined as hemoglobin $\geq$ 11 gm/dL, has also increased from 43 to 68 percent between 1997 and 1999.[13] CMS has also collected facility-specific data on performance measures mainly through billing and administrative forms and recently has taken steps to strengthen its systems to collect and disseminate facility-specific data (see appendix B and page 2).

The major dialysis corporations, as we have shown, also have been active in using facility-specific performance measures as tools of quality improvement. The lessons that they have learned in collecting and using clinical performance measures reinforce the directions that CMS is taking towards enhancing its current facility-specific reporting mechanisms. CMS is developing a new core data set, a mechanism to help ensure accurate reporting, a mechanism to provide ongoing evaluations of the measures, and a process to disseminate comparative data in a more timely fashion.

In this final section, we draw on the lessons learned by the dialysis corporations to identify the implications that we conclude they have for CMS. As CMS seeks, in the years ahead, to further tap into the potential of performance measures as a means of improving health care outcomes for dialysis patients, it will need to address these recommendations.

In presenting these recommendations, we offer two important caveats. One is that we do not intend to imply that the facilities that are part of the major dialysis corporations are the best or in any way deserve preferential treatment. As CMS continues to exert leadership in using clinical performance measures as tools for quality improvement, it must be attuned to their application in a full range of dialysis facilities, whether or not they are part of a corporate chain. Secondly, we recognize that performance measures are only part of the solution to improving care. The Medicare Payment Advisory Commission, and others, have noted that the current payment system for dialysis services is fragmented. This system inhibits the systematic, coordinated steps that dialysis facilities must take if they are to make effective use of performance measures to improve the quality of care. To continue to make substantial improvements, the fragmented nature of the payment system may need to be addressed so that it creates incentives to provide high quality care.[14]

Revise the Medicare Conditions for Coverage for dialysis facilities.

CMS is now in the process of drafting revisions to the Medicare Conditions for Coverage, regulations that all dialysis facilities receiving Medicare payments must adhere to. In our June 2000 report, we emphasized that it was important to revise the Conditions so that they serve as a more effective foundation for accountability. We cited six specific changes that, at a minimum, should be part of the revision.[15] Our review of the lessons learned by the dialysis corporations adds compelling support for two of the changes we called for. We address them below.

Require facility medical directors to exert leadership in quality improvement.

The corporations have learned that if performance measures are to be used effectively at the facility level, someone at the facility must take the lead to ensure that the nurses, attending physicians, and the technicians are all attuned to quality improvements. The medical director, who typically serves as a member of the facility's governing body, is in the best position to fulfill this leadership role. Without medical directors being fully committed to and engaged with quality improvement activities, important opportunities for enhancing patient care are likely to be missed.

Recognition of the significance of medical director leadership is not limited to the major dialysis corporations. The Renal Physicians Association has issued a position paper on the responsibilities of the medical director that calls for them to ensure that all attending physicians comply with Federal requirements.[16] One of the End-Stage Renal Disease Networks, the TransPacific Renal Network, has adopted a set of standards for facility leadership that are modeled on those of the Joint Commission on Accreditation of Healthcare Organizations and cite the medical director as the final authority within the facility.[17] And the Texas Department of Health, with input from the End-Stage Renal Disease Network's medical board and the renal community, issued a set of standards that among other things calls for medical directors to attend monthly quality improvement meetings.[18]

The current Medicare Conditions do not explicitly require the medical director to take the lead in quality improvement. It is time for them to catch up with developments such as those noted above and to state explicitly that the medical director must play a leadership role in using performance measurements to stimulate quality improvements. While the Conditions need not spell out that role in great detail, they should make it clear that the medical director is expected, on an ongoing basis, to lead quality improvement efforts.

CMS should also address in the Conditions what medical directors are expected to do when a quality problem is attributable to an attending physician who is not performing adequately. CMS should make clear that medical directors have the authority to conduct and/or initiate peer review and to address performance problems through directed education efforts. And, for more serious situations where patients have been put at risk

because of poor care medical care, CMS should make clear the medical director's responsibility to report the physician to an authoritative body, such as the facility's governing board, End-Stage Renal Disease Network, and/or the State Medical Board.

Require dialysis facilities to conduct their own quality improvement projects.

To varying degrees, the corporations conduct regional or national quality improvement efforts. But each of them places the primary focus at the facility level. They look to their facilities to use performance measurement as a mechanism of constructive change. They look to the facilities to compare their performance scores over time and with other facilities and to ask: how can we do better? The main role for the regional or central corporate offices is to support such facility-based efforts.

CMS can give added impetus to such facility-based efforts by enacting a Medicare requirement that facilities undertake quality improvement efforts.[19] The requirement need not stipulate the type of efforts, but should call upon the facilities to draw on performance measures, as well as, other sources of information to improve the quality of care provided. This expectation should apply even for facilities that have comparatively high performance scores. All facilities, it seems reasonable to assume, can do better.

Such a mandate need not preclude national or regional quality improvement projects but the corporate experience suggests that they should be of lesser significance than those that are facility-specific. It is essential here to recognize that improvement efforts are an add-on to ongoing care responsibilities and that it can be difficult to garner sufficient attention to them. This is particularly true in the many facilities coping with staff shortages and high turnover rates. To the extent that CMS and/or the Networks call for facilities to participate in national or regional efforts, the facilities' readiness and capability to generate their own intrinsic efforts may be lessened. This is an important policy consideration that warrants attention.

Examine ways to foster the commitment of attending physicians to performance measures.

This is a complicated issue, but our review of the corporate experiences suggests that without addressing it, the potential of performance measurement will not be fully tapped. Attending physicians are the ones who determine the course of treatment, prescribe medications, and monitor the overall health of the dialysis patient. For a facility to achieve sustained progress in its performance improvement efforts, these physicians must become active participants in such efforts. They must see themselves not just as a patient's physician, but as a part of the facility's team responsible for the patient's care. And, just as the facility must be held accountable for the quality of the care provided, so too must the individual physician.

The key question is how can CMS best foster such accountability and commitment by the attending physician? Our review suggests three directions. One is for CMS and/or the Networks to provide educational forums for nephrologists that clearly convey the value of performance measures and their relevance to everyday care of the patient. Both CMS and the corporations have undertaken such efforts. Perhaps they could collaborate on what approaches work best and warrant more attention in the future.

A second direction is to consider generating physician-specific report cards. One Network, as we noted in a prior report, has been doing this since 1997.[20] Three times a year it generates a *Physician Activity Sheet* that compares the performance of individual physicians to their peers at the facility, State, and Network level and to clinical guidelines on several performance measures collected by the Network. Similarly, two of the dialysis corporations we contacted provide physician-specific report cards so that physicians can see how their performance compares with their peers. It strikes us that such efforts to drive down the data to the physician level can be an important way to draw attending physicians more fully into improvement efforts and to hold them more fully accountable for their performance.

A third direction is for CMS to more fully address the expectations of attending physicians to contribute to and be responsive to quality improvement efforts and, more generally, to provide care to their patients. It could be instructive to review the extent and kind of expectations now set forth by facilities and what effects they seem to have concerning performance improvement. For example, several of the corporations provide standards that all attending physicians must meet in their facility bylaws. No such standards now exist at the Federal level. CMS may want to consider revising the Conditions for Coverage to require facilities to have a credentialing process in place for all attending physicians similar to the Medicare standards in place for hospitals.[21]

Develop more effective intervention strategies for dialysis facilities.

CMS relies on two separate organizations to oversee dialysis facilities: the End-Stage Renal Disease Networks and the State Survey Agencies. Each has its own expertise and authorities. The Networks have clinical expertise as they are comprised of local renal physicians and nurses, and the States have regulatory authority to enforce Medicare regulations.

Networks, equipped with facility-specific data from CMS, can use the data to guide the types of regional quality improvement projects they conduct each year. They should also use the data to help focus training and technical assistance with the facilities in need of improvements. Similarly, Networks should use the data to identify the top performers in order to understand why they are successful and disseminate best practices. Finally, Networks can use the data to help conduct more targeted peer review and to identify facilities that need to develop formal plans for corrective actions.

States can use the facility-specific data they receive from CMS to help identify facilities to survey and to ask targeted questions once on site. We recognize that there is concern with the States taking the measures too literally and jumping to false conclusions. However, it seems reasonable that States should have performance data available to them, as one tool among many, that they can use to help inform the survey process.[22]

Furthermore, CMS may want to consider expanding the enforcement options available for facilities that fail to comply with the Conditions for Coverage. Currently, CMS has very few options, short of terminating the facility from the Medicare program, to sanction dialysis facilities. CMS affords a wide range of enforcement options for other health care facilities. For example, under certain circumstances CMS can deny Medicare payments to all new admissions for nursing homes with deficiencies.[23] CMS may want to consider a similar option for dialysis facilities.

Even though both these entities complement one another and at times overlap, we found in our June 2000 report that the States and the Networks rarely communicate. This breakdown can lead to ineffective interventions.[24] In order for the States and the Networks to be more effective in using performance measures and intervening based on them, CMS needs to find ways that they can work together in a coordinated fashion.

One Network and State already collaborate extensively.[25] However this model has not been replicated around the country. The two major barriers to greater collaboration are liability for Network staff and volunteer members when they conduct work outside their CMS contracts and privacy protection laws that prevent Networks from freely sharing data with other entities. CMS will need to address these issues first, in order for more collaboration to take place between the Networks and the States.

Work with the corporations to share experiences and minimize burden on dialysis facilities.

Traditionally, CMS and its agents, the States and the Networks, have not had much interaction with the dialysis corporations. Its focus has been on the licensed facilities, not the parent corporations. Yet, the parent corporations, like CMS, are also engaged in the external quality oversight of dialysis facilities. From different vantage points, the two have many of the same concerns. Our review suggests that it could be beneficial for both parties, and most importantly for the patients, for more collaboration and sharing to take place.

CMS has taken some efforts to foster collaboration. At a recent CMS-sponsored conference for the End-Stage Renal Disease Networks, a presentation entitled "Accountability Panel: Corporate Dialysis QI [Quality Improvement] Representatives" was held that gave Network and corporate representatives the opportunity to discuss their activities.[26] Out of this session several practical solutions arose to foster more

communication, such as sharing names of regional corporate contact persons and providing the corporations with a list of all Network quality improvement projects. CMS has also indicated that its new information system for dialysis facilities, the Vital Information System for Improvement of Outcomes in Nephrology, will contain software that will allow facilities to abstract data from their existing databases to submit to CMS. This is especially helpful for facilities owned by dialysis corporations that have their own data systems already in place to collect data. The new software will eliminate the need for these facilities to enter the data twice. In our interviews, corporate officials also indicated that they were open to the possibility of sharing facility-specific data with CMS. In addition, CMS has held several stakeholder meetings to solicit input from the larger renal community that included corporate representatives.

We encourage CMS to continue to broaden its interactions with the dialysis corporations especially by encouraging more of the type of dialogue described above at the recent CMS-sponsored conference. It may want to consider sponsoring more meetings that include dialysis corporations, Network representatives, government officials, and State surveyors. The meetings could focus on practical solutions to foster greater collaboration among all these parties. Another concrete step that CMS should take is to share all its facility-specific data reports directly with the relevant corporations.

COMMENTS

We received written comments on the draft report from CMS, Forum of End-Stage Renal Disease Networks (Forum), Renal Physicians Association, National Renal Administrators Association, and the five corporate dialysis providers that were the focus of our inquiry: Renal Care Group, Fresenius Medical Care, Davita, Gambro Healthcare, and Dialysis Clinic, Inc. Their comments were strongly supportive of the lessons we presented and of the thrust of the recommendations we made. We include the full text of the comments in appendix C. On the basis of the comments, we made a number of clarifications and technical changes. Below we summarize and respond to some of the points made concerning key issues in our reports.

Medical Director Leadership

CMS expressed support for our recommendation that the Medicare Conditions be revised to require facility medical directors to exert leadership in quality improvement. It indicated that it will consider how the Conditions might express such a requirement. Other respondents also expressed support, but some raised concerns about how leadership might be defined and how it might relate to real world situations. We recognize the dangers of defining leadership in too detailed a fashion. But our inquiry and the responses we received to the draft reports reinforce the importance of firmly establishing the medical director's leadership responsibility and authority concerning quality improvement activities in a facility. CMS should seek feedback from key stakeholders on how this leadership role can best be expressed in the revised Medicare Conditions.

CMS and others supported our recommendation that medical directors be given explicit authority to initiate or conduct peer review of attending physicians who are found to be performing inadequately and to address performance problems through directed education efforts. However, in the case of situations where patients have been put at risk because of poor medical care, CMS and others expressed reservations about our recommendation that CMS should make clear the medical director's responsibility to report the physician to an authoritative body, such as the facility's governing board, the End-Stage Renal Disease Network, and/or the State Medical Board.

We are disappointed by the lack of support for this recommendation. We clarify here that we are referring to serious situations where the poor performance of a physician has clearly put a patient or patients at risk. Physicians, as part of their own State licensure, are already obligated to make such referrals to State medical boards. CMS, in its contract with the Networks, calls upon them to refer such cases to the Medicare Peer Review Organization, the State medical board, or the Office of Inspector General.[27] It would seem to follow for CMS to reinforce this reporting responsibility for medical directors in its Medicare Conditions.

Quality Improvement Projects

Our recommendation here drew attention to the value of facility-specific quality improvement projects, without necessarily precluding national or regional projects. The CMS indicated that it will consider including a requirement for such facility-specific projects in the revised Medicare Conditions. One of the corporate providers reinforced the point that sound quality improvement projects can be initiated centrally (by a corporation or by CMS) as well as by a facility itself. Another provider expressed concern that by adding quality improvement projects to a State survey agency's checklist could undercut the intent by emphasizing process over results. It suggested that such projects only be required "as part of a corrective action plan relating to substandard clinical outcomes."

We recognize there is value in both centrally-driven and facility-driven quality improvement projects. We also recognize the danger that a Medicare requirement for facility specific projects (as exists for example for hospitals) could emphasize process at the expense of substance and could, if enforced too rigidly, be a burden for smaller facilities. We would urge that CMS reflect an awareness of these dangers in the Conditions and in its enforcement of them. However, we continue to believe that the quality improvement projects have relevance for all facilities, not just those showing substandard clinical outcomes. The latter approach would tend to characterize such projects as part of a compliance regime more than an improvement vehicle relevant to all facilities.

Securing the Commitment of Attending Physicians to Performance Measures

The importance of achieving the commitment of attending physicians and the difficulties experienced in obtaining it were recurrent themes that surfaced during our inquiry. We addressed the issue in our recommendations section by calling for CMS to pursue three directions. The first was to provide educational forums for nephrologists that convey the value of performance measures and their relevance to the everyday care of the patient. CMS and others who commented on this recommendation indicated support for such forums.

The second direction we called for was to generate physician-specific report cards, as is already being done by at least one End-Stage Renal Disease Network and two of the dialysis corporations we reviewed. CMS indicated that its information system can not provide physician-specific data at this time, but that it will consider this recommendation as it further develops its system. Other respondents were more clearly concerned about this direction, noting concerns about methodological, legal, financial and other problems. We recognize the difficulties that can be associated with such reports cards. But there is real-world experience that can be drawn upon in developing and using them. And, within the context that measures are indicators, not outright indicators of good or bad performance, it would seem that physician-specific reports can play a valuable role in ensuring attending physicians become more fully engaged in improvement efforts.

Finally, the third direction we noted is the most sensitive of the three. Here we suggested not only a credentialing process for attending physicians but a consideration of more explicit standards for the care provided by attending physicians. With the Medicare payment to attending physicians, what standards of care are they expected to provide? CMS indicated it would consider our credentialing suggestion. Others expressed concern. Our aim here is to foster attention to the expectations that CMS ought to have of attending physicians and to how these expectations might be expressed and enforced. We believe this is an important area warranting further attention by CMS, the medical community, and others.

Intervention Strategies

CMS supported our recommendation that it examine ways in which the Networks and State survey agencies can work together more effectively in overseeing dialysis facilities. Others also expressed support. With respect to our suggestion that CMS consider expanding the enforcement options available to it, CMS noted it statutory limitations and that it is currently developing generic alternative sanctions for all types of providers. The need for having a broader array of sanction options is one that has come up previously in our review of the dialysis facilities and that we believe warrants further attention by CMS.

APPENDIX A

Glossary of Clinical Performance Measures

Albumin: A measure of the level of proteins in the blood, used to monitor the level of nutrition.

Anemia: Inadequate red blood cells, a common concern among dialysis patients that can lead to extreme fatigue and other complications.

Catheter: A type of vascular access. A tube placed in a patient's blood vessel, primarily used for temporary access to the blood stream.

Clotting events: Arteriovenous fistulas, both native and synthetic, can become clotted with the patient's blood causing complications for the dialysis patient.

Creatinine clearance: A measure used to determine adequacy in peritoneal patients. Creatinine clearance measures the removal of the protein creatine from the body.

Ferritin level: A measure of the level of iron stored within the body.

Hematocrit: A measure of the ratio of red blood cells to the plasma volume. Used to monitor anemia.

Hemoglobin: A measure of the amount of a specific protein in red blood cells that carries oxygen. Used to monitor anemia.

KT/V: A function of the amount of urea removed multiplied by the time on dialysis, divided by the volume of urea distribution, or approximately the amount of water in the body. Used to monitor the adequacy of the dialysis treatment.

Native arteriovenous (AV) fistula. A type of vascular access. A patient's own artery and vein are surgically joined to allow arterial blood to flow through a vein, usually placed in the forearm and takes several weeks to mature.

Parathyroid: A hormone that regulates calcium and phosphorus and is used to monitor bone disease.

Peritonitis: An inflammation of the peritoneum, a membrane that lines the stomach, that can occur in individuals receiving peritoneal dialysis.

Synthetic arteriovenous (AV) graft: A type of vascular access. A synthetic blood vessel is used to surgically join the patient's artery and vein, usually placed in the forearm and takes several weeks to mature.

Transferrin saturation (TSAT): A measure of iron immediately available to produce red blood cells. Used to manage and monitor anemia in dialysis patients.

Urea reduction ratio (URR): A measure of the amount of urea removed during dialysis, as determined by pre- and post-dialysis blood urea nitrogen levels. Used to monitor the adequacy of dialysis treatment.

Vascular access: The point of direct access to the blood stream for hemodialysis. There are three types: catheter, native arteriovenous fistula, and synthetic arteriovenous graft.

APPENDIX B

Federal Sources of Clinical Performance Measures

Collection and Validation

Medicare Billing and Administrative Data. CMS collects several facility-specific clinical performance measures through billing and administrative forms. They are urea reduction ratio, hematocrit, mortality, transplantation, and hospitalization. Facilities typically submit billing forms electronically to the fiscal intermediaries that process the Medicare claims, and then send the data onto CMS. Facilities also submit three key administrative forms, typically on paper, to the Networks that contain information on patient demographics, mortality, and facility practices.[28] Networks enter the data into CMS' data system. The Networks review and edit the data received by the facilities. Eventually CMS intends to collect these data electronically through the Vital Information System for Improvement of Outcomes in Nephrology. The administrative forms are currently undergoing revisions, and as part of this process CMS has solicited comments from the renal community on what to collect to help ensure the data is clinically relevant.

CMS' Clinical Performance Measures Project. This project began in 1994 and underwent significant revisions in 1998. Currently, the project collects over 16 clinical performance measures through the End-Stage Renal Disease Networks on a national sample of Medicare beneficiaries each year. The measures include the KT/V, urea reduction ratio, serum albumin, and hemoglobin. Facilities submit the data by filling out paper forms that they mail to the Networks. Networks enter the data into CMS' data system. The Networks validate a sample of the data.

Currently these data are not facility-specific. But CMS has committed to collecting these measures on all patients, from all providers as soon as it is able to put into place its new information system, the Vital Information System for Improvement of Outcomes in Nephrology.[29] CMS expects to fully implement this system in the year 2002.

To ensure the measures are clinically relevant, CMS relies on the Quality Improvement Committee, which is comprised of renal professionals representing many disciplines. The committee provides technical assistance to CMS on how and what to collect from facilities. Following the committee's recommendations, CMS has moved towards collecting KT/V and hemoglobin, more sophisticated measures, instead of the urea reduction ratio and hematocrit.

End-Stage Renal Disease Network Data. Several Networks collect facility-specific data on various performance measures but this varies widely from Network to Network.

Of the Networks that collect this data, some collect the data on paper forms and some collect it electronically.

Centers for Disease Control and Prevention's (CDC) National Surveillance of Dialysis Associated Disease. This voluntary survey, started in the early 1970s by the Centers for Disease Control and Prevention, monitors infectious disease rates, such as hepatitis B, within facilities. It also collects facility-specific information on vaccination rates, vascular access, staffing ratios, and reuse of hemodialyzers.

Analysis and Dissemination

CMS' Dialysis Facility Compare Website. Launched in January 2001, this website provides comparative, facility-specific reports to the public that includes descriptive information about the facility as well as its performance on three key indicators: urea reduction ratio, hematocrit, and mortality. The reports compare the facility to the nation, its State, and other facilities in its region. The data used in these reports comes from Medicare billing and administrative data.

Annual Report ESRD Clinical Performance Measures Project. Since 1995, this annual report has been publicly available on the Internet and in paper. It provides aggregate data at the national and Network level on over 16 clinical performance measures. The data collection does not allow for facility-specific analysis.

United States Renal Data System (USRDS) Annual Data Report. The USRDS Coordinating Center, funded by the National Institutes of Health, compiles data from multiple data sources, most of which come from Medicare billing and administrative data. Each year, it generates and disseminates an annual data report that provides economic and epidemiological trends at the Network and national level. This report is publicly available in paper and on the Internet. It does not provide facility-specific data.

CMS' Unit-Specific Reports. Since 1995, CMS, through the End-Stage Renal Disease Networks, has distributed annually these reports that are available to facilities and Networks. These reports contain facility-specific data that compare a facility to its peers on several key performance measures: mortality, hospitalization, transplantation, urea reduction ratio, hematocrit, and vascular access. The majority of the data in these reports comes from Medicare billing and administrative data.

Facility Data Reports for State surveyors. Since July 2001, CMS has distributed facility-specific reports that contain comparative, facility-specific data on various performance measures for use by State survey agencies. The measures include: urea reduction ratio, hematocrit, vascular access, infection rates, hospitalization, and mortality.

These reports are not publicly available. The majority of the data in these reports comes from Medicare billing and administrative data as well as data from the CDC survey.

State Data Reports. In July 2001, CMS distributed the first State Data Report to State Survey Agencies that provides aggregate data on the performance of the State as a whole on key performance measures as well as compares the performance across all the States. These reports are not publicly available.

Various Network Reports. Some Networks disseminate facility-specific reports to their facilities. The frequency of these reports and the performance measures they contain vary from Network to Network. Typically these reports are not publicly available.

Interventions and Improvements

End-Stage Renal Disease Networks. Networks obtain and review facility-specific data from CMS in the form of the reports mentioned above and/or from their own data collection efforts. Networks conduct annual regional quality improvement projects that address topic areas identified through clinical performance measures. They also work with poorly performing facilities to develop action plans to improve their quality of care. If facilities are not performing in line with Network standards, the Networks can require them to develop and implement a corrective action plan.

State Survey Agencies. CMS provides States with facility-specific performance reports that can be used to select facilities for Medicare certification surveys and to help inform the survey process. If a facility is not in compliance with Medicare regulations, the State can recommend CMS take action against the facility such as terminating them from the Medicare program.

APPENDIX C

Comments

In this appendix, we present the full comments of all parties that responded to our draft report. In order, the comments are from the following parties:

- Centers for Medicare & Medicaid
- Davita
- Dialysis Clinic Inc.
- Fresenius Medical Care North America
- Gambro Healthcare
- Renal Care Group
- Forum of the End-Stage Renal Disease Networks
- Renal Physicians Association
- National Renal Administrators Association

APPENDIX C

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: DEC 26 2001

TO: Janet Rehnquist
Inspector General
Department of Health and Human Services

FROM: Thomas A. Scully
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Inspection Report: *OIG Draft Reports on Clinical Performance Measures for Dialysis Facilities (OEI-01-99-00052, OEI-01-99-00053, and OEI-01-99-00054)*

Thank you for the opportunity to comment on the above-referenced OIG draft inspection reports regarding the clinical performance measures used to hold facilities accountable for the quality of care provided to dialysis patients. The information you have provided in the related draft reports will be very useful to us as we strengthen our existing programs to collect facility-specific clinical performance measures for dialysis facilities. We look forward to receiving the final reports regarding the results of your ongoing reviews.

The OIG recommended that the Centers for Medicare & Medicaid Services (CMS) should:

- Revise the Conditions for Coverage for facilities so that they require medical directors to exert leadership in quality improvement and require facilities to conduct their own improvement projects;
- Examine ways to foster the commitment of the attending physicians to performance measures;
- Develop more effective intervention strategies for facilities experiencing performance problems; and
- Work with the corporations to share experiences and minimize data reporting burdens on facilities.

The CMS generally concurs with the OIG's recommendations. We do not agree, however, that the Conditions of Coverage should be revised to specify that the medical director should report attending physicians to an authoritative body. We also believe that our ability to expand sanctions is limited by statute and so we can not expand sanction options as the OIG

recommends. Our responses and technical comments regarding the reports' recommendations are outlined below.

Report #1 - *Building on the Experiences of the Dialysis Corporations (OEI-01-99-00052)*

OIG Recommendation

Revise the Medicare Conditions for Coverage of Dialysis Facilities and require facility medical directors to exert leadership in quality improvement. The CMS should also address in the Conditions what medical directors are expected to do when a quality problem is attributable to an attending physician who is not performing adequately. It should make clear that: (1) medical directors have the authority to conduct peer review and to address performance problems though directed education, and (2) for more serious situations, it is the medical director's responsibility to report the physician to an authoritative body, such as the End-Stage Renal Disease (ESRD) Network and/or the state medical board.

CMS Response

CMS staff is looking at the regulatory requirements for medical directors and their role in providing leadership in quality improvement as recommended in the June 2000 OIG report. We agree to the extent that the proposed and final ESRD Conditions for Coverage require a medical director, the medical director should have a role in peer review and providing education on quality improvement. This aspect of the quality improvement recommendation will be considered in the revision of the ESRD conditions for coverage.

We believe the requirement for the medical director to report attending physicians for quality problems undermines your recommendation that the medical director function in a peer review and education role for the purposes of quality improvement. We support the philosophy that medical directors serve in a collegial continuous quality improvement role. The idea that a medical director should serve as an enforcer for "non-performing physicians" is in direct contrast to this philosophy. CMS has structured both the Peer Review Organizations and ESRD Network programs to function as quality partners with the provider community. In fact, the collegial quality improvement role is what has made the ESRD Networks so successful in assisting the ESRD facilities to improve outcomes for dialysis patients. Our goal is to encourage sound medical practice and develop quality standards relating to quality patient care. Medical directors and ESRD Networks should function in that capacity and not be placed in a competing role of enforcer vs quality improvement agent.

Lastly, the conditions of participation/coverage for other providers and suppliers do not place the medical directors with responsibility to report physicians to an authoritative body.

OIG Recommendation
Require dialysis facilities to conduct their own quality improvement projects.

CMS Response
This OIG recommendation will be considered in the revision of the ESRD Conditions for Coverage.

OIG Recommendation
Examine ways to foster the commitment of attending physicians to performance measures: Provide educational forums for nephrologists that convey the value of performance measures.

CMS Response
The CMS will encourage networks to provide educational forums for nephrologists on the value of performance measures. We will also continue to encourage dialogues between the networks and corporations so they can collaborate on what approaches will best reach the nephrology community.

OIG Recommendation
Generate physician-specific report cards.

CMS Response
Currently, physician specific data is not available. The CMS will take this recommendation under consideration in the development of vital information system to improve outcomes in nephrology (VISION).

OIG Recommendation
Consider requiring facilities to have a credentialing process for attending physicians.

CMS Response
This OIG recommendation will be considered in the revision of the ESRD Conditions for Coverage.

OIG Recommendation
Develop more effective intervention strategies for dialysis facilities.

CMS Response
The CMS plans to focus on exploring ways networks and state survey agencies can work together to coordinate efforts to improve care given in dialysis facilities.

OIG Recommendation
The CMS may want to consider expanding the sanction options available for dialysis facilities that fail to comply with the Conditions for Coverage. Currently, states have very few options, short of terminating the facility from the Medicare program, to sanction dialysis facilities. It may want to consider seeking the authority to deny Medicare payments to new admissions at facilities that fail to meet Medicare conditions.

CMS Response

The CMS authority in this area is limited by statute. Section 1881(c)(3) of the Act authorizes CMS to deny payments for new admissions or impose other alternative sanctions when the facility has failed to cooperate with ESRD network plans and goals, provided that such failure has not jeopardized patient health or safety. In addition, under section 1881(g)(1) of the Act, CMS may deny payment for new admissions if a facility's failure to comply with other conditions of participation has not jeopardized patient health and safety. Section 1881(f)(7)(C) of the Act calls for the denial of payment for those treatments not furnished in compliance with established protocols for the reuse of dialyers and bloodlines. Currently, CMS regulations authorize the imposition of alternative sanctions only in the case of a facility that has failed to cooperate with ESRD network plans and goals. The CMS is currently developing generic alternative sanctions for all types of providers.

OIG Recommendation

Work with corporations to share experiences and minimize burden on dialysis facilities.

CMS Response

We agree that CMS should consider ways to interact with the dialysis chains to share experiences and information. We agree that CMS should consider sponsoring more meetings with dialysis corporations, network representatives, government officials, and state surveyors.

Technical Comments

Page 1 - Third paragraph states that the five largest dialysis corporations account for three-fourths of all dialysis patients in the United States. Using the figures from the article cited, the top 5 chains account for 67 percent of the dialysis patients, and the top 10 chains account for about 70 percent of the patients.

Page 2 - Corporate Practices – Table 1. Albumin under the CMS column should be footnoted that it is only collected on incident patients. (The Dialysis Unit Specific Report only reports the serum albumin that is included on the Medical Evidence Form. This form is only completed when a patient is first diagnosed with ESRD.) The CMS column reflects those indicators reported in the Unit-Specific reports, Facility Data reports, and state-specific reports. The CMS funds the production of the Unit-Specific reports, the Facility Data reports, and the State-Specific reports by the University of Michigan Kidney Epidemiology and Cost Center (UMKECC).

Page 5 - The first full sentence states that ESRD medical directors lack the authority to take independent action concerning patients attended to by other physicians. In footnote 5, OIG supports its assertion by citing a 1998 letter in which CMS stated that ESRD regulations "do not explicitly empower a physician-director with the authority to take independent action with respect to patients attended by other physicians." While it is true that CMS ESRD regulations do not address that issue, this statement incorrectly implies that medical directors have no such authority in the absence of a specific statutory or regulatory authorization. Accordingly, the statement on page 5 and the corresponding footnote should be deleted. Alternatively, the report should be revised to recognize that medical directors may take "independent action" (which can encompass a number of options) in the absence of explicit statutory or regulatory authority.

Page 13 - The last sentence of footnote 6 incorrectly states that the main mission of ESRD networks is to ensure effective and efficient administration of ESRD Medicare benefits. This sentence should be deleted or revised to more accurately list the purposes of ESRD networks as set forth in section 1881(c)(2) of the Act.

Page 13 - The citation for footnote 12 should be changed to 42 CFR 488.408(d)(1)(i).

Report #2 - *Clinical Performance Measures for Dialysis Facilities Practices of the Major Dialysis Corporations, Supplemental Report # 1 (OEI-01-99-00053)*

The following are technical comments on this report:

Page 2 – The second paragraph states that the three administrative data forms that CMS collects from facilities contain key performance measures. Actually they do not contain key performance measures. The 2728 Medical Evidence form only requires patient laboratory values that are from blood tests drawn within 45 days prior to the first dialysis treatment or transplant. The 2744 Facility Survey form requires patient modality and census information. The 2746 Death Notification form requires cause of death type of information pertaining to a dialysis patient who has died.

Page 2 – In the third paragraph, we recommend that the first sentence be corrected to say, "Since 1995, CMS, via the ESRD networks, has distributed Unit-Specific reports that provide comparative, facility-specific data, which include mortality rates and hospitalization rates. Facility-specific urea reduction ratio and hematocrit levels were added to the reports after 1998." (The CMS does not receive copies of the Unit-Specific reports and does not directly distribute these reports to the facilities.)

Page 15 - The last sentence of footnote 3 should be deleted or revised as set forth above for identical text in footnote 6 on page 13 of the main report.

Appendix B – Same technical comment as CMS made above for page 2, table 1 in the main report regarding a footnote to the albumin level.

Report #3 - *Clinical Performance Measures for Dialysis Facilities Lessons Learned by the Major Dialysis Corporations and Implications for Medicare Supplemental Report #2 (OEI-01-99-00054).*

The CMS's comments to the recommendations in this report are the same as listed under the first report (#1) above – both reports list the same recommendations.

APPENDIX C

Page 6 – Janet Rehnquist

Technical Comments

Page 2 – The second paragraph states that the three administrative data forms that CMS collects from facilities contain key performance measures. Actually they do not contain key performance measures. The 2728 Medical Evidence form only requires patient laboratory values that are from blood tests drawn within 45 days prior to the first dialysis treatment or transplant. The 2744 Facility Survey form requires patient modality and census information. The 2746 Death Notification form requires cause of death type of information pertaining to a dialysis patient who has died.

Page 2 – In the third paragraph, we recommend that the first sentence be corrected to say, "Since 1995, CMS, via the ESRD Networks, has distributed Unit-Specific reports that provide comparative, facility-specific data, which include mortality rates and hospitalization rates. Facility-specific urea reduction ratio and hematocrit levels were added to the reports after 1998. The CMS does not receive copies of the Unit-Specific reports and does not directly distribute these reports to the facilities.

Page 3, paragraph 3, Lessons Learned – To say that state survey agencies use these reports "to assist in selecting" facilities for review is more accurate than to use the term "target."

Page 6 – The second paragraph states that the medical director should, where necessary, intervene with individual physicians or nurses whose performance may be adversely affecting the facility's overall performance. Typically the medical director will address nursing concerns to the facility nurse manager of director of nursing, who is the appropriate person who should intervene with an individual nurse.

Pages 6&7 - The last sentence on page 6, which continues on to page 7, states that ESRD medical directors lack the authority to take independent action concerning patients attended to by other physicians. This sentence and the related footnote number 11 on page 23 should be modified as set forth above in the comment regarding identical text on page 5 of the first report.

Page 9 – The first paragraph states, "For example, the urea reduction ratio can be derived several different ways." The urea reduction ratio is a simple ratio (or a percentage) of the post-dialysis blood urea nitrogen to the pre-dialysis blood urea nitrogen. It can be derived or calculated in only one way. It is how the post-dialysis blood sample is drawn that can provide a more favorable ratio or urea reduction ratio. The KT/V calculation can be done using a variety of calculations.

Page 20, Appendix B – The CMS's Dialysis Compare Web site. The correct name of the Web site is "Dialysis Facility Compare (DFC)." Also, the term "mortality" is not used on the Web site. "Patient survival" is the name of the measure displayed on the DFC Website.

Page 20, Appendix B – The CMS's Unit-Specific reports. Correct the first sentence to read "Since 1995, CMS, through the ESRD networks, has distributed these reports to the dialysis facilities annually." We recommend that the following be added to the end of this paragraph: "The CMS funds the production of the Unit Specific reports by UMKECC for the ESRD

networks. The networks receive these reports directly from UMKECC and distribute them to the dialysis facilities."

Page 22 - The last sentence of footnote 3 should be deleted or revised as set forth above for identical text in footnote 6 on page 13 of the main report.

Page 24 - The citation for footnote 22 should be changed to 42CFR 488.408(d)(1)(i).

APPENDIX C

DaVita™

Office of the Chief Medical Officer
4749 Grand Boulevard
New Port Richey, FL 34652
Tel: (727) 844-0891
Fax: (727) 844-3093
www.davita.com

November 18, 2001

Janet Rehnquist
Inspector General
Room 5246 Cohen Blvd
3301 Independence Ave. SW
Washington DC 20201

Dear Mrs. Rehnquist:

The teammates of DaVita congratulate you on the tone of your report. Please find enclosed some comments relating to the content. I do believe that there is a significant opportunity for the Dialysis Providers to work with CMS in improving overall quality. As you can see from the report the large Providers already have made a significant investment in our Quality Programs. All of these programs are an additional expense for which there is no reimbursement.

DaVita comments below:

- Page 4-paragraph 1: There is appears to be an assumption that inevitably the patients of the Medical Director comprise the majority of patients in the Dialysis Facility. There are many situations in our company where this is not the case. It also ties together the two when the thrust is to empower the Medical Directors to influence the quality of care in a more active manner. It also creates an association that may be misunderstood.

- Page iii "To exert leadership" is too broad without defining specifically the leadership role of the Medical Director as we have done in our "Medical Director Roles and Responsibilities"

- On page 5 in the first paragraph of the insert box-I would recommend that the last 6 lines be deleted which relate to the first bullet point on the number of patients of the Medical Director

- On page 5 second paragraph last two lines: this revocation of an Attending Privileges can occur if a mechanism is supplied in the Facility By-laws and the Role of Attending MD's is clearly delineated as we did in our Attending MD document

- Page 9-lesson 7: believe that more emphasis be placed on the diversity of data collection –particularly the exclusions used by the various companies

- Page 12-last 3 lines- This statement is too broad and premature giving diversity of data collection and lack of consensus on what describes "Quality of Care"

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Office of the Chief Medical Officer
4749 Grand Boulevard
New Port Richey, FL 34652
Tel: (727) 844-0891
Fax: (727) 844-3093
www.davita.com

- Page 14-line 3: the reference to reporting the Physician to the "State Medical Board" places an undue administrative burden on the company.-
- Page 15 revising of conditions of coverage regarding Credentialing – this report did not cover our present Credentialing processes and is out of the scope of work
- Page 9 paragraph 3: I would add a 3rd option "that the providers may develop their own system of corrective actions. DaVita has done so.
- Page 11: the process of sharing information should not place an added burden on the Providers-we already collect a large body of data that can be shared rather than requiring a new format

Overall we are grateful for the time you have spent with us to understand all of our quality improvement initiatives. We at DaVita are excited for the opportunity to work with other Providers and CMS to improve the care of Dialysis Patients throughout the United States.

Sincerely,

Charles J McAllister MD FACP
Chief Medical Officer

APPENDIX C

DIALYSIS CLINIC, INC.

A Non-Profit Corporation

1633 Church Street
Suite 500
Nashville, TN 37203
Phone: (615) 327-3061
Fax: (615) 329-2513

RESPONSE TO OIG REPORT

DCI is pleased to have the opportunity to comment upon the report concerning Clinical Performance Measures for Dialysis Facilities which was researched and authored by the Office of the Inspector General.

In general, the report outlines accurately the lessons that DCI has learned as to an effective approach to monitor and improve upon the quality of care in a dialysis facility. As outlined, critical to this effort is a mechanism to collect, collate and disseminate process and outcome data concerning the patients being treated, i.e., an effective medical information system. The importance of setting attainable clinical performance targets and putting in place, where needed, the procedural structure to allow their attainment has also been appropriately stressed in the report. Finally, the critical importance of the unit's medical director taking an active leadership role in both marshalling the staff of the dialysis facility, as well as gaining support and commitment of the unit" other attending physicians to achieve the clinical targets, is well laid out in the report.

What is not mentioned in the report, yet we believe should be, is the issue of "non-funded mandates." Since the inception of Medicare funding for the treatment of renal failure, the reimbursement for dialysis has continually eroded, even as the cost for providing this care has increased. One author has estimated that, adjusted for inflation, the composite rate has declined by about 64% since 1973. {Eggers} In fact, at DCI, our cost of providing dialysis care significantly exceeds the average composite rate for the areas in which our units are located. In many units, it has become a scramble to maintain viability by relying on non-Medicare payers to make up the difference, especially as our options in this area are becoming increasingly limited. Thus, any additional financial burden for these dialysis units adds to the economic stress, which is already being felt. We believe that it is important therefore, when considering mandated reporting or other mandated procedures within the dialysis unit, that the cost of these procedures be assessed and measures be considered to cover these costs. We believe that further financial pressure placed upon dialysis units carries the strong likelihood of resulting in erosion of, rather than the improved quality of care that we all desire.

Fresenius Medical Care

November 5, 2001

HHS/Office of Inspector General
Room 5246 Cohen Building
330 Independence Avenue, SW
Washington, DC 20201

Dear Sirs:

These comments summarize my review of the three draft inspection reports on how the five major dialysis corporations use clinical performance measures to hold facilities accountable for quality of care. In summary, I thought the report was even-handed, evaluated appropriate issues and, with a few exceptions, reflected the processes carried out by Fresenius Medical Care North America and, to my knowledge, our four competitors.

A. **Collecting and Using Facility-Specific Clinical Performance Measures**

There is information in Table II which I believe may be misleading and overstates the processes of monitoring carried out by the chain facilities. Table II compares the dialysis corporation practices in collecting and using facility-specific clinical performance measures. I believe the chart to be incorrect since I am unable to identify our own company, Fresenius Medical Care North America, from the information provided.

Several of the parameters in the left column are not clear in their meaning. For instance, in row #1 "Years of experience in collecting facility-specific performance measures" is not sufficiently explicit. Fresenius Medical Care commenced business in 1969 as NMC, and has collected and monitored clinical information since 1979. Reports of our results were presented in abstract form at the ASAIO in 1981. We began our Patient Statistical Profile reports (paper reports to facilities) in 1984 and subsequently provided this information to facilities electronically in 1989. DCI was incorporated in 1971 and to my knowledge had no electronic reporting system as of 1996. It is unknown to me what their clinical information distribution system was before then. Gambro resulted from sequential mergers of Community Dialysis Centers, REN and Vivra. Community Dialysis Centers is registered as commencing business in 1969, but it is not apparent when facility-specific clinical information was collected in their evolution. The first known information system originated with REN. DaVita resulted from a name change from TRC which had merged with RTC in 1996. These companies came into existence in 1979. RCG commenced business in 1994.

Fresenius Medical Care North America
Corporate Headquarters 95 Hayden Avenue Lexington

Fresenius Medical Care

What evidence is there that these companies collected and distributed facility-specific performance measures in their early existence? The information on facility-specific performance measures may be misleading, depending upon whether the authors of this report intend to refer to "hard copy" retrieval, analysis and distribution, or electronic retrieval and distribution of performance measures. Moreover, general clinical information was collected in earlier years, but it was not until the 1990s that "performance measures" were used. Thus, I believe the number of years stated in this column for some of the companies is misleading. The meaning of the column should be more specific and the companies should provide evidence of providing the defined activity.

The third column down "Data collected electronically from dialysis machines" is not specific. Fresenius Medical Care has several clinics that download dialysis treatment information, but only on a pilot basis. It is not routinely carried out in all facilities in our company. To my knowledge none of the companies has a dialysis delivery system that will routinely download all dialysis treatment parameters electronically in all facilities. Some may download certain specific data points. The amount of information available by this process at this time is likely not valuable in assessing and/or affecting facility performance. Similarly, in the columns "Frequency of data collection" and "Age of data by time disseminated" – different data are collected at different intervals; laboratory reports are collected on a daily basis at FMC and some, but not all, clinical information is collected on a per treatment basis. Other information is collected on a monthly basis. I believe this column is not clear in its meaning.

So, as to not exaggerate the capabilities of the chain facilities, I believe the parameters in this chart should be more clearly defined and the capabilities of each of the companies verified.

B. **Building on the Experience of the Dialysis Corporations**

Pages i and 9 – The report recommends that revised conditions for coverage of ESRD facilities require such facilities to conduct quality improvement projects. While we agree with this recommendation in concept—and impose a similar requirement on our own facilities—we question the effectiveness of making this a specific survey requirement. In practice, quality improvement projects are most effective when internally generated to achieve objectively established performance or outcome goals. We fear that adding a new requirement to the surveyors' "checklist" will subvert the laudable intentions of the proposal by emphasizing "process" over "results." A better approach would be to "encourage" facilities to conduct quality improvement projects as part of an overall quality outcomes management program, and only "require" that such projects be undertaken as part of a corrective action plan relating to substandard clinical outcomes.

Fresenius Medical Care

C. **Practices of the Major Dialysis Corporations**

Page 2 – The report notes that CMS is drafting new conditions for coverage (Subpart U) for dialysis facilities. To date, CMS staff have declined requests to discuss possible revisions or to engage in meaningful dialogue with industry representatives on this important topic. Elsewhere in your report, you urge greater cooperation and communication between CMS and the dialysis industry on quality improvement. We request that you broaden these recommendations to include a specific request that CMS consult with the dialysis industry in the development of revisions to Subpart U.

Page 2 – The report notes that CMS has distributed Unit-Specific Reports to dialysis facilities since 1995. We, as well as other chains, have requested that data for units owned or managed by a chain provider be furnished electronically to the corporate Medical Director of that chain provider for analysis. To date, not all of the networks have been willing to cooperate with these requests. We urge you to include a specific recommendation to CMS to direct the networks to make Unit-Specific Report data available, upon request, to corporate Medical Directors in electronic form.

Page 12 – We concur with your findings that the correct payment system for dialysis services is fragmented and must be reformed to create proper incentives for high quality care.

Sincerely,

J. Michael Lazarus, M.D.
Medical Director and
Senior Vice President of
Clinical Quality

JML/kr

xc: Aimée L. Golbitz
✓Norman J. Han
John Markus
Mark R. Yessian, Ph.D.

-3-

APPENDIX C

GAMBRO Healthcare

Scientific Affairs & Clinical Research
3951 SW 30th Avenue
Fort Lauderdale, FL 33312
USA

www.gambro.com

Tel 954 585 1123
Fax 954 585 1224

November 19, 2001

Janet Rehnquist, Esq
Inspector General
Office of the Inspector General
Room 5246
Cohen Building
3301 Independence Ave., SW
Washington DC 20201

Dear Ms Rehnquist,

Thank you for the opportunity to comment on the three reports of the Office of Inspector General (OIG) entitled:-

Clinical Performance Measures from Dialysis Facilities

1. Building on the Experiences of the Dialysis Corporations
2. Practices of the Major Dialysis Corporations
3. Lessons Learned by the Major Dialysis Corporations and Implications for Medicare

Senior executives and representatives from our Medical Advisory Board had the opportunity to interact with the OIG staff and express views, which are ably represented in each of the three reports. Each of the reports is well researched and the OIG should be commended on the conclusions reached and the recommendations detailed in the reports. These reports continue the efforts by the CMMS and OIG to improve the quality of care for dialysis patients and we welcome the opportunity to comment on the reports. We found each of the reports to be sufficiently detailed and perceptive to support the recommendations outlined in the first report, although we urge the OIG to include representation from the major dialysis corporations in developing a plan for their implementation.

We support the recommendation that the Conditions of Coverage must be strengthened and an important part of their strengthening involves holding facility medical directors accountable for exerting leadership in quality improvement through the implementation of programs at the facility level. From the corporate perspective we have followed this same process providing our facility medical directors with outcome performance data that compares their patient outcomes with their peers in the same region and rolling up the comparison to the geographic divisions and the corporation. Through access to the CMMS Internet website, it is now possible for medical directors

and consumers to compare their dialysis facility with other non-corporation facilities in a limited number of outcome benchmarks. The point that we want to stress is that facility-specific outcome data for comparison between facilities is available through the programs introduced by the major dialysis corporations in addition to that introduced by CMMS and the ESRD Network's role in quality improvement programs is well established.

There are, however, important considerations and shortfalls that the OIG should be made aware of if medical directors are to be held accountable for their outcomes relative to their peers. Several of these were detailed in the first report under "Lessons Learned by the Corporations" and we agree with all of the impediments to progress outlined in this section. In addition we would want to recognize that the outcome data is not adjusted for patient acuity, geographic region including urban versus non-urban locations, or differences in demographic variables, all of which influence outcomes. These important considerations need addressing to ensure that the system is fair and equitable if physicians and facilities are to be rewarded or censured for outcomes. Additionally it is difficult to hold any medical professional accountable for performance outcomes if there is a lack of consensus on the value of the outcome relative to other outcomes. An example of this might be the importance of achieving a KT/V of greater that 1.4 when there is no clear evidence that the patient benefits from a KT/V >1.2; or are dialysis adequacy benchmarks more important than anemia benchmarks or nutritional benchmarks. There is even a lack of consensus on whether the benchmarks themselves have been selected wisely and the best example of this is serum albumin that initially was thought to be the ideal benchmark for nutrition but has more recently been shown to reflect inflammation rather than nutritional status. Our own studies, and those of others suggest a hierarchy of importance in terms of the individual benchmarks predicting mortality and morbidity. Such a hierarchy should become the basis of an evidence-based approach to developing a balanced scorecard of outcome performance goals for facilities and medical directors.

Our corporation does have a large number of attending physicians who administer care to patients in our facilities. They are subject to a set of by-laws that address expectations by the Governing Body of the facility. The Medical director is part of the Governing Body and often the Chairperson of the Governing Body. This table of organization provides for oversight and peer review of the performance of attending physicians within our facilities. We agree with the findings in the report that attending physicians are not always drawn to facility based performance measures because of the location of their patients in different facilities. The general consensus of our attending physicians is that they would support physician-specific outcome reports and we commend the OIG for recognizing this issue as part of the recommendations. In regard to data relevance, minimum performance goals, definitions of them and timeliness of the data we applaud the OIG for the opinions included in that section. While we agree that a broad set of measures should be collected we do strongly urge the OIG and CMMS to include data collected from patients such as Health Related Quality of Life (HRQL) measures and Patient Satisfaction (PS) questionnaires. Such data has been shown to have important predictive power in terms of the patient's perspective on the modality prescribed and in HRQOL relationships with depression and mortality.

Intervention strategies to correct underperformance should be approached with careful thought and we agree with the report that such issues as confidentiality and liability must be included in the process to ensure cooperation and success. The movement of dialysis facilities from academic institutions into the community has removed such facilities from the checks-and–balances that

have been the hallmark of good medical practice. Such checks-and-balances include peer review at daily medical rounds, mortality and morbidity conferences, infection control committee reports and pharmacy committee reports to name a few. Such programs provide guidance and support on a daily basis to physicians practicing in academic institutions but are missing in the outpatient community dialysis facility. We are unsure if quality can be improved by adopting an inspection/discipline philosophy for the simple reason that the majority of physicians strive for good outcomes and the business success of the corporation is dependant upon low mortality and controlling morbidity. This is not to suggest that a facility that consistently shows a significant deviation (2SD) from the mean should not attract sanctions but rather suggest a reward program for facilities or physicians that consistently exceed expectations in a broad set of performance guidelines that include such diverse areas as HRQOL, PS, management of depression, staff turnover, reduction in the variability in outcomes (e.g. SD of Kt/V), access to transplantation and rehabilitation in addition to medical outcomes as judged by laboratory parameters and clinical issues (vascular access). Our own studies have documented the issues surrounding poor pre-dialysis care that has a tremendous impact on facility and physician outcomes suggesting that prevalent outcome data should be separated from incident outcome data.

We applaud the recommendation that dialysis corporations share outcome data and there have been significant improvements in the cooperation between executives, physicians, healthcare workers and quality managers in learning from each other by sharing experiences. As the revenue stream to physicians practicing nephrology has shown significant reductions in recent years their patient load has increased. Often our attending physicians have patients in dialysis facilities owned by competing corporations. The point we want to make here is that there are no revolutionary processes or disease management strategies by one corporation that exceed that of another and if there were it would soon be known by all. What is needed is an independent party who can sponsor meetings and information exchange so any better way of delivering care can be shared by all and we support that approach detailed in the recommendations. The CMMS would be an ideal group to initiate such an approach. In addition, the CMMS might afford themselves of an ideal opportunity to gain insight into the large number of patients on dialysis that they will inherit because they belong to commercial payers of their healthcare and are in the first three years of dialysis care.

In conclusion, we wish to extend our sincere thanks for the opportunity to comment on these three important reviews of the practices and lessons learned by our corporation and others in our endeavor to improve the lives of patients on dialysis. We respect very much the trust that our patients place in our ability to provide them with the very best of care and we also respect the trust that the taxpaying public has in us spending their money wisely to take care of their fellow Americans with end stage renal disease.

Sincerely,

Juan P. Bosch, MD
Chief Medical Officer
Gambro healthcare

Brian A. J. Walters, PhD, CLD.
VP Scientific Affairs & Clinical Research
Gambro Healthcare

3

Renal Care Group

GENERAL COMMENTS

The report "Clinical Performance Measures for Dialysis Facilities—Building on the Experiences of the Dialysis Corporation" (OEI-01-99-00052) accurately reflects the direction our company, Renal Care Group, is actively engaged in as it relates to improvement of process and patient outcomes in the facility and its relationship with its Medical Directors. We are also very appreciative and comfortable with the overall tone and content.

Within that context, we wish to offer the following suggestions:

1. Page 4, 1st paragraph – The assumption that Medical Directors "typically account for the majority of facility's patients" has implications that we wish CMS would not move toward. In the first place, there are many examples of facilities where the Medical Director has a minority of the patients; second, to state the issue as a conflict of having both direct physician-patient relationships and Medical Director responsibilities starts to blur the very clear line of distinction we believe it important CMS and the internal and external reviewers need to establish. Otherwise, the implication would be that corporate or CMS attempts to improve facility outcomes would necessarily interfere in the physician-patient relationship.

2. Page 4 – The requirements of Medical Director contracts spelling out leadership responsibilities: Although leadership is the essence of what corporations look for in Medical Directors, the term "leadership" is subjective and a difficult term to define or enforce; our preference would be to edit this into a term that moves toward "documented involvement" or "documented leadership" rather than language defining leadership.

3. Page 5 under Lesson 2 – The last paragraph suggests that facilities send reports to physicians of their individual performance. This should not, in our view, substitute for the responsibility of the Medical Director and facility for overall clinical performance outcomes. The Medical Director interaction with the primary care nephrologist (i.e. attending) should go beyond sending him or her such reports. The Medical Director should be empowered to require certain standards of care from all attendings in the facility.

4. Page 9 – Requiring facility Medical Directors to exert leadership in quality improvement: We do not think that a mandate for leadership is an easily accomplished government oversight responsibility and may be too vague; rather a documentation of involvement is a more rational requirement. The paragraph following requires Medical Directors to have the authority to conduct peer review. We would prefer that the Medical Directors have the authority to initiate peer review. As independent contractors, if they are conducting peer review, the process may not be privileged or confidential and may be open to discovery—an outcome that will result in an adversarial process.

5. Page 9, Section 2 – The Medical Director responsibility to report to an authoritative body: Under the present conditions of coverage, this would be a responsibility of the Governing Body, who determines the proper action. These two paragraphs mix the role of Medical Director and the Governing Body. Having stated this; we must add that the role of the facility Governing Body is an outdated concept in the context of provider ownership of a large number of facilities.

We wish that the report direct CMS to review the utility and relevance of Governing bodies of dialysis facilities to the current context.

6. In requiring the dialysis facilities to conduct their own quality improvement projects, the report suggests that this should be primarily or exclusively facility-related. We wish to add that CQI can be driven from either the specific facility or an overall corporate goal (for example, % of patients meeting a certain target) and often it can be both. I believe the language of the report should state that there is a requirement for a CQI process in some form to be underway in the facility.

7. Page 10 – Examine ways to foster the commitment of attending physicians to performance measures: This needs to be within a peer review process. The individual MD report cards is something that may or may not be the direction that we want to have for the physicians referring to us if they become concerned that this is going to be subject to an easy discovery. It is much safer to quantitate the facility's outcome, provide it to the Medical Director, and expect his/her active (documented) involvement in the improvement process. (Elsewhere, we refer to the expectation that the Medical Director be empowered to set the quality standards for all physicians admitting to the facility.)

Minor Comments and Corrections

(Based on the assumption that Renal Care Group is the company identified as Company #5)

1. Pg 2: Renal Care Group appears to be "Company #5." Add a checkmark in the table for Renal Care Group (Company #5), for the item of Hemoglobin measurement.

2. Pg 3: For Company #5, "frequency of dissemination of facility-specific performance reports" should be monthly, rather than quarterly. All facilities have their own data on a monthly basis, but we share with them market, regional, and company-wide data on a quarterly basis.

3. Pg 6, Lesson #5: "For example, one corporation established its target value for Kt/V… at 1.4, and further established that 90 percent of the patients within a facility should meet that target." If this refers to RCG, the target is 85%, rather than 90%. Otherwise, leave as is.

4. Pg 7, Line #2 (Lesson #8): "some corporations have built in automatic data edits into their computer software programs." Change the word "edits" to "audits," since the word "edit" implies that the software automatically changes data values, which is not the case. The software can do automatic audits (not edits), and then the quality assurance officer reviews the audits and initiates any changes to the data after corroboration with the facility.

5. Pg 8, Lesson #13: Although meeting performance standards are important, there is no mention of the value of an improvement trend. Please add a comment that for clinics with performance that does not meet a standard, evidence of a clear improvement trend is regarded as good performance, with meeting the standard as an ultimate target.

6. Pg 9, Paragraph 3: For attending physicians with poor performance, two actions are outlined. Please add a 3rd option that the providers may develop their own system of corrective actions.

7. Pg 10, Paragraph 1: Physician report cards are discussed. (Please see comments above about the potential discovery process.) In addition, not all providers have the capability of producing physician report cards, and this would add to the burden of data collection and the need for enhanced information systems. Funding is needed for these types of intervention to cover cost of staff time to collect data, and information systems to house and report on the data, etc.

8. Pg 11: Suggestions for more collaboration and sharing of information between ESRD providers and CMS would be beneficial. Nevertheless, we must insist that this process does not increase the data collection burden on the dialysis facilities/providers. The burden is already very high, and a large body of data is already being gathered that could be shared, rather than collecting new information, or collecting information in a different way.

APPENDIX C

FORUM OF END STAGE RENAL DISEASE NETWORKS

November 12, 2001

Janet Rehnquist
Inspector General
Department of Health and Human Services
Office of the Inspector General
Room 5246 Cohen Building
330 Independence Avenue, SW
Washington, DC 20201

Dear Madam:

The Forum of ESRD Networks appreciates the opportunity to review the reports from the Office of Inspector General, Clinical Performance Measures for Dialysis Facilities: Building on the Experiences of the Dialysis Corporations (OEI-0199-00052), Practices of the Major Dialysis Corporations, Supplemental Report #1 (OEI-01-99-00053), and Lessons Learned by the Major Dialysis Corporations and Implications for Medicare, Supplemental Report #2 (OEI – 01-99-00054). A team of reviewers, which included Network Executive Directors, nephrologists, Network Chairs, and Chairs of Medical Review Boards, reviewed the reports.

We found these reports to be focused, accurate and well reasoned. We agree with the overall conclusions of the reports, and with the recommendations to Medicare. We wish to make some specific comments and recommendations:

I. We lend our strong support to several lessons and recommendations:

- The authority of the Medical Director must be strengthened, particularly to effect quality improvement in facilities. A revision of the Medicare Conditions for Coverage must include specific authority of the Medical Director to improve the quality of care delivered to all patients in that facility. It should include more descriptive language about the Medical Director and nephrologist roles.
- Timely, comparative feedback to facilities of performance measures must be accomplished. It is not clear to us that the VISION system now in pilot tests (Networks 4, 6 and 8) will provide the best vehicle for effective information capture, transfer, processing, and feedback. An expanded information infrastructure has been recommended by the Forum of ESRD Networks, and should be built.
- The burdens on dialysis units for data collection and reporting must be minimized. An evaluation of the current burden should be conducted to develop a plan to reduce the data collection workload.
- Process or outcome measures should serve as a guide to possible performance problems, not as definitive indicators. Performance measures should be used to conduct internal quality improvement projects. Measures for accountability and to inform consumer and patient selection should also

1527 Huguenot Road • Midlothian, VA 23113 • 804/794-2586 • Fax: 804/378-7351
email: forum@forum.esrd.net • http://www.esrdnetworks.org

be developed. The strategic framework of the National Quality Forum and the recommendations of the Institute of Medicine (IOM) report, "Envisioning a National Healthcare Quality Report" should define the distinction between the various uses for performance measures.

- Intervene with facilities having performance problems in ways likely to motivate change. The IOM report "Crossing the Quality Chasm" suggests we explore better ways to align incentives and behavior of physicians, other members of the healthcare delivery team, and patients to foster improvement. We need to explore effective ways to accomplish such alignment, including positive incentives such as public recognition or financial rewards, as well as the more traditional regulatory remedies. A host of other incentives should be explored for patients and consumers.

II. **We suggest caution in these areas:**

- Clarify the difference between performance standards and practice guidelines. The NKF/DOQI, Renal Physicians Association, and other Clinical Practice Guidelines (CPGs) state explicitly that they are intended to be guides to inform decision making for patients and clinicians on best practices, not standards of care. Practice standards are far more stringent than CPGs, and care must be taken to differentiate between the two.
- Physician-specific report cards are fraught with methodological problems. A narrow focus on individual professional performance ignores the reality that many problems occur because of documented multiple system failures. Additionally, in many instances groups of nephrologists rather than individual physicians care for each patient. Sample size is often so small when individual physician outcomes are measured, that valid statistical comparisons cannot be made. While feedback of these data to practitioners may be helpful to those who evaluate the limitations and review the results, use of such data for oversight may lead to false conclusions. What is needed is a balanced approach, with a focus on both physician and other healthcare professional performance and an evaluation of the system.

III. **Additional Comments:**

- Networks already have developed effective intervention strategies for facilities experiencing performance problems. The Networks would benefit from additional funds and authority to act in these circumstances, and from additional data sharing, such as access to the Clinical Performance Data, billing and hospitalization data. The latter will require a commitment to expand the current information infrastructure to support quality improvement and inform decision-making by health care professionals and patients.
- Public availability of facility-specific clinical performance measures must be reviewed carefully. Some measures help beneficiaries to select facilities or therapies that are best for them, while other measures do not. Some measures reflect accurately the quality of care offered by that facility, while others do not. Medicare should determine what beneficiaries want, for example what measures or characteristics of dialysis facilities they want publicly displayed. The recommendations on the National Quality Forum and the IOM report "Crossing the Quality Chasm" should inform CMS policy decisions.

The Forum of ESRD Networks appreciates the opportunity to participate in the review of the Clinical Performance Measures for Dialysis Facilities reports of the Office of the Inspector General. We look forward to future involvement in this important area of ESRD care.

Sincerely,

Alan S. Kliger, M.D.
President, Forum of ESRD Networks

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APPENDIX C

RPA

RENAL PHYSICIANS ASSOCIATION

The Advocate for Excellence in Nephrology Practice

November 12, 2001

Janet Rehnquist, Inspector General
Office of Inspector General
Department of Health and Human Services
Cohen Building, Room 5246
330 Independence Avenue, SW
Washington, D.C. 20201

Dear Ms Rehnquist:

The Renal Physicians Association (RPA) is the professional organization of nephrologists whose goals are to insure optimal care under the highest standards of medical practice for patients with renal disease and related disorders. RPA acts as the national representative for physicians engaged in the study and management of patients with renal disease. We are writing to provide comments on the draft inspection reports generated by the OIG relating to the use of clinical performance measures by dialysis corporations to hold facilities accountable for the quality of care provided to dialysis patients.

Overall, the RPA is encouraged by the direction and tone of the draft reports and the draft recommendations developed by the OIG. The "broad stroke" principles underlying the recommendations are in alignment with a number of initiatives the RPA has pursued within our efforts to ensure that the care provided to the nation's chronic kidney disease population is of the highest quality possible. Further, RPA commends the OIG for generating reports and recommendations that positively foster the use of clinical performance measures to improve accountability for the quality of care provided among the major dialysis chains while avoiding the punitive orientation of previous efforts on the part of federal agencies responsible for oversight of these services.

RPA would welcome the opportunity to work collaboratively with the OIG in a partnership directed at advancing the principles captured in the recommendations, and in this spirit we offer the following comments. Our input is organized according to the recommendations included in the Executive Summary of the report entitled *"Building on the Experiences of the Dialysis Corporations."*

Revise the Medicare Conditions for Coverage

RPA strongly supports efforts to revise and update the Conditions for Coverage (CFC) for ESRD facilities so that they reflect the realities of current nephrology and dialysis practice. It is also our opinion that the CFC must be revised in a thoughtful and prospective manner that acknowledges the dynamic nature and future evolution of renal care. However, RPA also believes that CFC must realistically consider for

4701 Randolph Road • Suite 102 • Rockville, MD 20852
Phone: 301/468-3515 • Fax: 301/468-3521 • email: rpa@renalmd.org • www.renalmd.org

the complexities of the relationships between the organizations, nephrologists, and professional staff responsible for providing that care.

For example, it is the RPA's opinion that in general use of numerical standards should be avoided in the CFC. However, understanding that existence of such thresholds is likely a necessity in order to improve the baseline of care provided to the nation's ESRD population, we believe that the CFC should explicitly allow for periodic revision of any numerical standards that are in the CFC to facilitate a "raising of the bar" as the quality of dialysis care improves. Evidence-based flexibility in these standards will allow for changes in science and external forces affecting the delivery of care, such as familial and societal issues. This flexibility should include a list of justifiable exceptions for those instances where circumstances beyond the physician's control result in a failure to improve quality measures. RPA believes that accountability in this area should be assigned only if it is actionable, or within the control of, the physician or the facility medical director.

With regard to the effort to require facility medical directors to exert more leadership in quality improvement, we urge the OIG examine this issue in as "real-world" a context as possible and to consider broadening the focus of the interventions in this area beyond the responsibilities of the medical director alone. As noted above, the relationships within the dialysis facility are exceedingly complex. Rarely, if ever, will the facility medical director actually be the employer of the individual attending physician, and as a result the ability of the dialysis facility medical director to positively impact the behavior of poorly performing attending physicians is substantially limited at best. Once again, accountability in this area should be assigned only if it is actionable. Further, we urge the OIG to reconsider addressing the issue of the medical director's responsibility to report a physician to an authoritative body. It is our opinion that taking such a step would be so impractical in terms of patient access and daily workflow that it will virtually never occur, yet being outlined in this report may functionally make this action the subsequent, logical course of action.

Examine Ways to Foster the Commitment of Attending Physicians to Performance Measures

RPA concurs with the OIG that an enhanced commitment to performance measures on the part of attending physicians is a key element in ESRD quality improvement. As noted above, these performance measures must be evidence-based and must remain flexible in order to facilitate change as scientific advances evolve. We believe that educational forums with the purpose of highlighting the value and utility of performance measures in improving the quality of care provided to dialysis patients can play a critical role in the penetration and use of these measures. It is also RPA's opinion that additional attention to the responsibilities of the individual attending physicians can only serve to improve the quality of care provided to their patients and, in the absence of justifiable exceptions, work to enhance their patient's health outcomes.

RPA does urge caution in the development of physician-specific report cards. These tools can be extremely useful but the recurring issue of actionability on the part of the individual physician raises the questions of whether such profiling can be done fairly. RPA believes that the reorientation of such a reporting mechanism toward a more systems-based or team-based approach may have the effect of empowering all of the relevant clinical and administrative staff regarding quality improvement and simultaneously will be more effective in accounting for all of the influences on and components of the patient's care.

Develop More Effective Intervention Strategies for Dialysis Facilities

RPA believes that the OIG's recommendation relating to the interaction between the ESRD Networks, the State survey agencies, and CMS is critically important to achieving the goal of improving dialysis care. Resources must be devoted to enhancing the ability of these entities to communicate with each other, both on an organizational level and in an informational technology context.

Further, we support the OIG's suggestion that CMS look to expand sanction options for poorly performing facilities. The absence of an intermediate step in sanctioning facilities that are not satisfying the CFC short of termination significantly limits the options of Medicare and other agencies with oversight responsibility that may cause a reluctance to penalize poor performers. In those instances where a facility's lack of CFC compliance does lead to termination from the Medicare program, patient access will be adversely affected.

Work with Corporations to Share Experiences and Minimize Burdens on Dialysis Facilities

Similar to the previous recommendation regarding information sharing among public entities involved in oversight of the ESRD program, RPA concurs that increased collaboration between these entities and the dialysis industry would provide valuable insight into the perspectives and strategies for all parties. Such interaction will encourage a more thorough understanding of regulatory requirements and more rapid dissemination of quality improvement strategies and technological innovations. We fully support OIG's inclusion of this recommendation in the draft report and urge the OIG to pursue this recommendation with CMS to the maximum extent practicable.

RPA appreciates the opportunity to provide comments on the OIG's draft reports on clinical performance measures for dialysis facilities. As noted above, we would welcome the prospect to serve as a partner with the OIG in its efforts to improve the quality of care provided to the nation's dialysis patients, and stand ready as a resource for the OIG in its future endeavors.

Sincerely,

William F. Owen, Jr., M.D.
President

National Renal Administrators Association

November 9, 2001

HHS/Office of Inspector General
Room 5246
Cohen Building
330 Independence Avenue SW
Washington, D.C. 20201

Dear Inspector General Rehnquist:

On behalf of the National Renal Administrators Association (NRAA), I would like to thank you for the opportunity to comment on the three draft inspection reports on how five major dialysis corporations use clinical performance measures to hold their facilities accountable for the quality of care they provide to dialysis patients. The NRAA commends your office for taking a leadership role in finding ways to improve quality care. In particular, the association greatly appreciates your willingness to listen and learn from the renal community and believes this is the best approach to improving ESRD patient care.

The NRAA is a voluntary organization representing professional managers of dialysis facilities and centers throughout the United States. Our members manage dialysis units throughout the country that are owned by small providers and single independent units, as well as the major chains. NRAA members provide services in both free-standing and hospital-based facilities, which are for-profit and non-profit providers located in urban and rural areas. The association was founded to provide information and education to our members and to work with the Congress, the Administration, and other organizations on the Medicare ESRD program. NRAA is dedicated to providing quality of care in the most cost effective manner.

In general, the NRAA concurs with the lessons learned contained in your draft report, "Building on the Experiences of the Dialysis Corporations." We will confine our comments to this draft report as the other draft reports provide background material and discuss the same lessons and recommendations.

As the association represents many administrators who are employed by small providers and independent units, we urge you in your final recommendations to be cognizant of the more limited resources small providers have compared to the large chain organizations in their ability to make labor intensive and costly quality improvements. While the large chains have extensive financial and personnel resources to implement the recommendations, small providers do not have such resources.. Even a thousand dollars in additional costs would be a tremendous burden to small facilities with 4 to 6 stations. **The NRAA is very concerned that the recommendations will lead to mandates being placed on dialysis providers without additional reimbursement to pay for the mandates.** Below you will find comments on each of the lessons learned and proposed recommendations.

Lesson 1 - Look to Medical Directors To Exert Sustained Leadership Recommendation- Amend Conditions of Coverage to Implement This Proposal

NRAA would agree that the Medical Director should take an active leadership role in the dialysis facility and should hold the physicians who have patients in the facility accountable for the quality of care the patients receive. However, we would also agree with comments by the corporations that medical directors lack the authority to take independent action against the other physicians and have no real incentive to

11250 Roger Bacon Drive, Suite 8 • Reston, VA 20190-5202 • Phone (703) 437-4377 • Fax (703) 435-4390
E-mail: nraa@nraa.org • www.nraa.org

question or confront another physician's practice of medicine. Further, when a majority of the patients within a facility or small chain belong to one practice, it is more problematic to exert action on poor performance and even more problematic when the unit or units are owned by the Medical Director and there are no set standards on gathering the information needed for performance.

In order to over come the barriers to effective medical director leadership, the NRAA would agree that the ESRD Conditions of Coverage should be revised as recommended in the report. In addition, when medical directors are found to be negligent in performing their duties they personally should be held accountable and an acceptable action plan should be established that commits the medical director to specific remedial actions.

The NRAA does not believe the Conditions of Coverage should be revised to require facilities to have a credentialing process as dialysis facilities already have a rigorous credentialing process in place and most facilities require that the credentials be reviewed and approved by the medical staff and governing body of the facility.

Lesson 2 - Secure Commitment of Attending Physicians
Recommendations-CMS should conduct educational forums that emphasize the importance of performance measures, examine the possibility of physician specific report cards, and focus greater attention on the responsibilities of physicians. NRAA agrees with the recommendations. The ESRD Networks should hold educational forums as these can be key to gaining acceptance by physicians and facilities for agreed upon performance measures. Attending physicians must be accountable for their actions. The NRAA would further recommend that just as CMS posts dialysis unit specific information on a Website, that physician specific outcome data also be listed by facility. Physicians should be accountable for overseeing the outcomes of their patients. The NRAA would recommend that CMS consider requiring the ESRD Networks hold physicians accountable for certain quality outcomes. To develop mechanisms for accountability, the NRAA would recommend that CMS convene a meeting of renal related organizations including the Renal Physicians Association, National Renal Administrators Association, Renal Leadership Council and National Kidney Foundation.

Lessons 3/ 4/12 - Collect A Broad Set of Measures and Revisit Their Relevance Regularly
Recommendation-Require dialysis facilities to conduct their own quality improvement projects
Rather than requiring each dialysis facility to conduct its own quality improvement project, the NRAA believes that it would make sense to have dialysis facilities pick and choose from agreed upon quality improvement projects that include standard protocols for collecting the data. This approach would result in more meaningful projects and better data collections, as having each dialysis facility pick its own project without established protocols could lead to inaccurate or misleading data. Further, the NRAA is concerned that requiring the collection of a broad set of measures could be too difficult and costly for small facilities that have limited staff and can only manually collect the data. Therefore, the NRAA would recommend that the limitations of small providers be taken into account in developing the quality measures to be tracked. The NRAA also agrees that the measures should be revisited every few years to determine if they are still relevant indicators of quality. This will ensure that outdated measures are not being tracked.

Lessons 5/ 6 - Establish Minimum Performance Standards and Develop Performance Goals
NRAA agrees and recommends that CMS work with renal providers to establish minimum performance standards and goals for all facilities to aim toward. The association also believes that standards should be updated periodically to ensure that they are **current.** Further, they should be adjusted for the types of patients in the dialysis unit in order to prevent "cherry picking." Also, in setting goals there needs to be some allowance for non-compliant patients, homeless patients and other "outliers".

Lessons 7/ 8 - Apply Strict Definitions To Performance Measures, Check Accuracy Regularly
The NRAA is in complete agreement. Consistent definitions are needed across and within all facilities.

Without clear definitions and agreed upon data collection protocols the performance measures data become meaningless. The association would urge that CMS work with the renal community to develop the standard definitions, collection methods and methods to check for the accuracy of the data on a regular basis. CMS should consider asking the ESRD Networks to educate small facilities and those with high turnovers on these measures to ensure consistency with data collection efforts.

Lesson 9 - Minimize The Data Reporting Burden
As in our comments on Lesson 3, while the large companies have the resources to collect the data electronically, small and in particular rural units do not have the staff or equipment. Limiting the data reporting burden will be essential to the success of any quality improvement program.

Lessons 10/11 Disseminate Timely, Comparative Feedback of Performance Data
NRAA agrees that given the competitive nature of the dialysis industry comparative feedback can be a major motivator for improvement. The NRAA would like to see "timely" dissemination to mean monthly or quarterly so that the data is relevant and meaningful. Publishing old data as was done on CMS' Dialysis Compare Website was counter-productive and frustrated many providers who had improved their quality of care.

Lessons 13/14 - Use Performance Data As A Guide to Possible Performance Problems and Intervene In Ways Likely to Motivate Change
NRAA agrees that using quality data as a guide to judge performance is a better way to determine which facilities are performing as they should. The use of performance data should be taught to the state surveyors and the ESRD Networks, and they should work together on ways to motivate facilities to improve their care.

The NRAA has some concerns about expanding the sanctions options to deny Medicare payment for new admissions at facilities that fail to meet Medicare conditions. At times the problem lies with the physician and in these cases the association believes the sanction should be against the physician and not the facility. Further, when payment is restricted there is a potential of inadvertently restricting care for the current patients. A small or medium size unit in smaller communities is often the only provider of dialysis and therefore the new patients could be the losers. Also, new patients who come to the facility in acute conditions may actually cause the facility to be out of compliance with the Conditions of Coverage and as a result some growing facilities might not want to take these severely ill patients for fear that they would negatively impact their compliance with the Conditions of Coverage. The current system which requires the facility to work with the state surveyor and ESRD Network to come into compliance is a better approach to ensuring that all of the patients receive quality care.

As education is the key to improving quality of care, the NRAA would urge the OIG to expand its recommendations and ask CMS not only to sponsor meetings and conferences for itself and the corporations but invite the entire renal community to share data and information on ways to improve quality of care on a routine basis.

The NRAA again thanks the Office of the Inspector General for allowing the association to comment on the draft reports. Please contact NRAA Board of Directors, Ann Stivers (402-489-5339) or Anthony Messana (610-626-2782), if you would like further information concerning the association's comments and recommendations.

Sincerely,

Shelley Clark

Shelley Clark
NRAA President

APPENDIX D

Endnotes

1. Dialysis is the process of removing toxins from the body by diffusion across a semipermeable membrane, thereby compensating for kidney failure. There are two types of dialysis: hemodialysis and peritoneal dialysis. Hemodialysis involves the removal of toxins directly from the patient's blood stream, requiring direct access to the bloodstream. The patient's blood is cycled through an artificial kidney, an external machine, that removes the toxins and excess fluids from the blood. The artificial kidney machine uses a semipermeable membrane, called a hemodialyzer, to filter out the toxins from the blood. Peritoneal dialysis utilizes the patient's natural peritoneal membrane, located in the abdominal cavity, to remove toxins and excess fluids.

2. *The 2001 USRDS Annual Data Report Reference Tables*, The United States Renal Data System, Section J. Accessed via the Internet at [http://www.usrds.org/reference.htm].

3. The End-Stage Renal Disease Networks, established in 1976, are CMS main contractors for monitoring dialysis facilities. CMS relies on the 18 regional Networks to collect data from facilities, conduct annual quality improvement projects, and evaluate and resolve complaints. The main mission of the Networks as set out in the Statute is to ensure "effective and efficient administration of the benefits" provided under the end-stage renal disease program. Section 1881(c) of the Social Security Act.

4. CMS contracts with the State survey agencies, typically within departments of public health, to conduct on-site Medicare certification surveys of facilities and to investigate complaints, both in accordance with Medicare Conditions for Coverage for dialysis facilities.

5. Department of Health and Human Services, Office of Inspector General, *External Quality Review of Dialysis Facilities: A Call for Greater Accountability*, OEI-01-99-00050, June 2000, page 47.

6. See [http://www.medicare.gov/Dialysis/Home.asp].

7. Based on figures from, "The Ten Largest Renal Providers," Nephrology News and Issues, Vol. 15 No. 8, July 2001 p. 30, and *The 2001 USRDS Annual Data Report Reference Tables*, The United States Renal Data System, Section J. Accessed via the Internet at [http://www.usrds.org/reference.htm].

8. Ibid.

9. 42 C.F.R. Sec. 405, Subpart U.

10. CMS (Medicare) pays attending nephrologists for routine dialysis care through a monthly capitation payment.

11. CMS made this clear in a 1998 letter to an ESRD Network: "Significantly, the end-stage renal disease regulations do not explicitly empower a physician-director with the authority to take independent action with respect to patients attended by other physicians." Correspondence to Glenda Harbert, Executive Director of Network 14, from Kay Hall, Project Officer, Division of Clinical Standards and Quality, Health Care Financing Administration, on November 9, 1998.

12. CMS' comments to the Office of Inspector General Draft Inspection Reports on Clinical Performance Measures for Dialysis Facilities , dated December 26, 2001.

13. Department of Health and Human Services, Health Care Financing Administration, *2000 Annual Report ESRD Clinical Performance Measures Project*, December 2000. Accessed via the Internet on May 31, 2001 at [http://www.CMS.gov/quality/3m8.htm].

14. Under current policy, Medicare pays facilities on a prospective basis for a defined bundle of services (irrespective of dialysis method, dose, frequency, and patient acuity), and on a separately billable basis for many other services, such as injectable medications and nutritional therapy. It does not pay the facilities at all for noninvasive procedures used to monitor patient vascular access sites — a critical matter since vascular access complications are a major cause of hospitalizations. Medicare provides attending nephrologists a monthly capitated payment (unrelated to the facility payment) for their routine patient monitoring and pays separately for any inpatient care.

This fragmented payment system can result in facilities being held accountable for performance measures that they may have little control over. For example, many of the corporations collect the type of vascular access as a performance measure. However, facilities are not the ones who determine the type of vascular access a patient receives, and may have little influence over the surgeons that do.

The Institute of Medicine and others have long drawn attention to the dysfunctional aspects of this system and have called for reforms. See: Institute of Medicine, *Kidney Failure and the Federal Government* (Washington, D.C.: National Academy Press, 1991). Medicare Payment Advisory Commission, *Report to the Congress: Selected Medicare Issues*, June 1999; Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy*, March 2000; Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy*, March 2001.

15. The six changes we called for are the following: (1) strengthen the accountability of the dialysis facility governing body; (2) reinforce the accountability of the dialysis facility medical director for patient care; (3) require facilities to report electronically on standardized performance

measures determined by CMS; (4) require dialysis facilities to conduct their own quality improvement program; (5) require dialysis facilities to establish internal systems for identifying and analyzing the causes of medical injuries and medical errors; and (6) require dialysis facilities to monitor patient satisfaction.

16. "RPA/ASN Position Paper on the Nephrologists as Dialysis Facility Medical Director." Adopted by the RPA/ASN Board of Directors on April 21, 1996.

17. TransPacific Renal Network, *Organizational Standards of Quality of Care for ESRD Facilities*, Joint Commission adapted with permission, 1999.

18. Title 25 Texas Administrative Code, Chapter 117.41.

19. The minimum standards for dialysis facilities issued by the Texas Department of Health requires facilities to conduct their own internal quality improvement efforts.

20. Department of Health and Human Services, Office of Inspector General, *External Quality Review of Dialysis Facilities: Two Promising Approaches*, OEI-01-99-00051, June 2000.

21. 42 C.F.R. Sec. 482.22.

22. CMS has conducted training sessions for State surveyors on how to use these reports.

23. 42 C.F.R. Sec. 482.408(d)(1)(i).

24. Department of Health and Human Services, Office of Inspector General, *External Quality Review of Dialysis Facilities: A Call for Greater Accountability*, OEI-01-99-00050, June 2000.

25. Department of Health and Human Services, Office of Inspector General, *External Quality Review of Dialysis Facilities: Two Promising Approaches*, OEI-01-99-00051, June 2000.

26. The Centers for Medicare and Medicaid Services and Forum of End-Stage Renal Disease Networks Annual Meeting, June 10-13, 2001, Wyndham Baltimore Inner Harbor, Baltimore, Maryland.

27. Centers for Medicare &Medicaid, *ESRD Network Organization Manual*, Part 7 Sanction and ESRD Grievances, accessed via the Internet at [http://www.hcfa.gov/quality/5d.htm].

28. The three key forms are: medical evidence form (CMS-2728), facility survey form (CMS-2744), and death notification form (CMS-2746). CMS is in the process of updating these forms.

APPENDIX D

29. Department of Health and Human Services, Office of Inspector General, *External Quality Review of Dialysis Facilities: A Call for Greater Accountability*, OEI-01-99-00050, June 2000, page 47.