May 5, 2005

Dr. Mark McClellan  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Room 445-G  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC  20201

Re: CMS-3818-P: Conditions for Coverage for End Stage Renal Disease Facilities

Dear Administrator McClellan:

Kidney Care Partners (KCP) is pleased to have the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments about the Proposed Rule for the Conditions for Coverage for End Stage Renal Disease Facilities (Proposed Rule). 70 Fed. Reg. 6184 (2005). 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).

In brief, KCP applauds the agency’s efforts to shift the focus of the Conditions for Coverage from a process-orientated approach to a patient outcome point of view. Even so, we have some concerns that some of the proposed Conditions extend into clinical and health service delivery areas over which ESRD facilities have no control.

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1 A list of Kidney Care Partners coalition members is included in Attachment A.
To summarize, KCP believes:

- The shift to a patient-centered set of proposed Conditions appropriately allows facilities to focus on the quality of care they provide rather than on meeting specific process requirements that may have little or nothing to do with patient care;

- Given the fact that the ESRD program is the only Prospective Payment System (PPS) in the Medicare program that does not have an annual update mechanism, the agency should take into account the direct-cost impact of implementing the proposed Conditions for Coverage on dialysis facilities to ensure that they do not create an additional set of unfunded mandates on the program;

- CMS should hold facilities responsible for only those activities and outcomes over which they do have control; and

- As CMS recognizes, the Conditions for Coverage should maximize flexibility to ensure that patients receive high-quality care; however, some of the proposed Conditions are overly prescriptive and contrary to this goal.

In this letter, KCP does not provide an exhaustive analysis of each provision within the Proposed Rule. Rather, our members seek to provide the agency with overarching concerns and to explain them through specific examples. These examples are not exhaustive and do not identify all of the concerns KCP members have about the Proposed Rule. Rather, the examples point to the type of issues that warrant further evaluation and review by CMS.

We encourage the agency to review the comments submitted by individual KCP members for more detailed analyses of the individual provisions. Thus, we hope that CMS can look to our general recommendations to establish a set of general principles that it will use to evaluate each proposed Condition as the agency works to finalize the Proposed Rule. Specifically, we suggest that CMS evaluate the Conditions to ensure that each one:

- Allows facilities to provide high-quality care to patients without imposing unnecessary burdens;

- Is cost-effective and avoids placing significantly higher costs on facilities, especially if the benefit to patients is questionable;
Recognizes those activities and outcomes over which dialysis facilities are practically able to exercise control and does not hold them responsible for activities and outcomes that they cannot influence; and

• Provides dialysis facilities with sufficient flexibility to meet the individual needs of each patient.

I. KCP supports the shift to a patient-centered set of Conditions for Coverage because it emphasizes the importance of patient outcomes over process.

KCP applauds CMS's decision to focus on the quality of care patients on dialysis receive. We are particularly pleased that the agency has placed a new emphasis on patient satisfaction, outcomes, patient assessments, plans of care, and patient education. For example, we support the Conditions for Quality Assessment and Performance Improvement, as well as the adoption of the Centers for Disease Control and Prevention and the Association for the Advancement of Medical Instrumentation guidelines related to infection control and water quality and purity, respectively. We are also encouraged by the fact that CMS recognizes the need for better training of patient care dialysis technicians, but we are concerned that the proposed requirements are not sufficient in this area.

Ensuring high-quality care for patients with kidney disease remains the central focus of KCP. Our members have worked diligently to improve quality, as the ESRD Clinical Performance Measures Project recognized when it stated: “Since 1994, [we have] documented continued improvements, specifically in the areas of adequacy of dialysis and anemia management. The providers of dialysis services are to be commended for their ongoing efforts to improve patient care.”

Personnel Qualifications (§ 494.140(e)): One quality initiative that KCP strongly supports is the need for more consistent training for patient care dialysis technicians. As noted in the Proposed Rule, there are no federal requirements pertaining to the training of patient care dialysis technicians. 70 Fed. Reg. at 6222. KCP strongly supports efforts to establish uniform training and certification requirements for these technicians. This approach is consistent with that proposed in legislation introduced by Sens. Rick Santorum (R-PA) and Kent Conrad (D-ND) and Reps. Dave Camp (R-MI) and William Jefferson (D-LA). S. 635 and H.R. 1298 would require that patient care dialysis technicians receive uniform training and become certified,

indicating at least a minimum level of competency to provide dialysis-related services. These technicians would be required to repeat training or become recertified if 24 consecutive months pass during which they have not performed dialysis-related services. Service providers and renal dialysis facilities would provide performance reviews and in-service education to assure ongoing competency. Although KCP recognizes the importance of deferring to the states to regulate health care workers, the Medicare program has already established similar training requirements for unlicensed personnel in skilled nursing facilities. Given this, we urge CMS to modify the Proposed Rule to incorporate the training and certification requirements outlined in the legislation described above.

KCP supports on-the-job training of patient care technicians, but does not believe only RNs are capable of providing the necessary direct supervision. Historically, our members have successfully relied upon RNs, licensed practical nurses (LPNs), and experienced patient care technicians to train and mentor new patient care technicians. The Conditions for Coverage should recognize that any of these categories of health care workers are capable of providing various components of the training and mentoring of new patient care dialysis technicians. For example, in most cases, experienced patient care technicians can appropriately train and mentor new technicians if an RN has first assessed the learning needs of the trainee and appropriately delegated the training and mentoring to a qualified LPN or patient care technician. Allowing facilities to retain this flexibility would ensure that those providers within a dialysis facility who have the most experience in performing the specific tasks train and mentor new patient care technicians under the direct supervision of an RN. Therefore, KCP urges CMS to require that RNs directly supervise the training and mentoring of new patient care technicians, while delegating immediate supervision of these activities to qualified patient care technicians and LPNs. To ensure that the regulation clearly expresses these relationships, we also suggest that CMS define the term direct supervise to mean that the RN must be present in the dialysis facility and be immediately available to furnish assistance and direction throughout the performance of the training and mentoring activities; it does not mean the RN must be present in the room during the training and mentoring activities. CMS should also define the term immediate supervision to mean that the health care professional to whom the training and mentoring activities have been delegated is actually in the room with the new patient care technician and engaged in the training and mentoring activities.

**Recommendation:** KCP strongly encourages CMS to review carefully each proposed Condition to ensure that it allows facilities to provide high-quality care to patients without imposing unnecessary burdens.
II. KCP is concerned that the extensive nature of the Proposed Rule will result in significant increases in costs for facilities at a time when, as MedPAC recognizes, facilities must subsidize the cost of care due to Medicare’s longstanding under-funding of the ESRD program.

The ESRD composite rate is the only Medicare PPS without an annual update mechanism to adjust for changes in input prices and inflation. In its most recent report, MedPAC indicates that Medicare payments do not cover the costs dialysis facilities incur when caring for beneficiaries. The adequacy of Medicare payment has eroded during the past 20 years. Using 2005 dollars, the payment in 1983 was $134; today it is only $130.

The Proposed Rule is troubling because it would expand the scope of services dialysis facilities must provide without addressing the fact that dialysis facilities must subsidize the cost of care they provide to Medicare beneficiaries because of the failure of the Medicare program to appropriately fund the ESRD program. For example, it would require most facilities to install expensive new equipment for which the costs significantly outweigh the benefits the equipment would provide and would establish additional paperwork requirements that would duplicate what other providers already must do. KCP strongly urges CMS to review the Proposed Rule and eliminate those Conditions for Coverage that add significant costs to providing care for Medicare patients without directly providing benefits to patients, unless an annual update mechanism is established for the ESRD composite rate.

Physical Environment (§ 494.60): CMS’s Proposed Rule would increase the costs facilities incur by requiring the installation of new equipment, the benefit of which is doubtful. For example, it would require dialysis facilities to install automatic notification systems that would alert emergency personnel of a fire. 70 Fed. Reg. at 6197-200 (§ 494.60). Although the idea has merit, KCP is concerned that the cost of implementing the system outweighs the potential benefit. Dialysis facility staff is always on-site monitoring patients, as well as their physical surroundings. In the case of fire or another type of emergency, they are trained to contact emergency personnel immediately and to work to ensure the safety of all patients.

This proposed Condition would require a significant investment by many dialysis facilities while providing questionable benefits. One KCP member investigated the cost of an automated notification system in the Orlando area. Installation alone would exceed $3000. Monitoring would cost each facility approximately $186 per month. CMS’s calculation is much lower because the agency did not include the required back-up phone line that would cost approximately $106 per month. The agency’s installation estimate is extremely low, based upon current market prices. Assuming a conservative estimate that only half of U.S. dialysis facilities would need to install new systems, the total cost of this provision alone would be close to $5
In addition, dialysis facilities are frequently located in buildings in which they rent space and are limited by the lease as to what remodeling they may do. Also, some facilities are located in buildings that if sprinkler systems must be installed, they will have to be installed in all parts of the building. In these instances, facilities would be forced to relocate and be subject to the additional costs associated with such moves. Because of the financial difficulties facilities already face, it simply does not make sense to require them to shift scarce resources away from patient care to install new systems that will not result in significantly better safety for patients.

**Plan of Care (§ 494.90):** Similarly, KCP questions the benefit of duplicating the transplant referral tracking already required of transplant centers. KCP agrees that there is value in documenting in a patient’s record his/her transplant status as determined by a transplant center. 70 Fed. Reg. at 6207 (§ 494.90). It is a patient’s treating nephrologist who has that responsibility and prerogative. Additionally, given the scarce resources available to dialysis facilities, it does not make sense to require dialysis facilities to communicate quarterly with transplant centers and to track each patient’s transplant status. To the contrary, transplant centers are required to notify the dialysis facility of a patient’s transplant status following referral through their own Conditions of Participation. 70 Fed. Reg. at 6161 (§482.94(c)). When a patient’s status changes, the transplant center should contact the dialysis facility so that it can update the patient’s records.

Given the existing financial constraints on dialysis facilities, it simply does not make sense to require facilities to take money that would otherwise go to patient care and spend it installing new equipment or mandating new administrative duties that will provide questionable benefits to patients.

**Recommendation:** **KCP strongly encourages CMS to review carefully each proposed Condition to ensure that it is cost effective and avoids placing significantly higher costs on facilities, especially if the benefit to patients is questionable.**

**III.** KCP is concerned that some of the proposed Conditions for Coverage would inappropriately hold facilities responsible for activities and outcomes over which they do not have control.

KCP agrees that one of the primary objectives of the Conditions for Coverage should be to “establish performance expectations for facilities.” 70 Fed. Reg. at 6184. Although we are pleased that CMS has proposed revisions that are more patient centered and encourage patients to take a more active role in their treatment, we are deeply concerned that some of the changes would establish performance expectations that dialysis facilities do not have sufficient personnel
resources or authority to influence. We are also concerned that the Proposed Rule would hold dialysis facilities responsible for the activities of other providers, such as nursing facilities, rehabilitation facilities, transplant centers, pharmacists, and attending nephrologists, over which dialysis facilities have no control. Simply put, it is not appropriate for CMS to judge dialysis facilities for activities that they cannot influence and control. Therefore, we strongly urge CMS to modify the Proposed Rule to focus on those aspects of patient care that dialysis facilities have the ability to influence or control.

*Plan of Care (§ 494.90):* One area of concern is the proposed Condition that would require dialysis facilities to “provide the necessary care and service for the patient to achieve and sustain an appropriate level of productive activity, including vocational, as desired by the patient, including the educational needs of pediatric patients.” 70 Fed. Reg. at 6250 (§ 494.90) (emphasis added). KCP strongly believes patients on dialysis should remain as active and productive as possible. It is important that everyone in the kidney care community works to promote the physical and mental well being of patients.

The approach the agency proposes is problematic in this regard: as drafted, this proposed Condition seems to suggest that dialysis facilities are required to provide comprehensive rehabilitation care, which is outside of the specialized training of dialysis facility staff and beyond the scope of payment for dialysis services. KCP agrees that social workers should provide assessments and guidance to patients to help them understand better how to alter their lifestyles and work with other health care providers to increase their level of productive activity. Dialysis facilities and their staff can and should serve as a safety net for monitoring patient well-being and guiding patients in a way that allows them obtain the highest quality of life. However, the general language of the proposed Condition appears to require facilities to do much more than that. Given the current Medicare reimbursement rates, dialysis facilities cannot afford to hire rehabilitation specialists to provide comprehensive care. Rather than mandate that dialysis facilities provide this type of care, KCP strongly urges CMS to modify this Condition so that dialysis facilities are required to document that the social worker and facility staff have discussed with patients whether to seek referrals from their nephrologists for additional rehabilitation services (such as physical therapy, occupational therapy, counseling, and vocational rehabilitation).

The clearest example of how CMS could inappropriately hold dialysis facilities responsible for the activities of other providers over which they have no control is the proposed Condition to make dialysis facilities responsible for ensuring that each patient’s physician sees the patient at least once a month. 70 Fed. Reg. at 6250 (§ 494.90(b)(4)). Nephrologists are not employees of dialysis facilities. They are independent providers and receive payments separate and apart from the reimbursement dialysis facilities receive. KCP feels strongly that because the
Conditions for Coverage are meant to ensure that dialysis facilities that participate in the Medicare program meet certain requirements to promote patient care and that failure to meet these requirements may result in exclusion from the Medicare Program, it is inappropriate and counterproductive to hold dialysis facilities responsible for the actions of other providers over which the facilities have no control. Additionally, this Condition appears to be an attempt to regulate nephrologists indirectly. The Social Security Act prohibits CMS from “exercis[ing] supervision or control over the practice of medicine or the manner in which medical services are provided.” 42 U.S.C. § 1395. It is inappropriate for CMS to try to regulate how nephrologists practice medicine through the ESRD Conditions for Coverage. For these reasons, we urge CMS to eliminate this requirement.

**Care at Home (Preamble discussion of ESRD patients in nursing and skilled nursing facilities):** In the preamble of the Proposed Rule, CMS suggests that it is considering how to address the issues raised by providing dialysis to the frail elderly residing in nursing and skilled nursing facilities. 70 Fed. Reg. at 6212-14. Given that CMS has yet to propose regulatory text to address these issues, KCP looks forward to working with the agency as it begins exploring how to deal with this unique ESRD subpopulation. In the meantime, we strongly encourage CMS to clarify that until the agency provides more nursing facility-specific guidance the institution in which the patient is living (e.g., a nursing or skilled nursing facility) will be deemed to be the patients’ “home” for purposes of ESRD regulations. Without this specific designation, there will continue to be significant confusion that threatens the quality of care these patients receive.

**Recommendation:** KCP strongly encourages CMS to review carefully each proposed Condition to ensure that it recognizes those activities and outcomes over which dialysis facilities are practically able to exercise control and does not hold them responsible for activities and outcomes that they cannot influence.

**IV.** KCP is concerned that some of the proposed Conditions for Coverage are overly prescriptive and contrary to the goal of maximizing flexibility.

KCP appreciates CMS’s efforts to revise the Conditions for Coverage to “provide greater flexibility” for dialysis facilities. See 70 Fed. Reg. at 6187. We strongly believe greater flexibility will allow facilities to focus more on the individual needs of patients and less on general procedural requirements. For the most part, the Proposed Rule takes important steps that allow for this increased flexibility. However, KCP is concerned that the agency has not incorporated the need for flexibility into some of the Conditions. One example of this problem is the timeline
the agency proposes for conducting the patient assessment and establishing each patient’s individualized plan of care.

**Patient Assessment and Plan of Care (§§ 494.80 & 494.90):** The proposed patient assessment and plan of care timelines lack sufficient flexibility because they inappropriately focus on calendar days rather than on the number of visits patients make to a facility. 70 Fed. Reg. at 6203-10 (§§ 494.80 & 494.90). KCP agrees that patients should receive assessments and plans of care in a timely manner. However, by focusing on calendar days, rather than on the number of patient treatments in the facility, CMS ignores the reality that a patient may not receive treatments from a single dialysis facility during the first months of dialysis due to the patient’s unstable condition and need for re-hospitalization.

Because of this reality, KCP suggests that CMS modify the Proposed Rule to require that facilities have (1) **9 consecutive treatment sessions** during which to complete patients’ assessments and that reassessments for new patients occur within **36 treatment sessions** after the completion of the initial assessment and (2) **5 treatment sessions** after the initial assessment is complete to develop and implement the plan of care. These timelines correspond to the timelines set forth by CMS, but give providers the flexibility to adjust for individual patient needs.

**Recommendation:** KCP strongly encourages CMS to review carefully each proposed Condition to ensure that it provides dialysis facilities with sufficient flexibility to meet the individual needs of each patient.

V. Conclusion

Generally, KCP is pleased that CMS has published proposed Conditions for Coverage that recognize the importance of focusing on patient care. As the agency continues to consider how to modify the Conditions, our members would welcome the opportunity to meet with you and your staff to discuss these comments.

Sincerely,

Kent J. Thiry  
Chairman of the Board  
Kidney Care Partners
Attachment A

Abbott Laboratories
American Nephrology Nurses Association
American Regent, Inc.
Amgen
Baxter Healthcare Corporation
Bone Care International
California Dialysis Council
Centers for Dialysis Care
DaVita, Inc.
Fresenius Medical Care North America
Gambro Healthcare/USA
Genzyme
Medical Education Institute
National Kidney Foundation
National Renal Administrators Association
Northwest Kidney Centers
Physicians Dialysis, Inc.
Renal Care Group
Renal Physicians Association
Renal Support Network
Satellite Health Care
Sigma-Tau Pharmaceuticals, Inc.
Watson Pharma, Inc.