



August 7, 2008

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Re: CMS-3818-F: Final Rule, Conditions for Coverage for End Stage Renal Disease Facilities

Dear Dr. Straube and Mr. Hamilton:

Kidney Care Partners (KCP) is pleased to have the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments on the implementation of the Conditions for Coverage for End Stage Renal Disease Facilities Final Rule. CMS-3818-F. KCP is an alliance of members of the kidney care community that works with renal patient advocates, dialysis care professionals, providers, and suppliers to improve the quality of care of individuals with irreversible kidney failure, known as End Stage Renal Disease (ESRD).¹

We appreciate that there are two teams working on the Conditions. Thus, we have written to each of you and organized our comment letter to recognize the policy issues and the operational issues. We welcome the opportunity to work with both of your staffs to ensure the most efficient implementation of the Conditions and to seek policy reforms in areas in which we believe there will be practical difficulties with implementation that could compromise care delivery.

¹ A list of Kidney Care Partners coalition members is included in Attachment A.

In terms of the policy recommendations, KCP urges CMS to:

- ❖ Clarify the goal of the face-to-face visit requirement for home dialysis patients and modify the Conditions to allow facilities to achieve it in the most appropriate manner;
- ❖ Grandfather-in board-eligible physicians who are currently serving as medical directors and expand the categories of board-certification to include nephrology;
- ❖ Work with the ESRD community to develop a clear process, reporting requirements, and definitions when establishing clinical performance measures (CPMs); and
- ❖ Provide dialysis facilities with specific hospital data about patient stays to enhance coordination and achieve the goal of an integrated patient team and improve the quality of patient care.

On the operational front, we recommend that CMS:

- ❖ Work with the community to issue timely Interpretive Guidelines to provide needed clarity;
- ❖ Take a flexible approach when implementing the Conditions, particularly in the area of infection control, to minimize financial burdens and achieve desired results;
- ❖ Clarify the patient care technician certification process; and
- ❖ Provide clarification regarding the interaction of the Conditions with State laws and requirements.

Finally, there are two issues that overlap the policy and operational categories. In these areas, we recommend that CMS:

- ❖ Streamline the roll-out of CROWNWeb, by allowing all facilities to batch process and requiring facilities to submit only the data needed to calculate the CPMs for the facility report; and
- ❖ Reconsider the extent to which facilities must comply with the Life Safety Code, or provide additional time for facilities to do so.

I. Policy Issues

A. CMS should clarify the goal of the face-to-face visit requirement and modify the Conditions to allow facilities to achieve it in the most appropriate manner.

KCP shares CMS' commitment to ensuring that dialysis patients are evaluated and treated in a timely manner by qualified personnel. The Final Rule requires that patients be seen monthly by a physician, physician assistant, nurse practitioner, or clinical nurse specialist. KCP appreciates CMS' flexibility in allowing non-physician providers (NPP) to see patients; however, it is not clear what the Agency is hoping to accomplish by creating this requirement in the Final Rule, especially in the case of home dialysis and peritoneal dialysis (PD) patients. Therefore, we recommend a modification that would require a physician or NPP to see a home dialysis or PD patient either in the office or at the facility at least once every other month and a registered nurse to see such a patient at least once a month to monitor them, consistent with the plan of care and oversight of the attending physician. We also recommend that CMS indicate in the interpretive guidelines that facilities should demonstrate a good faith effort to ensure such visits occur, but that surveyors should recognize that patient compliance cannot be mandated. Finally, CMS should coordinate incentives between the Conditions and other relevant policies to be consistent with one another.

The community's concern focuses on home dialysis and PD patients. In-center patients are regularly monitored and assessed by a variety of health care professionals, including physicians and registered nurses, because they must come to the facilities to receive their treatments. Home dialysis and PD patients do not receive such frequent monitoring and assessment simply because they dialyze at home and do not come into the facility three times a week.

KCP agrees that these patients being supported by a provider or facility should be seen regularly. However, the Final Rule's requirement that a patient be seen monthly by a physician or NPP needs to include the flexibility of allowing a visit at the physician office to count toward this requirement and needs to recognize that facility visits, which focus on patient monitoring, are frequently performed by a registered nurse. The requirement for monthly face-to-face visits with a physician for home dialysis patients is inappropriate because it poses a burden and often times a hardship for many patients, especially those in rural and remote areas. In addition, a patient's physician may not always be present at the facility at the same time the patient is there.

That said, KCP understands the need for patients to be seen by a qualified practitioner, especially home dialysis patients whose interaction with a dialysis provider is limited. Although many physicians do see their patients monthly, it may be in their offices. Neither the Medicare program nor dialysis facilities can mandate how physicians practice medicine. It is more consistent with Medicare physician policies to require that a physician or NPP see a patient at least once every other month in the facility or office setting. This flexibility would also take into account physicians' and patients' schedules, which can often be difficult to match. Attendance at scheduled appointments is a shared goal of patients and providers. However, achieving 100 percent compliance is an extremely difficult challenge.

Given that the patient would see a physician at least once every other month, we believe it makes sense also to require that facilities make a good faith effort to have patients visit with registered nurses on a monthly basis for basic monitoring (e.g., drawing labs, blood pressure monitoring, etc.). In-center patients commonly receive such services from RNs. This requirement combined with the every other month physician requirement provides home and PD patients with regular physician and nurse monitoring visits in a manner that also recognizes the realities of clinical practice and patient circumstances.

B. CMS should grandfather-in board-eligible physicians who are currently serving as medical directors and expand the categories of board-certification to include nephrology.

KCP members support the goal to improve quality of care by ensuring that medical directors are appropriately qualified, yet we remain concerned that mandating board-certification in internal medicine or pediatrics for all medical directors will actually reduce quality, at least in the short-term. Becoming board-certified requires passing a test, usually at the beginning of a physician's career, and then renewing the certification periodically. Because the previous requirements for medical directors mandated that these physicians only be board-eligible, many medical directors who were once board-certified have not renewed the certification. It would be unfair to ask these physicians to sit for board certification again while their peers who may have maintained their board certified status did so only by paying a periodic fee. These physicians are no less qualified than those who renewed their certifications.

To address this issue, KCP strongly encourages CMS to adopt a grandfathering policy that deems current medical directors to have met the current standard if they are board-eligible. In addition, we recommend that a physician who is board-certified in nephrology also be eligible to serve as a medical director under the Conditions. Without such changes, we are concerned that it will be even more difficult for facilities to find board certified medical directors.

C. CMS should work with the ESRD community to develop a clear process, reporting requirements, and definitions when establishing clinical performance measures (CPMs).

1. Implement a Clear Process for Adopting CPMs and Other Quality Measures that Includes Opportunity for Community Comments

As you know, KCP strongly supports enhancing the current CPMs and developing quality measures that could eventually be used to link quality performance to payment. While the Proposed Rule for the CY 2009 Physician Fee Schedule provides physicians with the opportunity to comment on the ESRD measures that will be used as part of the Physician Quality Reporting Initiative (PQRI), the dialysis community did not have a similar opportunity to comment on the CPMs that CMS posted on its website in April 2008. Similarly, the Final Rule for the Conditions references the CPMs, but does not provide an opportunity for the community to comment. KCP strongly encourages CMS to provide the community with an opportunity to comment on any CPM,

including future quality measures that it intends to adopt that has not already been developed or endorsed through a national voluntary consensus standard setting process or that CMS has modified when seeking to adopt it.

In 2005, KCP led the effort to develop comprehensive facility and clinician-level measures for patients with kidney disease by founding the Kidney Care Quality Alliance (KCQA). There is no question that the community remains strongly supportive of the effort to develop community-based measures. Through its process, the KCQA developed seventeen measures, including both process- and outcomes-based measures, facility- and clinician-level measures, and patient education and satisfaction measures. KCQA submitted these measures to the National Quality Forum (NQF) for endorsement and then worked closely with CMS to harmonize the overlapping measures that the two organizations submitted. In August 2007, NQF endorsed a series of ESRD measures, including five of the KCQA measures.

While the NQF-endorsed measures make up the majority of the recently adopted CPMs, in many instances the endorsed measure specifications are not accurately reflected in CMS' released measure descriptions. This lack of conformity extends to a number of the KCQA measures as well. Thus, we are concerned that the measures descriptions may indicate that CMS intends the CPMs to be substantively different than the measures that received official NQF endorsement. At least in the case of the KCQA measures, it must be noted that these modifications would have been made without the permission of the measure owner. For example, with regard to the vascular access measures, the NQF endorsed a measure that calculates:

the percentage of all ESRD patients aged 18 years and older receiving hemodialysis and on dialysis for more than 90 days during the 12 month reporting year who have a functional autogenous AV fistula (defined as two needles used) or do not have such a fistula but have been seen by a vascular surgeon or other surgeon qualified in the area of vascular access for evaluation for permanent access at least once during the reporting year.

The CPM description does not include the requirement that the patient be on dialysis for more than 90 days and does not recognize that a referral to another "surgeon qualified in the area of vascular access" is permissible. Therefore, we request that CMS provide the community as soon as possible with the numerators, denominators, exclusions, and the detailed specifications and data elements for each measure to ensure that the NQF-endorsed specifications are reflected in the CPMs. In addition to the confusion over the relationship of the NQF-endorsed measures with the CPMs, KCP members continue to be concerned about the inclusion of four CPMs that were *not* endorsed by NQF. In particular, KCP urges the Agency to provide the community with the opportunity to comment on measures that were not endorsed by NQF or that are NQF-endorsed and have been modified.

CMS also recently released the Quality Measures Development Overview, which outlines the process it plans to use for adopting measures. Under this process, the Agency describes a fifteen step process it will use to develop measures. We applaud CMS for outlining this process publicly

and for recognizing the importance of obtaining public comment on the measures – not only through formal public comment opportunities, but also by working with the community through the Technical Expert Panel process.

KCP supports this process because it ensures that the community will have the opportunity to provide input on any measure before it is adopted. Given that Congress has mandated value-based purchasing for the Medicare ESRD program beginning in 2012, it is imperative that the entire kidney care community has the opportunity for meaningful input before any measures used as part of this program are adopted.

Therefore, we strongly recommend that before the new CPMs are implemented, CMS provide an opportunity for notice and comment for the current CPMs that were not endorsed by the NQF. We also support the use of notice and comment rulemaking for the adoption of measures in the future, especially if such measures have not been endorsed by the NQF.

2. Clarify the Data Reporting Requirements for the CPMs

Reporting of CPM data and submission of administrative data in electronic format represents two significant modifications of the previous Conditions. Accordingly, numerous questions should be addressed by CMS, including the data reporting intervals, the relationship between CROWNWeb and Dialysis Facility Compare and how provider reporting requirements differ between the two systems, the nature of the data that will be publicly reported, and the data CMS plans to share with providers. These and other questions should be clarified by CMS during the CPM process. To ensure that such issues are addressed before the implementation of the new CPMs, KCP encourages CMS to establish a technical expert panel or an equivalent entity that includes representatives from the community who can help resolve such questions.

KCP members are also concerned that current proposals surrounding the data collection for the CPMs require the facilities and providers to submit data beyond that which is needed to calculate the CPMs. Given the difficulty of launching the new data collection tool (CROWNWeb) and the concern that many members of the kidney care community will not be permitted to batch process, KCP urges CMS to limit its data request only to that necessary for reporting the CPMs. This policy not only relieves a burden on the facilities and providers, but also ensures that only the minimum amount of patient-identifiable data is being transmitted.

In addition, KCP seeks clarification from the Agency on the data elements that will be required for reporting the CPMs as, at this time, it is not clear. The January 2008 data dictionary, as well as the initial data collection paper forms, provide some direction, but include significantly more data points than would be necessary to calculate the CPMs. For example, with regard to the vascular access measures, the data dictionary calls for eleven different data elements that are not necessary to calculate the CPMs. In the case of the mineral metabolism-related measure, the data dictionary appears to request data regarding not only whether a patient's phosphate level was checked, but also what the value was. While the former data is needed to calculate the CPM, the latter is not. It is critically important to the kidney care community, especially to patients, that the data collection is

limited to the minimum amount necessary to allow for the calculation of the CPMs. Such a limitation would be consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Regulations. Therefore, KCP strongly urges CMS to limit its data collection to only those data points that will be needed to calculate the CPMs.

3. Work with the community to develop clear and concise definitions for collecting CPM data

In addition, CPM definitions should be developed on a consensus basis by providers to ensure that the definitions are widely-understood and supported. In order to report correctly, providers must understand clearly what they are expected to report. The best way to ensure clarity is to involve the providers in the definition setting process. The current data dictionary does not provide sufficient clarity to ensure that the data points requested will be interpreted in the same manner by each facility. Therefore, we strongly encourage the Agency to establish a small work group including members of the kidney care community to work through the definition issues in an expeditious manner that will permit the implementation of CROWNWeb to remain on schedule. If the clarification of the data definitions is not resolved, it will be impossible to establish benchmarks, which will make valid, fair pay-for-performance/value-based purchasing system impossible.

D. Provide dialysis facilities with the hospital data about patient stays to enhance coordination and improve quality of care.

KCP agrees with the emphasis on quality of care through the new Conditions for Coverage and believes that many of the new Conditions will help meet this important goal. However, the Final Rule does not address one of the gaps in patient care that should be addressed. As noted in the Preamble to the new Conditions, it is important to ensure coordination of care among the many providers and health care professionals who treat patients. The Conditions discuss in detail the interaction between facilities and health care professionals, but do not ensure such coordination between facilities and hospitals.

Perhaps the weakest link in the chain of care for dialysis patients is that which connects their admission and discharge from the hospital to their dialysis facility. Lack of admission diagnoses and missing or incomplete discharge diagnosis and plans may have enormous impact on facility decision-making regarding the provision of care, and potentially on patient survival. Because patients are at increased risk for death both when they change dialysis facilities and when they are discharged from the hospital, appropriate information transfer at both the beginning and end of hospitalization is an essential component of providing adequate care.

Patients may be admitted to the hospital from many different places (home, dialysis facility, or other locales). Often the only way a facility discovers the patient has been admitted is when he or she does not appear for dialysis. Currently, there is no obligatory information transfer that notifies the facility that the patient is hospitalized; this is usually accomplished in a haphazard fashion, either by phone contact from the hospital MD or inpatient dialysis nurse to the outpatient unit, or, occasionally even through the patient's family. Second, if no dedicated informatics system connects

the hospital to the dialysis facility, the patient's dialysis prescription, medications administered on dialysis, and summaries of other pertinent healthcare problems (including current medications) may not be available to the hospital physician providing care for the patient unless communicated verbally or by fax. Third, in the absence of this kind of communication, many hospitals are hesitant to volunteer to the dialysis unit-- when queried--that the patient has been admitted, the reason for that admission, and where the patient is. This lack of disclosure is often inaccurately regarded by the hospital as a HIPAA compliance issue and results in great inconvenience and cost to dialysis facilities, which waste resources preparing dialyzers and machines for patients who are hospitalized, and that cannot revise staffing requirements for the actual patient census.

Just as information transfer from facility to hospital is important in establishing dialysis prescription, correct medication dosing, and providing current medical history, the post-hospital course is determined by the appropriateness of discharge and adequate transfer of information back to the dialysis facility. Patients with ESRD change both physiologically and biochemically during the course of hospitalization. Those with prolonged hospitalizations may gain fluid weight, lose lean body mass, or sustain other intervening medical issues which result in major changes in their fluid and biochemical status. Such changes often obligate major revisions to the dialysis prescription and injectable medication orders upon return from the hospital, which if missed, have the potential for lethal consequences. Other critical issues, including oral medication changes, the need for further follow-up visits for ongoing issues and social services and dietary plans relating to immediate post-hospital care, are only infrequently transferred expeditiously to dialysis facilities. Unfortunately, this lack of data results in much of the remaining post-hospital care becoming guesswork. Thus, the crux of this issue: hospitalization is a common event for ESRD patients; these problems represent compelling quality improvement opportunities for all stakeholders involved in, and held accountable for, the outcomes of patient care.

Communicating this information to facilities at present falls to the dialysis nurse, the attending physician, resident, and their dictated medical records. Such summaries, however, are often generated by well-intentioned non-nephrologists or house staff, and may not provide complete information for effective transfer of care. In some instances, the discharge summary may not be dictated for a substantial interval following the patient's discharge, and crucial transfer information thus becomes unavailable. At present, there is simply no comprehensive, routine paradigm of information transfer between unit and hospital, whether in print, by fax, or by e-mail.

We suggest that obtaining the following information would eliminate the current gap in patient care:

- Automatic notification to the dialysis facility from the hospital of the patient's admission, service assignment, admission diagnosis, attending physician, overall condition, and whether there is any immediate need for dialysis;
- Similar exchange of information from the dialysis facility to the hospital, including dialysis prescription, medication list, expected dry weight, allergies, etc; and

- Appropriate data transfer from hospital to dialysis facility either just prior to or at time of discharge, to include:
 - Full dialysis prescription including dialysate, dry weight, heparin dose, and whether other new adjunct medication is required (including EPO dose, iron dose, vitamin D dose, and any other injectable medications).
 - The patient's estimated dry weight and date of last hospital dialysis.
 - The patient's most recent electrolyte levels.
 - Overall plan for further follow up, including dates and times for appointments established prior to discharge.
 - Need for any other adjunctive medication administration to continue in the outpatient setting (hyperalimentation, antibiotics, and duration of their treatment).
 - Problem list on discharge relating to the hospitalization, including ICD 9 codes.
 - Procedures undertaken in the hospital.
 - The results of x-rays and echocardiograms.
 - Narrative summary of hospitalization (if available).
 - Changes in routine outpatient medication regimens.
 - Death summary/autopsy report if patient expired during hospitalization (critical to facilities in CQI efforts, survival tracking, and M&M review).
 - The same information transfer should be provided for all admissions, regardless of length of stay.

II. Operational Issues

A. CMS should work with the community to issue timely Interpretive Guidelines that will provide needed clarity to patients, providers, and surveyors.

KCP encourages CMS to work with the ESRD community to promptly issue Interpretive Guidelines to assist patients and providers in understanding and implementing the new Conditions for Coverage. Additionally, we hope that the Agency will provide the community with the opportunity to provide comments on the Guidelines before they are final. We also urge CMS to ensure that surveyors do not seek to implement the Conditions until the Guidelines are final and the community has had time to make the necessary changes.

We applaud the agency for modernizing the Conditions to reflect advances in dialysis technology and standard care practices. Even though there is a great amount of detail in the Final Rule, the implementation requirements for many of the provisions remain unclear. Because the Final Rule represents the first significant regulatory changes to the Conditions in more than thirty years, many of these changes will require significant modifications to protocols and systems, which will take time to implement. Therefore, it is critical that CMS provide the Interpretive Guidelines as soon as possible to allow providers sufficient time to make the necessary changes. Additionally, KCP welcomes the opportunity to assist the Agency with identifying issues and suggesting potential

solutions as part of the process of developing the Interpretive Guidelines both formally and informally. KCP members also stand ready to assist in the surveyor training efforts the Agency plans to undertake.

B. CMS should take a flexible approach when implementing the Conditions, particularly in the area of infection control, to minimize damaging financial burdens and achieve desired results.

KCP urges CMS to recognize and address the financial burden posed by a number of the new Conditions by adopting a flexible approach to implementation. By their nature, regulatory requirements tend to increase costs to facilities and providers of services. In the context of health care, it is imperative that requirements not threaten access to care. Thus, any requirements in the Conditions that increase the financial burden on dialysis providers must be carefully implemented. KCP requests that the Agency take a flexible, cooperative approach to the implementation of the Final Rule. Doing so will lessen the burden on care providers. KCP's greatest concern along these lines is in the area of infection control.

KCP strongly supports the effort to improve infection control in the ESRD setting. However, many of the Conditions adopted for infection control create a significant burden on facilities while providing little improvement for patients. Generally, we support the goals of the Centers for Disease Control and Prevention (CDC) "Recommended Infection Control Practices for Hemodialysis Units at a Glance." Even though the goals of this document are laudable, the specifics related to their implementation are not always feasible in the real-world setting of dialysis facilities. For example, the CDC guidelines did not take cost or feasibility into account in its recommendation that an "isolation room" be provided for treating hepatitis B positive patients. For a number of existing facilities this requirement would require time-consuming and costly retrofitting of the existing facility. In addition, the recommendations require separate machines, equipment, instruments, supplies, and staff to care for the patient. This requirement means that dialysis facilities will need to use a new roll of tape for each patient. Although the Conditions allow for the same roll of tape to be used over multiple visits, the reality is that there is no place to store tape and retrieve it easily. Thus, the practical reality is that facilities will need to use a new roll of tape for each patient each session. This requirement is overly wasteful and costly; yet, there is no evidence that the decades long practice of sharing rolls of tape in a dialysis facility has in any way been implicated or found to be responsible for the transmission of infectious diseases.

Given the current nature of the reimbursement for dialysis, increases in costs that are not based on science and that are not likely to result in improvements in care should not be mandated. We welcome the opportunity to walk through other areas of concern in greater detail and to provide suggestions as to how to make the new Conditions more practically workable in the dialysis treatment setting.

C. CMS should clarify the patient care technician certification process.

KCP applauds CMS for recognizing the need to provide for appropriate patient care technician (PCE) training. As you are aware, KCP has consistently supported PCT certification as part of the Kidney Care Quality and Education Act, introduced by Sen. Kent Conrad and Reps. John Lewis and Dave Camp.

We seek clarification to ensure that facility-based training and testing recognized under State law meets the requirements set at § 494.140. Facility-based programs can provide training in all of the subjects outlined in the Final Rule, as well as address other issues that may arise at the facility level. A handful of States continue to rely on such programs for PCT training and certification. State law should supersede federal regulations in this case. Therefore, we encourage CMS to clarify in the upcoming guidance document that facility-based programs recognized by States qualify as training programs under this section.

D. CMS should provide clarification regarding the interaction of the Conditions with similar State laws and requirements.

The kidney care community agrees that updating the Conditions is critically important to ensuring that patients continue to receive high quality care. Given the national scope of many dialysis facilities and the mobility of today's dialysis patients, it is important that standards be as consistent as possible throughout the country. Even so, there are many States that have regulations that differ from the Final Rule. For example, South Carolina, Georgia, and Maryland all require patient care plans that do not contain exactly the same requirements or timelines as those set forth in the Final Rule. In these cases, KCP recommends that CMS clarify in guidance to the facilities and surveyors that facilities that meet more stringent State requirements should be deemed to be in compliance with the Conditions. Additionally, if a State adopts a regulation that directly conflicts with a Condition, the Agency should work with the State to resolve the issue and clarify in guidance which requirement a facility must meet.

III. *Overlapping policy and operational issues*

A. CMS should streamline the roll-out of CROWNWeb by allowing all facilities to batch process and requiring facilities to submit only the data needed to calculate the CPMs.

KCP members are concerned with the current plans to roll-out CROWNWeb. Specifically, our members believe that (1) all facilities should be permitted to batch process the information or be permitted to have the Networks enter the data on their behalf and (2) that the data provided by the facilities be directly linked to the CPMs.

KCP members appreciate the resource challenges facing the Agency; dialysis facilities face similar pressures as well. As we understand the implementation plan for CROWNWeb, it appears that only three dialysis facility organizations will be permitted to batch process the data required to

be submitted through CROWNWeb. The implementation of CROWNWeb will require facilities to shift from submitting CPM data on five percent of their patient population to 100 percent. While we understand the need to expand the data collection to the entire patient population, it will be impossible for small facilities with limited resources and staff to enter the amount of data required manually.

Requiring some dialysis facilities to manually enter data will be extremely expensive and time consuming. KCP members are concerned that such a requirement will force providers and facilities to take time away from caring for patients to complete the manual data entry. For example, a few members of KCP tested the HD and PD data collection forms CMS has already circulated. It took these providers between 20 – 25 minutes to complete each form. One company extrapolated this information to conclude that if it takes 20 minutes to complete the data entry per patient and there are 1300 patients, the process will require 433 hours for one round of data collection. If you assume that a medical receptionist who is paid at \$15.00/hour performs the work, the cost per 3-month reporting window is almost \$20,000. This number is extremely conservative because it does not include costs other than the salary of the employee. It is also not clear that only a medical receptionist will be needed to enter the data. Some members have suggested a registered nurse may be needed for certain data elements.

We encourage the Agency to work with the community to address this problem. KCP strongly supports the collection of CPM data on 100 percent of the patient population. We understand that this is the first step toward the value-based purchasing program outlined in the Medicare Improvements for Patients and Providers Act. Data must be timely and accurate for such a program to work. Therefore, we recommend that CMS consider alternatives to the current implementation plan. For example, Networks might be required to enter the data they receive electronically from facilities not permitted to batch. Another alternative is to create a transition system that provides CMS sufficient time to test facilities on a rolling basis. Under this scenario, facilities that are tested, and therefore permitted to batch data, would be required to submit 100 percent of the data. Those waiting to be tested would be required to submit the five percent sample required today. These are only two options. The community is committed to working with the Agency to find a solution to this problem.

B. CMS should reconsider the extent to which facilities must comply with the Life Safety Code, or provide additional time for facilities to do so.

The Final Rule requires each dialysis facility to meet the requirements of the National Fire Protection Association's Life Safety Code (LSC) (2000 edition). KCP appreciates CMS' flexibility in implementing certain aspects of this rule, including allowing grandfathering for certain requirements and providing extra time for compliance. However, KCP remains concerned that ensuring compliance with the LSC will present a tremendous burden and require significant expenditures by providers.

We appreciate the Agency's commitment to minimizing the financial burden on providers. KCP member organizations have begun the process of trying to comply with the LSC and are

concerned about the cost of coming into full compliance. For example, one KCP member that sought multiple quotes for the work determined that it would cost approximately \$10,000 per facility to meet the new requirement.

Given the enormous financial burden of compliance on dialysis facilities, KCP seeks to open a dialogue to work with CMS to find a way to decrease the financial burden. For example, the Agency could exempt facilities that meet local fire codes from retrofitting their existing buildings.

Until these issues can be resolved, we recommend that CMS provide thorough guidance to facilities and surveyors clearly indicating that facilities will not be found out of compliance for LSC-related matters.

IV. Conclusion

KCP members sincerely appreciate your past attention to our concerns in crafting the Final Rule. We look forward to working with the Agency to effectively implement the Rule. While this letter focuses on general comments and concerns shared by the kidney care community as a whole, individual KCP member organizations will be submitting detailed comments on the Final Rule shortly. Please do not hesitate to contact Kathy Lester at 202-457-6562 if you have questions regarding these comments.

Sincerely,



Edward R. Jones, M.D.
Chairman
Kidney Care Partners



Coalition Members:

Abbott Laboratories
AMAG Pharmaceuticals
American Kidney Fund
American Nephrology Nurses' Association
American Regent, Inc.
American Renal Associates, Inc.
American Society of Diagnostic and Interventional Nephrology
American Society of Nephrology
Amgen
Baxter Healthcare Corporation
Board of Nephrology Examiners and Technology
California Dialysis Council
Centers for Dialysis Care
DaVita, Inc.
Dialysis Patient Citizens
DSI, Inc.
Fresenius Medical Care North America
Fresenius Medical Care Renal Therapies Group
Genzyme
Kidney Care Council
National Association of Nephrology Technicians and Technologists
National Renal Administrators Association
Nephrology Nursing Certification Commission
Northwest Kidney Centers
Renal Advantage Inc.
Renal Physicians Association
Renal Support Network
Renal Ventures Management, LLC
Satellite Healthcare
U.S. Renal Care
Watson Pharma, Inc.