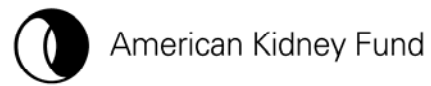


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May 19, 2005

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

RE: CMS-3818-P

Dear Dr. McClellan:

The American Kidney Fund is our nation's leading voluntary health organization serving people with and at risk for kidney disease through direct financial assistance, comprehensive education, clinical research and community service programs. The Fund is pleased to provide our comments on the proposed revisions to the Conditions of Coverage for End Stage Renal Disease (ESRD) Facilities (CMS-3818-P).

The Fund appreciates CMS' undertaking this ambitious effort to update the long-standing Conditions of Coverage. We also urge CMS to establish a process that allows more timely revisions as research, new knowledge and practices develop which improve the clinical management of patients with ESRD.

The Fund supports the agency's emphasis on patient-centered outcomes and on patients' participation in their care as stated in the preamble to the Conditions. We suggest this emphasis on patient-centered outcomes and patient participation in their care be translated into specific provisions in the body of the Conditions of Coverage. We believe there must also be specific provisions in the regulations adequately support dialysis centers in their provision of optimal patient care, including resources for rehabilitation services and attention to functional status and quality of life.

We strongly favor efforts to improve quality of care and patient outcomes in ESRD through patient participation in the multi-disciplinary care team and in the patient care planning process. Appropriate availability of staff (nephrologists, nurses, social workers and dietitians) for patient training and education is required. In addition, provisions to encourage the adoption of new and improved clinical practices and performance measures in the Conditions of Coverage are needed to continually improve patient outcomes.

We believe CMS must also consider the financial implications of these potential regulations on dialysis providers so that unintended negative consequences do not occur. There must be adequate financial resources available for dialysis facilities to implement many of the proposed conditions. Certain requirements, such as staff ratios and infection control nurses, have the potential to improve patient care, but also to increase costs, which must be fairly reimbursed. Over the last seven years ESRD facilities have received only a 3.6% increase in reimbursement for dialysis treatments provided. During the same time, because of market basket adjustments, hospitals have received a 12% increase and the Consumer Product Index has gone up 16.9%. The Fund supports CMS' efforts to further improve patient outcomes and believes payment policy must be adjusted concomitantly.

Finally, the Fund encourages CMS to convene a panel of patients and practicing nephrology professionals, including nurses, technicians, administrators, social workers, dietitians and nephrologists to assist in writing the interpretive guidelines which will be based on these Conditions of Coverage.

The Fund's specific comments on the Conditions of Coverage are listed below, by section.

Patient Safety

ESRD facilities should provide a safe and comfortable environment including the incorporation of the Life Safety codes for new facilities. Specifically,

- We endorse CMS' emphasis on infection control (**Section 494.30**). However, we believe the accountability for appropriate infection control should rest with the medical director who can delegate a qualified staff person, not necessarily a registered nurse, to act as infection control/safety officer. **(b)**
- Likewise, the Fund agrees with the importance of water quality standards (**Section 494.40**) and believes facilities should meet the most current AAMI standards for water treatment and dialyzer reprocessing (**Section 494.50**).
- We believe automated external defibrillators should be required at all facilities. (**Section 494.60**).

Patients Rights and Responsibilities--Section 494.70

The Fund believes that ESRD patients must be fully aware of and engaged in their treatment options and participate fully in decisions regarding their care.

- We suggest adding a requirement that facilities document that patients have demonstrated their understanding of the information provided or document that staff have made a concerted effort, as defined by written policy, to help the beneficiary understand established patients rights and responsibilities. **(a)(2)**
- We strongly support the language of **(a)(5)** which describes the right of patients to participate in the planning of their care and proposes patients be informed of their right to establish written advance directives describing an individual's preference with regard to the degree of medical care and treatment desired and who should make treatment decisions if the individual becomes incapacitated. We strongly support the proposal that the patient or designee must sign the care plan, regardless of participating in the planning process.

- In addition to informing patients of all available treatment modalities, including all home options, we advocate adding the requirement that patients must be notified of where treatments modalities are offered within a 120 mile radius if the facility does not provide a particular modality. **(a)(6)**
- We propose adding a requirement that patients have access to a qualified dietitian and social worker, as appropriate. Currently, social workers and dietitians often have unrealistic caseloads, cover multiple facilities and/or work part-time and patients often don't know how to contact them when needed.
- We also propose adding a requirement that patients should be informed at the initiation of treatment, that employment and/or schooling are possible for those requiring dialysis.
- We support the proposal that facilities should inform patients of its written transfer and discharge policies and procedures and make them available to all patients when they start dialysis. **(b)**.

We support the 30-day notice requirement for patient discharge **(b)(1)** and **(2)** except in the instance of actual or potential physical harm to patients or staff, in which case the facility should have the right

- to discharge the patient and local law enforcement authorities should be notified and informed of the patient's need for dialysis.
- The Fund urges CMS to add a condition that no patient be involuntarily discharged without documentation that a program was available and implemented to resolve inappropriate behavior except in an emergency situation, as above and that the facilities be required to involve the appropriate Networks in such situations.
- We also agree with the statement in the preamble that a patient should not be involuntarily discharged from a dialysis facility for non-adherence to the medical regimen and suggest that it be added to the regulations.

Patient Assessment-Section 494.8

The Fund believes patient assessment should include baseline and annual follow-up measurement of patients' functional status and well-being, using validated instruments (such as the widely used SF36) to determine physical and mental components scores. These can identify low scoring patients, scores changes over time and provide historical data supporting physical, occupational therapy referrals, or psychological referrals for constructive interventions. This would be particularly helpful for professionally addressing levels of depression, for which Medicare does provide some reimbursement services.

Patient Plan of Care--Section 494.90

The Fund strongly supports patients' right to be involved in their care, including participation in the multi-disciplinary care plan. We further suggest a requirement that the facility must document a patient has declined to participate.

- Regarding measures of dialysis outcomes (a)(1-3), the Fund believes the Conditions of Coverage should require facilities to adhere to the National Kidney Foundation KDOQI® guidelines and performance measures developed by CMS achieving minimum threshold values for dialysis adequacy, anemia management, nutrition, and vascular access. These are mostly evidence-based standards accepted by the nephrology community. Conditions of Coverage should be updated as the

science matures and/or new guidelines are established. CMS should enlist the panel of experts suggested earlier for developing the interpretive guidelines to assist with changes in the guidelines.

- Transplant status **(a) (5)**, we do not agree to deleting the requirement for someone from the transplant center sign the care plan as proposed. We suggest a transplant surgeon, physician, or transplant coordinator sign the plan, which documents the patients' degree of suitability and interest in transplantation. Successful transplantation has long been recognized as the preferred standard of care, and documentation of discussion and planning may lead to increased numbers being transplanted and decrease patient allegations of not having discussed transplantation during the patient care plan sessions at the dialysis center.
- The care plan should also stress rehabilitation goals with appropriate referrals to physical therapy, occupational therapy, psychological therapy and vocational counseling services as needed. The Fund also supports a requirement that facilities offer modalities and schedules which are work/study-friendly or provide a list of facilities which do.
- We suggest the addition of a requirement that patient care plan include a report on the self-care activities the patient performs or the basis for non-participation.

Care at Home-Section 494.100

The Fund supports the proposed regulations that facilities adopt the same clinical performance measure for home patients as those that are used for in-center patients.

Quality Assurance and Performance Improvement--Section 494.110

The Fund supports the proposal to require an ongoing facility-specific, patient-centered continuous quality improvement program that includes physical, mental and clinical health outcomes, using commonly agreed upon measures such as quality of life questionnaires including the short version of KDOQI[®] or SF36.

Personnel Qualifications-Section 494.140

The Fund believes that qualified health professionals are crucial to the provision of quality care in the ESRD setting. Data from the Dialysis Outcome Practice Pattern Study (DOPPS) have shown there is a strong association between the level of staff training and patient outcomes. We have the following specific comments.

- The Conditions of Coverage should continue to require that the Medical Director of a dialysis facility be either board certified or board eligible in nephrology.
- Clinical social work training is essential to provide appropriate counseling to patients for the complex psychosocial issues related to ESRD and its treatment. Therefore, we urge CMS to change the language regarding Social Workers **(d)** to include: 1) Completion of a course of study with specialization in clinical practice and receiving a masters degree from a graduate school of social work accredited by the Council on Social Work Education and 2) Licensure in the state in which s/he is practicing.

- The Fund supports the provisions related to Dialysis Technicians. However, we believe certification of dialysis technicians should be a goal of the ESRD program and urge CMS to develop a reasonable timeframe to accomplish this.

Governance -Section 494.180

- We strongly agree with the proposal that an RN must be present in the facility at all times when patients are being treated **(b) (2)**
- We support the newly proposed requirement for written approved training program for staff technicians **(b) (5)**
- The Fund supports the proposed section detailing specific conditions for the facility's transfer and discharge policies, and holding the facility accountable for staff adherence to these policies **(f)**

The American Kidney Fund appreciates this opportunity to comment on the proposed regulations. Since the Fund's mission is dedicated to improving patient access and quality of care and outcomes, we'd be please to meet with you to discuss our comments prior to the final promulgation of the regulations.

Sincerely,



Andrew Givens
Chair, Board of Trustees