Submitter : Dr. Ehsan Shahmir **Date:** 05/04/2005

Organization : Dr. Ehsan Shahmir

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

attaachment

CMS-3818-P-190-Attach-1.DOC

Attachment #190
Department of Health and Human Services
Centers for Medicare and Medicaid Services

Response from:
Ehsan Shahmir, MD
Nephrologist, Medical director of two dialysis unit at Vacaville, California

COMMENTS REGARDING FILE CODE CMS-3818-PD

General comments and observations;

1) **On the proposal to adopt a standard for requiring "Ultra Pure Water" to be used for Dialysis:**

Research has not proven that the use of "ultra pure" water offers any benefit. The cost to dialysis clinics could prove to be excessively burdensome

2) **RN coverage in a dialysis facility:**

It is to the patient's best interest to have sufficient RN coverage to meet the needs of the patient. One RN in the building may not be enough to provide safe coverage under many circumstances.
It would be preferable to establish safe guidelines and patient to RN ratio.
I recommend the requirement of the nurses to be according to the number of patients

3) **Dialysis Staff education:**

In reference to proposal to educate dialysis staff annually: It is reasonable and efficacious to do on-going education of the dialysis staff. Yearly re-visiting of all areas of education, as in initial dialysis training is generally not necessary. What is necessary and helpful are in-services and training for new policies and procedures as well as targeting areas of weakness which can be revealed by audits and observations by administrative staff. Annual skills updates and observations may be useful. The language should be clear, so individual inspectors cannot interpret the requirement differently, and dialysis clinics can comply without confusion.

COMMENTS SPECIFIC TO SPECIFIED CONDITIONS OF PARTICIPATION

ISSUE IDENTIFIER:

494.60 : PHYSICAL ENVIRONMENT

(c): patient care environment

The language used in section C1 regarding space requirements for dialysis facilities is ambiguous and can easily be interpreted differently by different inspectors; precise language and guidelines for space requirements would be preferable.

(c)(2) i and ii : temperature within the dialysis unit

Dialysis patients, by the very nature of their illness, generally have lower body temperatures. They often present to the dialysis unit with oral temperatures less than 98.6. It is sometimes necessary to run the temperature of the dialysis machine at an even lower temperature to help support blood pressure during dialysis. It is exceedingly unrealistic to put control of the dialysis clinic temperature at the discretion of multiple patients who will each have a different idea of comfortable temperatures.

The statement "make reasonable accommodations for patients who are not comfortable at the temperature that is comfortable for the majority" is vague and nebulous. The dialysis clinic would be placed under a condition that cannot realistically be met.

While the comfort of the dialysis patient is of prime importance, there are other issues in the dialysis clinic. Dialysis staff are forced by OSHA regulations to wear heavy, impermeable, long sleeved and full length personal protective gowns over full clothing. They are also shielded from fresh air flow for most of the day due to the wearing of face shields and masks. The Dialysis staff must be able to work continuously, moving from one task to the next. They often suffer from over-heating, sometimes to the point of profuse perspiration and faintness. Under these conditions, ability to move quickly and to **think clearly can be impaired** and **the patients safety may be compromised.** Facility temperatures must be conducive to the health and welfare of the dialysis staff as well as the patient.

Patients can use blankets to keep them warm, dialysis staff do not have any recourse. A temperature that is fair to all should be the standard.

There are also issues with temperatures of solutions such as the Paracetic Acid used for reprocessing and sterilizing dialyzers. This solution must be kept at a constant temperature of about 72 degrees. In older clinics where the air conditioning system may not be as sophisticated, the temperature of these solutions increase as the ambient temperature increases, creating unacceptable storage environments.

494.80 : PATIENT ASSESSMENT

(a) Standard: Assessment Criteria

(1) Evaluation of current health status, including co-morbid conditions

The language used in this sentence leaves the door open to hold dialysis clinics and staff responsible to address each of a patients co-morbid conditions, regardless of their significance in the dialysis setting. There are no boundaries or parameters set, thus leaving the area of assessment open to individual interpretation. While it may be appropriate for the Nephrologist and dialysis staff to address certain applicable co-morbidities, in general co-morbid conditions should be addressed and followed by the patient's primary physician.

It is unreasonable to expect dialysis clinics to be broad based health clinics; they have neither the staffing nor the financial resources to do so. In addition most of the

HMO's do not allow the Nephrolgist to order any test which is not related directly to the dialysis treatment and therefore this proposal creates a huge responsibility on the Nephrologist and dialysis unit staff while they do not have any authority to order necessary treatment or referrals.

(13) (b)Standard: Frequency of assessment for new patients:

(1) An initial comprehensive assessment must be conducted within 20 calendar days after the first dialysis treatment

The language in this section leaves no room for uncontrollable situations and thus sets the dialysis clinic up for failure in many circumstances. It is not uncommon to admit a patient or to receive a transfer patient who may need hospitalization within the 20 day time frame. There needs to be some language or clause to cover this unexpected situation. The original 30 day time frame is a much more accomplishable time frame (with exception as mentioned above) and allows for lab draws and other assessments, as well as giving reasonable time for the interdisciplinary team to gather.

494.90: PATIENT PLAN OF CARE

The first paragraph in this section includes the following language " plan of care.....must include measurable and expected outcomes and **estimated timetables to achieve these outcomes.**

The main concern here is that there are times when, even with the best and most conscientious intervention, patients do not or can not, for a variety of reasons, meet the expected outcomes.

The patient is a major player in the success or failure of many outcome goals. They are given choices and their right and freedom to choose to comply or not to comply with medical recommendations must be respected. Dialysis clinics should not be held responsible or payment reduced, when medical intervention is appropriate, yet outcomes or timetables fail to be met. The major concern is: " what will the Medicare response be, if all efforts fail to aid the patient to achieve the expected outcomes?"

(6) Rehabilitation status

The language in this section is ambiguous and leaves much opportunity for misinterpretation by individual inspectors. "**Must provide the necessary care and services** for the patient to achieve and sustain an appropriate level of productive activity.....etc" .

While providing **referrals for services** is reasonable and standard, it is not reasonable to expect the Dialysis clinic staff to do more than providing the referral. Dialysis clinics have neither the resources nor the funds to provide for anything beyond referrals or to provide necessary information.

(c)Standard: Transplantation referral tracking

It is unrealistic to expect the dialysis team to be responsible to maintain communication with the Transplant facility. Once a transplant referral is made and the patient is seen, it is more appropriate that the Transplant Coordinator and

the Transplant Center be held accountable for communication with the patient and the dialysis facility.

This language makes the dialysis team responsible for others' area of service and scope of practice. This requirement also takes individual responsibility away from the patient, who should be encouraged to be independent and personally accountable for as much as possible in their lives. A patient who takes an active role in their care is much more likely to achieve a desired outcome.

Once the referral is made, the burden of responsibility should not rest with the dialysis team.

494.140 : CONDITION: PERSONEL QUALIFICATIONS

(b) Standard: Nursing services

(2) Charge nurse

The standards for the dialysis clinic must be held as high as possible. While many practical nurses may have adequate experience and aptitude to be a charge nurse, it is the Registered Nurse who is trained to do so and is legally responsible. By allowing the practical nurses to assume charge nursing responsibilities we may compromise the patient's safety .

(c) Standard: Dietitian

(3) Work experience

The requirement of one year's professional work experience is unnecessary as long as the Dietitian Candidate has met the conditions for registration with the Commission on Dietetic Registration and is supervised by an experienced Renal Dietitian. It is highly improbable and unlikely that one year experience will better prepare them to work with Renal patients, as this area is such a highly specialized area that one has to work in the field to gain expertise as a Renal Dietitian.

To require this length of time in professional work experience will lead to the potential loss of excellent candidates who could be trained and mentored by experienced and qualified people.

494.30; infection control

Despite CDC recommendation for monitoring and testing for hepatitis C, dialysis patients have not been screened for two reasons:

1. The cost of the testing is not covered by CMC
2. Diagnosis of the hepatitis C does not change the dialysis treatment.

I recommend that the primary care physicians and the HMOs caring for the dialysis patients to perform the test and treat them accordingly.

Thank you for your consideration.

Sincerely,
Ehsan Shahmir, MD

Submitter : Ms. Linda Coy **Date:** 05/04/2005

Organization : Ms. Linda Coy

Category : Social Worker

Issue Areas/Comments

Issues 11-20

Personnel Qualifications

My name is Linda Coy and I am currently employed as a nephrology social worker for a major dialysis corporation in Maryland. I have become aware of the proposed hemodialysis COC and wish to state my comments regarding such. It is difficult to meet the many various, bio-psychosocial-cultural-spiritual needs of the patients that I serve with a caseload that often exceeds 140 patients. I agree with the recommendation of the Council of Nephrology Social Workers that a ratio of 75 patients per full-time equivalent social worker. In addition, when caseloads exceed 75 patients per full-time equivalent social worker, a case aide is employed to manage tasks that are clerical in nature not limited to admissions, billing, insurance coverage concerns, transportation and travel. As a master level clinically licensed social worker, I am equipped to address psychosocial issues related to hemodialysis however it is almost impossible to accomplish this with given caseload. Several case studies have indicated that hemodialysis patients greatly benefit from appropriate access to their nephrology social worker. Improved outcomes have also been indicated from nephrology social work intervention. As an advocate for the End Stage Renal Disease community, it is believed that implementation of a reasonable nephrology social worker to patient ratio be established for the benefit of the patient as well as the dialysis facility.

Submitter : Ms. M. Kathy Harty **Date:** 05/04/2005

Organization : DaVita

Category : Nurse Practitioner

Issue Areas/Comments

Issues 1-10

Infection Control

I think it is necessary to specify that staff caring for Hepatitis B antigen positive patients in a hemodialysis unit with both Hepatitis B antigen negative and positive patients cannot care for both Hepatitis B antigen positive pts and hepatitis B negative pts on the same pt shift. Staffing ratios imposed upon clinics interfere with good judgement and effective infection control. It is unreallistic to think that a pct caring for a Hepatitis B positive pt in isolation and also assigned pts outside the isolation area would not expose the negative pts to Hepatitis B.

Submitter : Mrs. Gloria Wood **Date:** 05/05/2005

Organization : Mrs. Gloria Wood

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I think it would be best if all dialysis units had to pool the money they recieve for payment from private insurance, Medicare and Medicaid so that all patients could recieve equal quality care, including same choice of machine as private insurance patients and appropriate time on machine not linked to cost.

Submitter : Dr. ilyas iliya **Date:** 05/05/2005

Organization : St. Luke's Hospital

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

As a nephrologist, I am very concerned that we do not have coverage for providing dialysis care for our SNF patients at our facility. It would improve the cost and quality of care of our patients to be able to provided it in situ.

CMS-3818-P-195

Date: 05/05/2005

Submitter : Dr. Timothy Page

Organization : Prairie Lakes Healthcare System

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-195-Attach-1.RTF

CMS-3818-P-195-Attach-2.RTF

Attachment #195
April 29, 2005

Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
Attention CMS-3818-P
PO Box 8012
Baltimore, MD 21244-8012

To Whom It May Concern On the Regulatory Comments Review Committee:

Please consider my comments regarding the revision of the regulations for care of the ESRD patients.

Theresa Kwechin RN

Re: Comments on proposed revision of requirements of ESRD 42 CFR Parts 400, 405, 412, 413, 414, 488, and 494.
CMS –3818-P

III Provisions of Proposed Part 494 Subpart A-General Provisions:

A. **Basis and Scope** (Proposed § 494.1)
All facilities should be recertified every three years to ensure appropriate oversight for this high-risk patient population. Facilities that have condition level deficiencies should be placed on yearly surveillance cycles till such a time as they have demonstrated safe care for two consecutive years. Money should be allocated to step up surveillance for the ESRD facilities that have not been able to meet the minimal requirements for safe and adequate care of the ESRD patient. Monetary sanctions should be in the regulatory language for facilities that do not meet condition level requirements for two recertification cycles.

B. **Definitions** (Proposed § 494.10)
I disagree with the proposed new definition of Home Dialysis. Home Dialysis should not include NF/SNF. If maintenance dialysis is being provided in these settings, then it must be done under the direct supervision of a Federally Certified Provider. All patients that receive dialysis are entitled to the same quality care and should be protected by regulations that govern their care without exception to their living in SNF/NF. Staff that provides dialysis in institutionalized settings must be trained and supervised under the direction of a Registered Nurse or Physician specifically trained in Dialysis. All patients that receive dialysis HD or PD must receive so with a dialysis trained RN onsite at all times while the patient is receiving dialysis regardless of the

setting. Definition of Home Dialysis should remain exclusive of an institutionalized setting.

C. **Compliance with Federal, State, and Local Laws and Regulations** (Proposed § 494.20)

I agree with the proposal that dialysis facilities must be in compliance with appropriate Federal, State, and local laws and regulations regarding drug and medical device usage.

IV. Provisions of Proposed Part 494 Subpart B (Patient Safety)

A. **Infection Control** (Proposed § 494.30)

I agree with Proposed requirement that facilities demonstrate that they follow CDC "Recommended Infection Control Practices for Hemodialysis Units" with the following exception: HBV infection is still a significant potential problem for hemodialysis patients in an "in-center" setting. There is documented evidence of conversions each year. CDC does not recommend that HBV positive patients use the designated isolation rooms or areas exclusively. Multiple interpretations have been submitted to the State Agencies from CDC that allows "immune" patients to use "positive" machines in isolation rooms and stations. For the protection of this "more at risk" population, truly dedicated isolation rooms, stations, machines and equipment should be used for HBV infected patients only and without exception. "HBV immunity" as defined as anti-HBs >10 mIU/ml is not protection for life. ESRD patients have demonstrated immune deficiencies and are labeled as "poor responders". The current CDC recommendation for annual surveillance for anti-ABs does not ensure adequate protection for patients that are potentially exposed to virus from known infected patients by allowing "immune protected" patients to be dialyzed in isolation rooms or areas designated for HBs AG carriers. There should be very strong language in this regulation to prohibit this practice.

I do not agree with the CDC endorsement of allowing medication vials that are labeled "single dose only" that have no bacteriostatic agent in the solution to be used and penetrated multiple times within a four-hour period (i.e. erythropoietin). This is not a safe practice, not enforced by the facilities and contrary to the manufacturer's recommendation. This dangerous practice is only "allowed" for ESRD patients. There is documented evidence of an out break of serratia liquefaciens from contamination of erythropoietin vials at a hemodialysis center even before this practice was endorsed by CDC.

B. **Water Quality** (Proposed § 494.40)

I agree with the inclusion of a separate condition regarding water quality.
I agree with the proposed frequency of water purity testing.
I agree with proposed requirement for a minimum of two carbon tanks regardless of the current composition of its source water. This should be in place, as an emergency back up should the water treatment system in the community change. ESRD facilities must commit to being able to be more self

sufficient and more able to respond to the emergency needs of their patients. Without the back up of a second carbon tank, should the only tank connected to the system saturate the entire water system must be shut down. Patients must therefore be transferred to other facilities, more often to the hospital back up unit. This emergency plan puts an undue strain on the resources of the community hospitals.
I agree with the proposed regulation that the bicarbonate concentrate be used within the specified time as recommended by the manufacturer.
I agree with the CMS adoption of the current AAMI standards for minimum safety requirements for water treatment. I also agree that water quality is of vital importance to health and well being of the dialysis patient. Surveillance of the safety of the product water used for dialysis includes frequent monitoring of culture and endotoxin levels. Many facilities are now conducting "onsite testing" of endotoxins with little or no quality controls. Regulation should require that facilities use only certified labs for (specifically certified for environmental cultures) analysis of bacteria growth and LAL testing.

C. **Reuse of Hemodialyzers and Bloodlines** (Proposed § 494.50)
Heat disinfection of hemodialyzers should be banned from all ESRD Facilities. It is a failed attempt to eliminate chemical disinfection from the reuse process. Many facilities have abandoned this form of reuse, but those facilities that still practice heat disinfection of hemodialyzers are plagued with blood leaks that have had a devastating effect on the patients. The facilities that use heat disinfection do little more than count the number of blood leaks each month as part of their QA monitoring. Experience has shown us that there is no solution in sight to correct the defect in the process. Each time a hemodialyzer leaks during treatment the patient may lose up to 250cc of blood. Rupture of the internal fibers of the dialyzer also exposes the patient to infectious contamination. The quality controls that need be in place to prevent blood leaks are work intensive, unsupervised by licensed personnel and are not enforced by facility leadership personnel. Facilities historically under report the number of blood leaks that occur. At the very least, a task force should be developed to examine the safety of this practice.

D. **Physical Environment** (Proposed § 494.60)
I disagree with the proposal that small rural facilities be exempt from the defibrillator requirement. These facilities are less likely to have a physician available to act in an emergency and these units are frequently far from available EMS or hospital services. These facilities should also be required to have an AED on site and without the option of manual defibrillator. The use of a manual defibrillator requires the presence of a physician.

I disagree with the deletion of the requirement of a nursing/monitoring station from which adequate surveillance of patients receiving dialysis services can be made. Contrary to CMS comment, design of the ESRD facilities is a physical environment issue. Since regulation requires that only one

professional nurse be available for patient care in the unit, it is imperative that that one nurse has easy visual access to as many patients as possible. Even if facilities were required to have a nurse call system, due to the advanced age and multiple co-morbidities of the patients, a vast number of patients are not able to use the call system.

V. Proposed Part 494 Subpart C (Patient Care)

A. **Patient's Rights** (§ 494.70)

ESRD patients are often forced by facilities to sign "waivers" for early termination of treatments as described as against medical advice. I strongly recommend that there be language in the regulation to protect patients whose request for toileting, pain management etc. is resolved not only by termination of treatment. At the very least, licensed personnel should first assess patients who are forced by a universal facility policy to terminate treatment. Protection of patient's dignity should fall on qualified personnel.

I recommend that there be regulatory language that includes that patients have a right to be free from sexual, verbal, or physical abuse, intimidation and harassment.

I recommend that all patients should be afforded the right to be informed of who their caregivers are and their credentials. All staff should be required to wear easily read nametags with their job titles.

I agree that there are rare circumstances when a facility must act immediately to discharge a patient due to criminal and dangerous behavior in the unit. I also recognize that facilities have discharged patients for lack of payment from the uninsured. Without an accepting facility, these patients are left to use the hospital emergency rooms for care. This alternative puts an exhaustive stress on the resources of the hospitals and it is substandard care for these patients. I recommend that before a facility can resort to this action as a permanent solution, a mandated referral should be made to the ESRD network for alternative solutions and arbitration on behalf of the patient if needed.

B. **Patient Assessment** (Proposed § 494.80)

I agree with the proposed addition of the condition of patient assessment.

I agree with the 3-month time frame for reassessment of new patients. The newly diagnosed ESRD patients are usually too sick or depressed to participate in life altering decisions regarding their care and treatment plan. Frequently, it is the referring physician who chooses the treatment modality on behalf of the patient.

I strongly recommend that CMS mandate that a Registered Nurse or physician conducts all patient assessments. There should also be language in

the regulation that states all medications are administered by licensed personnel.

C. **Patient Plan of Care** (Proposed § 494.90)
I agree with proposed elimination of the requirement of a separate long-term program.

I agree with the proposal to eliminate the requirement that a transplant surgeon directly sign the care plan. The role of the transplant surgeon is to educate the interdisciplinary team as to the inclusion/exclusion criteria for each program and to be able to keep current of the patients changing needs. Part of the intent of the existing regulation was to ensure the appropriate and timely communication of patient information between the transplant center and the dialysis facility. I recommend that there be written documentation from the transplant center of the active transplant status of the patient. This documentation should be updated at least annually. The dialysis center should develop a formal means to communicate to the transplant center the condition of the patient and the changing needs of the patient. For stable patients this could be annual to coincide with the proposed annual reassessment of the patient. Each facility should designate a Registered Nurse to act as Transplant Coordinator or Liaison whose responsibilities would be to; maintain and update the transplant list; communicate to the various transplant centers changes in the patient's status; ensure all necessary histocompatibility testing is drawn and sent out to the transplant centers; and also to be an in-center resource for the patients to assist in education and updates on transplant services.

I agree with the proposal that the patient sign their care plan to assure that the patient is aware of the treatment plan.

I recommend that if patients are not being referred for home dialysis, then the exclusion criteria used must be documented in the patient's plan of care.

I agree with the requirement that the patients be expected to meet minimum threshold values for the patient plan of care. These clinical goals are measurable; outcome oriented and evidenced based. If a patient does not meet minimum threshold values for adequacy, then the physician must develop an action plan.

I strongly recommend that for anemia management, each patient's prescription for erythropoitin be individualized. Many facilities have put in place a general policy for dosing of medications by use of a sliding scale without consideration for each individual patient's needs, All medications to be administered to ESRD patients should have an individualized order from the physician specific for that patient.

I agree with the NKF -K/DOQI Guidelines as minimum standards for dialysis adequacy and anemia management. These guidelines have been universally adopted as evidenced-based community accepted standards.

I agree that the proposed time frame of 30 days to complete the patient assessment and plan of care is ample time. A timely and comprehensive needs assessment by the team is critical for the benefit of the patient to begin to adjust to dialysis and move toward emotional and physical health. Rehabilitation goals of the dialysis patient are most likely to be achieved if initiated early in the course of the treatment plan.

I strongly agree that physicians be required to see their in-center patients periodically, while those patients are being dialyzed in the dialysis facility. It would be near impossible for physicians to formulate a comprehensive assessment and to trouble shoot problems that occur during treatment having never seen the dialysis center. It is also quite comforting for the patients to have their physicians familiar with the environment they are receiving treatment in. It also empowers the patients to have a physician as actively involved in their care as is possible. Regardless of facility policy, when patients are asked who would they complaint to if they were having a problem with the center or treatment, they almost always answer their doctor.

D. **Condition: Care at Home** (Proposed § 494.100)

I agree that providing dialysis services in nursing homes is, in theory, ideal. The travel to dialysis centers for this fragile group of patients is very disruptive to their lifestyle and most times interferes with their care and treatment plan. I agree that dialysis centers in long term care institutions should not be an undue burden to the SNF. Unfortunately, our experience has been that the physical environment, staffing and overall service in the nursing home units is inferior to the in-center facilities. The dialysis units in the SNF/NF are usually quite small and the facilities find providing all the required services for dialysis patients cost prohibitive. There is therefore a tendency for the dialysis unit to rely on the SNF to provide some of the minimal service requirements or these services are not provided at all. Especially lacking are social services, dietary counseling and adequate oversight of the water treatment system. We all want these units to be successful but we can't turn our backs to the poor care being delivered. This is our most vulnerable group of patients in the ESRD population. CMS should develop a task force to assist these small units to be able to come into compliance with the requirements for minimum standards of care.

I do not agree that dialysis can be performed and supervised by the SNF staff. If dialysis is taking place in the nursing home, then the same requirements for care apply as for the in-center patients. That is that a qualified Registered Nurse be on site and directly supervising the

treatments whenever patients are being dialyzed. This patient population is more likely then any other group to have more serious and more frequent complications. These patients are also less likely to be able to participate in their care.

E. **Condition: Quality Assessment and Performance Improvement** (Proposed § 494.110)

I agree with the inclusion of a separate condition for QAPI.

I recommend that the Program scope include mortality reviews, surveillance of the water treatment system, review of infection control programs and a comprehensive central venous catheter reduction program.

I agree with the proposal that would require facilities to take action that will result in performance improvement and track performance to assure standards are met and that improvements are sustained over time.

I strongly disagree with the need for a "risk adjuster" for a facility wide performance measure. The minimum threshold values to be incorporated in QAPI are evidenced based and have proven to have an impact on patient mortality and morbidity. What patients will be exempt from this standard? Facilities must move away from the culture that one dialysis prescription fit all. A comprehensive and meaningful QAPI program will assist facilities to identify problems and come up with solutions to satisfy the needs of all their patients.

F. **Condition: Special Purpose Renal Dialysis Facilities** (Proposed § 494.120)

I agree with the proposed changes to make access to care for patients in disaster conditions more available.

G. **Laboratory Services** (Proposed § 494.130)

I agree to retain the existing requirements.

VI. Provisions of Proposed Subpart D: Administration

A. **Personnel Qualifications** (Proposed § 494.140)

I disagree with the proposed change in the qualifications of the facility Medical Director. CMS should retain the requirement that the Medical Director be Board Certified or Board eligible. Board Certification is the accepted industry standard for evidence of proficiency in a particular specialty.

I disagree that the nurse responsible for each shift may be a LPN. I strongly recommend that a Registered Nurse be onsite at all times while patients are being dialyzed. The nursing shortage should not justify the use of unqualified staff.

I agree that some of the tasks often assigned to the social worker such as: investigation into Medicare benefits, eligibility for Medicaid, housing, and medications should be handled by other facility staff in order for the MSW to participate fully with the interdisciplinary team so that optimal outcomes of care may be achieved.

I agree with the minimum qualification of a high school diploma or GED for dialysis technicians. I also agree that the training for dialysis technicians should be under the direct supervision of a Registered Nurse and that the training be a minimum of three months.

I strongly agree with the implementation of a training program that is specific to technicians who monitor the water treatment system. Annual validation of skills should be incorporated into the training program.

I recommend that each ESRD facility have routine consultations with a qualified Pharmacist. This would be to review facility policies on acquisition of medications, safe storage, medication administration and medical record review for medication errors.

B. **Condition: Responsibilities of the Medical Director** (Proposed § 494.150)

I agree with the expansion of the language in this condition that assigns more accountability to the Medical Director regarding the overall care of the patients.

There should be a requirement for annual renewal of credentials and evaluation of the attending physicians by the Medical Director. This annual evaluation should include, at a minimum, compliance with:

1. Timely actions for patients who do not meet the measurable threshold values noted in "Care of the Patient".
2. Attendance at interdisciplinary care meetings.
3. Minimum requirement for in-center patient visits.
4. QAPI recommendations
5. Mortality/Morbidity reviews.
6. Completion of quality patient assessments and reassessments.
7. Completeness of medical record requirements.
8. Condition of Patient's Rights.
9. Adherence to on-call schedule and requirements.
10. Current CPR certification
11. Attendance at fire/safety/disaster drills.
12. Annual health screen

C. **Relationship with ESRD Network** (§ 494.160)

No comment.

D. **Condition: Medical Records** (§ 494.170)

I disagree with the proposed elimination of the requirement that facilities have written policies and procedures for record keeping. The facility staff need guidance to ensure that patients' rights of confidentiality are adhered to.

I recommend that all discharged patients medical records be completed within 30 days inclusive of mortality reviews. This is ample time to collect all necessary data and it is within the timeframe of at least one cycle of required monthly labs to evaluate threshold values.

I recommend that each facility work toward a system to improve documentation of medication administration and decrease the incidence of or potential for medication errors. Most facilities do not have a centralized record of all medications administered and physician orders (exclusive of standard maintenance dialysis orders). Most facilities document "other" orders such as, antibiotics or pulses of iron administration, on the daily treatment record. As the daily treatment records are archived, the order and record of administration is not readily available. This practice has lead to multiple medication errors in ESRD facilities. The success or failure of these new systems should be followed by QAPI. This is in keeping with CMS new focus on achieving better patient outcomes.

I agree with the elimination of the requirement of a medical records supervisor.

E. **Condition: Governance** (Proposed § 494.180)

I agree that in a typical unit, the volume, scope, and complexity of administrative, financial, and operational responsibilities requires the day-to-day attention of a separate CEO/administrative position. Because of the volume of responsibilities I recommend that CMS limit the number of facilities an administrator may operate. It is not unusual to have administrators be responsible for 4 or more facilities.

I agree to retain the existing requirement that a dialysis facility ensure that an adequate number of qualified personnel are present whenever patients are undergoing dialysis. I also appreciate the difficulty CMS would have devising a common regulation that would encompass the multitude of differences and complexities of the various State licensing and certification laws, and union contracts. I do however recommend that CMS require that each individual facility have a written policy that describes safe staffing in their unit, given their patient population, the acuity of the patients they care for, the availability of personnel resources and in compliance with State law. Each safe staffing policy should include:

1. RN/patient ratio.
2. LPN/patient ratio
3. Social worker/patient ratio
4. Dietician/patient ratio
5. PCT/patient ratio

This would allow each facility the flexibility to make decisions regarding their personnel needs without CMS being too prescriptive. It will also protect the patients from inadequate staffing. The facility should evaluate their staffing policy at least annually in their QAPI program.

I agree with the proposal that would require a written approved training program for patient care technicians. I agree with the criteria posed but would add specific training on patient rights and sensitivity training. This training should be reinforced by formal classes at least annually. The only proposed criteria for consideration for a facility to hire a PCT is a high school diploma or GED. Many of the people hired for these positions have never worked with sick, frail or elderly people. They can feel quite challenged dealing with the day-to-day-demands of working with the chronically ill. It takes training to develop the skills needed to effectively and compassionately care for "difficult" patients (as I often hear dialysis patients described). Dialysis patients are fearful of retaliation from their caregivers. We are all shamed by this fact. Providing appropriate, consistent and quality training for health care workers in ESRD facilities is the place to start to improve care.

I agree to the proposal that facilities be responsible for their staff adherence to the facility's discharge or transfer policies and procedures. I recommend that for patients who are discharged against their will and before a facility can resort to this action as a permanent solution, a mandated referral should be made to the ESRD Network for alternative solutions and arbitration on behalf of the patient if needed.

I agree that data from ESRD facilities be mandatory instead of voluntary. I recommend that random audits be conducted by the ESRD Networks to validate accuracy of data submitted since data submitted is self-reported.

Thank you for this opportunity to comment.
You may contact me at:
Rtheresa@aol.com

Submitter : michelle dunkley **Date:** 05/05/2005

Organization : michelle dunkley

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-3818-P-196-Attach-1.DOC

Attachment #196
April 29, 2005

Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
Attention CMS-3818-P
PO Box 8012
Baltimore, MD 21244-8012

To Whom It May Concern On the Regulatory Comments Review Committee:

Please consider my comments regarding the revision of the regulations for care of the ESRD patients.

Theresa Kwechin RN

Re: Comments on proposed revision of requirements of ESRD 42 CFR Parts 400, 405, 412, 413, 414, 488, and 494.
CMS –3818-P

III Provisions of Proposed Part 494 Subpart A-General Provisions:

A. **Basis and Scope** (Proposed § 494.1)
All facilities should be recertified every three years to ensure appropriate oversight for this high-risk patient population. Facilities that have condition level deficiencies should be placed on yearly surveillance cycles till such a time as they have demonstrated safe care for two consecutive years. Money should be allocated to step up surveillance for the ESRD facilities that have not been able to meet the minimal requirements for safe and adequate care of the ESRD patient. Monetary sanctions should be in the regulatory language for facilities that do not meet condition level requirements for two recertification cycles.

B. **Definitions** (Proposed § 494.10)
I disagree with the proposed new definition of Home Dialysis. Home Dialysis should not include NF/SNF. If maintenance dialysis is being provided in these settings, then it must be done under the direct supervision of a Federally Certified Provider. All patients that receive dialysis are entitled to the same quality care and should be protected by regulations that govern their care without exception to their living in SNF/NF. Staff that provides dialysis in institutionalized settings must be trained and supervised under the direction of a Registered Nurse or Physician specifically trained in Dialysis. All patients that receive dialysis HD or PD must receive so with a dialysis trained RN onsite at all times while the patient is receiving dialysis regardless of the

setting. Definition of Home Dialysis should remain exclusive of an institutionalized setting.

C. **Compliance with Federal, State, and Local Laws and Regulations** (Proposed § 494.20)

I agree with the proposal that dialysis facilities must be in compliance with appropriate Federal, State, and local laws and regulations regarding drug and medical device usage.

IV. Provisions of Proposed Part 494 Subpart B (Patient Safety)

A. **Infection Control** (Proposed § 494.30)

I agree with Proposed requirement that facilities demonstrate that they follow CDC "Recommended Infection Control Practices for Hemodialysis Units" with the following exception: HBV infection is still a significant potential problem for hemodialysis patients in an "in-center" setting. There is documented evidence of conversions each year. CDC does not recommend that HBV positive patients use the designated isolation rooms or areas exclusively. Multiple interpretations have been submitted to the State Agencies from CDC that allows "immune" patients to use "positive" machines in isolation rooms and stations. For the protection of this "more at risk" population, truly dedicated isolation rooms, stations, machines and equipment should be used for HBV infected patients only and without exception. "HBV immunity" as defined as anti-HBs >10 mIU/ml is not protection for life. ESRD patients have demonstrated immune deficiencies and are labeled as "poor responders". The current CDC recommendation for annual surveillance for anti-ABs does not ensure adequate protection for patients that are potentially exposed to virus from known infected patients by allowing "immune protected" patients to be dialyzed in isolation rooms or areas designated for HBs AG carriers. There should be very strong language in this regulation to prohibit this practice.

I do not agree with the CDC endorsement of allowing medication vials that are labeled "single dose only" that have no bacteriostatic agent in the solution to be used and penetrated multiple times within a four-hour period (i.e. erythropoietin). This is not a safe practice, not enforced by the facilities and contrary to the manufacturer's recommendation. This dangerous practice is only "allowed" for ESRD patients. There is documented evidence of an out break of serratia liquefaciens from contamination of erythropoietin vials at a hemodialysis center even before this practice was endorsed by CDC.

B. **Water Quality** (Proposed § 494.40)

I agree with the inclusion of a separate condition regarding water quality.
I agree with the proposed frequency of water purity testing.
I agree with proposed requirement for a minimum of two carbon tanks regardless of the current composition of its source water. This should be in place, as an emergency back up should the water treatment system in the community change. ESRD facilities must commit to being able to be more self

sufficient and more able to respond to the emergency needs of their patients. Without the back up of a second carbon tank, should the only tank connected to the system saturate the entire water system must be shut down. Patients must therefore be transferred to other facilities, more often to the hospital back up unit. This emergency plan puts an undue strain on the resources of the community hospitals.
I agree with the proposed regulation that the bicarbonate concentrate be used within the specified time as recommended by the manufacturer.
I agree with the CMS adoption of the current AAMI standards for minimum safety requirements for water treatment. I also agree that water quality is of vital importance to health and well being of the dialysis patient. Surveillance of the safety of the product water used for dialysis includes frequent monitoring of culture and endotoxin levels. Many facilities are now conducting "onsite testing" of endotoxins with little or no quality controls. Regulation should require that facilities use only certified labs for (specifically certified for environmental cultures) analysis of bacteria growth and LAL testing.

C. **Reuse of Hemodialyzers and Bloodlines** (Proposed § 494.50)
Heat disinfection of hemodialyzers should be banned from all ESRD Facilities. It is a failed attempt to eliminate chemical disinfection from the reuse process. Many facilities have abandoned this form of reuse, but those facilities that still practice heat disinfection of hemodialyzers are plagued with blood leaks that have had a devastating effect on the patients. The facilities that use heat disinfection do little more than count the number of blood leaks each month as part of their QA monitoring. Experience has shown us that there is no solution in sight to correct the defect in the process. Each time a hemodialyzer leaks during treatment the patient may lose up to 250cc of blood. Rupture of the internal fibers of the dialyzer also exposes the patient to infectious contamination. The quality controls that need be in place to prevent blood leaks are work intensive, unsupervised by licensed personnel and are not enforced by facility leadership personnel. Facilities historically under report the number of blood leaks that occur. At the very least, a task force should be developed to examine the safety of this practice.

D. **Physical Environment** (Proposed § 494.60)
I disagree with the proposal that small rural facilities be exempt from the defibrillator requirement. These facilities are less likely to have a physician available to act in an emergency and these units are frequently far from available EMS or hospital services. These facilities should also be required to have an AED on site and without the option of manual defibrillator. The use of a manual defibrillator requires the presence of a physician.

I disagree with the deletion of the requirement of a nursing/monitoring station from which adequate surveillance of patients receiving dialysis services can be made. Contrary to CMS comment, design of the ESRD facilities is a physical environment issue. Since regulation requires that only one

professional nurse be available for patient care in the unit, it is imperative that that one nurse has easy visual access to as many patients as possible. Even if facilities were required to have a nurse call system, due to the advanced age and multiple co-morbidities of the patients, a vast number of patients are not able to use the call system.

V. Proposed Part 494 Subpart C (Patient Care)

A. **Patient's Rights** (§ 494.70)

ESRD patients are often forced by facilities to sign "waivers" for early termination of treatments as described as against medical advice. I strongly recommend that there be language in the regulation to protect patients whose request for toileting, pain management etc. is resolved not only by termination of treatment. At the very least, licensed personnel should first assess patients who are forced by a universal facility policy to terminate treatment. Protection of patient's dignity should fall on qualified personnel.

I recommend that there be regulatory language that includes that patients have a right to be free from sexual, verbal, or physical abuse, intimidation and harassment.

I recommend that all patients should be afforded the right to be informed of who their caregivers are and their credentials. All staff should be required to wear easily read nametags with their job titles.

I agree that there are rare circumstances when a facility must act immediately to discharge a patient due to criminal and dangerous behavior in the unit. I also recognize that facilities have discharged patients for lack of payment from the uninsured. Without an accepting facility, these patients are left to use the hospital emergency rooms for care. This alternative puts an exhaustive stress on the resources of the hospitals and it is substandard care for these patients. I recommend that before a facility can resort to this action as a permanent solution, a mandated referral should be made to the ESRD network for alternative solutions and arbitration on behalf of the patient if needed.

B. **Patient Assessment** (Proposed § 494.80)

I agree with the proposed addition of the condition of patient assessment.

I agree with the 3-month time frame for reassessment of new patients. The newly diagnosed ESRD patients are usually too sick or depressed to participate in life altering decisions regarding their care and treatment plan. Frequently, it is the referring physician who chooses the treatment modality on behalf of the patient.

I strongly recommend that CMS mandate that a Registered Nurse or physician conducts all patient assessments. There should also be language in

the regulation that states all medications are administered by licensed personnel.

C. **Patient Plan of Care** (Proposed § 494.90)
I agree with proposed elimination of the requirement of a separate long-term program.

I agree with the proposal to eliminate the requirement that a transplant surgeon directly sign the care plan. The role of the transplant surgeon is to educate the interdisciplinary team as to the inclusion/exclusion criteria for each program and to be able to keep current of the patients changing needs. Part of the intent of the existing regulation was to ensure the appropriate and timely communication of patient information between the transplant center and the dialysis facility. I recommend that there be written documentation from the transplant center of the active transplant status of the patient. This documentation should be updated at least annually. The dialysis center should develop a formal means to communicate to the transplant center the condition of the patient and the changing needs of the patient. For stable patients this could be annual to coincide with the proposed annual reassessment of the patient. Each facility should designate a Registered Nurse to act as Transplant Coordinator or Liaison whose responsibilities would be to; maintain and update the transplant list; communicate to the various transplant centers changes in the patient's status; ensure all necessary histocompatibility testing is drawn and sent out to the transplant centers; and also to be an in-center resource for the patients to assist in education and updates on transplant services.

I agree with the proposal that the patient sign their care plan to assure that the patient is aware of the treatment plan.

I recommend that if patients are not being referred for home dialysis, then the exclusion criteria used must be documented in the patient's plan of care.

I agree with the requirement that the patients be expected to meet minimum threshold values for the patient plan of care. These clinical goals are measurable; outcome oriented and evidenced based. If a patient does not meet minimum threshold values for adequacy, then the physician must develop an action plan.

I strongly recommend that for anemia management, each patient's prescription for erythropoitin be individualized. Many facilities have put in place a general policy for dosing of medications by use of a sliding scale without consideration for each individual patient's needs, All medications to be administered to ESRD patients should have an individualized order from the physician specific for that patient.

I agree with the NKF -K/DOQI Guidelines as minimum standards for dialysis adequacy and anemia management. These guidelines have been universally adopted as evidenced-based community accepted standards.

I agree that the proposed time frame of 30 days to complete the patient assessment and plan of care is ample time. A timely and comprehensive needs assessment by the team is critical for the benefit of the patient to begin to adjust to dialysis and move toward emotional and physical health. Rehabilitation goals of the dialysis patient are most likely to be achieved if initiated early in the course of the treatment plan.

I strongly agree that physicians be required to see their in-center patients periodically, while those patients are being dialyzed in the dialysis facility. It would be near impossible for physicians to formulate a comprehensive assessment and to trouble shoot problems that occur during treatment having never seen the dialysis center. It is also quite comforting for the patients to have their physicians familiar with the environment they are receiving treatment in. It also empowers the patients to have a physician as actively involved in their care as is possible. Regardless of facility policy, when patients are asked who would they complaint to if they were having a problem with the center or treatment, they almost always answer their doctor.

D. **Condition: Care at Home** (Proposed § 494.100)

I agree that providing dialysis services in nursing homes is, in theory, ideal. The travel to dialysis centers for this fragile group of patients is very disruptive to their lifestyle and most times interferes with their care and treatment plan. I agree that dialysis centers in long term care institutions should not be an undue burden to the SNF. Unfortunately, our experience has been that the physical environment, staffing and overall service in the nursing home units is inferior to the in-center facilities. The dialysis units in the SNF/NF are usually quite small and the facilities find providing all the required services for dialysis patients cost prohibitive. There is therefore a tendency for the dialysis unit to rely on the SNF to provide some of the minimal service requirements or these services are not provided at all. Especially lacking are social services, dietary counseling and adequate oversight of the water treatment system. We all want these units to be successful but we can't turn our backs to the poor care being delivered. This is our most vulnerable group of patients in the ESRD population. CMS should develop a task force to assist these small units to be able to come into compliance with the requirements for minimum standards of care.

I do not agree that dialysis can be performed and supervised by the SNF staff. If dialysis is taking place in the nursing home, then the same requirements for care apply as for the in-center patients. That is that a qualified Registered Nurse be on site and directly supervising the

treatments whenever patients are being dialyzed. This patient population is more likely then any other group to have more serious and more frequent complications. These patients are also less likely to be able to participate in their care.

E. **Condition: Quality Assessment and Performance Improvement** (Proposed § 494.110)

I agree with the inclusion of a separate condition for QAPI.

I recommend that the Program scope include mortality reviews, surveillance of the water treatment system, review of infection control programs and a comprehensive central venous catheter reduction program.

I agree with the proposal that would require facilities to take action that will result in performance improvement and track performance to assure standards are met and that improvements are sustained over time.

I strongly disagree with the need for a "risk adjuster" for a facility wide performance measure. The minimum threshold values to be incorporated in QAPI are evidenced based and have proven to have an impact on patient mortality and morbidity. What patients will be exempt from this standard? Facilities must move away from the culture that one dialysis prescription fit all. A comprehensive and meaningful QAPI program will assist facilities to identify problems and come up with solutions to satisfy the needs of all their patients.

F. **Condition: Special Purpose Renal Dialysis Facilities** (Proposed § 494.120)

I agree with the proposed changes to make access to care for patients in disaster conditions more available.

G. **Laboratory Services** (Proposed § 494.130)

I agree to retain the existing requirements.

VI. Provisions of Proposed Subpart D: Administration

A. **Personnel Qualifications** (Proposed § 494.140)

I disagree with the proposed change in the qualifications of the facility Medical Director. CMS should retain the requirement that the Medical Director be Board Certified or Board eligible. Board Certification is the accepted industry standard for evidence of proficiency in a particular specialty.

I disagree that the nurse responsible for each shift may be a LPN. I strongly recommend that a Registered Nurse be onsite at all times while patients are being dialyzed. The nursing shortage should not justify the use of unqualified staff.

I agree that some of the tasks often assigned to the social worker such as: investigation into Medicare benefits, eligibility for Medicaid, housing, and medications should be handled by other facility staff in order for the MSW to participate fully with the interdisciplinary team so that optimal outcomes of care may be achieved.

I agree with the minimum qualification of a high school diploma or GED for dialysis technicians. I also agree that the training for dialysis technicians should be under the direct supervision of a Registered Nurse and that the training be a minimum of three months.

I strongly agree with the implementation of a training program that is specific to technicians who monitor the water treatment system. Annual validation of skills should be incorporated into the training program.

I recommend that each ESRD facility have routine consultations with a qualified Pharmacist. This would be to review facility policies on acquisition of medications, safe storage, medication administration and medical record review for medication errors.

B. **Condition: Responsibilities of the Medical Director** (Proposed § 494.150)

I agree with the expansion of the language in this condition that assigns more accountability to the Medical Director regarding the overall care of the patients.

There should be a requirement for annual renewal of credentials and evaluation of the attending physicians by the Medical Director. This annual evaluation should include, at a minimum, compliance with:

1. Timely actions for patients who do not meet the measurable threshold values noted in "Care of the Patient".
2. Attendance at interdisciplinary care meetings.
3. Minimum requirement for in-center patient visits.
4. QAPI recommendations
5. Mortality/Morbidity reviews.
6. Completion of quality patient assessments and reassessments.
7. Completeness of medical record requirements.
8. Condition of Patient's Rights.
9. Adherence to on-call schedule and requirements.
10. Current CPR certification
11. Attendance at fire/safety/disaster drills.
12. Annual health screen

C. **Relationship with ESRD Network** (§ 494.160)

No comment.

D. **Condition: Medical Records** (§ 494.170)

I disagree with the proposed elimination of the requirement that facilities have written policies and procedures for record keeping. The facility staff need guidance to ensure that patients' rights of confidentiality are adhered to.

I recommend that all discharged patients medical records be completed within 30 days inclusive of mortality reviews. This is ample time to collect all necessary data and it is within the timeframe of at least one cycle of required monthly labs to evaluate threshold values.

I recommend that each facility work toward a system to improve documentation of medication administration and decrease the incidence of or potential for medication errors. Most facilities do not have a centralized record of all medications administered and physician orders (exclusive of standard maintenance dialysis orders). Most facilities document "other" orders such as, antibiotics or pulses of iron administration, on the daily treatment record. As the daily treatment records are archived, the order and record of administration is not readily available. This practice has lead to multiple medication errors in ESRD facilities. The success or failure of these new systems should be followed by QAPI. This is in keeping with CMS new focus on achieving better patient outcomes.

I agree with the elimination of the requirement of a medical records supervisor.

E. **Condition: Governance** (Proposed § 494.180)

I agree that in a typical unit, the volume, scope, and complexity of administrative, financial, and operational responsibilities requires the day-to-day attention of a separate CEO/administrative position. Because of the volume of responsibilities I recommend that CMS limit the number of facilities an administrator may operate. It is not unusual to have administrators be responsible for 4 or more facilities.

I agree to retain the existing requirement that a dialysis facility ensure that an adequate number of qualified personnel are present whenever patients are undergoing dialysis. I also appreciate the difficulty CMS would have devising a common regulation that would encompass the multitude of differences and complexities of the various State licensing and certification laws, and union contracts. I do however recommend that CMS require that each individual facility have a written policy that describes safe staffing in their unit, given their patient population, the acuity of the patients they care for, the availability of personnel resources and in compliance with State law. Each safe staffing policy should include:

1. RN/patient ratio.
2. LPN/patient ratio
3. Social worker/patient ratio
4. Dietician/patient ratio
5. PCT/patient ratio

This would allow each facility the flexibility to make decisions regarding their personnel needs without CMS being too prescriptive. It will also protect the patients from inadequate staffing. The facility should evaluate their staffing policy at least annually in their QAPI program.

I agree with the proposal that would require a written approved training program for patient care technicians. I agree with the criteria posed but would add specific training on patient rights and sensitivity training. This training should be reinforced by formal classes at least annually. The only proposed criteria for consideration for a facility to hire a PCT is a high school diploma or GED. Many of the people hired for these positions have never worked with sick, frail or elderly people. They can feel quite challenged dealing with the day-to-day-demands of working with the chronically ill. It takes training to develop the skills needed to effectively and compassionately care for "difficult" patients (as I often hear dialysis patients described). Dialysis patients are fearful of retaliation from their caregivers. We are all shamed by this fact. Providing appropriate, consistent and quality training for health care workers in ESRD facilities is the place to start to improve care.

I agree to the proposal that facilities be responsible for their staff adherence to the facility's discharge or transfer policies and procedures. I recommend that for patients who are discharged against their will and before a facility can resort to this action as a permanent solution, a mandated referral should be made to the ESRD Network for alternative solutions and arbitration on behalf of the patient if needed.

I agree that data from ESRD facilities be mandatory instead of voluntary. I recommend that random audits be conducted by the ESRD Networks to validate accuracy of data submitted since data submitted is self-reported.

Thank you for this opportunity to comment.
You may contact me at:
Rtheresa@aol.com

Submitter : **Date: 05/05/2005**

Organization :

Category : **End-Stage Renal Disease Facility**

Issue Areas/Comments

GENERAL

GENERAL

A help button should be at each dialysis station. A trash can should be at each station. A clinic nephrologist should not difficult to call when needed in an emergency. He should not be able to tell the patient to see his PCP for a problem he can take care of.
Nurses should have much better training at putting in needles and should not be hired if they can't perform.

Submitter : Mr. Robert Duval **Date:** 05/05/2005

Organization : Mr. Robert Duval

Category : Individual

Issue Areas/Comments

Issues 11-20

Governance

I am a hemodialysis patient and I wish to comment on 494.180. The first comment is in regards to 494.180(b)(2). I would like to recommend that a RN be present in the hemodialysis treatment area at all times that patients are being treated. If something happens and I need a RN, it would be preferable if they were close at hand as opposed to somewhere in the building. The second comment is in support of 494.180(b)(5)(i through viii). I support dialysis patient care technician certification. It is a very scary proposition to not know the capabilities of technicians who one day are working at a local restaurant and the next day taking care of me on hemodialysis. You see and hear all kinds of things sitting in a dialysis chair. Please consider making it easier for patients to comment on regulations that impact on our lives (i.e., utilizing your Dialysis Facility Compare Web site to notify patients of proposed regulations). In any case, thanks for the opportunity to comment.

Submitter : Mr. Raymond Cord MHP, PA-C **Date:** 05/05/2005

Organization : American Academy of Nephrology PAs

Category : Physician Assistant

Issue Areas/Comments

GENERAL

GENERAL

Please See Attachment for Comment

CMS-3818-P-199-Attach-1.DOC

Attachment #199

April 22, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3818-P
PO Box 8012
Baltimore, MD 21244-8012

Dear CMS Team,

I am writing on behalf of The American Academy of Nephrology Physician Assistants (AANPA). Our organization is the national nephrology specialty chapter of the American Academy of Physician Assistants (AAPA) which represents over 55,000 clinically practicing PAs.

We welcome the opportunity to comment on the CMS Program; Conditions for Coverage for End Stage Renal Disease; Proposed Rules. These proposals cover 42 CFR Parts 400, 405, 410, 412, 413, 414, 488, and 494.

We are impressed at the amount of work that went into these revisions and applaud those that put in the time to prepare this extensive document.

As an organization, we do have an important concern. Physician Assistants (PAs) are currently providing daily assessment and ongoing care of patients in dialysis facilities across the nation. These physician services provided by PAs are currently reimbursed through CMS. Unfortunately, Physician Assistants are not appropriately included in the proposed policies. This could lead to problems with patient access to care, reimbursement for physician services provided by PAs as well as regulatory and liability issues.

PAs function as dependant practitioners with their supervising physician counter part. Statistics from the US Bureau of Labor and Statistics coupled with data on the number of chronic kidney disease patients, indicates that the number of patients starting dialysis is quickly outpacing the number of nephrologists available to adequately care for them. The Physician Assistant specializing in Nephrology is the natural compliment to the nephrologist by extending quality nephrology physician services to this increasingly needy population. The RPA (Renal Physician Association), ASN (American Society of Nephrology) and CMS have accepted Physician Assistants in Nephrology as a natural compliment to the multidisciplinary team.

The particular area of concern is CFR 494.9 "Plan of Care" where specifically it states:

Proposed Sec. 494.90(b)(4) would specify that the facility must ensure every patient is seen at least monthly by a physician providing the ESRD care as evidenced by a monthly progress note that is either written in the beneficiary's medical record by the physician or communicated from the physician's office and placed in the beneficiary's medical record.

This statement seems to exclude the Physician Assistant from seeing the patient for the purpose of the monthly progress note.

AANPA encourages the Centers for Medicare and Medicaid Services (CMS) to amend the language in 494.90(b)(4)to read: "***Sec. 494.90(b)(4) The facility must ensure every patient is seen at least monthly by a physician or physician assistant providing the ESRD care as evidenced by a monthly progress note that is either written in the beneficiary's medical record by the physician/or physician assistant or communicated from the physician's office and placed in the beneficiary's medical record.***

Please strongly consider our suggestion so that the spirit of this proposed policy to improve quality patient care does not end up limiting that same access to quality care by eliminating the PAs from the health care team.

Feel free to contact me with any questions.

Sincerely,

Raymond Cord MHP, PA-C
President
American Academy of Nephrology Physician Assistants

44 Canadian Geese Road

Submitter : **Arlene Antonoff** **Date: 05/05/2005**

Organization : **Arlene Antonoff**

Category : **Social Worker**

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

CMS-3818-P-200-Attach-1.DOC

Attachment #200
From: Arlene Antonoff, L.C.S.W.
24307 Baxter Drive
Malibu, CA 90265

494.60 Condition
Physical Environment.
(c) Patient care environment

Add to c1: Require facilities to be accessible to people with disabilities.
Rationale: Americans with Disabilities Act
Reference: ADA

Add to c1: Require facilities to maintain an office specifically for confidential interviews with patients and families and to provide privacy during body exposure.
Rationale: HIPAA privacy
Reference: *Protecting the Privacy of Patients' Health Information*

Comment: I support the inclusion of the proposed (c) (2) regarding facility temperature.
Rationale: A common complaint from dialysis patients is the facility climate. A patient-centered care approach dictates that facilities need to have a plan in place to accommodate patients' preferences for climate, and address the concerns of patients who are not comfortable.

494.70 Condition
Patients' Rights
(a) Standard: Patients' rights

Add: (2) Require facility to ask the patient to *demonstrate understanding* of information provided.
Rationale: Without this requirement, it would be very easy for staff to believe that they had informed a patient without realizing that, in fact, the patient did not understand the information.
References: Johnstone, 2004; Juhnke & Curtin, 2000; ?Kaveh & Kimmel, 2001

Comment & Addition to a6: I support the language of a6 with the recommended addition of requiring facilities to inform patients of all available treatments (in-center hemodialysis, CAPD, CCPD, conventional home hemodialysis, daily home hemodialysis, nocturnal home hemodialysis, transplant), and to provide a list of facilities where treatments are offered within 120 miles if the facility does not offer that treatment.

Rationale: I support a requirement that a facility inform patients about all available treatment modalities and settings to enable patients to make an informed decision regarding the most appropriate course of treatment that meets their needs. To assist dialysis patients in achieving the optimal quality of life, patients need education about each modality and must have access to the widest array of treatment choices possible. For patients to truly have choices in their modalities, they must not only know what types of treatment exist, but where they can be obtained. Home Dialysis Central (www.homedialysis.org) has a searchable database of clinics that offer any type of home dialysis and US maps for each home modality showing a 120 mile radius from clinic locations.

Comment: I support the language of a5
Rationale: Advance directives establish in writing an individual's preference with respect to the degree of medical care and treatment desired or who should make treatment decisions if the individual should become incapacitated and lose the ability to make or communicate medical decisions.

Add: (new 17) "Have access to a qualified social worker and dietitian as needed"
Rationale: Social workers and dietitians often have large caseloads, cover multiple clinics and/or work part-time, and patients often do not know how to contact them when needed.
References: Bogatz, Colasanto, Sweeney, 2005; Forum of ESRD Networks, 2003; ?Merighi & Ehlebracht, 2004a

Add: (new 18) "Be informed that full- or part-time employment and/or schooling is possible on dialysis"
Rationale: New patients do not know what to expect from dialysis and may be told that they must go on disability, when paid employment (with insurance) or schooling may be possible for them, particularly if they have access to evening shifts, transplant or home dialysis therapies. The purpose of dialysis is to permit the highest possible level of functioning despite kidney failure, thus this element of rehabilitation is crucial.
References:? Curtin et al,1996; ?Rasgon et al, 1993, 1996

Add: (new 19) "Have a work-friendly modality (PD or home hemodialysis) or schedule that accommodates work or school"
Rationale: Same as above for new 18.
References: Same as above for new 18, plus:Mayo 1999

Add: (new 20) "Receive referral for physical or occupational therapy, and/or vocational rehabilitation as needed"
Rationale: These interventions have been shown to improve patient rehabilitation outcomes.
References:? Beder, 1999; ?Dobrof et al., 2001; ?Witten, Howell & Latos, 1999.

Add: (new 21) "Attend care planning meetings with or without representation."

Rationale: Promoting patient participation in care requires that patients have the right to attend their own care planning meetings.

Add: (new 22) "Request an interdisciplinary conference with the care team, medical director and/or nephrologists."
Rationale: Patients don't realize that they can convene a care conference, and this is one way to obtain feedback from the team outside of the normal care planning meeting, which might only be done once/year.

Add: (new 23) "Refuse cannulation by a nurse or technician if access problems occurred with that staff member in the past until evidence of retraining is provided. Patients may also request another staff person to observe cannulation."
Rationale: Patients have only a limited number of potential vascular access sites, and if a staff person was responsible for causing access damage or hospitalization in the past, patients must have the right to protect themselves by refusing care from that staff person. Despite the obvious interpersonal and convenience issues this will cause for facilities, this is a patient safety issue that also has the potential to reduce cost to the system of hospitalization from vascular access problems. This will also encourage clinics to help their staff improve their cannulation skills and teach patients to self-cannulate.

Add: (new 24) "Be informed that self-cannulation is possible and be offered training to self cannulate."
Rationale: Having a single, consistent cannulator can help preserve vascular accesses and reduce hospitalizations. Since the patient is always present for the hemodialysis treatment, he or she should be encouraged whenever possible to become his/her own cannulator. Clinics should not be allowed to have a policy denying a willing patient the right to learn to self-cannulate.

Add: (new 25) "Be informed of topical analgesics for needle pain and how to obtain them"
Rationale: Needle fear and needle pain are largely unaddressed issues in hemodialysis, despite the large (14-15 gauge) needles that must be used at each treatment. Patients should be able to undergo a painless treatment, and low-cost, over-the-counter, 4% lidocaine preparations are available that will not harm the access and will provide pain relief. Patients should be told that these products exist and where to obtain them.
Reference:? McLaughlin et al., 2003

Add: (new 26) "Receive counseling from a qualified social worker to address concerns related to the patient's adjustment to illness, including changes to life-style and relationships because of his illness, developmental issues affected by his illness, and any behavior that negatively affects his health or standing in the facility."

Rationale: Patients are faced with numerous adjustment issues due to ESRD and its treatment regimes. Master's level social workers are clinically trained to intervene within areas of need that are essential for optimal patient functioning and adjustment
References: McKinley & Callahan, 1998; Vourlekis & Rivera-Mizzoni, 1997

494.70 Condition
Patients' Rights
(b) Standard: Right to be informed regarding the facility's discharge and transfer policies.
Add to b1: "Receive counseling and support from the team to resolve behavioral issues and be informed of behaviors that will lead staff to notify police or refer for evaluation of risk to self or others"
Rationale: Facilities should be encouraged first to try counseling to resolve difficult situations
References: Forum of ESRD Networks, 2003; Johnstone S, et al, 1997; King & Moss, 2004; Rau-Foster, 2001; Renal Physicians Association and American Society of Nephrology, 2000

Add: (new 2) "Not be involuntarily discharged from the facility for non-adherence with the treatment plan, including missing or shortening in-center hemodialysis treatments, excessive fluid weight gain, or lab tests that would suggest dietary indiscretions unless it can be shown that the patient's behavior is putting other patients or the facility operations at risk."
Rationale: The ESRD Networks and the preamble of these proposed Conditions for Coverage have both stated that non-compliance should not be a basis for involuntary discharge from lifesaving dialysis treatment. Patients often are not educated as to the reasons why these behaviors may be harmful to them; it is therefore inappropriate to refuse them care due to their lack of knowledge. If consistent difficulties are noted with a patients' ability to follow the treatment plan, a team evaluation should be initiated to investigate and address all potential factors. For example, a patient who is trying to maintain a full-time job to support a family may choose to leave treatment early rather than risk losing employment; or a patient who is taking a medication that causes dry mouth may be unable to follow the fluid limits for in-center hemodialysis.
References: Forum of ESRD Networks, 2003; Johnstone S, et al., 1997; King & Moss, 2004; Rau-Foster, 2001; Renal Physicians Association and American Society of Nephrology, 2000

Change: (renumbered 3) Delete or define "reducing...ongoing care."
Rationale: This phrase is unclear.

494.70 Condition
Patients' Rights
(c) Standard: Posting of rights.

Add: "Facilities with patients who cannot read the patients' rights poster must provide an alternate method to inform these patients of their rights which can be verified at survey."
Rationale & References: Americans with Disabilities Act, Civil Rights Act

494.80 Condition
Patient assessment

(a) Standard: Assessment criteria.
Change: The language of "social worker" in the first sentence to "qualified social worker"
Rationale: This will clarify any ambiguity of the social work role.

Add: (a1) "...and functioning and well-being using the SF-36 or other standardized survey that permits reporting of or conversion to a physical component summary (PCS) score and mental component summary (MCS) score and all domains of functioning and well-being measured by that survey. If the MCS or mental health domain score is low, assess for major depression using the PHQ-2 or another validated depression survey or referring the patient to further mental health evaluation."
Rationale: The preamble to the *Conditions for Coverage* discussed the importance of measuring functioning and well-being—but stated that there was "no consensus" about which measure to use. In fact, the literature clearly supports the value of the PCS and MCS scores to independently predict morbidity and mortality among tens of thousands of ESRD patients—and these scores can be obtained from any of the tools currently in use to measure functioning and well-being. The composite scores (PCS and MCS) have been proven to be as predictive of hospitalization and death as serum albumin or Kt/V. Scores can be improved through qualified social work interventions.
References: DeOreo, 1997; Kalantar-Zadeh, Kopple, Block, Humphreys, 2001; Knight et al. 2003; Kroenke, Spitzer & Williams, 2003; Lowrie, Curtin, LePain & Schatell, 2003; Mapes et al., 2004

Comment: I support the language of a2, a3, a4, a5, a6

Change: (a7) to "Evaluation of psychosocial needs (such as but not limited to: coping with chronic illness, anxiety, mood changes, depression, social isolation, bereavement, concern about mortality & morbidity, psycho-organic disorders, cognitive losses, somatic symptoms, pain, anxiety about pain, decreased physical strength, body image issues, drastic lifestyle changes and numerous losses of [income, financial security, health, libido, independence, mobility, schedule flexibility, sleep, appetite, freedom with diet and fluid], social role disturbance [familial, social, vocational], dependency issues, diminished quality of life, relationship changes; psychosocial barriers to optimal nutritional status, mineral metabolism status, dialysis access, transplantation referral, participation

in self care, activity level, rehabilitation status, economic pressures, insurance and prescription issues, employment and rehabilitation barriers)."
Rationale: Much like the elaboration of a1, a4, a8, a9, elaborating what "psychosocial issues" entails will ensure national coherence of the exact psychosocial issues that must be assessed for each patient. There is clear literature that identifies these psychosocial issues throughout this response.

Comment: CNSW supports the language of a8
Add: (a9)(new i) "The facility must include in its evaluation a report of self-care activities the patient performs. If the patient does not participate in care, the basis for nonparticipation must be documented in the medical record (i.e., cognitive impairment, refusal, etc.)."
Rationale: Life Options research has found that patients on dialysis 15 years or longer who participated actively in their own care did better; follow-up research with a random sample of 372 in-center hemodialysis patients found participation in self-care is correlated with higher functioning and well-being, which, in turn, predicts reduced hospitalization and mortality.
References: Curtin, Bultman, Schatell & Chewning, 2004; ?Curtin & Mapes, 2001

Add: (9)(new ii) "If the patient is not referred for home dialysis, the basis for non-referral must be documented in the medical record. Lack of availability of home dialysis in the facility is not a legitimate basis for non-referral."
Rationale: Requiring that the basis for non-referral for home dialysis be documented will help to ensure that patients have access to these therapies and will provide needed data for QAPI purposes.

Comment: I support the language of a10, a11, a12, a13
Change: (b1) to "An initial comprehensive assessment and patient care plan must be conducted within 30 calendar days after the first dialysis treatment.

Rationale: We recommend combining an initial team assessment and care plan as they work in concert: a care plan should address areas for intervention as identified in the assessment. Permitting 30 days for assessment and development of a care plan allows for full team participation and adequate assessment of patient needs.

Comment: I support the language of b2

Change: (d2iii) to "significant change in psychosocial needs as identified in 494.80 a7."
Rationale: Referring back to the specific psychosocial issues recommended to be added to 494.80 a7 will eliminate any ambiguity of needs to reassess ***Add:*** (v) "Physical debilitation per patient report, staff observation, or reduced physical

component summary (PCS) score on a validated measure of functioning and well-being."
Rationale: Low PCS scores predict higher morbidity and mortality in research among ESRD patients.
References: DeOreo, 1997; ?Kalantar-Zadeh, Kopple, Block, Humphreys, 2001; ?Knight et al. 2003; ?Kroenke, Spitzer & Williams, 2003; Lowrie, Curtin, LePain & Schatell, 2003; ?Mapes et al., 2004

Add: (new vi) "Diminished emotional well-being per patient report, staff observation, or reduced mental component summary (MCS) score on a validated measure of functioning and well-being."
Rationale: Low MCS scores predict higher morbidity and mortality in research among ESRD patients. Low MCS scores are also linked to depression and skipping dialysis treatments.
References: DeOreo, 1997; Kalantar-Zadeh, Kopple, Block, Humphreys, 2001; Knight et al. 2003; Kroenke, Spitzer & Williams, 2003; Lowrie, Curtin, LePain & Schatell, 2003; Mapes et al., 2004

Add: (new vii) "Depression per patient report, staff observation or validated depression screening survey"
Rationale: Multiple studies report a high prevalence of untreated depression in dialysis patients; depression is an independent predictor of death.
References: Andreucci et al., 2004.; Kimmel, 1993; Kimmel, 1998; Kutner et al., 2000.; Wuerth, Finklestein & Finklestein, 2005

Add: (new viii) "Loss of or threatened loss of employment per patient report"
Rationale: Poor physical and mental health functioning have been linked to increased hospitalizations and death. Loss of employment is linked to depression, social isolation, financial difficulties, and loss of employer group health plan coverage. Identifying low functioning patients early and targeting interventions to improve their functioning should improve their physical and mental functioning and employment outcomes.
References: ?Blake, Codd, Cassidy & O'Meara, 2000; ?Lowrie, Curtin, LePain & Schatell, 2003; ?Mapes et al., 2004; ?Witten, Schatell & Becker, 2004

Add: (a) the *patient* to those developing the plan and include: "If the patient or his or her representative does not participate in care planning, the basis for nonparticipation must be noted in the patient's medical record, the patient or his or her representative must initial the reason provided, and sign the care plan."
Rationale: The patient must be explicitly listed as part of the care planning process

Add: (new 3) "*Psychosocial status*. The interdisciplinary team must provide the necessary care and services to achieve and sustain an effective psychosocial status."

Rationale & References: Eighty-nine percent of ESRD patients report experiencing significant lifestyle changes from the disease (Kaitelidou, et al., 2005). The chronicity of end stage renal disease and the intrusiveness of its required treatment provide renal patients with multiple disease-related and treatment-related psychosocial stressors that affect their everyday lives (Devins et al., 1990). Researchers including Auslander, Dobrof & Epstein (2001), Burrows-Hudson (1995), and Kimmel et al. (1998) have found that psychosocial issues negatively impact health outcomes of patients and diminish patient quality of life. Therefore, "psychosocial status" must be considered as equally important as other aspects of the care plan.

Add: (new 6) Home dialysis status. All patients must be informed of *all* home dialysis options, including CAPD, CCPD, conventional home hemodialysis, daily home hemodialysis, and nocturnal home hemodialysis, and be evaluated as a home dialysis candidate. When the patient is a home dialysis candidate, the interdisciplinary team must develop plans for pursuing home dialysis. The patient's plan of care must include documentation of the
(i) Plan for home dialysis, if the patient accepts referral for home dialysis;
(ii) Patient's decision, if the patient is a home dialysis candidate but declines home dialysis; or
(iii) Reason(s) for the patient's non-referral as a home dialysis candidate as documented in accordance with § 494.80(a)(9)(ii) of this part.
Rationale: Home therapies allow greater flexibility, patient control, fewer dietary and fluid restrictions, need for fewer medications, potential for improved dialysis adequacy, and improved likelihood of employment. CMS has stated encouragement of home dialysis as a goal. Every patient must be informed of home dialysis options, evaluated for candidacy for home dialysis, and, if not a candidate, the reason(s) why not should be reported. This allows quality assessment and improvement activities to be undertaken in the area of home dialysis.

Add: (renumbered 8) "Rehabilitation status. The interdisciplinary team must provide the necessary care and services to:
(i) maximize physical and mental functioning as measured minimally by physical component summary (PCS) score and mental component summary (MCS) score on a validated measure of functioning and well-being (or an equally valid indicator of physical and mental functioning),
(ii) help patients maintain or improve their vocational status (including paid or volunteer work) as measured by annually tracking the same employment categories on the CMS 2728 form
(iii) help pediatric patients (under the age of 18 years) to obtain at least a high school diploma or equivalency as measured by annually tracking student status.
(iv) Reasons for decline in rehabilitation status must be documented in the patient's medical record and interventions designed to reverse the decline."
Rationale: The goals of the current proposed section are vague, not measurable, and not actionable. To improve rehabilitation outcomes, facilities

must meet certain standards. From the perspective of the Medical Education Institute, which administers the Life Options Rehabilitation Program, "rehabilitation" can be measured by a functioning and well-being vocational assessment. Functioning and well-being (measured minimally as PCS and MCS) predict morbidity and mortality. Annually tracking employment status through Networks using the same categories on the CMS 2728 and including this as a QAPI would improve the likelihood that rehabilitation efforts would be successful.

Add to 3b: "If the expected outcome is not achieved, the interdisciplinary team must describe barriers encountered, adjust the patient's plan of care to either achieve the specified goals or establish new goals, and explain why new goals are needed."
Rationale: When goals are not met, barriers must be identified and goals re-examined for feasibility of success. Sometimes barriers can be eliminated so original goals can be met; other times, new goals must be set that are more reasonable.

Comment: I support the language of (c) and recommend its inclusion in the final conditions. In addition, I would also like to see language which would outline the responsibilities of transplant centers and their responsibilities for following up and informing dialysis units of the transplant status of patients referred for transplant.

Add to d: "The patient care plan must include, as applicable, education and training for patients and family members or caregivers or both, and must document training the following areas in the patient's medical record:
(i) The nature and management of ESRD
(ii) The full range of techniques associated with treatment modality selected, including effective use of dialysis supplies and equipment in achieving and delivering the physician's prescription of Kt/V or URR, and effective erythropoietin administration (if prescribed) to achieve and maintain a hemoglobin level of at least 11 gm/dL
(iii) How to follow the renal diet, fluid restrictions, and medication regimen
(iv) How to read, understand, and use lab tests to track clinical status
(v) How to be an active partner in care
(vi) How to achieve and maintain physical, vocational, emotional and social well-being
(vii) How to detect, report, and manage symptoms and potential dialysis complications
(viii) What resources are available in the facility and community and how to find and use them
(ix) How to self-monitor health status and record and report health status information
(x) How to handle medical and non-medical emergencies
(xi) How to reduce the likelihood of infections
(x) How to properly dispose of medical waste in the dialysis facility and at home

Rationale: Life Options Research has demonstrated among 372 randomly-selected in-center hemodialysis patients that higher levels of dialysis knowledge are correlated with higher mental component summary (MCS) scores on the SF-12, which are, in turn, predictive of longer survival and lower hospitalization. The specific aspects of education delineated above are what Life Options believes to be core skills that ESRD patients must gain in order to become active partners in care, producing their own best health outcomes and monitoring the safety and quality of the care that is delivered to them.
References: ?Curtin, et al. 2002; Curtin, Klag, Bultman & Schatell, 2002; ?Curtin, Sitter, Schatell & Chewning, 2004; ?Johnstone, et al., 2004

494.100 Condition
Care at home.

Comment: I agree that services to home patients should be at least equivalent to those provided to in-center patients.
Rationale: Home dialysis patients are patients of the ESRD facility and are entitled to the same rights, services, and efforts to achieve expected outcomes as any other patient of the facility.

Add: (new 3iv) "Implementation of a social work care plan"
Rationale & References: Eighty-nine percent of ESRD patients report experiencing significant lifestyle changes from the disease (Kaitelidou, et al., 2005). The chronicity of end stage renal disease and the intrusiveness of treatment provide renal patients with multiple disease-related and treatment-related psychosocial stressors that affect their everyday lives (Devins et al., 1990). Researchers including Auslander, Dobrof & Epstein (2001), Burrows-Hudson (1995), and Kimmel et al. (1998) have found that psychosocial issues negatively impact health outcomes of patients and diminish patient quality of life. Therefore, a social work care plan is as equally important as other aspects of training for home patients. It is important to specify a "social work care plan" to ensure that it is conducted by a qualified social worker as identified below.

494.100 Condition
Care at home.
(c) Standard: Support services.

Add to 1i: "Periodic monitoring of the patient's home adaptation, including at minimum an annual visit to the patient's home by all facility personnel if geographically feasible (RN, social worker, dietitian, and machine technician) in accordance with the patient's plan of care."
Rationale: Members of the interdisciplinary team can offer better care to patients after seeing the patient in his/her home environment where they can observe barriers and supports first-hand. The members should be specified to ensure equal visitation of the team members across all dialysis units. The language of

this part of the proposed conditions is vague and subject to varying interpretation (i.e. exactly who are the "facility personnel" who will visit the patient's home?)

Add to 1iv: "Patient consultation with all members of the interdisciplinary team, as needed."
Rationale: The language of this part of the proposed conditions is vague and subject to varying interpretation

NEW CONDITION **Staff assisted skilled nursing home dialysis**
Add: A new condition for dialysis provided in a nursing home setting (that is not incorporated into the "home" condition 494.100)
Rationale: Nursing home dialysis is typically provided by staff. Home dialysis (PD or home hemodialysis) is typically performed by a trained patient and/or a helper. Making these treatments equivalent obscures important differences between them, including the staff training/supervisory needs of nursing home dialysis patients. To include care in a nursing facility/skilled nursing facility (NF/SNF) under "care at home" is inappropriate. There is a tremendous difference in what CMS must do to protect the health and safety of highly functioning, trained patients who do self-care at home (or have assistance from a trained helper at home) and patients who require personnel in an NF/SNF to perform dialysis because they are too debilitated to travel to a dialysis facility.
Reference: Tong & Nissenson, 2002
Add: Language to this proposed condition that would mandate " A Nursing facility/Skilled Nursing Facility providing full-care dialysis to residents with ESRD, must be certified as a dialysis facility and comply with all sections of this rule, including personnel qualifications."
Rationale: Patients receiving dialysis in NF or SNF should not be deprived of essential services that they would normally receive in an outpatient dialysis facility, including consultation with a qualified nephrology social worker. While NFs and SNFs may employ social workers, these social workers may not hold a master's degree and will not have the specialized knowledge of the complex social and emotional factors affecting the dialysis patient. To ensure that the health and safety of NF or SNF hemodialysis patients is protected, any proposed requirements should specifically incorporate Secs 494.70, 494.80 and 494.90 of the proposed conditions of coverage.

§494.110 Condition
Quality assessment and performance improvement.
(a) Standard: Program scope

Add: (1) "The program must include, but not be limited to, an ongoing program that achieves measurable improvement in physical, mental, and clinical health outcomes and reduction of medical errors by using indicators or performance measures associated with improved physical and mental health outcomes and with the identification and reduction of medical errors."

Rationale: To ensure patient-centered care, patient functioning and well-being must be one of the quality indicators that is monitored and improved.
Add: (2)(new iii) "Psychosocial status."
Rationale & References: Eighty-nine percent of ESRD patients report experiencing significant lifestyle changes from the disease (Kaitelidou, et al., 2005). The chronicity of end stage renal disease and the intrusiveness of its required treatment provide renal patients with multiple disease-related and treatment-related psychosocial stressors that affect their everyday lives (Devins et al., 1990). Researchers including Auslander, Dobrof & Epstein (2001), Burrows-Hudson (1995), and Kimmel et al. (1998) have found that psychosocial issues negatively impact health outcomes of patients and diminish patient quality of life. Therefore, "psychosocial status" must be considered as equally important as other aspects of quality improvement. CNSW has many resources and tools, available through the National Kidney Foundation, that can be used to track social work quality. ***Add***: (2)(new ix) "Functioning and well-being as measured by physical component summary (PCS) and mental component summary (MCS) scores (or other equally valid measure of mental and physical functioning) and vocational status using the same categories as reported on the CMS 2728 form"
Rationale: These scores provide a baseline and ongoing basis for QAPI activities to improve patient rehabilitation outcomes.

Comment: I agree that dialysis providers must measure patient satisfaction and grievances. I support the use of a standardized survey (such as the one being currently developed by CMS) for measuring patients' experience and ratings of their care. Such a survey would provide information for consumer choice, reports that facilities can use for internal quality improvement and external benchmarking against other facilities, and finally, information that can be used for public reporting and monitoring purposes. The survey should be in the public domain and consist of a core set of questions that could be used in conjunction with existing surveys.

494.140 Condition
Personnel qualifications

Comment: I support the recommendation that this section be renamed "Personnel qualifications and responsibilities", with the addition of specified personnel responsibilities to each team member's qualifications. If it is decided that adding "personnel responsibilities" to this section is inappropriate, I would support the alteration of 494.150 to be renamed "Condition: Personnel Responsibilities" and include a discussion of the responsibilities of each team member (instead of just the medical director as is currently proposed). I support possible responsibilities for social workers in the next section, where it is commented on "494.140 Condition Personnel qualifications (d) Standard: Social worker." These suggestions can be used in a new "responsibilities" section.

Rationale & References: It is critically important to clearly delineate personnel responsibilities in some fashion in these new conditions of coverage to ensure that there is parity in the provision of services to beneficiaries in every dialysis unit in the country. It is just as important to outline each team member's responsibilities, as it is the medical director's, as is currently proposed. This is especially important regarding qualified social work responsibilities. Currently, many master's level social workers are given responsibilities and tasks that are clerical in nature and which prevent the MSW from participating fully with the patient's interdisciplinary team so that optimal outcomes of care may be achieved. It is imperative that the conditions of coverage specify the responsibilities of a qualified social worker so that dialysis clinics do not assign social workers inappropriate tasks and responsibilities. Tasks that are clerical in nature or involve admissions, transportation, travel, billing, and determining insurance coverage prohibit nephrology social workers from performing the clinical tasks central to their mission (Callahan, Witten & Johnstone, 1997). Russo (2002) found among the nephrology social workers that he surveyed 53% were responsible for making transportation arrangements for patients, and 46% of the nephrology social workers in his survey were responsible for making dialysis transient arrangements (which involved copying and sending patient records to out-of-town units). Only 20% of his respondents were able to do patient education. In the Promoting Excellence in End-of-Life Care 2002 report, End-Stage Renal Disease Workgroup Recommendations to the Field, it was recommend that dialysis units discontinue using master's level social workers for clerical tasks to ensure that they will have sufficient time to provide clinical services to their patients and their families. Merighi and Ehlebracht (2004b; 2004c; 2005), in a survey of 809 randomly sampled dialysis social workers in the United States, found that:

- 94% of social workers did clerical tasks, and that 87% of those respondents considered these tasks to be outside the scope of their social work training.
- 61% of social workers were solely responsible for arranging patient transportation.
- 57% of social workers were responsible for making travel arrangements for patients who were transient, which required 9% of their work time.
- 26% of social workers were responsible for initial insurance verification.
- 43% of social workers tracked Medicare coordination of benefit periods.
- 44% of social workers were primarily responsible for completing patient admission paperwork.
- 18% of social workers were involved in collecting fees from patients. (Respondents noted that this could significantly diminish trust and cause damage to the therapeutic relationship).

- Respondents spent 38% of their time on insurance, billing and clerical tasks vs. 25% of their time spent assessing and counseling patients.
- Only 34% of the social workers thought that they had enough time to sufficiently address patients' psychosocial needs.

This evidence clearly demonstrates that without clear definition and monitoring of responsibilities assigned to the qualified social work (as is the current case), social workers are routinely assigned tasks that are inappropriate, preventing them from doing appropriate tasks. For all of these reasons, I strongly support the addition of "personnel responsibilities" to the new conditions of coverage (either in this section, or the next section).

494.140 Condition
Personnel qualifications
(d) Standard: Social worker.

Change the language of d to: *Social worker.* The facility must have a qualified social worker who—(1) Has completed a course of study with specialization in clinical practice, and holds a masters degree from a graduate school of social work accredited by the Council on Social Work Education; (2) Meets the licensing requirements for social work practice in the State in which he or she is practicing; and (3) Is responsible for the following tasks: initial and continuous patient assessment and care planning including the social, psychological, cultural and environmental barriers to coping to ESRD and prescribed treatment; provide emotional support, encouragement and supportive counseling to patients and their families or support system; provide individual and group counseling to facilitate adjustment to and coping with ESRD, comorbidities and treatment regimes, including diagnosing and treating mood disorders such as anxiety, depression, and hostility; providing patient and family education; helping to overcome psychosocial barriers to transplantation and home dialysis; crisis intervention; providing education and help completing advance directives; promoting self-determination; assisting patients with achieving their rehabilitation goals (including: overcoming barriers ; providing patients with education and encouragement regarding rehabilitation; providing case management with local or state vocational rehabilitation agencies); providing staff in-service education regarding ESRD psychosocial issues; recommending topics and otherwise participating in the facility's quality assurance program; mediating conflicts between patients, families and staff; participating in interdisciplinary care planning and collaboration, and advocating on behalf of patients in the clinic and community-at-large. The qualified social worker will not be responsible for clerical tasks related to transportation, transient arrangements, insurance or billing, but will supervise the case aide who is responsible for these tasks.
Rationale & References: Clinical social work training is essential to offer counseling to patients for complex psychosocial issues related to ESRD and its treatment regimes. Changing the language of this definition will make the definition congruent to that of a qualified social worker that is recommended by

CNSW for the transplant conditions of coverage. At the same time, **I strongly do not support the elimination of the "grandfather" clause of the previous conditions of coverage,** which exempted individuals hired prior to the effective date of the existing regulations (September 1, 1976) from the social work master's degree requirement. The few remaining clinicians who have worked tirelessly with renal patients throughout a period of great change and who have shown themselves to be competent, useful, knowledgeable and who were appropriately welcomed to the field as clinicians at a unique time in the history of dialysis should not be penalized because we now arbitrarily decide to rescind the commitment we made to them. As discussed in the preamble for these conditions, the importance of the professional social worker is recognized, and I believe there is a need for the requirement that the social worker have a master's degree, **with the only exception being those who were "grandfathered in."** I agree that since the extension of Medicare coverage to individuals with ESRD, the ESRD patient population has become increasingly more complex from both medical and psychosocial perspectives. In order to meet the many and varied psychosocial needs of this patient population,I agree that qualified master's degree social workers (MSW) trained to function autonomously are essential, with the exception of those who were grandfathered in. I agree that these social workers must have knowledge of individual behavior, family dynamics, and the psychosocial impact of chronic illness and treatment on the patient and family. This is why we argue that a specialization in clinical practice must be maintained in the definition.

Master's level social workers are trained to think critically, analyze problems, and intervene within areas of need that are essential for optimal patient functioning, and to help facilitate congruity between individuals and resources in the environment, demands and opportunities (Coulton, 1979; McKinley & Callahan, 1998; Morrow-Howell, 1992; Wallace, Goldberg, & Slaby, 1984). Social workers have an expertise of combining social context and utilizing community resource information along with knowledge of personality dynamics. The master of social work degree (MSW) requires two years of coursework and an additional 900 hours of supervised agency experience beyond what a baccalaureate of social work degree requires. An MSW curriculum is the only curriculum, which offers additional specialization in the biopsychosocialcultural, person-in-environment model of understanding human behavior. An undergraduate degree in social work or other mental health credentials (masters in counseling, sociology, psychology or doctorate in psychology, etc.) do not offer this specialized and comprehensive training in bio-psycho-social assessment and interaction between individual and the social system that is essential in dialysis programs. The National Association of Social Workers Standards of Classification considers the baccalaureate degree as a basic level of practice (Bonner & Greenspan, 1989; National Association of Social Workers, 1981). Under these same standards, the Masters of Social Work degree is considered a specialized level of professional practice and requires a demonstration of skill or competency in performance (Anderson, 1986). masters-prepared social workers are trained in conducting empirical evaluations of their own practice interventions

(Council on Social Work Education). Empirically, the training of a masters-prepared social worker appears to be the best predictor of overall performance, particularly in the areas of psychological counseling, casework and case management (Booz & Hamilton, Inc., 1987; Dhooper, Royse & Wolfe, 1990). The additional 900 hours of supervised and specialized clinical training in an agency prepares the MSW to work autonomously in the dialysis setting, where supervision and peer support is not readily available. This additional training in the biopsychosocial model of understanding human behavior also enables the masters-prepared social worker to provide cost-effective interventions such as assessment, education, individual, family and group therapy and to independently monitor the outcomes of these interventions to ensure their effectiveness.

The chronicity of end stage renal disease and the intrusiveness of required treatment provide renal patients with multiple psychosocial stressors including: cognitive losses, social isolation, bereavement, coping with chronic illness, concern about worsening health and death, depression, anxiety, hostility, psycho-organic disorders, somatic symptoms, lifestyle, economic pressures, insurance and prescription issues, employment and rehabilitation barriers, mood changes, body image issues, concerns about pain, numerous losses (income, financial security, health, libido, strength, independence, mobility, schedule flexibility, sleep, appetite, freedom with diet and fluid), social role disturbance (familial, social, vocational), dependency issues, and diminished quality of life (DeOreo, 1997; Gudes, 1995; Katon & Schulberg, 1997; Kimmel et al., 2000; Levenson, 1991; Rabin, 1983; Rosen, 1999; Vourlekis & Rivera-Mizzoni, 1997). The gravity of these psychosocial factors necessitates an assessment and interventions conducted by a qualified social worker as outlined above.

It is clear that social work intervention can maximize patient outcomes:

- Through patient education and other interventions, nephrology social workers are successful in improving patient's adherence to the ESRD treatment regime. Auslander and Buchs (2002), and Root (2005) have shown that social work counseling and education led to reduced fluid weight gains in patients. Johnstone and Halshaw (2003) found in their experimental study that social work education and encouragement were associated with a 47% improvement in fluid restriction adherence.
- Beder and colleagues (2003) conducted an experimental research study to determine the effect of cognitive behavioral social work services. They found that patient education and counseling by nephrology social workers was significantly associated with increased medication compliance. This study also determined that such interventions improved patients' blood pressure. Sikon (2000) discovered that social work counseling can reduce patients' anxiety level. Several researchers have determined that nephrology social work counseling significantly improves ESRD patient quality of life (Chang, Winsett, Gaber & Hathaway, 2004; Frank, Auslander & Weissgarten, 2003; Johnstone, 2003).

Nephrology social work interventions also tend to be valued by patients. Siegal, Witten, and Lundin's 1994 survey of ESRD patients found that 90% of

respondents "believed that access to a nephrology social worker was important" (p.33) and that patients relied on nephrology social workers to assist them with coping, adjustment, and rehabilitation. Dialysis patients have ranked a "helpful social worker" as being more important to them than nephrologists or nurses (Rubin, et al., 1997). In a study by Holley, Barrington, Kohn and Hayes (1991), 70% of patients said that social workers gave the most useful information about treatment modalities compared to nurses and physicians. These researchers also found that patients thought that social workers were twice as helpful as nephrologists in helping them to choose between hemodialysis and peritoneal dialysis for treatment.

494.140 Condition
Personnel qualifications

Add: (e) Standard: Case aide. Dialysis units that have more than 75 patients per full time social worker must employ a case aide who- As supervised by the unit social worker, performs clerical tasks involving admissions, transfers, billing, transportation arrangements, transient treatment paperwork and verifies insurance coverage.

Rationale & References: I agree with the preamble that dialysis patients need essential social services including transportation, transient arrangements and billing/insurance issues. I also firmly agree with the preamble that these tasks should not be handled by the qualified social worker (unless the social worker has fewer than 75 patients per full time equivalent social worker), as caseloads higher than this prevent the MSW from participating fully with the interdisciplinary team so that optimal outcomes of care may be achieved. It is imperative that the conditions of coverage identify a new team member who can provide social service assistance-the preamble recommends that these clerical tasks should be done by someone other than the MSW, but does not specify who that person is- adding this section (e) will eliminate any ambiguity surrounding this issue, and ensure adherence to this recommendation across all settings. Tasks that are clerical in nature or involve admissions, billing, and determining insurance coverage prevent nephrology social workers from performing the clinical tasks central to their mission (Callahan, Witten & Johnstone, 1997). Russo (2002) found that all of the nephrology social workers that he surveyed felt that transportation was not an appropriate task for them, yet 53% of respondents were responsible for making transportation arrangements for patients. Russo found that 46% of the nephrology social workers in his survey were responsible for making dialysis transient arrangements (which involved copying and sending patient records to out-of-town units), yet only 20% were able to do patient education. In the Promoting Excellence in End-of-Life Care's 2002 report, End-Stage Renal Disease Workgroup Recommendations to the Field, workgroup members recommended that dialysis units discontinue using master's level social workers for clerical tasks to ensure that they will have sufficient time to provide clinical services to their patients and their families. Merighi and

Ehlebracht (2004b; 2004c; 2005), in a survey of 809 randomly sampled dialysis social workers in the United States, found that:

- 94% of social workers did clerical tasks, and that 87% of those respondents considered these tasks to be outside the scope of their social work training.
- 61% of social workers were solely responsible for arranging patient transportation.
- 57% of social workers were responsible for making travel arrangements for patients who were transient, taking 9% of their time.
- 26% of social workers were responsible for initial insurance verification.
- 43% of social workers tracked Medicare coordination periods.
- 44% of social workers were primarily responsible for completing admission packets.
- 18% of social workers were involved in collecting fees from patients. Respondents noted that this could significantly diminish therapeutic relationships and decrease trust.
- Respondents spent 38% of their time on insurance, billing and clerical tasks vs. 25% of their time spent counseling and assessing patients.
- Only 34% of the social workers thought that they had enough time to sufficiently address patient psychosocial needs.

This evidence clearly demonstrates that there needs to be another team member who can handle these clerical social service needs. This position would be cost-effective, as the person in this role can help patients obtain insurance coverage for dialysis that they normally would not have and increase facility's reimbursement. As discussed and referenced below in detail, I support the recommendation of a ratio of 75 patients per full-time equivalent social worker. If a dialysis clinic has fewer patients per full-time equivalent social worker than less than 75:1, the social worker can address concrete social service needs of patients. However, patient ratios over 75 patients per full-time equivalent social worker require a case aide.

§494.180 Condition
Governance.
(b1) Standard. Adequate number of qualified and trained staff.

Add: (1i) No dialysis clinic should have more than 75 patients per one full time social worker.

Rationale & References: A specific social worker-patient ratio must be included in the conditions of coverage. Currently, there are no such national ratios and as a result social workers have caseloads as high as more than 300 patients per social worker in multiple, geographically separated, clinics. This is highly variable among different dialysis units-letting dialysis clinics establish their own ratios will

leave ESRD care in the same situation as we have now with very high social work caseloads. For many years, CNSW has had an acuity-based social work-patient ratio (contact the National Kidney Foundation for the formula) which has been widely distributed to all dialysis units. This has largely been ignored by dialysis providers, who routinely have patient-to-social work ratios of 125-300. The new conditions of coverage must either identify an acuity-based social work staffing ratio model to be used in all units (I support CNSW's staffing ratio), or set a national patient-social worker ratio. Leaving units to their own devices regarding ratios will not affect any change, as is evidenced by today's large caseloads and variability in such. CNSW has determined that 75:1 is the ideal ratio. If CMS refuses to include language about social work ratios, we strongly urge that the final conditions include language for "an acuity-based social work staffing plan developed by the dialysis clinic social worker" (rather than having nursing personnel who have limited understanding of social work training or role to determine social work staffing).

Large nephrology social work caseloads have been linked to decreased patient satisfaction and poor patient rehabilitation outcomes (Callahan, Moncrief, Wittman & Maceda, 1998). It is also the case that social workers report that high caseloads prevent them from providing adequate clinical services in dialysis, most notably counseling (Merighi, & Ehlebracht, 2002, 2005). In Merighi and Ehlebracht's (2004a) survey of 809 randomly sampled dialysis social workers in the United States, they found that only 13% of full time dialysis social workers had caseloads of 75 or fewer, 40% had caseloads of 76-100 patients, and 47% had caseloads of more than 100 patients.

In a recent study by Bogatz, Colasanto, and Sweeney (2005), nephrology social workers reported that large caseloads hindered their ability to provide clinical interventions. Social work respondents in this study reported caseloads as high as 170 patients and 72% of had a median caseload of 125 patients. The researchers found that 68% of social workers did not have enough time to do casework or counseling, tasks mandated by the current conditions of coverage, 62% did not have enough time to do patient education, and 36% said that they spent excessive time doing clerical, insurance, and billing tasks. One participant in their study stated: 'the combination of a more complex caseload and greater number of patients to cover make it impossible to adhere to the federal guidelines as written. I believe our patients are being denied access to quality social work services' (p.59).

Patient-social work ratios are critical so that social workers can effectively intervene with patients and enhance their outcomes. It is clear that social work intervention can maximize patient outcomes (doing these requires reasonable ratios):

- Through patient education and other interventions, nephrology social workers are successful in improving patient's adherence to the ESRD treatment regime. Auslander and Buchs (2002), and Root (2005) have shown that social work counseling and education led to reduced fluid weight gains in patients. Johnstone and Halshaw (2003) found in their

experimental study that social work education and encouragement were associated with a 47% improvement in fluid restriction adherence.

- Beder and colleagues (2003) conducted an experimental research study to determine the effect of cognitive behavioral social work services. They found that patient education and counseling by nephrology social workers was significantly associated with increased medication compliance. This study also determined that such interventions improved patients' blood pressure. Sikon (2000) discovered that social work counseling can reduce patients' anxiety level. Several researchers have determined that nephrology social work counseling significantly improves ESRD patient quality of life (Chang, Winsett, Gaber & Hathaway, 2004; Frank, Auslander & Weissgarten, 2003; Johnstone, 2003). A study currently being conducted by Cabness shows that social work intervention is related to lower depression.

Nephrology social work interventions also tend to be valued by patients. Siegal, Witten, and Lundin's 1994 survey of ESRD patients found that 90% of respondents "believed that access to a nephrology social worker was important" (p.33) and that patients relied on nephrology social workers to assist them with coping, adjustment, and rehabilitation. Dialysis patients have ranked a "helpful social worker" as being more important to them than nephrologists or nurses by Rubin, et al. (1997). In a study by Holley, Barrington, Kohn and Hayes (1991), 70% of patients said that social workers gave the most useful information about treatment modalities compared to nurses and physicians. These researchers also found that patients thought that social workers were twice as helpful as nephrologists in helping them to choose between hemodialysis and peritoneal dialysis for treatment.

§494.180 Condition
Governance.
(b4) Standard. Adequate number of qualified and trained staff.

Comment: I agree that all employees must have an opportunity for continuing education and related development activities.

§494.180 Condition
Governance.
(b5) Standard. Adequate number of qualified and trained staff

Add (5ix): Add "Psychosocial issues related to ESRD and its treatment regimes, as provided by the facility social worker."
Comment: Technicians have the most contact with patients and need to be attuned to patients' psychosocial issues so as to most effectively collaborate with the social worker and achieve patient outcomes

§494.180 Condition
Governance.

(h) Standard: Furnishing data and information for ESRD program administration.

(h) Standard: Furnishing data and information for ESRD program administration.
Add: (3)(new iv) "Annual reporting of facility aggregate functioning and well-being (physical component summary scores and mental component summary scores) and vocational rehabilitation status according to categories on the CMS 2728 form."
Rationale: These data would be easy to collect, would permit comparisons between clinics, and would serve as a basis for QAPI.

REFERENCES

ADA, Title III, Part 36, Subpart A, Section 36.303, auxiliary aids (http://www.usdoj.gov/crt/ada/reg3a.html#Anchor-97857)

?ADA Title III, Part 36, Subpart A, Section 36.304, removal of barriers (http://www.usdoj.gov/crt/ada/reg3a.html#Anchor-91481)

Anderson, R. (1986). The CSWE Accrediting Standards for Social Work Education. *Social Work in Education*. CCC Code: 0162-7961/86.

Andreucci, V. E., et al. Dialysis Outcomes and Practice Patterns Study (DOPPS) data on medications in hemodialysis patients. *Am J Kidney Dis.* 44(5 Suppl 3):61-7, 2004.

Auslander, G. K., Buchs, A. (2002). Evaluating an activity intervention with hemodialysis patients in Israel. Social Work Health Care. 35(1-2):407-23.

Auslander, G., Dobrof, J., & Epstein, I. (2001). Comparing social work's role in renal dialysis in Israel and the United States: the practice-based research potential of available clinical information. *Social Work in Health Care*, 33(3/4), 129-151.

Beder, J. (1999). Evaluation research on the effectiveness of social work intervention on dialysis patients: the first three months. *Social Work in Health Care*, 30(1), 15-30.

Beder, J., Mason, S., Johnstone, S., Callahan, M. B., & LeSage, L. (2003). Effectiveness of a social work psychoeducational program in improving adherence behavior associated with risk of CVD in ESRD patients. *Journal of Nephrology Social Work*, 22, 12-22.

Blake C, Codd MB, Cassidy A, O'Meara YM. Physical function, employment and quality of life in end-stage renal disease. *J Nephrol.* 13(2):142-9, 2000. Bogatz, S., Colasanto, R., & Sweeney, L. (2005). Defining the impact of high patient/staff ratios on dialysis social workers. *Nephrology News & Issues*, Jan, 55-60.

Bonner, C., Dean, R., & Greenspan, R. (1989) Standards for Practice: The Development of the Clinical Social Worker in the First Two Years. *The Clinical Supervisor* 1989. 7(4), 31-45.

Booz, A., & Hamilton, Inc. (1987) *The Maryland Social Work Services Job Analysis and Personnel Qualifications Study.* Prepared for the Department of Human Resources State of Maryland

Burrows-Hudson, S. (1995). Mortality, morbidity, adequacy of treatment, and quality of life. *ANNA Journal*, 22(2), 113-121.

Callahan, M. B., Moncrief, M., Wittman, J., & Maceda, M. (1998). Nephrology social work interventions and the effect of caseload size on patient satisfaction and rehabilitation interventions. *Journal of Nephrology Social Work*, 18, 66-79.

Callahan, M. B., Witten, B., & Johnstone, S. (1997). Improving quality of care and social work outcomes in dialysis. *Nephrology News & Issues*, 2(4), 42-43.

Chang, C. F., Winsett, R. P., Gaber, A. O., & Hathaway, D. K. (2004) Cost-effectiveness of post-transplantation quality of life intervention among kidney recipients, *Clinical Transplantation*, 18(4), 407-415.

Coulton, C. (1979). A study of the person-environment fit among the chronically ill. *Social Work in Health Care*, 5(1), 5-17.

Council on Social Work Education: Commission on Accreditation, *Handbook of Accreditation Standards and Procedures* (Fourth Edition). Subsection B5.7.9 and M5.7.11 and Subsection B5.7.7 and M5.7.8, pp. 99, 137.

Curtin RB, Oberley ET, Sacksteder P, Friedman A. (1996). Differences between employed and nonemployed dialysis patients. *Am J Kidney Dis.* 27(4):533-40.

Curtin RB, Mapes DL. (2001) Health care management strategies of long-term dialysis survivors.*Neph Nurs J.* 28(4):385-394.

?Curtin RB, Bultman DC, Schatell D, Chewning BA. (2004) Self-management, knowledge, and functioning and well-being of patients on hemodialysis. *Neph Nurs J* 31(4):378-387.

Curtin RB, Bultman DC, Thomas-Hawkins C, Walters BA, Schatell D. Hemodialysis patients' symptom experiences: effects on physical and mental functioning. *Nephrol Nurs J.*;29(6):562, 567-74; discussion 575, 598, 2002.

Curtin RB, Klag MJ, Bultman DC, Schatell D. Renal rehabilitation and improved patient outcomes in Texas dialysis facilities. Am J Kidney Dis.;40(2):331-8, 2002.

?Curtin RB, Sitter DC, Schatell D, Chewning BA. Self-management, knowledge, and functioning and well-being of patients on hemodialysis. *Nephrol Nurs J* 31(4):378-86, 396; quiz 387, 2004.

DeOreo, P. B. (1997). Hemodialysis patient-assessed functional health status predicts continued survival, hospitalization, and dialysis-attendance compliance. *American Journal of Kidney Diseases.* 30(2), 204-212.

Devins, G. M., Mandin, H., Hons, R. B., Burgess, E. D., Klassen, J., Taub, K., Schorr, S., Letourneau, P. K., & Buckle, S. (1990), Illness intrusiveness and quality of life in end-stage renal disease: comparison and stability across treatment modalities. *Health Psychology*, 9(2), 117-142.

Dhooper, S., Royse, D., & Wolfe, L. (1990) Does social work education make a difference? *Social Work Education,* 1990, 35 (1), 57-61.

Dobrof, J., Dolinko, A., Lichtiger, E., Uribarri, J., & Epstein, I. (2001) Dialysis patient characteristics and outcomes: the complexity of social work practice with end-stage renal; disease population. *Social Work in Health Care*, 33, 105-128.

Forum of ESRD Networks. *Designing a Collaborative Action Plan with ESRD Stakeholders,* 2003. (http://www.esrdnetworks.org/DPPCFinalReport.pdf)

Frank, A., Auslander, G. K., & Weissgarten, J. (2003). Quality of life of patients with end-stage renal disease at various stages of the illness. *Social Work in Health Care*, 38(2), 1-27.

Gudes, C. M. (1995). Health-related quality of life in end-stage renal failure. *Quality of Life* ESRD Network of Texas (2002). Social Services Practice Recommendations. *http://www.esrdnetwork.org/professional_standards.htm*

Holley, J. L., Barrington, K., Kohn, J., & Hayes, I. (1991). Patient factors and the influence of nephrologists, social workers, and nurses on patient decisions to choose continuous peritoneal dialysis. *Advances in Peritoneal Dialysis*, 7, 108-110.

Johnstone, S. (2003). Evaluating the impact of a physical rehabilitation program for dialysis patients. *Journal of Nephrology Social Work*, 22, 28-30.

Johnstone, S. & Halshaw, D. (2003) Making peace with fluid social workers lead cognitive-behavioral intervention to reduce health-risk behavior. *Nephrology News & Issues* (12), 20-31.

Johnstone, S., Seamon, V. J., Halshaw, D., Molinair, J., & Longknife, K. (1997). The use of medication to manage patient-staff conflict in the dialysis clinic. *Advances in Renal Replacement Therapy*, 4(4), 359-371.

Johnstone, S., Walrath, L., Wohlwend, V., & Thompson, C. (2004). Overcoming early learning barriers in hemodialysis patients: the use of screening and educational reinforcement to improve treatment outcomes. *Advances in Chronic Kidney Disease*, 11(2), 210-216.

Juhnke, J & Curtin, R.B. (2000) New study identifies ESRD patient education needs. *Nephrology News & Issues*14(6):38-9.

Kalantar-Zadeh, K., Kopple, J. D., Block, G., & Humphreys, M. H. (2001). Association among SF36 quality-of-life measures and nutrition, hospitalization, and mortality in hemodialysis. *Journal of the American Society of Nephrology*, 12, 2797-2806.

Kaitelidou, D., Maniadakis, N., Liaropouls, L., Ziroyanis, P., Theodorou, M., & Siskou, O. (2005). Implications of hemodialysis treatment on employment patterns and everyday life of patients. *Dialysis & Transplantation,* 34(3), 138-147, 185.

Katon, W., & Schulberg, H. (1997). Epidemiology of depression in primary care. *General Hospital Psychiatry,*14, 237-247.

Kaveh K & Kimmel PL. (2001). Compliance in hemodialysis patients: multidimensional measures in search of a gold standard. *American Journal of Kidney Diseases* 37(2):244-66.

Kimmel, P., Peterson, R., Weihs, K., Simmens, S., Boyle, D., Verne, D., Alleyne, S., & Cruz, I. Veis, J (2000). Multiple measurements of depression predict mortality in a longitudinal study of chronic hemodialysis outpatients. *Kidney International*, 5(10), 2093-2098.

Kimmel, P., Peterson, R., Weihs, K., Simmens, Alleyne, S., Cruz, I., & Veis, J (1998). Psychosocial factors, behavioral compliance and survival in urban hemodialysis patients. *Kidney International*, 54, 245-254.

?Kimmel PL et al Survival in hemodialysis patients: the role of depression. *J Am Soc Nephrol.* 4(1):12-27, 1993.

King K, Moss AH. The frequency and significance of the "difficult" patient: The nephrology community's perceptions. *Adv Chronic Kidney Dis.* 2004 Apr;11(2):234-9.

Knight EL et al. The association between mental health, physical function, and hemodialysis mortality. *Kidney Int.* 63(5):1843-51 2003.

Kroenke K, Spitzer RL, Williams JB. The Patient Health Questionnaire-2: validity of a two-item depression screener. *Med Care.* 41(11):1284-92, 2003.

Kutner NL et al. Functional impairment, depression, and life satisfaction among older hemodialysis patients and age-matched controls: a prospective study. *Arch Phys Med Rehabil.* 81(4):453-9, 2000.

Levenson, J., & Olbrisch, M. (2000). Psychosocial screening and candidate selection. In P. Trzepacz & A. DiMartini (Eds.), *The transplant patient: biological, psychiatric, and ethical issues in organ transplantation* (pp. 21-41). Cambridge: Cambridge University Press.

Lowrie EG, Curtin RB, LePain N, Schatell D. Medical outcomes study short form-36: a consistent and powerful predictor of morbidity and mortality in dialysis patients. *Am J Kidney Dis.* 41(6):1286-92, 2003.

Mapes, D., Bragg-Gresham, J. L. Bommer, J. Fukuhara, S., McKevitt, P., & Wikstrom, B (2004). Health-related quality of life in the dialysis outcomes and practice patterns Study (DOPPS) American Journal of Kidney Diseases, 44 suppl(5), 54-60.

Mayo K. (1999)Can evening dialysis services improve the chances of rehabilitation? A Network #7 study. *Nephrol News Issues.* 13(6):37-8.

McKinley, M., & Callahan, M.B. (1998). Utilizing the case management skills of the nephrology social worker in a managed care environment. In National Kidney

Foundation (Ed.), *Standards of practice for nephrology social work, 4th ed*, (pp. 120-128). NY: National Kidney Foundation.

McLaughlin K, Manns B, Mortis G, Hons R, Taub K. (2003). Why patients with ESRD do not select self-care dialysis as a treatment option. *Am J Kidney Dis.* 41(2):380-5.

Merighi, J. R., & Ehlebracht, K. (2005). Emotional Exhaustion and Workload Demands in Renal Social Work Practice, *Journal of Nephrology Social Work*, 24, 14-20, *Journal of Nephrology Social Work*, in press

Merighi, J. R., & Ehlebracht, K. (2004a). Workplace resources, patient caseloads, and job satisfaction of renal social workers in the United States. *Nephrology News & Issues*, 18(4), 58-63.

Merighi, J. R., & Ehlebracht, K. (2004b). Issues for renal social workers in dialysis clinics in the United States. *Nephrology News & Issues*, 18(5), 67-73.

Merighi, J. R., & Ehlebracht, K. (2004c). Unit-based patient services and supportive counseling. *Nephrology News & Issues*, 18(6), 55-60.

Morrow-Howell, N. (1992). Clinical case management: the hallmark of gerontological social work. *Geriatric Social Work Education*, 18, 119-131.

National Association of Social Workers (1981) *Standards for the classification of social work practice*. Maryland: National Association of Social Workers.

Promoting Excellence in End-of-Life Care (2002), *End-Stage Renal Disease Workgroup Recommendations to the Field,* Missoula, MT: The Robert Wood Johnson *Protecting the Privacy of Patients' Health Information* (http://www.hhs.gov/news/facts/privacy.html)

Rasgon SA, Chemleski BL, Ho S, Widrow L, Yeoh HH, Schwankovsky L, Idroos M, Reddy CR, Agudelo-Dee L, James-Rogers A, Butts E. (1996). Benefits of a multidisciplinary predialysis program in maintaining employment among patients on home dialysis. *Adv Perit Dial.* 12:132-5.

Rabin, P. L. (1983). Psychiatric aspects of end-stage renal disease: diagnosis and management. In W. J. Stone & P. L. Rabin (Eds.) *End-Stage renal disease: an integrated approach, (*pp. 111-147). NY: Academic Press.

Rasgon, S., Schwankovsky, L., James-Rogers, A., Widrow, L., Glick, J., & Butts, E. (1993). An intervention for employment maintainence among blue-collar workers with end-stage renal disease. *American Journal of Kidney Diseases*, 22(3), 403-412.

Rau-Foster M. The dialysis facility's rights, responsibilities, and duties when there is conflict with family members. *Nephrol News Issues.* 15(5):12-4, 2001.

Renal Physicians Association and American Society of Nephrology. *Clinical Practice Guideline on Shared Decision Making in the Appropriate Initiation of and Withdrawal from Dialysis*

Rosen, L. S. (1999). Common psychosocial factors in the treatment of end stage renal disease. *Journal of Nephrology Social Work*, 19, 69-72.

Russo, R. (2002). The role of the renal social worker in the 21st century. *Nephrology News & Issues*, 16(3), 38,40.

Rubin, H., Jenckes, M., Fink, N., Meyer, K., Wu, A., Bass, E., Levin, N., & Powe, N. (1997). Patient's view of dialysis care: development of a taxonomy and rating of importance of different aspects of care. *American Journal of Kidney Disease*, 30(6), 793-801.

Siegal, B., Witten, B., Lundin, A.P (1994). Patient access and expectations of nephrology social workers. *Nephrology News and Issues*, April, 32-33,40.

Sikon, G. M. (2000). Pre-dialysis education reduces anxiety in the newly diagnosed chronic renal failure patient. *Dialysis & Transplantation*, 6, 346, 344-345.

Tong E. M. & Nissenson, A. R. (2002). Dialysis in nursing homes. *Seminars in Dialysis.* 15(2):103-6.

Vourlekis, B., & Rivera-Mizzoni, R. (1997). Psychosocial problem assessment and ESRD patient outcomes. *Advanmces in Renal Replacement Therapy*, 4(2), 136-144.

Wallace, S., Goldberg, R., & Slaby, A. (1984). *Guide for clinical social work in health care*. NY: Praeger Publishers.Witten B, Howell P, Latos D. (1999). Improving employment outcomes: the renal care team's role. *Nephrol News Issues*. 13(3):46-8.

Witten B, Schatell DR, Becker BN. Relationship of ESRD working-age patient employment to treatment modality. (Abstract) *J Am Soc Nephrol.* 2004; 15:633A.

Wuerth D, Finklestein SH, Finklestein FO. The identification and treatment of depression in patients maintained on dialysis. *Semin Dial.* 18(2):142-6, 2005.

Submitter : Ms. Stella Smetanka **Date:** 05/05/2005

Organization : Health Law Clinic, University of Pittsburgh Law S.

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Submitter : **Dr. Christopher Blagg** **Date: 05/05/2005**

Organization : **Northwest Kidney Centers, Seattle**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-202-Attach-1.DOC

Attachment #202
By Electronic Submission

May 4, 2005

The Honorable Mark B. McClellan, MD, PhD
Administrator, Centers for Medicare and Medicaid Services
US Department of Health and Human Services
Attention: CMS-3818-P
PO Box 8012
Baltimore, MD 21244-8012

Re: CMS-3818-P. Comments Regarding Conditions for Coverage for End-Stage Renal Disease Facilities: Proposed Rule

Dear Dr. McClellan

As a nephrologist with some 40 years experience with home hemodialysis I would like to comment particularly on areas in the proposed rule dealing with this and with the frequency of physician visits.

Care at Home

I am in general agreement with the whole of this section (although I think CMS needs to review the costs and the present inadequate reimbursement for home hemodialysis training).

This section asks for comments on whether "home" should include dialysis in a nursing home or skilled nursing facility. I feel strongly that the latter two sites should be clearly separated from home dialysis as dialysis provided by nursing home or SNF staff is done without involvement of the patient or family in a setting that is totally different to the patient's home and where more than one patient may be treated at the same time. Patients in these settings are likely to be older and potentially sicker than patients dialyzing at home. Consequently, I feel strongly that nursing home and SNF dialysis requires different criteria to be developed by CMS, rather than continuing to include these under "home dialysis." Incidentally, I have been told that where dialysis is done in a prison, this too is included as "home dialysis."

Nevertheless there are good reasons to provide dialysis for some patients in nursing homes or SNFs and regulations should be written separately specifically to protect this vulnerable patient population. I support the recommendation from the AAKP that a technical expert panel should be convened to assist CMS in developing regulations for this.

I am also writing to the USRDS to ask that their Annual Reports should separate true home hemodialysis from hemodialysis occurring in these other sites.

Patient Plan of Care (494-90) Page 6202

Home hemodialysis has been a goal of CMS and its predecessors since the start of the Medicare ESRD Program because of the many well recognized advantages for suitable patients who wish to do this. These include better survival and quality of life, greater opportunity for rehabilitation, greater patient control of their treatment and so on. It is obvious that with any chronic disease, the more the patient knows and takes part in their own treatment the better their outcome. Home hemodialysis is also important as it gives the opportunity for more dialysis by the use of longer hours of treatment as compared with what is usual in the U.S. today and/or for more frequent dialysis. The latter obviously provides the best patient outcomes today as has been shown in many centers here and abroad.

Consequently, *all* patients must be informed of all modalities of treatment, including conventional three times weekly home hemodialysis either by day or overnight, more frequent daily or nightly home hemodialysis, and the various modalities of peritoneal dialysis. The patient's plan of care should document that they have been fully informed of all treatments, whether the patient has been referred for home dialysis and the plan that has been developed, whether the patient has declined home dialysis and why, and whether the patient has not been considered as a home dialysis candidate and the reasons for this.

As most dialysis units currently do not provide home hemodialysis training and support and some do not provide peritoneal dialysis, the care plan must include documentation that all patients have also been informed of the nearest units providing these modalities of home dialysis.

Proposed Section 494.90 (b) (4) Page 6209

While agreeing that all patients should be seen at least monthly, at least one U.S. study has shown that frequency of physician contact had no effect on patient survival, overall patient rating of their care, hospitalization rates and quality of life measures (Plantings et al: Frequency of patient-physician contact and patient outcomes in hemodialysis care. J Am Soc Nephrol, 2004; 15:238-9). This is in contrast to the results reported in the DOPPS Study from Europe quoted in the document. Our experience in Seattle over many years has shown that a routine monthly office visit by a patient, whether they are dialyzing at home or in the unit, is associated with a high quality of care and excellent. Patients like the convenience, privacy and opportunity to really talk to the physician rather than brief contacts on dialysis. Of course, patients with problems need to be seen more often. Thus I do not support the suggestion that physicians be expected to see patents dialyzing in a unit periodically, believing that this should be at physician discretion and patient need.

I would be happy to provide any further information related to these brief comments. I am delighted in general with the proposed Conditions of Coverage and only sorry that it has taken so long for them to be generated.

Sincerely,

Christopher R. Blagg MD, FRCP
Professor Emeritus of Medicine, University of Washington
Executive Director Emeritus, Northwest Kidney Centers
Seattle, Washington

Tel: 206-234-8791
Fax: 206-230-4916
Email: blaggc@hotmail.com

Submitter : **Ms. Laurice Whitfield** **Date: 05/05/2005**

Organization : **BIMC Yorkville Dialysis**

Category : **Social Worker**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

Issues 1-10

Definitions

III. Provision of Proposed Part 494 Subpart A General Practices
B. Definitions
Home or home dialysis should not be used for furnishing dialysis treatments in nursing home facilities. It is not the same set up. The dialysis facilities are evaluated by the same guidelines as the HD facilities.

Submitter : Thomas Weinberg **Date:** 05/05/2005

Organization : DaVita Inc.

Category : End-Stage Renal Disease Facility

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-3818-P-204-Attach-1.DOC

Attachment #204

May 4, 2005

Via Overnight Courier

Center for Medicaid and Medicare Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave., S.W.
Washington, D.C. 20201

Re: **File Code: CMS-3818-P**
Comments to Proposed Conditions of Coverage

Dear Secretary Leavitt and Administrator McClellan:

DaVita writes to comment on the proposed *Medicare Program: Proposed Conditions for Coverage for End Stage Renal Disease Facilities*, 70 Fed. Reg. 6184 (Feb. 4, 2005). We would like to make several general comments first and then comment in detail on a number of the proposed Conditions.

DaVita is pleased that the proposed conditions increase the focus on patients and emphasize teamwork. DaVita's core values are aligned with your goals of improving patient care, facilitating teamwork, and adopting the principles of continuous improvement.

While the proposed Conditions seek to achieve these goals, they contain three formidable negative themes. These themes will adversely affect individual dialysis facilities and the dialysis community in general if not tempered in the Final Rule. They are:

- A strong attempt to micromanage process;
- Unfunded mandates and a tremendous disconnect between the proposed Conditions of Coverage and the current inadequate payment policy, particularly apparent in the role of the Registered Nurse; and
- Assumption of responsibilities by CMS and Medicare that properly rest with individual states or physicians.

With respect to the conflict between the proposed Conditions and the current payment system, the challenges facing dialysis providers have never been more clearly defined. In its January 2005 report, MedPAC acknowledges that dialysis facilities are suffering losses in 2005 on Medicare patients. (As a result, MedPAC recommends a 2.5% increase

to the composite rate in 2006.) There is no financial room for error by dialysis facilities treating Medicare patients.

As a result of Medicare's insufficient payments to providers, dialysis providers have become more and more efficient in their delivery of care—including making difficult choices regarding deployment of nurses, social workers, technicians, dieticians, and other health care workers. Even though providers have sought these efficiencies with increasing intensity over the last decade, the reported quality of care achieved by dialysis facilities has steadily risen.

In spite of the necessary and appropriate tradeoffs made by providers over the last decade, the proposed Conditions appear to seek to require providers to reverse the efficiencies they gained and to burden dialysis staff with responsibilities that properly should be in the purview of physicians or to micromanage how facilities deploy their resources. We caution the Secretary to avoid this approach.

Before addressing the specific sections of the proposed Conditions, we would like to comment generally on one of the consistent themes of the proposed rules. This theme relates to the role of the registered nurse in the dialysis facility.

Registered nurses are a limited resource in American healthcare. Their role should focus around the following activities:

- Patient assessment, care planning and implementation and patient teaching are core activities of the registered nurse.
- Treatment and medication administration by appropriately licensed medical professional and appropriate delegation and supervision to licensed practical nurses and unlicensed assistive personnel.
- Patient safety activities relating to oversight and supervision of care provided in the Facilities.
- Outcomes and protocol management in conjunction with the Physician.
- Participation in quality improvement and patient care meetings and troubleshooting and investigations of incidents.

Time spent on *collection* of data would seem to be not an essential function as opposed to *participating in analysis*. The above statements inherently include the obvious fact the CMS payments for dialysis services must reflect appropriate costs of registered nurse activities. The present payment structure is currently not adequate for any expansion of the registered nurse role.

Indeed, if the present payment structure remains unaltered, it is likely in the near future that given the salary requirements and shortages of nurses, that dialysis facilities will need to look at delivery of care models that function with minimal in-center nursing. This very real possibility needs to be given careful review and analysis by CMS.

Comments to Proposed Conditions of Coverage

I. Patient Safety Conditions

Infection Control— **Proposed § 494.30** (a) Standard: Oversight. The facility must— (2) Designate a *registered nurse as the* infection control or safety officer,	**Change Proposed:** **Delete:** "*registered nurse as the*" **Rationale:** A registered nurse should not be required to serve as the infection control or safety officer. While we recognize and support the importance of vigilant control of infection as a separate condition for coverage, dialysis facilities currently have policies and procedures in place that are updated as new guidelines are set forth by agencies such as the Centers of Disease Control and Prevention. We agree that there is the need for a designated infection control or safety officer, but this does not require a registered nurse because the information that will be documented and analyzed by the designated individual will be reported to the facility chief executive officer and to the quality improvement committee (the composition of which includes a registered nurse). Although a registered nurse is qualified and is the preferred member of the interdisciplinary team to serve in this capacity, this may place an undue burden on the registered nurses who are employed by the dialysis facility. Nurses are a scarce resource in all health care venues and this requirement may also limit registered nurse involvement in performing tasks that are solely within the scope of practice of the registered nurse.

Isolation Rooms—Proposed § 494.30(a) The facility must demonstrate that it follows standard infection control precautions by implementing— **(1)** *The "Recommended Infection Control Practices for Hemodialysis Units at a Glance[]" . . .* **(2)** Patient isolation procedures to minimize the spread of infectious agents and communicable diseases	**Change proposed:** Clarify the language of the regulation, and the preamble statements at 70 Fed. Reg. 6192, that not each and every dialysis facilities is required to adhere to that portion of the CDC "Recommended Infection Control Practices for Hemodialysis Units at a Glance" that would require an isolation room or area for patients with hepatitis B. **Rationale:** No additional requirements are necessary that would require mandatory isolation rooms for hepatitis B. The rate of hepatitis B has consistently declined and there is no evidence that our present policy is inadequate. This is an example within the proposed rules of an unfunded mandate with no corresponding positive public health impact.

Water Systems—"Compliance with Laws and Regulations"—Proposed § 494.20 The preamble states: "We propose to retain the requirement that dialysis facilities must be in compliance with applicable Federal, State, and local laws and regulations pertaining to fire safety, equipment, and any other relevant health and safety issues. We are also proposing that dialysis facilities must be in compliance with the appropriate Federal, State, and local laws and regulations regarding drug and medical device usage. An example of meeting applicable Federal regulations is that the dialysis facility must use FDA-approved/cleared medical devices and adhere to the devices' labeling instructions." 70 Fed Reg. at 6191	**Change Proposed:** **Rationale:** There is no federal regulation requiring dialysis facilities to use FDA approved/cleared medical devices. FDA-approval/clearance regulations are directed toward manufacturers or suppliers of medical devices—not users. In particular, we would like to point out that manufacturers or suppliers of water purification systems who market their product for use in hemodialysis are required to submit premarket notification (510(k)'s) as described in the FDA document "Guidance for the Content of Premarket Notifications for Water Purification Components and Systems for Hemodialysis" issued May 30, 1977. There are many water treatment systems in current use that were installed prior to issuance of the May 1997 FDA guidance document for water system regulatory submissions. These older systems may be safe, effective and fully meet the most recent ANSI/AAMI recommendations. Their replacement with 510(k)-cleared systems would incur needless expense. An assessment for compliance with ANSI/AAMI recommendations is a more meaningful measure of water purification system safety than whether the system manufacturer or supplier has obtained FDA marketing clearance. This would involve potentially replacing parts of any and all water treatment system installed before 1997. We believe that this was not your intent and represents poor language choice and thus needs to be resolved.

Water Quality—Proposed § 494.40 (a) *Standard: Water purity.* Water used for dialysis meets the following water quality standards and equipment requirements of the Association for the Advancement of Medical Instrumentation (AAMI) published in ''Water Treatment Equipment for Hemodialysis Applications,'' ANSI/AAMI RD62: 2001, which are incorporated by reference.	**Change Proposed:** The regulations should not incorporate by reference "Concentrates for Hemodialysis" ANSI/AAMI RD61:2000, "Water Treatment for Hemodialysis Applications" ANSI/AAMI RD62:2001, as stated in Subsection (a), but rather should incorporate only "Dialysate for Hemodialysis" ANSI/AAMI RD52:2004, as referenced in Subsection (a)(2)(C). **Rationale:** "Dialysate for Hemodialysis" is aimed specifically at users. Furthermore, because it is the most recent document, it contains the most up-to-date ANSI/AAMI recommendations.
Water Quality—Proposed § 494.40(2)(i) The preamble states that "Bacteria and bacterial endotoxin levels of water must be measured— ++ Where water enters the dialyzer reprocessing equipment . . . ."	**Change Proposed:** The proposal to draw bacterial and bacterial endotoxin samples where water enters reprocessing equipment should be modified to alternatively allow drawing such samples where the dialyzer is connected to the reuse system. **Rationale:** This change is inconsistent with the recommendations contained in "Reuse of Hemodialyzers" ANSI/AAMI RD47-2002/A1:2003.
Water Quality —Proposed § 494.40 The preamble states that "Bacteria and bacterial endotoxin levels of water must be measured— ++ Outlet of the water storage tanks, if used . . . ."	**Change Proposed:** The proposal to draw monthly bacterial and bacterial endotoxin samples at the outlet of water storage tanks, if used, should be withdrawn. **Rationale:** Routine, monthly testing is not needed for this sample location. Note that ANSI/AAMI RD52:2004 states that testing from this location... "may be necessary during initial qualification of a system or when troubleshooting the cause of contamination within the distribution loop."

Water Quality—Proposed § 494.40 The preamble states that "Bacteria and bacterial endotoxin levels of water must be measured— ++ Concentrate or from the bicarbonate concentrate mixing tank . . . ."	**Change Proposed:** The proposal to draw monthly bacterial and bacterial endotoxin samples from concentrate or from the bicarbonate mixing tank should be modified to be where water enters equipment used to prepare bicarbonate or water from the bicarbonate mixing tank. **Rationale:** This change is consistent with the recommendations of ANSI/AAMI RD52:2004. Note that ANSI/AAMI RD52:2004 gives the rationale in section A.4.2.2 for not routinely testing bicarbonate concentrate for bacterial or endotoxin levels.
Water Quality—Proposed § 494.40 The preamble states: "Ultrapure dialysate has received attention in the clinical literature and the working draft AAMI standards ''Dialysate for Hemodialysis'' RD52 contains guidelines pertaining to ultrapure dialysate. We are not proposing a requirement for ultrapure dialysate at this time but we do invite comment on this topic." 70 Fed. Reg. at 6195.	**Change Proposed:** We would like to respond to the invitation to comment on ultrapure dialysate. **Rationale:** In our opinion, there is increasing evidence that ultrapure dialysate offers important benefits to our patients. However, there are presently no definitive studies and there are significant technical, therapeutic and logistic questions that remain unanswered. For example, the bacterial culture methods needed to ensure the quality of ultrapure dialysate are not currently available in the typical outpatient setting. It is premature to require ultrapure dialysate. We are hopeful, however, that future developments will clearly establish its benefits and offer the means for routine, widespread use.

Water Quality—Proposed § 494.40 The Preamble states that "we are requesting comments on whether the current AAMI guidance regarding carbon tanks is adequate to address all potential health and safety problems associated with chlorine, chloramines, and unannounced variations in source water. Specifically, we seek comments regarding where there is sufficient evidence to require Medicare-participating dialysis facilities to maintain at least two carbon tanks (that is, primary and backup) as part of their water treatment system, regardless of the current composition of its source water." 70 Fed. Reg. at 6247.	**Change Proposed:** We would like to respond to the invitation to comment on whether two carbon tanks should be required regardless of source water composition. **Rationale:** We believe that, unless the source water contains a substance monitored downstream of a primary carbon tank, there is no basis for requiring a second (backup) carbon tank.

<table>
<tr><td rowspan="2">Physical Environment—Proposed § 494.60
(e) Standard: Fire safety. (1) The dialysis facility must meet applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference in § 403.744(a)(1)(i) of this chapter).
(2) Chapter 5 of the 2000 edition of the Life Safety Code does not apply to a dialysis facility.
(3) If CMS finds that a State has a fire and safety code imposed by State law that adequately protects a dialysis facility's patients, CMS may allow the State survey agency to apply the State's fire and safety code instead of the Life Safety Code.</td><td>Change Proposed:
Strike ". . . CMS finds that" and ". . . that adequately protects a dialysis facility's patients, CMS may allow . . ." from subsection §494.60(e)(3), and replace the word "to" with "shall" in the same subsection.</td></tr>
<tr><td>Rationale:
Rather than proposing an additional standard in specifications regarding fire walls and fire alarm systems it would be more appropriate for the facility to comply with respective state or local fire and building regulations. Buildings are inspected on a regular basis by State regulatory agencies both during and after construction.

We support the use of Automated External Defibrillators ("AEDs") in the dialysis facility because training staff in the use of these could be accomplished with CPR training. The use of non-automated defibrillators require staff to be certified in Advanced Cardiac Life Support ("ACLS"). ACLS courses are not readily available to dialysis facilities, are time consuming, and are costly.</td></tr>
<tr><td rowspan="2">Defibrillators—Proposed § 494.60(c)
(3) Emergency equipment and plans.
Emergency equipment, including, but not limited to, . . . defibrillator, . . . must be on the premises at all times and immediately available.</td><td>Change Proposed:</td></tr>
<tr><td>Rationale:
We agree that it would be appropriate for each facility to have a defibrillator. This is a new mandate and a potentially expensive one. Therefore, we strongly recommend that CMS pay for the defibrillators in a one-time grant. Given the present reimbursement for a treatment by CMS which is below facility costs, such an economic burden should be born by the federal government.</td></tr>
</table>

Suction—Proposed § 494.60(c) (3) *Emergency equipment and plans.* Emergency equipment, including, but not limited to, . . . suction, . . . must be on the premises at all times and immediately available.	**Change Proposed:** We recommend deleting the requirement for a suction machine. **Rationale**: This is rarely used and is costly to maintain.

II. Patient Clinical Care

Patient Assessment—Proposed § 494.80 (b) Standard: Frequency of assessment for new patients. (1) An initial comprehensive reassessment *must be conducted within 20* calendar days after *first dialysis treatment.*	**Changes Proposed:** **Replace:** "*must be conducted within 20*" with "should be completed within 30 days" **Clarify:** "*first dialysis treatment*" refers to the first treatment in the outpatient dialysis facility. **Rationale:** The Preamble requests comments from the community regarding the timing of the Patient Assessment. Patients who are new to dialysis may be unstable and are often subject to hospitalization during their first 90 days of dialysis. Also, members of the interdisciplinary team may be part-time employees who are not in the facility every day. Finally, a patient may begin dialysis somewhere other than the dialysis facility that ultimately will be his or her regular clinic. Thus, the proposed conditions of coverage should specify that a ***target*** date for completion of the comprehensive patient assessment of 30 days from the first dialysis treatment in the outpatient dialysis facility. DaVita's current policy is to require the assessment to be completed within 30 days of a patient's first appearance at one of our facilities. An even better method would be to target the assessment to occur after 13 *consecutive* treatments in the dialysis facility.

Patient Assessment—Proposed § 494.80(a) The proposed subsection lists specific elements that must be contained in the Patient Assessment.	**Change Proposed:** Delete §494.80(a)(1)—(13) or modify subsection (a) to generally state the requirements of a Patient Assessment. **Rationale:** We question the need for CMS to list components of the assessment criteria, consistent with CMS's stated goal to eliminate unnecessary requirements The interdisciplinary team will be able to develop an appropriate assessment tool. The exact form of that tool should not be mandated.
Plan of Care—Proposed §§ 494.90 The Preamble states that "[i]n proposed § 494.90 we would specify that the patient's plan of care must include measurable and expected outcomes and estimated timetables to meet the patient's medical and psychosocial needs as identified in the initial and subsequent comprehensive assessments." 70 Fed. Reg. at 6205.	**Change Proposed:** The Secretary should clarify this section to make clear that the dialysis facility is not responsible for setting or meeting timetables for meeting patients' medical and psychosocial needs. **Rationale:** The proposal to have "estimated timetables to meet patient's medical and psychosocial needs as identified..." is an example of micromanagement that provides no added value to patient care. This should be determined by the number of co-morbidities as well as the patient's social, economic and psychological support structures. No clinical matrix exists in the literature that would allow for definitive response times to be calculated given the large number of situations that exist now and are possible in the future.

Patient Plan of Care—Proposed § 494.90 (a) Standard: Development of patient plan of care. (6) Rehabilitation status. The interdisciplinary team *must provide the necessary care and services* for the patient to achieve and sustain an appropriate level of productive activity, including vocational, as desired by patient, including the educational needs of pediatric patients.	**Change Proposed:** **Clarify or delete:** *"must provide the necessary care and service".* **Rationale:** We question the need for CMS to list components of the patient plan of care, consistent with CMS's stated goal in the Introduction section of the Preamble to eliminate unnecessary requirements. The interdisciplinary team, if meeting the personnel qualifications as defined in the proposed regulations and who participate in the quality assessment and performance improvement program, will be able to develop the plan of care that should not be mandated, but would include measurable and expected patient outcomes to conform to current evidence-based community-accepted standards. We recognize the importance of rehabilitation, the ultimate goal of renal rehabilitation and the need for the interdisciplinary team to inform and education the patient about the value of rehabilitation. The preamble states that the responsibility of the facility and the interdisciplinary team is to refer patients to appropriate agencies and health professionals for additional services that the facility cannot provide. The actual language of the condition suggests, however, that the facility is held accountable for providing this directly. We recommend CMS change the language to reflect what CMS intended in the preamble.

Patient Communication Regarding Suitability for Transplantation or Home Dialysis— **Proposed § 494.80(a)(1):** The patient's comprehensive assessment must include, but is not limited to, the following: . . . . (10) Evaluation of suitability for a transplantation referral, based on criteria developed by the prospective transplantation center and its surgeon(s). If the patient is not suitable for transplantation referral, the basis for nonreferral must be documented in the patient's medical record. **Proposed § 494.90(a)(5)** (5) *Transplantation status.* When the patient is a transplantation referral candidate, the interdisciplinary team must develop plans for pursuing transplantation. The patient's plan of care must include documentation of the— (i) Plan for transplantation, if the patient accepts to transplantation referral; (ii) Patient's decision, if the patient is a transplantation referral candidate but	**Change Proposed:** This language requiring such extensive involvement by dialysis facilities and their personnel in the decisions concerning transplantation should be stricken or significantly rewritten to emphasize that the ultimate responsibility for educating patients, for subsequent referral, and for follow up on referrals, rests with physicians, in consultation with their patients. **Rationale:** The responsibility for informing patients of their suitability for transplantation and or home dialysis is that of the physician, not the dialysis provider. We have no objection to providing information to the patient on these modalities, but the decision to proceed with one or the other should be that of the physician and patient alone, and the Secretary inappropriately places that responsibility with the dialysis facility in these proposed Conditions. Dialysis facility personnel do not have the education and training to make decisions regarding transplantation or to counsel how to make them. Likewise, tracking correspondence from the transplant unit to the patient and physician needs to necessarily be between these parties. Any such condition should be based on the study and endorsement of the American College of Physicians or other physician organizations. With respect to maintaining exclusion criteria developed by the transplant center and having the facility apply these to individual patients, this is beyond the reasonable scope of practice and knowledge base of usual dialysis staff with the exception of experienced RNs. Also many facilities have patients transplanted at several different Centers. Each transplant center uses different criteria for inclusion or exclusion of a patient on the transplant waiting list. Thus, the team would have multiple challenges to work

declines the transplantation referral; or (iii) Reason(s) for the patient's nonreferral as a transplantation candidate as documented in accordance with § 494.80(a)(10) of this part **Proposed § 494.90(c)** c) *Standard: Transplantation referral tracking.* The interdisciplinary team must track the results of each kidney transplant center referral and must monitor the status of any facility patients who are on the transplant wait list. The team must communicate with the transplant center regarding patient transplant status at least quarterly or more frequently if necessary.	through when it refers to more than one transplant center. Coordinating this in a large facility will require near full time personnel who will be taking away a function of the physician and or his or her staff. The transplantation rate in the United States and any concern about it should not use the Conditions of Coverage as a vehicle of solution. Finally, here, as in other places within the draft Conditions, the Secretary incorrectly assumes that dialysis facilities can or should direct Physician behavior and prescribing decisions.

Condition: Care at Home—Proposed § 494.100	**Change Proposed:** We believe the section concerning Care at Home should include a requirement that a home dialysis provider should either own an in-center facility within a minimum of 35-50 miles of the homecare patient site of service, or, alternatively, have a written arrangement with a designated backup in-center service provider, including the on-call availability of a nurse.
	Rationale: This would permit a homecare patient to more readily be admitted to an in-center program in the case of equipment failure or other emergency.
Alternative Sanctions—Proposed § 488.606 (a) *Basis for application of alternative sanctions*. CMS may, as an alternative to termination of Medicare coverage, impose one of the sanctions specified in paragraph (b) of this section if CMS finds that— (1) *The supplier fails to participate in the activities and pursue the goals of the ESRD network that is designated to encompass the supplier's geographic area . . .*	**Change Proposed:** This subsection should be deleted entirely.
	Rationale: There necessarily needs to be clarification of "goals for ESRD Networks." Who defines these and how are they validated and communicated to Facilities? What are the checks and balances on Network behavior? How do facilities legitimately demur to requests from Networks that are overly burdensome or repetitive?

III. Administration Conditions

Condition: Personnel Qualifications—Proposed § 494.140 (e) Standard: Patient care dialysis technicians. Patient care dialysis technicians. (3) Have completed *at least 3 months experience, following* a training program that is approved by the medical director and governing body. This experience must be under the *direct* supervision of a registered nurse, and be focused on …	**Change Proposed:** **Delete:** "*at least 3 months experience, following*" and "*direct*" **Rationale.** CMS should not mandate the minimum length of the training program. The availability of training materials to all dialysis providers and improvements to the training process may allow for patient care technicians to be trained and working independently sooner than 3 months. At DaVita, we use several methods for evaluating the patient care technician as he/she completes the steps in the training program and demonstrates the skills required for providing a safe and effective dialysis treatment. These tools also assist our clinical education teams to determine whether additional training time is required. We acknowledge the comments in the preamble regarding CMS's concern to ensure that care is provided by qualified and trained patient care technicians who meet certain basic qualifications and are able to demonstrate the necessary competencies to perform the assigned duties of their positions. While the preamble references the past and current efforts by states to regulate dialysis technicians, we believe that CMS did not address an important aspect of the scope of practice of the licensed nurse. According to State nurse practice acts, rules, and ESRD-specific regulations, the licensed nurse—usually the registered nurse—must perform patient assessments, develop/implement a plan of care, and execute the treatment and medication orders prescribed by appropriately licensed medical staff (as defined by each State). These rules and regulations also state whether the licensed nurse may delegate certain tasks to other licensed (such as practical nurses) or unlicensed personnel (such as patient care technicians) within the generally accepted principles of delegation.

	It is therefore our opinion that the registered nurse, unless State rules and regulations specify otherwise (such as in the case of a practical nurse), is responsible for the nursing care that is given to patients under his/her care, whether or not the registered nurse is in direct supervision of the individual to whom the task is delegated. Therefore we believe it is appropriate for the registered nurse to delegate the experience of the training the patient care technician to another, using generally accepted principles of delegation: right task, right circumstance, right person, right direction/communication, and right supervision). It would be more reasonable to have a focused Preceptor program such as DaVita has as an alternative. Thus requiring an organized Preceptor program with periodic evaluations seems more appropriate.
Medical Directors—Proposed § 494.140(a) (a) *Standard: Medical director.* (l) The medical director must be a physician who has completed a board approved training program in nephrology and has at least 12 months of experience providing care to patients receiving dialysis.	**Change Proposed:** We request clarification in the Preamble that the language that medical directors must have "12 months experience providing care to patients receiving dialysis" should be interpreted to include clinical care experience in fellowship training.
	Rationale: We approve of the language in the proposed Conditions of the Medical Director dealing with "problem Nephrologists," but suggest that there be some reasonable basis for protection from lawsuits for the Medical Director related to this activity.

Core Performance Measures and VISION—Proposed § 494.180	**Change Proposed:** 1. Delay mandatory electronic participation in the CPM until VISION is operational. 2. Delete the provision of the proposed Rule, see, e.g., 70 Fed. Reg. at 6231 and 6241, that would require larger dialysis organizations ("LDOs") to subsidize smaller organizations by charging LDOs for VISION and giving it for free to smaller organizations.
	Rationale: The proposal for full participation in the CPM is a reasonable goal. However this cannot be implemented until the VISION and project is operational. This project has been consistently delayed and we have concerns regarding the universal applicability of VISION to all dialysis organizations. With respect to the proposed subsidy by LDOs, while we support the CPM and its expansion, including the need for the data to be transmitted electronically, these benefits are not so great as to offset the burden that would be imposed on LDOs if CMS required them to subsidize other providers. Dialysis reimbursement is not currently adequate. CMS should either pay for the improvements needed to implement VISION or press for appropriate reimbursement changes that would make it cost-effective for all dialysis organizations—large and small—to incur themselves the expense of implementing it.

Condition: Governance—Proposed § 494.180 (b) Standard: Adequate number of qualified and trained staff… (1) An adequate number of qualified personnel are present whenever patients are undergoing dialysis so that the patient/staff ratio is appropriate to the level of dialysis care given and meets the needs of patients; (2) A *registered* nurse is present in the facility at all times that patients are being treated"	**Change Proposed:** **Replace:** "*registered*" with "licensed" **Rationale:** CMS should not mandate the presence of a registered nurse at all times that patients are being treated because the Boards of Nursing in each State set forth in their nurse practice acts, rules and dialysis specific regulations the scope of practice of the licensed nurse, both registered and practical. The dialysis community finds itself in the unique position of responding to the needs of our patients and their access to dialysis care without unnecessary travel. Unfortunately this means that facilities located in a rural setting may not always have access to registered nurses with experience in dialysis. With the nursing shortage limiting the availability of professional (registered) nurses, we are concentrating our efforts on preserving the registered nurse to perform those things that, by law, only he/she can perform, while maximizing the role and function of the licensed practical nurse and unlicensed assistive personnel to safely and effectively provide care for our patients.
Acuity-Based Staffing—Proposed § 494.180(b)(1) and Request for Comment, Preamble at 70 Fed. Reg. at 6229: "We are soliciting public comment on whether we should include a requirement for an acuity-based staffing plan in § 494.180(b)(1) to ensure that every dialysis facility has ''adequate staffing'' and appropriate staff-to-patient ratios to meet the needs of its patients."	**Change Proposed:** CMS should not incorporate a requirement for an acuity-based staffing plan. **Rationale:** We believe "acuity" would be difficult to define and to maintain as changes frequently occur on a patient by patient basis from treatment to treatment. We agree with the comments in the Preamble that state that the nurse responsible for nursing services should develop the staffing plan and assignments based on the parameters set forth (patients treated per shift, individual patient characteristics/needs, expertise and experience of staff, physical layout of the treatment area, available technology and support services). Such a plan is a more nursing-sensitive model, as advocated by the American Nurses Association's "Principles for Nurse Staffing." There is no compelling evidence in the outpatient dialysis setting, however, to suggest that mandated ratios will improve outcomes.

Rehabilitation Status—Proposed §§ 494.90(a)(6) (6) *Rehabilitation status.* The interdisciplinary team *must provide* the necessary care and services 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.	**Change Proposed:** Strike this section entirely. **Rationale:** Without additional funding a redefinition of dialysis facilities' fundamental roles, dialysis facilities cannot also act as comprehensive rehabilitation coordinating centers. Such a requirement will necessitate additional support to the social worker in an administrative capacity, which is also well beyond the present payment mechanism. In addition, social workers may not be educated or trained to direct rehabilitation services. Rehabilitation is a different kind of care, requiring a different expertise. Moreover, the discussion of this requirement in this proposed subsection and in the Preamble, 70 Fed. Reg. at 6207-08, is so vague that it leaves dialysis facilities dangerously exposed to the individual preferences of surveyors without well-defined clinical objectives. Indeed, the Secretary notes that there is currently no agreed measure of rehabilitation status. 70 Fed. Reg. at 6208.

Registered Dietitian—Proposed § 494.140 (c) *Standard: Dietitian.* The facility must have a dietitian who must— . . . . (3) Have a minimum of one year's professional work experience in clinical nutrition *as a registered dietitian.*	**Change Proposed:** Delete "as a registered dietitian" in order to clarify that a dietitian's one year of clinical experience may be before or after he or she receives their registration. **Rationale:** We agree with requirements for a registered dietitian. However, we disagree with minimum of one year of professional work experience in clinical nutrition as a registered dietitian. Many dietitians obtain clinical experience prior to obtaining registration status. The professional work experience conducted during internship should apply to the experience requirement. Therefore, we recommend a change to read registered dietitian with one year of clinical experience. (The proposed requirement may result in hardship in rural dialysis centers). Also, all inexperienced renal dietitians who are new to a facility should be required to participate in training conducted by an experienced renal dietitian. This is DaVita's policy and practice.

Social Worker 494.140 (d) *Standard: Social worker.* The facility must have a social worker who— (1) Holds a master's degree in social work from a school of social work accredited by the Council on Social Work Education; and (2) Meets the practice requirements for social work practice in the State in which he or she is employed. The Preamble states that *"Facility social worker services include counseling services, long-term behavioral and adaptation therapy, and grieving therapy."* 70 Fed. Reg. at 6222.	**Change Proposed:** Delete this section entirely, or, in the alternative, eliminate from the preamble the statement that "Facility social worker services include counseling services, long-term behavioral and adaptation therapy, and grieving therapy." **Rationale:** We believe the proposed requirement to provide counseling services and long-term behavioral and adaptive therapy is fraught with potential patient danger and is not reflective of the realities of the functional role of the social worker in dialysis facilities. Many social workers are not adept at providing individual therapy and the expansion of their activities into this role provides a potential minefield of potential unwanted clinical results. Social workers spend a great percentage of their time providing for the "social" requirements of patients. This can be focused on food, clothing, shelter, transportation, and financial resources (including Medicare and insurance coverage). These are major factors contributing to the well being of patients. These are clearly in the province of the social worker, and there are no other staff members who have the training or preparation to handle the complex psychosocial issues presented by our patients to assume this function.

	By contrast, the requirement for extensive "counseling activities" by the social worker is not reflective of the present capacity of the social worker. It is pertinent to note that many social workers are not trained in this capacity or would require extensive additional training. If this is indeed the intent of the Conditions, we would expect CMS to provide funding for such education. In conjunction with this CMS should adjust the composite rate upwards to allow for additional staff. With the potential for about 1,200 Social Workers in DaVita, and a conservative estimate of $15,000 per professional, the additional cost would be at least $18 million to cover the educational expenses of social workers and an additional expense to cover new employees to assist social workers. Social workers will continue, of course, to provide emotional support and crisis intervention. The proposed Conditions, if adopted, will require an extensive increase in dialysis costs, and should not be pursued without a corresponding increase in dialysis funding.

Pharmacist—Existing § 405.2136(f)(1)(vi) and Preamble at 70 Fed. Reg. at 6224: "We invite comments regarding what role, if any, the pharmacist should play within the dialysis facility as well as the facility's appropriate responsibility for pharmaceutical services and the efficient use of medications in the new conditions for coverage."	**Change Proposed:** There should be no requirement that dialysis facilities have a pharmacist—either part time or full time—on their staff. **Rationale:** Such a requirement is unnecessary and would be unduly burdensome, with no material corresponding benefit. Under the present reimbursement formula, which does not cover the current cost of providing treatments and pharmaceuticals to dialysis patients, it is unrealistic to discuss the addition of a pharmacist to the team. The nephrologist has expertise in dosing and interactions of drugs commonly used in ESRD. Moreover, the dialysis facility lacks the expertise to manage a licensed pharmacist. The average salary of a pharmacist is $73,000 as outlined by the APA. Given 1,200 units, this would necessitate an increase in the composite rate of $876 million on a full time basis. Even if the required pharmacists would be only part-time, the resulting cost would be staggering. This is another example of an unrealistic relationship between the proposed condition and payment policy.

IV. Additional Comments

In addition to the comments above to specific questions, there are several general comments that we would like to make:

- The present CMS hematocrit measurement audit policy, which relates specifically to the provision of Erythropeoeitin (EPO) to dialysis patients, may preclude all patients from reaching an Hematocrit > 33, as proposed in the draft Conditions. We request that the Secretary specifically address in its Final Rule the interplay between these proposed Conditions of Coverage and any anemia-related coverage, payment, or audit policy established by CMS or the Secretary. We see no evidence that the authors of the proposed Conditions are mindful of CMS's and various fiscal intermediaries' policies and practices

regarding EPO, and how they may affect the laudable outcomes standard stated in the proposed Conditions.

- The Patient satisfaction survey (CAHPS) is not operational and should not be employed until the pilot is reviewed and it is extensively revised. DaVita and others have commented extensively on the risks and shortcomings of the early drafts of the CAHPS and we look forward to the data developed through the piloting currently undertaken by CMS with respect to these surveys.

- At the present time, CMS is preparing for a demonstration project to evaluate issues related and feasibility of an expanded outpatient dialysis bundle into the facility composite rate. We wish to comment that much more and detailed information is required before this issue can be approached and that discussion or reference to this is inappropriate at this time. The drivers behind laboratory and pharmaceutical utilization need to be understood in greater detail. More importantly, a consensus on what constitutes ideal ESRD therapy, in all its manifestations, needs to be achieved.

Once again, DaVita wishes to commend you on these proposed Conditions and looks forward to presenting our comments and proposals in person. We wish to emphasize, however, that new mandates for expansions of services can not be instituted without a change in the present rate of reimbursement. We encourage you to consider the matters presented in depth.

Sincerely,

DAVITA INC.

By: Charles P. McAllister
Chief Medical Officer

Thomas L. Weinberg
Vice President

LeAnne Zumwalt
Vice President

Submitter : Mr. Rosario (Russ) Lazzaro **Date:** 05/05/2005

Organization : Holy Name Hospital

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Please see attached comments.

CMS-3818-P-205-Attach-1.DOC

Holy Name Hospital

Member
NewYork-Presbyterian Healthcare System
Affiliate: Columbia University College of Physicians & Surgeons

Attachment #205
Mark B. McClellan, MD, PhD, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
File Code: CMS-3818-P
PO Box 8012
Baltimore, MD 21244-8012

Wednesday, May 04, 2005

Dear Dr. McClellan:

Please accept my comments regarding the proposed revisions to the Conditions for Coverage for End Stage Renal Disease Facilities. Specifically, I wish to comment on Proposed § 494.140 ("Personnel Qualifications") as this section addresses the possible role of a pharmacist within a dialysis facility/unit. I appreciate that this acknowledges the well-documented contributions a pharmacist can make to the safe and effective use of drugs in the dialysis patient population.

As a pharmacist, I understand the complexity of drugs and the unwanted consequence side effects that may cause either potential or permanent harm to this vulnerable patient population.

Pharmacists must be part of any dialysis facility's healthcare team for the following reasons:

- the complex nature of drug therapy in dialysis patients (multiple),
- the pharmacokinetic complexity of drugs during dialysis (dializability),
- the vulnerability of patients for adverse drug-related outcomes (co-morbid diseases),
- the need for storage, preparation & administration of drugs within the dialysis unit,
- the need for cost effective drug therapy,
- the training of pharmacists that prepares them to serve in dialysis facilities.

Pharmacists' as healthcare providers have the most clinical knowledge in pharmacotherapy, are best qualify to review drugs, recognize duplicative therapy, prevent potential adverse reactions and could have the most significant positive impact in this heavily medicated patient population.

Thank you for your time and consideration in this matter.

Rosario (Russ) Lazzaro, MS, RP
Director of Pharmacy Holy Name Hospital
Tel: (201) 833-3056, Ext. 3819
Fax (201) 833-7112

lazzaro@mail.holyname.org

Submitter : Mrs. Lori Kapsner **Date:** 05/05/2005

Organization : CentraCare Dialysis

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

Submitter : Dr. Paul M. Palevsky **Date:** 05/05/2005

Organization : ESRD Network 4, Inc.

Category : Other

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-3818-P-207-Attach-1.DOC

ESRD Network 4, Inc. 4

: Working for you

40 24th Street, Suite 410
The Crane Building
Pittsburgh, PA 15222

Attachment #207
May 4, 2005

Mark McClellan, MD, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-3818-P
PO Box 8012
Baltimore, MD 212447-8012

RE: Medicare Program: Conditions for Coverage for End Stage Renal Disease Facilities (CMS-3818-P); Proposed Rule

Dear Dr. McClellan:

I am writing on behalf of the Medical Review Board of ESRD Network 4, Inc., the Quality Improvement Organization for patients with end-stage kidney disease in Pennsylvania and Delaware, to provide input on selected portions of the proposed rule revising the Conditions for Coverage (CFC) for ESRD facilities.

In general, we commend CMS for developing a thoughtful and progressive revision to the currently outdated CFC, which have not been revised for nearly three decades. In particular, we applaud CMS for linking the CFC to technical standards and clinical practice guidelines established by recognized professional organizations and for establishing process oriented quality assessment and performance improvement (QAPI) as the cornerstone for assurance of quality patient care. We note, however, that the technical standards and clinical practice guidelines that are referenced in the revised CFC are continually updated, mandating that the CFC be updated on an ongoing basis as revisions to these standards and guidelines are released.

In the section below, we address specific issues which we hope that CMS will consider in revising the CFC as well as addressing specific issues for which CMS solicited comments.

Subpart A – General Provisions

Definitions (§494.10)

In the proposed CFC, CMS proposes that dialysis services for ESRD patients in Nursing Facilities and Skilled Nursing Facilities be included under the regulations for Home Dialysis (§494.110). We believe that this is ill advised and recommend that CMS include separate definitions for *nursing facility dialysis* and *skilled nursing facility dialysis* that are distinct from the definition of *home dialysis* (*vide infra*).

Subpart B – Patient Safety

Physical Environment (§494.60)

CMS solicits comments as to whether small, predominantly rural, dialysis facilities, should receive special consideration for an exemption for the requirement for having a defibrillator on site. We applaud CMS for proposing that facilities be required to have defibrillators on site (with preference for the use of automated external defibrillators, AEDs). We believe that this should be a requirement of all facilities, regardless of size. In particular, in rural facilities, where access to emergency response services may not be as rapid as in urban and suburban locations, we believe that providing an exemption for this emergency equipment is inappropriate.

Subpart C – Patient Care

Patients Rights (§494.70)

While we recognize that the proposed CFC are regulations directed at facilities, we believe that it is important that CMS acknowledge and address the coexistent beneficiary responsibility to participate, to the extent permitted by physical, medical and psychological limitations, to participate in efforts to optimize their own care. There is a need to ensure that the CFC fosters the model of patient participation as a key member of the treatment team (ensuring patient-centeredness, one of the Institute of Medicine's six domains of quality medical care). As written, the proposed rule can be construed as placing responsibility entirely on the facility, creating a potential basis for an adversarial relationship between beneficiaries and the patient care team.

Advance Care Planning

In this section, CMS provides the right to "be informed about and participate, if desired, in all aspects of his or her care, including advance directives..." While we applaud CMS for incorporating this right to advance care planning we urge CMS to strengthen the wording to make advance care planning, including the designation of a preferred surrogate decision-maker and designation of treatment preferences, if desired, a requirement for dialysis facilities, just as it is for other types of healthcare facilities under BORA, 1990. In addition, CMS should consider making review of advance care planning a component of the required patient assessment and treatment plan (§494.80 and §494.90). In addition, the right of a patient to refuse resuscitation in the event of cardiopulmonary arrest should also be stated as a patient right.

Patient Discharge from Facilities

The issue of patient discharge from facilities has become an increasingly difficult issue. While the CFC requires that patients be informed regarding facility discharge and transfer policies, we recommend that CMS incorporate the key elements of the recommendations of the Dialysis Patient-Provider Conflict (DPC) National Task Force, organized by the Forum of ESRD Networks and on which CMS was a critical participant into these conditions. These recommendations address the rights and responsibilities of both the beneficiary and provider within the Medicare entitlement system including (1) the legal right of providers to refuse to treat

patients who are acting violently or are physically abusive, thereby jeopardizing the safety of others; (2) the requirement that the physician must fulfill ethical obligations and take steps to avoid legal abandonment of patients prior to terminating the physician-patient relationship; and (3) the requirement of both the physician and the dialysis facility to provide reasonable assistance to the patient in securing life prolonging treatment with another facility and/or nephrologist.

Patient Assessment (§494.80)

The CFC specifies that the initial comprehensive assessment must be conducted within 20 calendar days after the first dialysis treatment. This requirement is potentially problematic. The conditions do not define what constitutes the first dialysis treatment. Since the "first" dialysis treatment may not necessarily occur in the same dialysis facility as the patient's chronic care, the conditions should be revised to specify the first dialysis treatment ***in the facility***. In addition, the 20 day window for completion of this assessment is arbitrary and may be unreasonable for rural facilities and facilities covered by geographically challenged nephrology practices. We would suggest that the requirement be changed to completion of the comprehensive assessment within ***30 days***.

CMS requests comment on whether the proposed 3-month timeframe for reassessment of new patients is reasonable and consistent with meeting patient needs. We believe that this timeframe is appropriate.

Care at Home (§494.100)

We have significant concerns regarding the inclusion of dialysis services for patients residing in nursing facilities (NF) or skilled nursing facilities (SNF) as subpart of the section on care at home. While this may be appropriate for patients residing in NF who are capable of providing self-care dialysis, we believe that this is not appropriate for patients residing in NF and SNF who require the staff of those facilities to assist or provide the entirety of the dialysis services. Patients requiring care at NF and SNF comprise an extremely vulnerable population. We believe that it is necessary to ensure that the dialysis care provided these beneficiaries, if not capable of self care dialysis, must be subject to as stringent regulation and oversight as patients receiving care in dialysis facilities. We are concerned that including these proposed regulations as a subpart of the requirements for Care at Home does not sufficiently ensure this level of care and suggest that this be included under a separate section. In developing the rules for dialysis services for NF and SNF beneficiaries, the higher acuity of care of these patients must be recognized. As such, it is critical that the regulations ensure that nursing coverage, training and monitoring be at least as stringent as for patients dialyzing in a dialysis facility.

Quality Assessment and Performance Improvement (§494.110)

We applaud CMS for inclusion of a quality improvement model for optimizing the care of Medicare's ESRD beneficiaries as a key component of the CFC. We believe that the use of the QAPI methodology has been proven to be a highly effective way to improve the care of ESRD beneficiaries, as manifested by the initiatives of the ESRD Networks and continuing

improvements in the benchmarks included in the annual Clinical Performance Measures reports. We are concerned however, that the measures specified for inclusion in the facility quality improvement program may not remain appropriate over time and that no mechanism for updating these measures has been proposed. We propose that CMS establish a methodology within the CFC to periodically review and update or replace the minimum set of measures for the QAPI process, including establishment of target performance goals to be met by facilities.

In the proposed rule, CMS requests comment on the appropriateness of establishing facility specific standards for enforcement. We believe that this proposal is not appropriate for several reasons. First and foremost, we believe that the prosed rule inappropriately uses the National Kidney Foundation's K/DOQI guidelines as a standard of care, contradicting its Disclaimer and Acceptable Use Policy which explicitly state:

> *These guidelines are based upon the best information available at the time of publication. They are designed to provide information and assist decision-making. They are not intended to define a standard of care, and should not be construed as one.*

The concept that all patients should be expected to meet defined treatment goals is fundamentally flawed. There are multiple technical and biological reasons why it may not be possible or appropriate for individual patients to meet specific treatment goals. For example, a patient with an underlying hemoglobinopathy may not have had a hemoglobin level of at least 11 g/dL prior to the development of kidney disease. There is therefore no reason to expect that patient to maintain a hemoglobin of at least 11 g/dL while on dialysis. It is also critical that any standards have a strong evidence basis. While, arguably, this is the case for the minimum delivered dose of hemodialysis, similar consensus does not exist regarding the corresponding goals for peritoneal dialysis, as evidenced by the discrepancy between the cited target Kt/V for CAPD of 1.7 per week and the actual K/DOQI guideline which specifies a target of 2.0 per week (http://www.kidney.org/professionals/kdoqi/guidelines_updates/doqiuppd_v.html#15 accessed on 5/3/2005). Furthermore, while the K/DOQI guideline for the delivered dose of CAPD claims to be evidence based, the guidelines for CCPD and NIPD are opinion based, and therefore are not suitable for performance standards.

As an alternative to establishment of fixed numerical thresholds, CMS should consider adopting statistical methodology to identify poorly performing dialysis facilities for targeted quality improvement activities. For facility-specific quality measurement data that is normally distributed, a threshold of 2 standard deviations below the mean might be reasonable. (For measures with skewed distributions, the comparable threshold would be approximately the 2.5^{th} percentile.) Facilities below this threshold would need to show improvement through structured reporting of QAPI data. The selection of measures to be included in these performance expectations would need to be updated on a periodic basis, as patterns of care evolve over time.

Subpart – D

Responsibilities of the Medical Director (§494.150)

CMS specifically is soliciting comments on adding language to this regulation to more specifically state Medical Director responsibilities in regard to ESRD facility attending physicians. We believe that it is important for CMS to explicitly define the Medical Director's responsibility to ensure the quality and safety of all care provided to beneficiaries at an ESRD facility. It is critical that the Medical Director be provided with the necessary authority in regard to other facility attending physicians and staff. We believe that this should be accomplished by requiring governing bodies to empower their Medical Directors in dealing with attending physicians or other staff members who are not performing adequately. Facility by-laws should be required to include processes for peer-review with the option for remedial and disciplinary actions, under the supervision of the Medical Director.

Governance (§494.180)

As proposed, the regulations for medical staff appointments do not require any process for periodic reappointment. The process of periodic recredentialing provides an effective mechanism for oversight and review of physician activity and compliance with facility rules. We believe that it would be advisable to include a requirement for periodic recredentialing in the regulations.

On behalf of the Medical Review Board of ESRD Network 4, Inc., I thank you for the opportunity to comment on the proposed Conditions for Coverage and commend CMS on this proposed rule.

Sincerely yours,

Paul M. Palevsky, MD
Chair, Medical Review Board

Submitter : Michael Rottman **Date:** 05/05/2005

Organization : Physicians Dialysis of America

Category : End-Stage Renal Disease Facility

Issue Areas/Comments

GENERAL

GENERAL

See attachement

CMS-3818-P-208-Attach-1.DOC

Attachment #208
Care at Home

2 Dialysis of Patients at Nursing Facilities and Skilled Nursing Facilities.

In order to make all options truly available to all patients who can benefit from them Home dialysis should be allowed to NF/SNF residents who are only there short term for rehabilitation or brief recovery time admissions. Allowing this will greatly increase the likelihood of those patients being discharged in a timely manner. When NF/SNF patients are required to go out for their dialysis they often miss the therapies and treatments that they have been admitted for, either as a result of the travel time or as a result of their being too tired upon returning to actively participate in these therapies. Dialyzing these short-stay patients in the NF/SNF allows the dialysis schedule to be worked around the therapy schedule and not vice versa.

With regard to caregiver ratios and nursing coverage.

Paragraph C starts by saying:

> *The existing regulations (§405.2162(b)) require that a licensed professional (for example, physician, registered nurse, or licensed practical nurse) experienced in rendering ESRD care is on duty to oversee ESRD patient care whenever patients are being dialyzed.*

This is not correct. This is only a requirement for a dialysis center and not a requirement for home dialysis.

NF/SNF patients should be dialyzed in the same manner as all other home patients. When a trained caregiver is administering the treatment on a one-on-one basis there should be no requirement for a nurse at the NF/SNF just as there is no requirement for this at any other home of the patient. Multiple simultaneous treatments should not be allowed to be administered by a single caregiver in the home setting. This will ensure that the NF/SNF patients are being safely treated.

Section D Training, states that the training that is sufficient for home patients is sufficient for caregivers who will administer treatments to NF/SNF patients. We agree with this and feel that this further strengthens the position that an RN not be required for any home dialysis patient, whether they are in their own home or in a NF/SNF.

Finally, the reality of the nursing supply would make it virtually impossible to comply with a requirement that each NF/SNF that has home dialysis patients have an RN on duty at that facility while patients are dialyzing. Therefore, home dialysis will not be able to be provided to NF/SNF residents. This is contradictory to the stated goal of making this therapy available to more patients.

Submitter : Mrs. amy eckert **Date:** 05/05/2005

Organization : purity dialysis center

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-3818-P-209-Attach-1.DOC

Attachment #209
May 3, 2005

Centers for Medicare and Medicaid Services
Attention: CMS-3818-P
P. O. Box 8012
Baltimore, MD 21244-8012

Re: CMS Proposed Conditions
For Coverage for ESRD Facilities

To Whom It May Concern:

Please consider the following comments regarding the Proposed Conditions for Coverage for ESRD Facilties. Although the following response format suggests that comments reflect only those of CNSW, my additional/alternative feedback will be written in *italics*.

Thank you for your consideration of the following opinions.

Sincerely,
Amy Eckert, LCSW
Purity Dialysis Centers – New Berlin
13900 W. National Ave.
New Berlin, WI 53151

LOCATION OF COC	COMMENTS
494.10 Definitions Dialysis facility *NEW* Staff assisted skilled nursing home dialysis	***Add:*** A new category for dialysis provided in a nursing home setting ***Rationale***: Nursing home dialysis is typically provided by staff. Home dialysis (PD or hon by a trained *patient* and/or a helper. Important differences exist between them, including nursing home dialysis patients.
494.20. Condition Compliance with Federal, State, and local laws and regulations	***Add:*** "Facilities must accommodate mobility, hearing, vision, or other disabilities or langu ***Rationale***: Healthcare settings are covered entities under the Americans with Disabilities
494.60 Condition Physical Environment. (c) Patient care environment	***Add to c1***: Require facilities to be accessible to people with disabilities. ***Rationale***: Americans with Disabilities Act ***Reference:*** ADA ***Add to c1***: Require facilities to have a place *available* for confidential interviews with pat privacy during body exposure. *Patient/family interviews may still take place chairside wit* ***Rationale***: HIPAA privacy ***Comment***: *I highly support the inclusion of the proposed (c) (2) regarding facility temper* ***Rationale*: A common complaint from dialysis patients is in regards to the facility** approach dictates that facilities need to have a plan in place to accommodate patients' p concerns of patients who are not comfortable. *This issue should be addressed minimall unit Patient Satisfaction Surveys or on Care Plans if temperature is a barrier to treatmen*
494.70 Condition	.

Patients' Rights (a) Standard: Patients' rights	***Comment:*** *Dialysis units should inform, encourage and assist, via the unit's qualified so worker, the completion of an advanced directive, and documentation of this intervention.* ***Add***: (new 17) "Have access to a qualified social worker and dietitian as needed" ***Rationale:*** Social workers and dietitians often have large caseloads, cover multiple clinic often do not know how to contact them when needed. ***References:*** Bogatz, Colasanto, Sweeney, 2005; Forum of ESRD Networks, 2003; Meri ***Add***: (new 18) "Be informed that full- or part-time employment and/or schooling is possib ***Rationale***: The purpose of dialysis is to permit the highest possible level of functioning d of rehabilitation is crucial. ***References:*** Curtin et al,1996; Rasgon et al, 1993, 1996 ***Add***: (new 19) "Have a work-friendly modality (PD, *incenter hemodialysis,*or home hemo accommodates work or school", *such as incenter treatment after 5pm.* ***References:*** Same as above for new 18, plus:Mayo 1999 ***Add***: (new 20) "Receive referral for physical or occupational therapy, and/or vocational re ***Rationale:*** These interventions have been shown to improve patient rehabilitation outcor ***References:*** Beder, 1999; Dobrof et al., 2001; Witten, Howell & Latos, 1999. ***Add***: (new 21) "Attend care planning meetings with or without representation." ***Rationale:*** Promoting patient participation in care requires that patients have the right to meetings. ***Add***: (new 22) "Request an interdisciplinary conference with the care team, medical direc ***Rationale***: Patients don't realize that they can convene a care conference, and this is on team outside of the normal care planning meeting, which might only be done once/year. ***Add***: (new 25) "Be informed of topical analgesics for needle pain and how to obtain them ***Rationale***: Patients should be able to undergo a painless treatment, and low-cost, over-t are available that will not harm the access and will provide pain relief. Patients should be where to obtain them. ***Reference:*** McLaughlin et al., 2003 ***Add***: (new 26) "Receive counseling from a qualified social worker to address concerns re illness, including changes to life-style and relationships because of his illness, developm any behavior that negatively affects his health or standing in the facility." ***Rationale***: Patients are faced with numerous adjustment issues due to ESRD and its trea workers are trained to intervene within areas of need that are essential for optimal patien ***References:*** McKinley & Callahan, 1998; Vourlekis & Rivera-Mizzoni, 1997
494.70 Condition Patients' Rights (b) Standard: Right to be informed regarding the facility's discharge and transfer policies.	***Add to b1***: "Receive counseling and support from the team to resolve behavioral issues lead staff to notify police or refer for evaluation of risk to self or others". *However, 911 sh danger to patients or staff.* ***Rationale***: Facilities should be encouraged first to try counseling to resolve difficult situa ***References:*** Forum of ESRD Networks, 2003; Johnstone S, et al, 1997; King & Moss, 2(Physicians Association and American Society of Nephrology, 2000 ***Add***: (new 2) "Not be involuntarily discharged from the facility for non-adherence with the shortening in-center hemodialysis treatments, excessive fluid weight gain, or lab tests tha unless it can be shown that the patient's behavior is putting other patients or the facility c ***Rationale:*** The ESRD Networks and the preamble of these proposed Conditions for Cov compliance should not be a basis for involuntary discharge from lifesaving dialysis treatm as to the reasons why these behaviors may be harmful to them; it is therefore inappropria lack of knowledge. If consistent difficulties are noted with a patients' ability to follow the t should be initiated to investigate and address all potential factors..

	References: Forum of ESRD Networks, 2003; Johnstone S, et al., 1997; King & Moss, 2 Physicians Association and American Society of Nephrology, 2000
494.70 Condition Patients' Rights (c) Standard: Posting of rights.	***Add***: "Facilities with patients who cannot read the patients' rights poster must provide an patients of their rights which can be verified at survey." ***Rationale & References***: Americans with Disabilities Act, Civil Rights Act
494.80 Condition Patient assessment (a) Standard: Assessment criteria.	***Change***: The language of "social worker" in the first sentence to "qualified social worker" ***Rationale***: This will clarify any ambiguity of the social work role. ***Add***: (a1) "...and functioning and well-being ***with the optional use*** *of* the SF-36 or other reporting of or conversion to a physical component summary (PCS) score and mental co domains of functioning and well-being measured by that survey. If the MCS or mental he major depression ***with the optional use*** *of* the PHQ-2 or another validated depression s mental health evaluation." ***Rationale***: ***Although literature supports the value of the PCS and MCS scores, mandatory use of specific tools could result in avoidance of staff for patients who such interventions as cumbersome, difficult or repetitive. Mandatory use of tools r negate the qualified social worker's ability to manage other patient needs beyond administration and assessment of tools and their outcomes. SF- 36 is a tool whicl be effectively administered to patients who cannot read or have limited or no Engl.*** ***Comment:*** I support the language of a2, a3, a4, a5, a6, a8 ***Change***: (a7) to *Evaluation of psychosocial needs (such as but not limited to: coping witl chronic illness, mental health, bereavement, concern about mortality & morbidity, losses, body image issues, lifestyle changes and losses, social role disturbance, dependency iss relationship changes; transplantation referral, participation in self care, activity level, reha insurance and prescription issues, employment and rehabilitation barriers.* ***Comment:*** I support the language of a10, a11, a12, a13
494.80 Condition Patient assessment (b) Standard. Frequency of assessment for new patients	***Change***: (b1) to "An initial comprehensive assessment and patient care plan must be co the first dialysis treatment." ***Rationale***: *Permitting **30 days** for assessment and development of a care plan allows fc assessment of patient needs.* ***Comment:*** *(b2) The comprehensive reassessment enables team evaluation of the patie adherence to new treatment plan, accuracy of plan, and rehabilitation needs including pa dialysis regimen.*
494.80 Condition Patient assessment (d) Standard: Patient reassessment	***Change***: (d2iii) to "significant change in psychosocial needs as identified in 494.80 a7." ***Rationale***: Referring back to the specific psychosocial issues recommended to be addec ambiguity of needs to reassess ***Add***: (v) "Physical debilitation per patient report, staff observation, or reduced physical c validated measure of functioning and well-being." ***Rationale***: Low PCS scores predict higher morbidity and mortality in research among ES ***References:*** DeOreo, 1997; Kalantar-Zadeh, Kopple, Block, Humphreys, 2001; Knight e 2003; Lowrie, Curtin, LePain & Schatell, 2003; Mapes et al., 2004 ***Add***: (new vi) "Diminished emotional well-being per patient report, staff observation, or re (MCS) score on a validated measure of functioning and well-being." ***Rationale:*** Low MCS scores predict higher morbidity and mortality in research among ES also linked to depression and skipping dialysis treatments. ***Add***: (new vii) "Depression per patient report, staff observation or validated depression s ***Rationale:*** Multiple studies report a high prevalence of untreated depression in dialysis p

	predictor of death. ***References:*** Andreucci et al., 2004.; Kimmel, 1993; Kimmel, 1998; Kutner et al., 2000.; \ ***Add***: (new viii) "Loss of or threatened loss of employment per patient report" ***Rationale***: Identifying low functioning patients early and targeting interventions to improv physical and mental functioning and employment outcomes. ***References:*** Blake, Codd, Cassidy & O'Meara, 2000; Lowrie, Curtin, LePain & Schatell, Schatell & Becker, 2004
494.90 Condition Patient plan of care. (a) Standard: Development of patient plan of care.	***Add***: (a) *the patient to those developing the plan.* ***Rationale***: The patient must be explicitly listed as part of the care planning process ***Add***: (new 3) "*Psychosocial status*. The interdisciplinary team must provide the necessar sustain an effective psychosocial status." ***Rationale & References***: Eighty-nine percent of ESRD patients report experiencing sigr disease (Kaitelidou, et al., 2005) Psychosocial issues negatively impact health outcomes of life. Therefore, "psychosocial status" must be considered as equally important as othe ***Add***: (new 6) *Home dialysis status.* ***Rationale***: Every patient must be informed of home dialysis options, evaluated for candi candidate, the reason(s) why not should be reported. ***Add***: (renumbered 8) "Rehabilitation status. The interdisciplinary team must provide the necessary care and services to: (i) maximize physical and mental functioning, the quality of life indicators which ***may be*** summary (PCS) score and mental component summary (MCS) score on a validated mea an equally valid indicator of physical and mental functioning), (ii) help patients maintain or improve their vocational status (including paid or volunteer v the same employment categories on the CMS 2728 form (iii) help pediatric patients (under the age of 18 years) to obtain at least a high school dip annually tracking student status. (iv) Reasons for decline in rehabilitation status must be documented in the patient's med to reverse the decline." ***Comment: Measurement tools should be optional but not mandatory for rehabilitation assessment.***
494.90 Condition Patient plan of care. (b) Standard: Implementation of the patient care plan.	***Add to 3b***: "If the expected outcome is not achieved, the interdisciplinary team must des patient's plan of care to either achieve the specified goals or establish new goals, and ex ***Rationale***: When goals are not met, barriers must be identified and goals re-examined.
494.90 Condition Patient plan of care. (c) Standard: Transplantation referral tracking	***Comment:*** I support the language of (c) and recommends its inclusion in the final condit see language which would outline the responsibilities of transplant centers and their resp informing dialysis units of the transplant status of patients referred for transplant.
494.90 Condition Patient plan of care. (d) Standard: Patient education and training.	***Add to d***: "The patient care plan must include, as applicable, education and training for p caregivers or both, and must document training the following areas in the patient's medic (i) The nature and management of ESRD (ii) The full range of techniques associated with treatment modality selected, including ef equipment in achieving and delivering the physician's prescription of Kt/V or URR, and e prescribed) to achieve and maintain a hemoglobin level of at least 11 gm/dL (iii) How to follow the renal diet, fluid restrictions, and medication regimen (iv) How to read, understand, and use lab tests to track clinical status (v) How to be an active partner in care (vi) How to achieve and maintain physical, vocational, emotional and social well-being

	(vii) How to detect, report, and manage symptoms and potential dialysis complications (viii) What resources are available in the facility and community and how to find and use (ix) How to self-monitor health status and record and report health status information (x) How to handle medical and non-medical emergencies (xi) How to reduce the likelihood of infections (x) How to properly dispose of medical waste in the dialysis facility and at home **Rationale**: Life Options Research has demonstrated that ESRD patients must gain in orc producing their own best health outcomes and monitoring the safety and quality of the ca ***References;*** Curtin, et al. 2002; Curtin, Klag, Bultman & Schatell, 2002; Curtin, Sitter, Sc et al., 2004
494.100 Condition Care at home.	***Comments:*** Services to home patients should be at least equivalent to those provided tc **Rationale**: Home dialysis patients are patients of the ESRD facility and are entitled to the achieve expected outcomes as any other patient of the facility. ***Add***: (new 3iv) "Implementation of a social work care plan" ***Rationale & References***: A social work care plan is as equally important as other aspec important to specify a "social work care plan" to ensure that it is conducted by a qualified
494.100 Condition Care at home. (c) Standard: Support services.	***Add to 1i***: *"Monitoring of the patient's home adaptation, as indicated by home dialysis program administrator as needed and if geographically feasible in accordance with the p.* ***Add to 1iv***: "Patient consultation with all members of the interdisciplinary team, as need ***Rationale***: The language of this part of the proposed conditions is vague and subject to '
NEWCONDITION Staff assisted skilled nursing home dialysis	***Add:*** A new condition for dialysis provided in a nursing home setting (that is not incorpor. ***Rationale***: To include care in a nursing facility/skilled nursing facility (NF/SNF) under "ca a tremendous difference in what CMS must do to protect the health and safety of highly f self-care at home (or have assistance from a trained helper at home) and patients who re perform dialysis because they are too debilitated to travel to a dialysis facility. ***Reference:***Tong & Nissenson, 2002 ***Add:*** Language to this proposed condition that would mandate " A Nursing facility/Skillec dialysis to residents with ESRD, ***monitored by a dialysis facility and comply with all s*** ***Rationale***: Patients receiving dialysis in NF or SNF should not be deprived of essential s receive in an outpatient dialysis facility, including consultation with a qualified nephrology may employ social workers, these social workers may not hold a master's degree and wi of the complex social and emotional factors affecting the dialysis patient. To ensure that hemodialysis patients is protected, any proposed requirements should specifically incorp of the proposed conditions of coverage.
§494.110 Condition Quality assessment and performance improvement. (a) Standard: Program scope.	***Add***: (1) *"The program must include, but not be limited to, an ongoing program that achie improvement in physical, mental, and clinical health outcomes and reduction of medical* ***Rationale:*** To ensure patient-centered care, patient functioning and well-being must be monitored and improved, ***however, assessment tools should not be mandated.*** ***Add***: (2)(new iii) "Psychosocial status." ***Rationale & References***: "Psychosocial status" must be considered as equally importan improvement. CNSW has many resources and tools, available through the National Kidn track social work quality. ***Comment:*** Dialysis providers must measure patient satisfaction and griev of a standardized survey (such as the one being currently developed by C experience and ratings of their care. Such a survey would provide informa reports that facilities can use for internal quality improvement and externa facilities, and finally, information that can be used for public reporting and survey should be in the public domain and consist of a core set of questio conjunction with existing surveys. ***Documentation of facility response a means of communicating such corrections to patients is crucial to th process. Patients who perceive that their feedback does not result in***

	change often decline to participate in subsequent patient satisfactio
494.140 Condition Personnel qualifications	***Comment:*** *This section should be renamed "Personnel qualifications and with the addition of specified personnel responsibilities to each team mem alternatively, 494.150 could be renamed "Condition: Personnel Responsit of the responsibilities of each team member. Responsibilities for social wc comment on "494.140 Condition Personnel qualifications (d) Standard: Sc can be used in a new "responsibilities" section.* ***Rationale & References****: Currently, many master's level social workers a tasks that are clerical in nature and which prevent the MSW from participa interdisciplinary team so that optimal outcomes of care may be achieved. conditions of coverage specify the responsibilities of a qualified social wor assign social workers inappropriate tasks and responsibilities. Tasks that admissions, billing, and determining insurance coverage prohibit nephrolo performing the clinical tasks central to their mission (Callahan, Witten & Jc Ehlebracht (2004b,2004c,2005) found that:* • *26% of social workers were responsible for initial insurance v* • *44% of social workers were primarily responsible for complet paperwork.* • *18% of social workers were involved in collecting fees from p* ***that this could significantly diminish trust and cause dar relationship).*** • *Respondents spent 38% of their time on insurance, billing an time spent assessing and counseling patients.* *This evidence clearly demonstrates that without clear definition and monit to the qualified social work (as is the current case), social workers are rou inappropriate, preventing them from doing appropriate tasks.*
494.140 Condition Personnel qualifications (d) Standard: Social worker.	**Change the language of (d) to**: *Social worker. The facility must have a q Has completed a course of study with specialization in clinical practice, ar graduate school of social work accredited by the Council on Social Work E licensing requirements for social work practice in the State in which he or responsible for tasks including but not limited to: initial and continuous pat planning including the social, psychological, cultural and environmental ba prescribed treatment; provide supportive counseling to patients and their f treatment; providing patient and family education; help completing advan patients with achieving rehabilitation goals.* ***Rationale & References****: Clinical social work training is essential to offer complex psychosocial issues related to ESRD and its treatment regimes. "grandfather" clause of the previous conditions of coverage, which exemp effective date of the existing regulations (September 1, 1976) from the soc work master's degree requirement. Qualified master's degree social worke autonomously are essential. We agree that these social workers must hav*

	behavior, family dynamics, and the psychosocial impact of chronic illness family. A specialization in clinical practice must be maintained in the defin workers are trained to think critically, analyze problems, and intervene wit essential for optimal patient functioning, and to help facilitate congruity be in the environment, demands and opportunities (Coulton, 1979; McKinley Howell, 1992; Wallace, Goldberg, & Slaby, 1984). An undergraduate degr health credentials (masters in counseling, sociology, psychology or docto offer this specialized and comprehensive training in bio-psycho-social ass between individual and the social system that is essential in dialysis progr Work degree is considered a specialized level of professional practice an skill or competency in performance (Anderson, 1986).
§494.180 Condition Governance. (b1) Standard. Adequate number of qualified and trained staff.	***Add***: (1i) No dialysis clinic should have more than 75 patients per one full ***Rationale & References***: *A specific social worker-patient ratio must be included in the conditions of coverage. Currently, there are no such national ratios and as a result socia more than 300 patients per social worker in multiple, geographically separated, clinics. This is highly variable among different dialysis units-letting dialysis clinics establish their same situation as we have now with very high social work caseloads. For many years, C work-patient ratio (contact the National Kidney Foundation for the formula) which has be units. The new conditions of coverage must either identify an acuity-based social work s units (I would recommend CNSW's staffing ratio), or set a national patient-social worker regarding ratios will not affect any change, as is evidenced by today's large caseloads a determined that 75:1 is the ideal ratio. If CMS refuses to include language about social w conditions include language for "an acuity-based social work staffing plan developed by t* *Large nephrology social work caseloads have been linked to decreased patient rehabilitation outcomes (Callahan, Moncrief, Wittman & Maceda, 1998). It is also the cas caseloads prevent them from providing adequate clinical services in dialysis, most notab 2002, 2005). In Merighi and Ehlebracht's (2004a) survey of 809 randomly sampled dialy they found that only 13% of full time dialysis social workers had caseloads of 75 or fewe patients, and 47% had caseloads of more than 100 patients.*
§494.180 Condition Governance. (b4) Standard. Adequate number of qualified and trained staff.	***Comment:*** All employees must have an opportunity for continuing education and related

Submitter : **Ms. Sherryl Behrens** **Date:** **05/05/2005**

Organization : **Gambro Healthcare**

Category : **Social Worker**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-210-Attach-1.DOC

Attachment #210

Issue Identifier	CNSW Comment on Conditions for Coverage for End Stage Renal Disease Facilities File code CMS–3818–P
LOCATION OF COC	PROPOSED DIALYSIS COC that are identified in this document can be found at: http://a257.g.akamaitech.net/7/257/2422/09feb20050800/edocket.access.gpo.gov/2005/pdf/1622.pdf
494.10 Definitions Dialysis facility *NEW* Staff assisted skilled nursing home dialysis	***Add:*** A new category for dialysis provided in a nursing home setting ***Rationale***: Nursing home dialysis is typically provided by staff. Home dialysis (PD or home hemodialysis) is typically performed by a trained *patient* and/or a helper. Making these treatments equivalent ignores the important differences between them, including the staff training/supervisory needs of nursing home dialysis patients. ***Reference:***? Tong & Nissenson, 2002
494.20. Condition Compliance with Federal, State, and local laws and regulations	***Add:*** "Facilities must accommodate mobility, hearing, vision, or other disabilities or langua and communication barriers" ***Rationale***: Healthcare settings are covered entities under the Americans with Disabilities A ***References:*** ADA
494.60 Condition Physical Environment. (c) Patient care environment	***Add to c1***: Require facilities to be accessible to people with disabilities. ***Rationale***: Americans with Disabilities Act ***Reference:*** ADA ***Add to c1***: Require facilities to have a place for confidential interviews with patients and families and to provide for privacy during body exposure. ***Rationale***: HIPAA privacy ***Reference:*** *Protecting the Privacy of Patients' Health Information* ***Comment***: CNSW Supports the inclusion of the proposed (c) (2) regarding facility temperature. ***Rationale***: A common complaint from dialysis patients is in regards to the facility climate. patient-centered care approach dictates that facilities need to have a plan in place to accommodate patients' preferences for climate, and address the concerns of patients who ar not comfortable.
494.70 Condition Patients' Rights (a) Standard: Patients' rights	***Add***: (2) Require facility to ask the patient to *demonstrate understanding* of information provided. ***Rationale***: Without this requirement, it would be very easy for staff to believe that they had informed a patient without realizing that, in fact, the patient did not understand the information. ***References:*** Johnstone, 2004; Juhnke & Curtin, 2000; ?Kaveh & Kimmel, 2001 ***Comment & Addition to a6:*** CNSW supports the language of a6 with the recommended addition of requiring facilities to inform patients of all available treatments (in-center hemodialysis, CAPD, CCPD, conventional home hemodialysis, daily home hemodialysis, nocturnal home hemodialysis, transplant), and to provide a list of facilities where treatment: are offered within 120 miles if the facility does not offer that treatment. ***Rationale:*** We propose to require that a facility inform patients about all available treatmen modalities

12

and settings, so patients can make an informed decision regarding the most appropriate course of treatment that meets their needs. To assist dialysis patients in achieving the optimal quality of life, patients need education about each modality and must have access to the widest array of treatment choices possible. For patients to truly have choices in their modalities, they must not only know what types of treatment exist, but where they can be obtained. Home Dialysis Central (www.homedialysis.org) has a searchable database of clinics that offer any type of home dialysis and US maps for each home modality showing a 120 mile radius from clinic locations.
Comment: CNSW supports the language of a5
Rationale: Advance directives establish in writing an individual's preference with respect to the degree of medical care and treatment desired or who should make treatment decisions if the individual should become incapacitated and lose the ability to make or communicate medical decisions.
Add: (new 17) "Have access to a qualified social worker and dietitian as needed"
Rationale: Social workers and dietitians often have large caseloads, cover multiple clinics and/or work part-time, and patients often do not know how to contact them when needed.
References: Bogatz, Colasanto, Sweeney, 2005; Forum of ESRD Networks, 2003; ?Merighi & Ehlebracht, 2004a
Add: (new 18) "Be informed that full- or part-time employment and/or schooling is possible on dialysis"
Rationale: New patients do not know what to expect from dialysis and may be told that they must go on disability, when paid employment (with insurance) or schooling may be possible for them, particularly if they have access to evening shifts, transplant or home dialysis therapies. The purpose of dialysis is to permit the highest possible level of functioning despite kidney failure, thus this element of rehabilitation is crucial.
References:? Curtin et al,1996; ?Rasgon et al, 1993, 1996
Add: (new 19) "Have a work-friendly modality (PD or home hemodialysis) or schedule that accommodates work or school"
Rationale: Same as above for new 18.
References: Same as above for new 18, plus:?Mayo 1999
Add: (new 20) "Receive referral for physical or occupational therapy, and/or vocational rehabilitation as needed"
Rationale: These interventions have been shown to improve patient rehabilitation outcomes.
References:? Beder, 1999; ?Dobrof et al., 2001; ?Witten, Howell & Latos, 1999.
Add: (new 21) "Attend care planning meetings with or without representation."

3

Rationale: Promoting patient participation in care requires that patients have the right to attend their own care planning meetings.
Add: (new 22) "Request an interdisciplinary conference with the care team, medical director and/or nephrologists."
Rationale: Patients don't realize that they can convene a care conference, and this is one way to obtain feedback from the team outside of the normal care planning meeting, which might only be done once/year.

Add: (new 23) "Refuse cannulation by a nurse or technician if access problems occurred with that staff member in the past until evidence of retraining is provided. Patients may also request another staff person to observe cannulation."
Rationale: Patients have only a limited number of potential vascular access sites, and if a staff person was responsible for causing access damage or hospitalization in the past, patients must have the right to protect themselves by refusing care from that staff person. Despite the obvious interpersonal and convenience issues this will cause for facilities, this is a patient safety issue that also has the potential to reduce cost to the system of hospitalization from vascular access problems. This will also encourage clinics to help their staff improve their cannulation skills and teach patients to self-cannulate.
Add: (new 24) "Be informed that self-cannulation is possible and be offered training to self cannulate."
Rationale: Having a single, consistent cannulator can help preserve vascular accesses and reduce hospitalizations. Since the patient is always present for the hemodialysis treatment, he or she should be encouraged whenever possible to become his/her own cannulator. Clinics should not be allowed to have a policy denying a willing patient the right to learn to self-cannulate.
Add: (new 25) "Be informed of topical analgesics for needle pain and how to obtain them"
Rationale: Needle fear and needle pain are largely unaddressed issues in hemodialysis, despite the large (14-15 gauge) needles that must be used at each treatment. Patients should be able to undergo a painless treatment, and low-cost, over-the-counter, 4% lidocaine preparations are available that will not harm the access and will provide pain relief. Patients should be told that these products exist and where to obtain them.
Reference:? McLaughlin et al., 2003
Add: (new 26) "Receive counseling from a qualified social worker to address concerns related to the patient's adjustment to illness, including changes to life-style and relationships because of his illness, developmental issues affected by his illness, and any behavior that negatively affects his health or standing in the facility."
Rationale: Patients are faced with numerous adjustment issues due to ESRD and its treatment regimes. Master's level social workers are trained to intervene within areas of need that are essential for optimal

patient functioning and adjustment References: McKinley & Callahan, 1998; Vourlekis & Rivera-Mizzoni, 1997	
494.70 Condition Patients' Rights (b) Standard: Right to be informed regarding the facility's discharge and transfer policies.	Add to b1: "Receive counseling and support from the team to resolve behavioral issues and be informed of behaviors that will lead staff to notify police or refer for evaluation of risk to self or others" Rationale: Facilities should be encouraged first to try counseling to resolve difficult situations References: Forum of ESRD Networks, 2003; Johnstone S, et al, 1997; King & Moss, 2004; Rau-Foster, 2001; Renal Physicians Association and American Society of Nephrology, 2000

	Add: (new 2) "Not be involuntarily discharged from the facility for non-adherence with the treatment plan, including missing or shortening in-center hemodialysis treatments, excessive fluid weight gain, or lab tests that would suggest dietary indiscretions unless it can be shown that the patient's behavior is putting other patients or the facility operations at risk." Rationale: The ESRD Networks and the preamble of these proposed Conditions for Coverage have both stated that non-compliance should not be a basis for involuntary discharge from lifesaving dialysis treatment. Patients often are not educated as to the reasons why these behaviors may be harmful to them; it is therefore inappropriate to refuse them care due to their lack of knowledge. If consistent difficulties are noted with a patients' ability to follow the treatment plan, a team evaluation should be initiated to investigate and address all potential factors. For example, a patient who is trying to maintain a full-time job to support a family may choose to leave treatment early rather than risk losing employment; or a patient who is taking a medication that causes dry mouth may be unable to follow the fluid limits for in-center hemodialysis. References: Forum of ESRD Networks, 2003; Johnstone S, et al., 1997; King & Moss, 2004; Rau-Foster, 2001; Renal Physicians Association and American Society of Nephrology, 2000 Change: (renumbered 3) Delete or define "reducing...ongoing care." Rationale: This phrase is unclear.
494.70 Condition Patients' Rights (c) Standard: Posting of rights.	Add: "Facilities with patients who cannot read the patients' rights poster must provide an alternate method to inform these patients of their rights which can be verified at survey." Rationale & References: Americans with Disabilities Act, Civil Rights Act
494.80 Condition Patient assessment (a) Standard: Assessment criteria.	Change: The language of "social worker" in the first sentence to "qualified social worker" Rationale: This will clarify any ambiguity of the social work role. Add: (a1) "...and functioning and well-being using the SF-36 or other standardized survey that permits reporting of or conversion to a physical component summary (PCS) score and mental component summary (MCS) score and all domains of functioning and well-being measured by that survey. If the MCS or mental health domain score is low, assess for major depression using the PHQ-2 or another validated depression survey or referring the patient to further mental health evaluation."

45

Rationale: The preamble to the Conditions for Coverage discussed the importance of measuring functioning and well-being—but stated that there was "no consensus" about which measure to use. In fact, the literature clearly supports the value of the PCS and MCS scores to independently predict morbidity and mortality among tens of thousands of ESRD patients—and these scores can be obtained from any of the tools currently in use to measure functioning and well-being. The composite scores (PCS and MCS) have been proven to be as predictive of hospitalization and death as serum albumin or Kt/V. Scores can be improved through qualified social work interventions.
References: ?DeOreo, 1997; ?Kalantar-Zadeh, Kopple, Block, Humphreys, 2001; ?Knight et al. 2003; ?Kroenke, Spitzer & Williams, 2003; Lowrie, Curtin, LePain & Schatell, 2003; ?Mapes et al., 2004
Comment: CNSW supports the language of a2, a3, a4, a5, a6
Change: (a7) to "Evaluation of psychosocial needs (such as but not limited to: coping with chronic illness, anxiety, mood changes, depression, social isolation, bereavement, concern about mortality & morbidity, psycho-organic disorders, cognitive losses, somatic symptoms, pain, anxiety about pain, decreased physical strength, body image issues, drastic lifestyle changes and numerous losses of [income, financial security, health, libido, independence, mobility, schedule flexibility, sleep, appetite, freedom with diet and fluid], social role disturbance [familial, social, vocational], dependency issues, diminished quality of life, relationship changes; psychosocial barriers to optimal nutritional status, mineral metabolism status, dialysis access, transplantation referral, participation in self care, activity level, rehabilitation status, economic pressures, insurance and prescription issues, employment and rehabilitation barriers)."
Rationale: Much like the elaboration of a1, a4, a8, a9, elaborating what "psychosocial issues" entails will ensure national coherence of the exact psychosocial issues that must be assessed for each patient. There is clear literature that identifies these psychosocial issues throughout this response.
Comment: CNSW supports the language of a8
Add: (a9)(new i) "The facility must include in its evaluation a report of self-care activities the
patient performs. If the patient does not participate in care, the basis for nonparticipation must be documented in the medical record (i.e., cognitive impairment, refusal, etc.)."
Rationale: Life Options research has found that patients on dialysis 15 years or longer who participated actively in their own care did better; follow-up research with a random sample of 372 in-center hemodialysis patients found participation in self-care is correlated with higher functioning and well-being, which, in turn, predicts reduced hospitalization and mortality.
References: Curtin, Bultman, Schatell & Chewning, 2004; ?Curtin & Mapes, 2001
Add: (9)(new ii) "If the patient is not referred for home dialysis, the basis for non-referral must be documented in the medical record. Lack of availability of home dialysis in the facility is not a legitimate

6

basis for non-referral."
Rationale: Requiring that the basis for non-referral for home dialysis be documented will

help to ensure that patients have access to these therapies and will provide needed data for QAPI purposes. Comment: CNSW supports the language of a10, a11, a12, a13	
494.80 Condition Patient assessment (b) Standard. Frequency of assessment for new patients	Change: (b1) to "An initial comprehensive assessment and patient care plan must be conducted within 30 calendar days after the first dialysis treatment." Rationale: We recommend combining an initial team assessment and care plan as they work in concert: a care plan should address areas for intervention as identified in the assessment. Permitting 30 days for assessment and development of a care plan allows for full team participation and adequate assessment of patient needs. Comment: CNSW supports the language of b2
494.80 Condition Patient assessment (d) Standard: Patient reassessment	Change: (d2iii) to "significant change in psychosocial needs as identified in 494.80 a7." Rationale: Referring back to the specific psychosocial issues recommended to be added to 494.80 a7 will eliminate any ambiguity of needs to reassess Add: (v) "Physical debilitation per patient report, staff observation, or reduced physical component summary (PCS) score on a validated measure of functioning and well-being." Rationale: Low PCS scores predict higher morbidity and mortality in research among ESRD patients. References: DeOreo, 1997; ?Kalantar-Zadeh, Kopple, Block, Humphreys, 2001; ?Knight et al. 2003; ?Kroenke, Spitzer & Williams, 2003; Lowrie, Curtin, LePain & Schatell, 2003; ?Mapes et al., 2004 Add: (new vi) "Diminished emotional well-being per patient report, staff observation, or reduced mental component summary (MCS) score on a validated measure of functioning and well-being." Rationale: Low MCS scores predict higher morbidity and mortality in research among ESRD patients. Low MCS scores are also linked to depression and skipping dialysis treatments. References: DeOreo, 1997; ?Kalantar-Zadeh, Kopple, Block, Humphreys, 2001; ?Knight et al. 2003; ?Kroenke, Spitzer & Williams, 2003; Lowrie, Curtin, LePain & Schatell, 2003; ?Mapes et al., 2004 Add: (new vii) "Depression per patient report, staff observation or validated depression screening survey" Rationale: Multiple studies report a high prevalence of untreated depression in dialysis patients; depression is an independent predictor of death. References: ?Andreucci et al., 2004.; ?Kimmel, 1993; ?Kimmel, 1998; ?Kutner et al., 2000.; ?Wuerth, Finklestein & Finklestein, 2005

	Add: (new viii) "Loss of or threatened loss of employment per patient report"

Rationale: Poor physical and mental health functioning have been linked to increased hospitalizations and death. Loss of employment is linked to depression, social isolation, financial difficulties, and loss of employer group health plan coverage. Identifying low functioning patients early and targeting interventions to improve their functioning should improve their physical and mental functioning and employment outcomes. References: ?Blake, Codd, Cassidy & O'Meara, 2000; ?Lowrie, Curtin, LePain & Schatell, 2003; ?Mapes et al., 2004; ?Witten, Schatell & Becker, 2004	
494.90 Condition Patient plan of care. (a) Standard: Development of patient plan of care.	Add: (a) the patient to those developing the plan and include: "If the patient or his or her representative does not participate in care planning, the basis for nonparticipation must be noted in the patient's medical record, the patient or his or her representative must initial the reason provided, and sign the care plan." Rationale: The patient must be explicitly listed as part of the care planning process Add: (new 3) "Psychosocial status. The interdisciplinary team must provide the necessary care and services to achieve and sustain an effective psychosocial status." Rationale & References: Eighty-nine percent of ESRD patients report experiencing significant lifestyle changes from the disease (Kaitelidou, et al., 2005). The chronicity of end stage renal disease and the intrusiveness of its required treatment provide renal patients with multiple disease-related and treatment-related psychosocial stressors that affect their everyday lives (Devins et al., 1990). Researchers including Auslander, Dobrof & Epstein (2001), Burrows-Hudson (1995), and Kimmel et al. (1998) have found that psychosocial issues negatively impact health outcomes of patients and diminish patient quality of life. Therefore, "psychosocial status" must be considered as equally important as other aspects of the care plan. Add: (new 6) Home dialysis status. All patients must be informed of all home dialysis options, including CAPD, CCPD, conventional home hemodialysis, daily home hemodialysis, and nocturnal home hemodialysis, and be evaluated as a home dialysis candidate. When the patient is a home dialysis candidate, the interdisciplinary team must develop plans for pursuing home dialysis. The patient's plan of care must include documentation of the (i) Plan for home dialysis, if the patient accepts referral for home dialysis; (ii) Patient's decision, if the patient is a home dialysis candidate but declines home dialysis; or (iii) Reason(s) for the patient's non-referral as a home dialysis

	candidate as documented in accordance with § 494.80(a)(9)(ii) of this part. 7Rationale: Home therapies allow greater flexibility, patient control, fewer dietary and fluid restrictions, need for fewer medications, potential for improved dialysis adequacy, and improved likelihood of employment. CMS has stated encouragement of home dialysis as a goal. Every patient must be informed of home dialysis options, evaluated for candidacy for home dialysis, and, if not a candidate, the reason(s) why not should be reported. This allows quality assessment and improvement activities to be undertaken

in the area of home dialysis. Add: (renumbered 8) "Rehabilitation status. The interdisciplinary team must provide the necessary care and services to: (i) maximize physical and mental functioning as measured minimally by physical component summary (PCS) score and mental component summary (MCS) score on a validated measure of functioning and well-being (or an equally valid indicator of physical and mental functioning), (ii) help patients maintain or improve their vocational status (including paid or volunteer work) as measured by annually tracking the same employment categories on the CMS 2728 form (iii) help pediatric patients (under the age of 18 years) to obtain at least a high school diploma or equivalency as measured by annually tracking student status. (iv) Reasons for decline in rehabilitation status must be documented in the patient's medical record and interventions designed to reverse the decline." Rationale: The goals of the current proposed section are vague, not measurable, and not actionable. To improve rehabilitation outcomes, facilities must meet certain standards. From the perspective of the Medical Education Institute, which administers the Life Options Rehabilitation Program, "rehabilitation" can be measured by a functioning and well-being vocational assessment. Functioning and well-being (measured minimally as PCS and MCS) predict morbidity and mortality. Annually tracking employment status through Networks using the same categories on the CMS 2728 and including this as a QAPI would improve the likelihood that rehabilitation efforts would be successful.	
494.90 Condition Patient plan of care. (b) Standard: Implementation of the patient care plan.	Add to 3b: "If the expected outcome is not achieved, the interdisciplinary team must describe barriers encountered, adjust the patient's plan of care to either achieve the specified goals or establish new goals, and explain why new goals are needed." Rationale: When goals are not met, barriers must be identified and goals re-examined for feasibility of success. Sometimes barriers can be eliminated so original goals can be met; other times, new goals must be set that are more reasonable.
494.90 Condition Patient plan of care. (c) Standard:	Comment: CNSW supports the language of (c) and recommends its inclusion in the final conditions. In addition, we would also like to see language which would outline the responsibilities of

Transplantation referral tracking	transplant centers and their responsibilities for following up and informing dialysis units of the transplant status of patients referred for transplant.
494.90 Condition Patient plan of care. (d) Standard: Patient education and training.	Add to d: "The patient care plan must include, as applicable, education and training for patients and family members or caregivers or both, and must document training the following areas in the patient's medical record: (i) The nature and management of ESRD (ii) The full range of techniques associated with treatment modality selected, including effective use of dialysis supplies and equipment in achieving and delivering the physician's prescription of Kt/V or URR, and effective erythropoietin administration (if prescribed) to achieve and maintain a hemoglobin level of at

least 11 gm/dL (iii) How to follow the renal diet, fluid restrictions, and medication regimen (iv) How to read, understand, and use lab tests to track clinical status (v) How to be an active partner in care (vi) How to achieve and maintain physical, vocational, emotional and social well-being (vii) How to detect, report, and manage symptoms and potential dialysis complications (viii) What resources are available in the facility and community and how to find and use them (ix) How to self-monitor health status and record and report health status information (x) How to handle medical and non-medical emergencies (xi) How to reduce the likelihood of infections (x) How to properly dispose of medical waste in the dialysis facility and at home Rationale: Life Options Research has demonstrated among 372 randomly-selected in-center hemodialysis patients that higher levels of dialysis knowledge are correlated with higher mental component summary (MCS) scores on the SF-12, which are, in turn, predictive of longer survival and lower hospitalization. The specific aspects of education delineated above are what Life Options believes to be core skills that ESRD patients must gain in order to become active partners in care, producing their own best health outcomes and monitoring the safety and quality of the care that is delivered to them. References: ?Curtin, et al. 2002; Curtin, Klag, Bultman & Schatell, 2002; ?Curtin, Sitter, Schatell & Chewning, 2004; ?Johnstone, et al., 2004	
494.100 Condition Care at home.	Comment: CNSW agrees that services to home patients should be at least equivalent to those provided to in-center patients. Rationale: Home dialysis patients are patients of the ESRD facility and are entitled to the same rights, services, and efforts to achieve expected outcomes as any other patient of the facility. Add: (new 3iv) "Implementation of a social work care plan" Rationale & References: Eighty-nine percent of ESRD patients report experiencing significant lifestyle changes from the disease (Kaitelidou, et al., 2005). The chronicity of end stage renal disease and the intrusiveness

	of treatment provide renal patients with multiple disease-related and treatment-related psychosocial stressors that affect their everyday lives (Devins et al., 1990). Researchers including Auslander, Dobrof & Epstein (2001), Burrows-Hudson (1995), and Kimmel et al. (1998) have found that psychosocial issues negatively impact health outcomes of patients and diminish patient quality of life. Therefore, a social work care plan is as equally important as other aspects of training for home patients. It is important to specify a "social work care plan" to ensure that it is conducted by a qualified social worker as identified below.
494.100 Condition Care at home. (c) Standard: Support services.	Add to 1i: "Periodic monitoring of the patient's home adaptation, including at minimum an annual visit to the patient's home by all facility personnel if geographically feasible (RN, social worker, dietitian, and machine technician) in accordance with the patient's plan of care." 9Rationale: Members of the interdisciplinary team can offer better care to patients after seeing the patient

10

in his/her home environment where they can observe barriers and supports first-hand. The members should be specified to ensure equal visitation of the team members across all dialysis units. The language of this part of the proposed conditions is vague and subject to varying interpretation (i.e. exactly who are the "facility personnel" who will visit the patient's home?) Add to 1iv: "Patient consultation with all members of the interdisciplinary team, as needed." Rationale: The language of this part of the proposed conditions is vague and subject to varying interpretation	
NEWCONDITION Staff assisted skilled nursing home dialysis	Add: A new condition for dialysis provided in a nursing home setting (that is not incorporated into the "home" condition 494.100) Rationale: Nursing home dialysis is typically provided by staff. Home dialysis (PD or home hemodialysis) is typically performed by a trained patient and/or a helper. Making these treatments equivalent obscures important differences between them, including the staff training/supervisory needs of nursing home dialysis patients. To include care in a nursing facility/skilled nursing facility (NF/SNF) under "care at home" is inappropriate. There is a tremendous difference in what CMS must do to protect the health and safety of highly functioning, trained patients who do self-care at home (or have assistance from a trained helper at home) and patients who require personnel in an NF/SNF to perform dialysis because they are too debilitated to travel to a dialysis facility. Reference:?Tong & Nissenson, 2002 Add: Language to this proposed condition that would mandate " A Nursing facility/Skilled Nursing Facility

	providing full-care dialysis to residents with ESRD, must be certified as a dialysis facility and comply with all sections of this rule, including personnel qualifications." Rationale: Patients receiving dialysis in NF or SNF should not be deprived of essential services that they would normally receive in an outpatient dialysis facility, including consultation with a qualified nephrology social worker. While NFs and SNFs may employ social workers, these social workers may not hold a master's degree and will not have the specialized knowledge of the complex social and emotional factors affecting the dialysis patient. To ensure that the health and safety of NF or SNF hemodialysis patients is protected, any proposed requirements should specifically incorporate Secs 494.70, 494.80 and 494.90 of the proposed conditions of coverage.
§494.110 Condition Quality assessment and performance improvement. (a) Standard: Program scope.	Add: (1) "The program must include, but not be limited to, an ongoing program that achieves measurable improvement in physical, mental, and clinical health outcomes and reduction of medical errors by using indicators or performance measures associated with improved physical and mental health outcomes and with the identification and reduction of medical errors." Rationale: To ensure patient-centered care, patient functioning and well-being must be one of the quality indicators that is monitored and improved. Add: (2)(new iii) "Psychosocial status." Rationale & References: Eighty-nine percent of ESRD patients report experiencing significant lifestyle

changes from the disease (Kaitelidou, et al., 2005). The chronicity of end stage renal disease and the intrusiveness of its required treatment provide renal patients with multiple disease-related and treatment-related psychosocial stressors that affect their everyday lives (Devins et al., 1990). Researchers including Auslander, Dobrof & Epstein (2001), Burrows-Hudson (1995), and Kimmel et al. (1998) have found that psychosocial issues negatively impact health outcomes of patients and diminish patient quality of life. Therefore, "psychosocial status" must be considered as equally important as other aspects of quality improvement. CNSW has many resources and tools, available through the National Kidney Foundation, that can be used to track social work quality.
Add: (2)(new ix) "Functioning and well-being as measured by physical component summary (PCS) and mental component summary (MCS) scores (or other equally valid measure of mental and physical functioning) and vocational status using the same categories as reported on the CMS 2728 form"
Rationale: These scores provide a baseline and ongoing basis for QAPI activities to improve patient rehabilitation outcomes.
Comment: CNSW agrees that dialysis providers must measure patient

satisfaction and grievances. CNSW supports the use of a standardized survey (such as the one being currently developed by CMS) for measuring patients' experience and ratings of their care. Such a survey would provide information for consumer choice, reports that facilities can use for internal quality improvement and external benchmarking against other facilities, and finally, information that can be used for public reporting and monitoring purposes. The survey should be in the public domain and consist of a core set of questions that could be used in conjunction with existing surveys.	
494.140 Condition Personnel qualifications	Comment: CNSW recommends that this section be renamed "Personnel qualifications and responsibilities", with the addition of specified personnel responsibilities to each team member's qualifications. If it is decided that adding "personnel responsibilities" to this section is inappropriate, we would suggest the alteration of 494.150 to be renamed "Condition: Personnel Responsibilities" and include a discussion of the responsibilities of each team member (instead of just the medical director as is currently proposed). CNSW suggests possible responsibilities for social workers in the next section, where we comment on "494.140 Condition Personnel qualifications (d) Standard: Social worker." These suggestions can be used in a new "responsibilities" section. Rationale & References: It is critically important to clearly delineate personnel responsibilities in some fashion in these new conditions of coverage to ensure that there is parity in the provision of services to beneficiaries in every dialysis unit in the country. It is just as important to outline each team member's responsibilities as it is the medical director's, as is currently proposed. This is especially important regarding qualified social work responsibilities. Currently, many master's level social workers are given responsibilities and tasks that are clerical in nature and which prevent the MSW from participating fully

with the patient's interdisciplinary team so that optimal outcomes of care may be achieved. It is imperative that the conditions of coverage specify the responsibilities of a qualified social worker so that dialysis clinics do not assign social workers inappropriate tasks and responsibilities. Tasks that are clerical in nature or involve admissions, transportation, travel, billing, and determining insurance coverage prohibit nephrology social workers from performing the clinical tasks central to their mission (Callahan, Witten & Johnstone, 1997). Russo (2002) found among the nephrology social workers that he surveyed 53% were responsible for making transportation arrangements for patients, and 46% of the nephrology social workers in his survey were responsible for making dialysis transient arrangements (which involved copying and sending patient records to out-of-town units). Only 20% of his respondents were able to do patient education. In the Promoting Excellence in End-of-Life Care 2002 report, End-Stage Renal Disease Workgroup Recommendations to the Field, it was recommend that dialysis units discontinue using master's level social workers for clerical tasks to ensure that they

will have sufficient time to provide clinical services to their patients and their families. Merighi and Ehlebracht (2004b; 2004c; 2005), in a survey of 809 randomly sampled dialysis social workers in the United States, found that: 1 • 94% of social workers did clerical tasks, and that 87% of those respondents considered these tasks to be outside the scope of their social work training. 2 • 61% of social workers were solely responsible for arranging patient transportation. 3 • 57% of social workers were responsible for making travel arrangements for patients who were transient, which required 9% of their work time. 4 • 26% of social workers were responsible for initial insurance verification. 5 • 43% of social workers tracked Medicare coordination of benefit periods. 6 • 44% of social workers were primarily responsible for completing patient admission paperwork. 7 • 18% of social workers were involved in collecting fees from patients. (Respondents noted that this could significantly diminish trust and cause damage to the therapeutic relationship). 8 • Respondents spent 38% of their time on insurance, billing and clerical tasks vs. 25% of their time spent assessing and counseling patients. 9 • Only 34% of the social workers thought that they had enough time to sufficiently address patients' psychosocial needs. This evidence clearly demonstrates that without clear definition and monitoring of responsibilities assigned to the qualified social work (as is the current case), social workers are routinely assigned tasks that are inappropriate, preventing them from doing appropriate tasks. For all of these reasons, CNSW is strongly urging the addition of "personnel responsibilities" to the new conditions of coverage (either in this section, or the next section).	
494.140 Condition Personnel qualifications (d) Standard: Social worker.	Change the language of d to: Social worker. The facility must have a qualified social worker who—(1) Has completed a course of study with specialization in clinical practice, and holds a masters degree from a graduate school of social work accredited by the Council on Social Work Education; (2) Meets the licensing requirements for social work practice in the State in which he or she is practicing; and (3) Is responsible for the following tasks: initial and continuous patient assessment and care planning including the social, psychological, cultural and environmental barriers to coping to ESRD and prescribed treatment; provide emotional support, encouragement and supportive counseling to patients and their families or support system; provide individual and group counseling to facilitate adjustment to and coping with ESRD, comorbidities and treatment regimes, including diagnosing and treating mood disorders such as anxiety, depression, and hostility; providing patient and family education; helping to overcome psychosocial barriers to transplantation and home dialysis; crisis intervention; providing education and help completing advance directives; promoting self-determination; assisting

patients with achieving their rehabilitation goals (including: overcoming barriers ; providing patients with education and encouragement regarding rehabilitation; providing case management with local or state vocational rehabilitation agencies); providing staff in-service education regarding ESRD psychosocial issues; recommending topics and otherwise participating in the facility's quality assurance program; mediating conflicts between patients, families and staff; participating in interdisciplinary care planning and collaboration, and advocating on behalf of patients in the clinic and community-at-large. The qualified social worker will not be responsible for clerical tasks related to transportation, transient arrangements, insurance or billing, but will supervise the case aide who is responsible for these tasks.
Rationale & References: Clinical social work training is essential to offer counseling to patients for complex psychosocial issues related to ESRD and its treatment regimes. Changing the language of this definition will make the definition congruent to that of a qualified social worker that is recommended by CNSW for the transplant conditions of coverage. CNSW supports the elimination of the "grandfather" clause of the previous conditions of coverage, which exempted individuals hired prior to the effective date of the existing regulations (September 1, 1976) from the social work master's degree requirement. As discussed in the preamble for these conditions, we recognize the importance of the professional social worker, and we believe there is a need for the requirement that the social worker have a master's degree. We agree that since the extension of Medicare coverage to individuals with ESRD, the ESRD patient population has become increasingly more complex from both medical and psychosocial perspectives. In order to meet the many and varied psychosocial needs of this patient population, we agree that qualified master's degree social workers (MSW) trained to function autonomously are essential. We agree that these social workers must have knowledge of individual behavior, family dynamics, and the psychosocial impact of chronic illness and treatment on the patient and family. This is why we argue that a specialization in clinical practice must be maintained in the definition.

13Master's level social workers are trained to think critically, analyze problems, and intervene within areas of need that are essential for optimal patient functioning, and to help facilitate congruity between individuals and resources in the environment, demands and opportunities (Coulton, 1979; McKinley & Callahan, 1998; Morrow-Howell, 1992; Wallace, Goldberg, & Slaby, 1984). Social workers have an expertise of combining social context and utilizing community resource information along with knowledge

of personality dynamics. The master of social work degree (MSW) requires two years of coursework and an additional 900 hours of supervised agency experience beyond what a baccalaureate of social work degree requires. An MSW curriculum is the only curriculum, which offers additional specialization in the biopsychosocialcultural, person-

in-environment model of understanding human behavior. An undergraduate degree in social work or other mental health credentials (masters in counseling, sociology, psychology or doctorate in psychology, etc.) do not offer this specialized and comprehensive training in bio-psycho-social assessment and interaction between individual and the social system that is essential in dialysis programs. The National Association of Social Workers Standards of Classification considers the baccalaureate degree as a basic level of practice (Bonner & Greenspan, 1989; National Association of Social Workers, 1981). Under these same standards, the Masters of Social Work degree is considered a specialized level of professional practice and requires a demonstration of skill or competency in performance (Anderson, 1986). masters-prepared social workers are trained in conducting empirical evaluations of their own practice interventions (Council on Social Work Education). Empirically, the training of a masters-prepared social worker appears to be the best predictor of overall performance, particularly in the areas of psychological counseling, casework and case management (Booz & Hamilton, Inc., 1987; Dhooper, Royse & Wolfe, 1990). The additional 900 hours of supervised and specialized clinical training in an agency prepares the MSW to work autonomously in the dialysis setting, where supervision and peer support is not readily available. This additional training in the biopsychosocial model of understanding human behavior also enables the masters-prepared social worker to provide cost-effective interventions such as assessment, education, individual, family and group therapy and to independently monitor the outcomes of these interventions to ensure their effectiveness.

The chronicity of end stage renal disease and the intrusiveness of required treatment provide renal patients with multiple psychosocial stressors including: cognitive losses, social isolation, bereavement, coping with chronic illness, concern about worsening health and death, depression, anxiety, hostility, psycho-organic disorders, somatic symptoms, lifestyle, economic pressures, insurance and prescription issues, employment and rehabilitation barriers, mood changes, body image issues, concerns about pain, numerous losses (income, financial security, health, libido, strength, independence, mobility, schedule flexibility, sleep, appetite, freedom with diet and fluid), social role disturbance (familial, social, vocational), dependency issues, and diminished quality of life (DeOreo, 1997; Gudes, 1995; Katon & Schulberg, 1997; Kimmel et al., 2000; Levenson, 1991; Rabin, 1983; Rosen, 1999; Vourlekis & Rivera-Mizzoni, 1997). The gravity of these psychosocial factors necessitates an assessment and interventions conducted by a qualified social worker as outlined above.

It is clear that social work intervention can maximize patient outcomes:

1 • Through patient education and other interventions, nephrology social workers are successful in improving patient's adherence to the ESRD treatment regime. Auslander and Buchs (2002), and Root (2005) have shown that social work counseling and education led to reduced fluid weight gains in patients. Johnstone and Halshaw (2003) found in their experimental study that social work education and encouragement were associated with a 47% improvement in fluid restriction

1 adherence.

2 • Beder and colleagues (2003) conducted an experimental research study to determine the effect of cognitive behavioral social work services. They found that patient education and counseling by nephrology social workers was significantly associated with increased medication compliance. This study also determined that such interventions improved patients' blood pressure. Sikon (2000) discovered that social work counseling can reduce patients' anxiety level. Several researchers have determined that nephrology social work counseling significantly improves ESRD patient quality of life (Chang, Winsett, Gaber & Hathaway, 2004; Frank, Auslander & Weissgarten, 2003; Johnstone, 2003). Nephrology social work interventions also tend to be valued by patients. Siegal, Witten, and Lundin's 1994 survey of ESRD patients found that 90% of respondents "believed that access to a nephrology social worker was important" (p.33) and that patients relied on nephrology social workers to assist them with coping, adjustment, and rehabilitation. Dialysis patients have ranked a "helpful social worker" as being more important to them than nephrologists or nurses (Rubin, et al., 1997). In a study by Holley, Barrington, Kohn and Hayes (1991), 70% of patients said that social workers gave the most useful information about treatment modalities compared to nurses and physicians. These researchers also found that patients thought that social workers were twice as helpful as nephrologists in helping them to choose between hemodialysis and peritoneal dialysis for treatment.	
494.140 Condition Personnel qualifications	Add: (e) Standard: Case aide. Dialysis units that have more than 75 patients per full time social worker must employ a case aide who- As supervised by the unit social worker, performs clerical tasks involving admissions, transfers, billing, transportation arrangements, transient treatment paperwork and verifies insurance coverage. Rationale & References: We agree with the preamble that dialysis patients need essential social services including transportation, transient arrangements and billing/insurance issues. We also firmly agree with the preamble that these tasks should not be handled by the qualified social worker (unless the social worker has fewer than 75 patients per full time equivalent social worker), as caseloads higher than this prevent the MSW from participating fully with the interdisciplinary team so that optimal outcomes of care may be achieved. It is imperative that the conditions of coverage identify a new team member who can provide social service assistance-the preamble recommends that these clerical tasks should be done by someone other than the MSW, but does not specify who that person is-adding this section (e) will eliminate any ambiguity surrounding this issue, and ensure adherence to this recommendation across all settings. Tasks that are clerical in nature or involve admissions, billing, and determining insurance coverage prevent nephrology social workers from performing the clinical tasks central to their mission (Callahan, Witten & Johnstone, 1997). Russo (2002) found that all of the nephrology social workers that he surveyed felt that transportation was not an appropriate task for them, yet 53% of

	respondents were responsible for making transportation arrangements for patients. Russo found that 46% of the nephrology social workers in his

15

survey were responsible for making dialysis transient arrangements (which involved copying and sending patient records to out-of-town units), yet only 20% were able to do patient education. In the Promoting Excellence in End-of-Life Care's 2002 report, End-Stage Renal Disease Workgroup Recommendations to the Field, workgroup members recommended that dialysis units discontinue using master's level social workers for clerical tasks to ensure that they will have sufficient time to provide clinical services to their patients and their families. Merighi and Ehlebracht (2004b; 2004c; 2005), in a survey of 809 randomly sampled dialysis social workers in the United States, found that:

1 • 94% of social workers did clerical tasks, and that 87% of those respondents considered these tasks to be outside the scope of their social work training.

2 • 61% of social workers were solely responsible for arranging patient transportation.

3 • 57% of social workers were responsible for making travel arrangements for patients who were transient, taking 9% of their time.

4 • 26% of social workers were responsible for initial insurance verification.

5 • 43% of social workers tracked Medicare coordination periods.

6 • 44% of social workers were primarily responsible for completing admission packets.

7 • 18% of social workers were involved in collecting fees from patients. Respondents noted that this could significantly diminish therapeutic relationships and decrease trust.

8 • Respondents spent 38% of their time on insurance, billing and clerical tasks vs. 25% of their time spent counseling and assessing patients.

9 • Only 34% of the social workers thought that they had enough time to sufficiently address patient psychosocial needs.

This evidence clearly demonstrates that there needs to be another team member who can handle these clerical social service needs. This position would be cost-effective, as the person in this role can help patients obtain insurance coverage for dialysis that they normally would not have and increase facility's reimbursement. As discussed and referenced below in detail, CNSW recommends a ratio of 75 patients per full-time equivalent social worker. If a dialysis clinic has fewer patients per full-time equivalent social worker than less than 75:1, the social worker can address concrete social service needs of patients. However, patient ratios over 75 patients per full-time equivalent social worker require a case aide.

§494.180 Condition Governance. (b1) Standard. Adequate number of qualified and trained staff.	Add: (1i) No dialysis clinic should have more than 75 patients per one full time social worker. Rationale & References: A specific social worker-patient ratio must be included in the conditions of coverage. Currently, there are no such national ratios and as a result social workers have caseloads as high as more than 300 patients per social worker in multiple, geographically separated, clinics. This is highly variable among different dialysis units-letting dialysis clinics establish their own ratios will leave ESRD care in the same situation as we

	have now with very high social work caseloads. For many years, CNSW has had an acuity-based social work-patient ratio (contact the National Kidney Foundation for the formula) which has been widely distributed to all dialysis units. This has largely been ignored by dialysis

16

providers, who routinely have patient-to-social work ratios of 125-300. The new conditions of coverage must either identify an acuity-based social work staffing ratio model to be used in all units (we would recommend CNSW's staffing ratio), or set a national patient-social worker ratio. Leaving units to their own devices regarding ratios will not affect any change, as is evidenced by today's large caseloads and variability in such. CNSW has determined that 75:1 is the ideal ratio. If CMS refuses to include language about social work ratios, we strongly urge that the final conditions include language for "an acuity-based social work staffing plan developed by the dialysis clinic social worker" (rather than having nursing personnel who have limited understanding of social work training or role to determine social work staffing).

Large nephrology social work caseloads have been linked to decreased patient satisfaction and poor patient rehabilitation outcomes (Callahan, Moncrief, Wittman & Maceda, 1998). It is also the case that social workers report that high caseloads prevent them from providing adequate clinical services in dialysis, most notably counseling (Merighi, & Ehlebracht, 2002, 2005). In Merighi and Ehlebracht's (2004a) survey of 809 randomly sampled dialysis social workers in the United States, they found that only 13% of full time dialysis social workers had caseloads of 75 or fewer, 40% had caseloads of 76-100 patients, and 47% had caseloads of more than 100 patients.

In a recent study by Bogatz, Colasanto, and Sweeney (2005), nephrology social workers reported that large caseloads hindered their ability to provide clinical interventions. Social work respondents in this study reported caseloads as high as 170 patients and 72% of had a median caseload of 125 patients. The researchers found that 68% of social workers did not have enough time to do casework or counseling, tasks mandated by the current conditions of coverage, 62% did not have enough time to do patient education, and 36% said that they spent excessive time doing clerical, insurance, and billing tasks. One participant in their study stated: 'the combination of a more complex caseload and greater number of patients to cover make it impossible to adhere to the federal guidelines as written. I believe our patients are being denied access to quality social work services' (p.59).

Patient-social work ratios are critical so that social workers can effectively intervene with patients and enhance their outcomes. It is clear that social work intervention can maximize patient outcomes (doing these requires reasonable ratios):

1 • Through patient education and other interventions, nephrology social workers are successful in improving patient's adherence to the ESRD treatment regime. Auslander and Buchs (2002), and Root (2005) have shown that social work counseling and education led to reduced fluid weight gains in patients. Johnstone and Halshaw (2003) found in their experimental study that social work education and encouragement were associated with a 47% improvement in fluid restriction adherence.

2 • Beder and colleagues (2003) conducted an experimental research study to determine

the effect of cognitive behavioral social work services. They found that patient education and counseling by nephrology social workers was significantly associated with increased medication compliance. This study also determined that such interventions improved patients' blood pressure. Sikon (2000)

17

1 discovered that social work counseling can reduce patients' anxiety level. Several researchers have determined that nephrology social work counseling significantly improves ESRD patient quality of life (Chang, Winsett, Gaber & Hathaway, 2004; Frank, Auslander & Weissgarten, 2003; Johnstone, 2003). A study currently being conducted by Cabness shows that social work intervention is related to lower depression. Nephrology social work interventions also tend to be valued by patients. Siegal, Witten, and Lundin's 1994 survey of ESRD patients found that 90% of respondents "believed that access to a nephrology social worker was important" (p.33) and that patients relied on nephrology social workers to assist them with coping, adjustment, and rehabilitation. Dialysis patients have ranked a "helpful social worker" as being more important to them than nephrologists or nurses by Rubin, et al. (1997). In a study by Holley, Barrington, Kohn and Hayes (1991), 70% of patients said that social workers gave the most useful information about treatment modalities compared to nurses and physicians. These researchers also found that patients thought that social workers were twice as helpful as nephrologists in helping them to choose between hemodialysis and peritoneal dialysis for treatment.	
§494.180 Condition Governance. (b4) Standard. Adequate number of qualified and trained staff.	Comment: CNSW agrees that all employees must have an opportunity for continuing education and related development activities.
§494.180 Condition Governance. (b5) Standard. Adequate number of qualified and trained staff.	Add (5ix): Add "Psychosocial issues related to ESRD and its treatment regimes, as provided by the facility social worker." Comment: Technicians have the most contact with patients and need to be attuned to patients' psychosocial issues so as to most effectively collaborate with the social worker and achieve patient outcomes.
§494.180 Condition Governance. (h) Standard: Furnishing data and information for ESRD program administration.	(h) Standard: Furnishing data and information for ESRD program administration. Add: (3)(new iv) "Annual reporting of facility aggregate functioning and well-being (physical component summary scores and mental component summary scores) and vocational rehabilitation status according to categories on the CMS 2728 form." Rationale: These data would be easy to collect, would permit comparisons between clinics, and would serve as a

	basis for QAPI.

REFERENCES

ADA, Title III, Part 36, Subpart A, Section 36.303, auxiliary aids (http://www.usdoj.gov/crt/ada/reg3a.html#Anchor-97857)

?ADA Title III, Part 36, Subpart A, Section 36.304, removal of barriers (http://www.usdoj.gov/crt/ada/reg3a.html#Anchor-91481)

Anderson, R. (1986). The CSWE Accrediting Standards for Social Work Education. Social Work in Education. CCC Code: 0162-7961/86.

Andreucci, V. E., et al. Dialysis Outcomes and Practice Patterns Study (DOPPS) data on medications in hemodialysis patients. Am J Kidney Dis. 44(5 Suppl 3):61-7, 2004.

Auslander, G. K., Buchs, A. (2002). Evaluating an activity intervention with hemodialysis patients in Israel. Social Work Health Care. 35(1-2):407-23.

Auslander, G., Dobrof, J., & Epstein, I. (2001). Comparing social work's role in renal dialysis in Israel and the United States: the practice-based research potential of available clinical information. Social Work in Health Care, 33(3/4), 129-151.

Beder, J. (1999). Evaluation research on the effectiveness of social work intervention on dialysis patients: the first three months. Social Work in Health Care, 30(1), 15-30.

Beder, J., Mason, S., Johnstone, S., Callahan, M. B., & LeSage, L. (2003). Effectiveness of a social work psychoeductional program in improving adherence behavior associated with risk of CVD in ESRD patients. Journal of Nephrology Social Work, 22, 12-22.

Blake C, Codd MB, Cassidy A, O'Meara YM. Physical function, employment and quality of life in end-stage renal disease. J Nephrol. 13(2):142-9, 2000.

Bogatz, S., Colasanto, R., & Sweeney, L. (2005). Defining the impact of high patient/staff ratios on dialysis social workers. Nephrology News & Issues, Jan, 55-60.

Bonner, C., Dean, R., & Greenspan, R. (1989) Standards for Practice: The Development of the Clinical Social Worker in the First Two Years. The Clinical Supervisor 1989. 7(4), 31-45.

Booz, A., & Hamilton, Inc. (1987) The Maryland Social Work Services Job Analysis and Personnel Qualifications Study. Prepared for the Department of Human Resources State of Maryland

Burrows-Hudson, S. (1995). Mortality, morbidity, adequacy of treatment, and quality of life. ANNA Journal, 22(2), 113-121.

Callahan, M. B., Moncrief, M., Wittman, J., & Maceda, M. (1998). Nephrology social work interventions and the effect of caseload size on patient satisfaction and rehabilitation interventions. Journal of Nephrology Social Work, 18, 66-79.

Callahan, M. B., Witten, B., & Johnstone, S. (1997). Improving quality of care and social work outcomes in dialysis. Nephrology News & Issues, 2(4), 42-43.

Chang, C. F., Winsett, R. P., Gaber, A. O., & Hathaway, D. K. (2004) Cost-effectiveness of post-transplantation quality of life intervention among kidney recipients, Clinical Transplantation, 18(4), 407-415.

Coulton, C. (1979). A study of the person-environment fit among the chronically ill. Social Work in Health Care, 5(1), 5-17.

Council on Social Work Education: Commission on Accreditation, Handbook of Accreditation Standards and Procedures (Fourth Edition). Subsection B5.7.9 and M5.7.11 and Subsection B5.7.7 and M5.7.8, pp. 99, 137. 19

Curtin RB, Oberley ET, Sacksteder P, Friedman A. (1996). Differences between employed and nonemployed dialysis patients. Am J Kidney Dis. 27(4):533-40.

Curtin RB, Mapes DL. (2001) Health care management strategies of long-term dialysis survivors.Neph Nurs J. 28(4):385-394.

?Curtin RB, Bultman DC, Schatell D, Chewning BA. (2004) Self-management, knowledge, andfunctioning and well-being of patients on hemodialysis. Neph Nurs J 31(4):378-387.

Curtin RB, Bultman DC, Thomas-Hawkins C, Walters BA, Schatell D. Hemodialysis patients' symptom experiences: effects on physical and mental functioning. Nephrol Nurs J.;29(6):562, 567-74; discussion 575, 598, 2002.

Curtin RB, Klag MJ, Bultman DC, Schatell D. Renal rehabilitation and improved patient outcomes in Texas dialysis facilities. Am J Kidney Dis.;40(2):331-8, 2002.

?Curtin RB, Sitter DC, Schatell D, Chewning BA. Self-management, knowledge, and functioning and well-being of patients on hemodialysis. Nephrol Nurs J 31(4):378-86, 396; quiz 387, 2004.

DeOreo, P. B. (1997). Hemodialysis patient-assessed functional health status predicts continued survival, hospitalization, and dialysis-attendance compliance. American Journal of Kidney Diseases. 30(2), 204-212.

Devins, G. M., Mandin, H., Hons, R. B., Burgess, E. D., Klassen, J., Taub, K., Schorr, S., Letourneau, P. K., & Buckle, S. (1990), Illness intrusiveness and quality of life in end-stage renal disease: comparison and stability across treatment modalities. Health Psychology, 9(2), 117-142.

Dhooper, S., Royse, D., & Wolfe, L. (1990) Does social work education make a difference? Social Work Education, 1990, 35 (1), 57-61.

Dobrof, J., Dolinko, A., Lichtiger, E., Uribarri, J., & Epstein, I. (2001) Dialysis patient characteristics and outcomes: the complexity of social work practice with end-stage renal; disease population. Social Work in Health Care, 33, 105-128.

Forum of ESRD Networks. Designing a Collaborative Action Plan with ESRD Stakeholders, 2003. (http://www.esrdnetworks.org/DPPCFinalReport.pdf)

Frank, A., Auslander, G. K., & Weissgarten, J. (2003). Quality of life of patients with end-stage renal disease at various stages of the illness. Social Work in Health Care, 38(2), 1-27.

Gudes, C. M. (1995). Health-related quality of life in end-stage renal failure. Quality of Life ESRD Network of Texas (2002). Social Services Practice Recommendations. http://www.esrdnetwork.org/professional_standards.htm

Holley, J. L., Barrington, K., Kohn, J., & Hayes, I. (1991). Patient factors and the influence of nephrologists, social workers, and nurses on patient decisions to choose continuous peritoneal dialysis. Advances in Peritoneal Dialysis, 7, 108-110.

Johnstone, S. (2003). Evaluating the impact of a physical rehabilitation program for dialysis patients. Journal of Nephrology Social Work, 22, 28-30.

Johnstone, S. & Halshaw, D. (2003) Making peace with fluid social workers lead cognitive-behavioral intervention to reduce health-risk behavior. Nephrology News & Issues (12), 20-31.

Johnstone, S., Seamon, V. J., Halshaw, D., Molinair, J., & Longknife, K. (1997). The use of medication to manage patient-staff conflict in the dialysis clinic. Advances in Renal Replacement Therapy, 4(4), 359-371.

Johnstone, S., Walrath, L., Wohlwend, V., & Thompson, C. (2004). Overcoming early learning barriers in hemodialysis patients: the use of screening and educational reinforcement to improve treatment outcomes. Advances in Chronic Kidney Disease, 11(2), 210-216. 20

Juhnke, J & Curtin, R.B. (2000) New study identifies ESRD patient education needs. Nephrology News & Issues14(6):38-9.

Kalantar-Zadeh, K., Kopple, J. D., Block, G., & Humphreys, M. H. (2001). Association among SF36 quality-of-life measures and nutrition, hospitalization, and mortality in hemodialysis. Journal of the American Society of Nephrology, 12, 2797-2806.

Kaitelidou, D., Maniadakis, N., Liaropouls, L., Ziroyanis, P., Theodorou, M., & Siskou, O. (2005). Implications of hemodialysis treatment on employment patterns and everyday life of patients. Dialysis & Transplantation, 34(3), 138-147, 185.

Katon, W., & Schulberg, H. (1997). Epidemiology of depression in primary care. General Hospital Psychiatry,14, 237-247.

Kaveh K & Kimmel PL. (2001). Compliance in hemodialysis patients: multidimensional measures in search of a gold standard. American Journal of Kidney Diseases 37(2):244-66.

Kimmel, P., Peterson, R., Weihs, K., Simmens, S., Boyle, D., Verne, D., Alleyne, S., & Cruz, I. Veis, J (2000). Multiple measurements of depression predict mortality in a longitudinal study of chronic hemodialysis outpatients. Kidney International, 5(10), 2093-2098.

Kimmel, P., Peterson, R., Weihs, K., Simmens, Alleyne, S., Cruz, I., & Veis, J (1998). Psychosocial factors, behavioral compliance and survival in urban hemodialysis patients. Kidney International, 54, 245-254.

?Kimmel PL et al Survival in hemodialysis patients: the role of depression. J Am Soc Nephrol. 4(1):12-27, 1993.

King K, Moss AH. The frequency and significance of the "difficult" patient: The nephrology community's perceptions. Adv Chronic Kidney Dis. 2004 Apr;11(2):234-9.

Knight EL et al. The association between mental health, physical function, and hemodialysis mortality. Kidney Int. 63(5):1843-51 2003.

Kroenke K, Spitzer RL, Williams JB. The Patient Health Questionnaire-2: validity of a two-item depression screener. Med Care. 41(11):1284-92, 2003.

Kutner NL et al. Functional impairment, depression, and life satisfaction among older hemodialysis patients and age-matched controls: a prospective study. Arch Phys Med Rehabil. 81(4):453-9, 2000.

Levenson, J., & Olbrisch, M. (2000). Psychosocial screening and candidate selection. In P. Trzepacz & A. DiMartini (Eds.), The transplant patient: biological, psychiatric, and ethical issues in organ transplantation (pp. 21-41). Cambridge: Cambridge University Press.

Lowrie EG, Curtin RB, LePain N, Schatell D. Medical outcomes study short form-36: a consistent and powerful predictor of morbidity and mortality in dialysis patients. Am J Kidney Dis. 41(6):1286-92, 2003.

Mapes, D., Bragg-Gresham, J. L. Bommer, J. Fukuhara, S., McKevitt, P., & Wikstrom, B (2004). Health-related quality of life in the dialysis outcomes and practice patterns Study (DOPPS) American Journal of Kidney Diseases, 44 suppl(5), 54-60.

Mayo K. (1999)Can evening dialysis services improve the chances of rehabilitation? A Network #7 study. Nephrol News Issues. 13(6):37-8.

McKinley, M., & Callahan, M.B. (1998). Utilizing the case management skills of the nephrology social worker in a managed care environment. In National Kidney

Foundation (Ed.), Standards of practice for nephrology social work, 4th ed, (pp. 120-128). NY: National Kidney Foundation. 21

McLaughlin K, Manns B, Mortis G, Hons R, Taub K. (2003). Why patients with ESRD do not select self-care dialysis as a treatment option. Am J Kidney Dis. 41(2):380-5.

Merighi, J. R., & Ehlebracht, K. (2005). Emotional Exhaustion and Workload Demands in Renal Social Work Practice, Journal of Nephrology Social Work, 24, 14-20, Journal of Nephrology Social Work, in press

Merighi, J. R., & Ehlebracht, K. (2004a). Workplace resources, patient caseloads, and job satisfaction of renal social workers in the United States. Nephrology News & Issues, 18(4), 58-63.

Merighi, J. R., & Ehlebracht, K. (2004b). Issues for renal social workers in dialysis clinics in the United States. Nephrology News & Issues, 18(5), 67-73.

Merighi, J. R., & Ehlebracht, K. (2004c). Unit-based patient services and supportive counseling. Nephrology News & Issues, 18(6), 55-60.

Morrow-Howell, N. (1992). Clinical case management: the hallmark of gerontological social work. Geriatric Social Work Education, 18, 119-131.

National Association of Social Workers (1981) Standards for the classification of social work practice. Maryland: National Association of Social Workers.

Promoting Excellence in End-of-Life Care (2002), End-Stage Renal Disease Workgroup Recommendations to the Field, Missoula, MT: The Robert Wood Johnson Protecting the Privacy of Patients' Health Information (http://www.hhs.gov/news/facts/privacy.html)

Rasgon SA, Chemleski BL, Ho S, Widrow L, Yeoh HH, Schwankovsky L, Idroos M, Reddy CR, Agudelo-Dee L, James-Rogers A, Butts E. (1996). Benefits of a multidisciplinary predialysis program in maintaining employment among patients on home dialysis. Adv Perit Dial. 12:132-5.

Rabin, P. L. (1983). Psychiatric aspects of end-stage renal disease: diagnosis and management. In W. J. Stone & P. L. Rabin (Eds.) End-Stage renal disease: an integrated approach, (pp. 111-147). NY: Academic Press.

Rasgon, S., Schwankovsky, L., James-Rogers, A., Widrow, L., Glick, J., & Butts, E. (1993). An intervention for employment maintainence among blue-collar workers with end-stage renal disease. American Journal of Kidney Diseases, 22(3), 403-412.

Rau-Foster M. The dialysis facility's rights, responsibilities, and duties when there is conflict with family members. Nephrol News Issues. 15(5):12-4, 2001.

Renal Physicians Association and American Society of Nephrology. Clinical Practice Guideline on Shared Decision Making in the Appropriate Initiation of and Withdrawal from Dialysis

Rosen, L. S. (1999). Common psychosocial factors in the treatment of end stage renal disease. Journal of Nephrology Social Work, 19, 69-72.

Russo, R. (2002). The role of the renal social worker in the 21st century. Nephrology News & Issues, 16(3), 38,40.

Rubin, H., Jenckes, M., Fink, N., Meyer, K., Wu, A., Bass, E., Levin, N., & Powe, N. (1997). Patient's view of dialysis care: development of a taxonomy and rating of importance of different aspects of care. American Journal of Kidney Disease, 30(6), 793-801.

Siegal, B., Witten, B., Lundin, A.P (1994). Patient access and expectations of nephrology social workers. Nephrology News and Issues, April, 32-33,40.

Sikon, G. M. (2000). Pre-dialysis education reduces anxiety in the newly diagnosed chronic renal failure patient. Dialysis & Transplantation, 6, 346, 344-345.

Tong E. M. & Nissenson, A. R. (2002). Dialysis in nursing homes. Seminars in Dialysis. 15(2):103-6.

Vourlekis, B., & Rivera-Mizzoni, R. (1997). Psychosocial problem assessment and ESRD patient outcomes. Advanmces in Renal Replacement Therapy, 4(2), 136-144.

Wallace, S., Goldberg, R., & Slaby, A. (1984). Guide for clinical social work in health care. NY: Praeger Publishers.Witten B, Howell P, Latos D. (1999). Improving employment outcomes: the renal care team's role. Nephrol News Issues. 13(3):46-8.

Witten B, Schatell DR, Becker BN. Relationship of ESRD working-age patient employment to treatment modality. (Abstract) J Am Soc Nephrol. 2004; 15:633A.

Wuerth D, Finklestein SH, Finklestein FO. The identification and treatment of depression in patients maintained on dialysis. Semin Dial. 18(2):142-6, 2005.

Submitter : **Dr. Stephen Fadem** **Date: 05/05/2005**

Organization : **Kidney Associates, PLLC**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS?3818?P
PO Box 8012
Baltimore, MD 21244? 8012

Subject: CMS?3818?P, Comments Regarding Conditions for Coverage for End Stage Renal Disease Facilities; Proposed Rule

Dear Dr. McClellan:

CMS is to be commended for the development of these Conditions for Coverage. My comments are brief because for the most part they are on target, and truly serve to address an endeavor by CMS to help drive the quality and performance of the health industry. The American Association of Kidney Patients (AAKP) has submitted comments to you, and has made some excellent points. Likewise, the Renal Physician?s Association has submitted comments that address many of the concerns of physician providers.
I really feel that many of the inefficiencies and problems that we face in the management of dialysis patients can be remedied as our industry migrates to more effective information technology. I remain highly dedicated to this process.
My personal comments will thus be brief, but I want to strongly stress two points:

Condition: QAPI - Quality Assessment and Performance Improvement (?494.110)

AV fistula - 494.110(a)(2)(iv) A major situation regarding av fistulae placement is that patients are not eligible for Medicare until their first day of dialysis, and thus if they are not insured, must have their first treatments with a catheter. The Conditions should somehow address this barrier by extending the QAPI plan to the patients in Stage IV kidney disease (GFR 15 - 30 ml/min). This will help us as medical directors gather data regarding the barriers to the Fistula First Initiative that can be used to synchronized our efforts to extend Medicare eligibility to this segment, as this might require legislation. I think that the Medical Director should be held accountable for fistulae monitoring and management because this is multidisciplinary, involving several groups of physicians as well as others at all levels.

Implementation of the Patient Plan of Care - Comment on Monthly Physician Visit (? 494.90(b)(4)).

I strongly endorse the provision that the dialysis facility must ensure that all dialysis patients are seen by a physician providing the ESRD care at least monthly, as evidenced by a monthly progress note placed in the medical record, and periodically, while ESRD patient is receiving in-center dialysis. Personally, I feel that it should be a condition for reimbursement to a dialysis facility just as it is for the physician. There should be a clause in the provision for situations where monthly visits are not possible because of geography, and an exception that these patients can visit the physician?s office on a regular basis. Also, there should be encouragement for different physician groups to cooperate in managing the patients simply because often a different physician reinforcing the same concepts of adherence lends credibility and better buy in at the patient level. This provision will be practical, and will also give the dialysis facilities incentives to cooperate effectively and create better communication tools to contact physicians when patient dialysis times are different than scheduled, and more importantly, when patients insist on decreasing the length of dialysis, or miss altogether. It is all too often that the reason a patient is not seen during treatment is a severe misunderstanding or disregard for the basics that underlie their dialysis prescription. In some, though not all of these circumstances, increased direct patient-doctor time can remedy these conditions.

Best regards,

Stephen Z. Fadem, M.D., FACP
Managing Physician
Kidney Associates, PLLC
713-795-5511
mailto: fadem@nephron.com
web: http://nephron.com
web: http://nephron.us

Submitter : **Date: 05/05/2005**

Organization :

Category : **Social Worker**

Issue Areas/Comments

GENERAL

GENERAL

re: 494.140 (CMS-3818-P)
I do not think it is practical for social workers in a dialysis clinic to be removed from clerical work given the low rates of reimbursement from Medicare for dialysis services. I think social workers have the training to be flexible enough to be competent in a variety of roles. Also, I think it is just fine for bachelor social workers to be placed in a dialysis clinic as long as they are supervised by Master's level staff. I am an LCSW currently working in a dialysis clinic and I supervise 2 bachelor level social workers.

Submitter : Mrs. Darlene Rodgers **Date:** 05/05/2005

Organization : Intermountain ESRD Network, Inc. (Network #15)

Category : Other Government

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-213-Attach-1.DOC

CMS-3818-P-213-Attach-2.DOC

Conditions for Coverage Draft Language	ESRD Network #15 Comments
§ 494.10 Definitions Dialysis facility means an entity that provides (1) outpatient maintenance services; or (2) home dialysis training and support services; or (3) both. A dialysis facility may be an independent or hospital-based (as described in § 413.74(b) and (c) of this chapter) or a self-care dialysis unit that furnishes only self-dialysis services.	Change to: Dialysis facility means an entity that provides (1) outpatient maintenance dialysis services; or (2) home dialysis training and support services; or (3) in-facility self-care services; or (4) any combination of the these modalities. A dialysis facility may be an independent or hospital-based unit (as described in § 413.74(b) and (c) of this chapter).
§ 494.10 Definitions Self-dialysis means dialysis performed with little or no professional assistance by an ESRD patient or caregiver who has completed an appropriate course of training as specified in § 494.100(a) of this part.	Add the following: Patient self-cannulation is one aspect of self-dialysis; cannulation alone is hardly self-care dialysis therefore, facilities that teach patients self-cannulation skills without instruction on an entire self-dialysis curriculum would not be held to the certification standards in § 494.100 of this part.
§494.180 Condition: Governance (f) Standard: Discharge and transfer policies and procedures. (1) Governing Body must ensure that all staff follows the facility's patient discharge and transfer policies and procedures. The medical Director ensures that no patient is discharged or transferred from the facility unless: (i) The patient or payer no longer reimburses the facility for the ordered services; (ii) The facility ceases to operate; (iii)The transfer is necessary for the patient's welfare because the facility can no longer meet the patient's documented medical needs; or (iv)The facility has reassessed the patient and determined that the patient's behavior is disruptive and abusive to the extent that the delivery of care to the patient or the ability of the facility to operate effectively is seriously impaired, in which case the medical director ensures that the patient's interdisciplinary team: (1) Documents the reassessments, ongoing problem(s), and efforts made to resolve the problem(s) and enters this documentation into the patient's medical record;	Change formatting to allow for "reasons" for discharge" under (f) Change (iii) to: The transfer is necessary for the patient's welfare because the facility can no longer meet the patient's medical needs and goals as documented in the patient's plan of care, specified in § 494.90

Conditions for Coverage Draft Language	ESRD Network #15 Comments
(2) Obtains a written physician's order that must be signed by both the medical director and the patient's attending physician concurring with the patient's discharge or transfer from the facility; (3) Attempts to place the patient in another facility and documents that effort; and (4) Notifies the State survey agency and the ESRD Network that services the area (where the facility is located) of the involuntary transfer or discharge. (2) Add →	Add the following: (2) The Governing Body of facilities approached to accept the patient must ensure that the patient is not summarily declined a transfer without following the individual facility's policies and procedures for patient admission (including patient interview and medical records review, if applicable).
§494.30 Condition: Infection Control Reporting infection control issues to the dialysis facility's CEO or administrator and the quality improvement committee…	Add: Medical Director should be notified of infection control issues.
§494.50 Condition: Water Quality Water used for dialysis meets the following water quality standards and equipment requirements of the Association for the Advancement of Medical Instrumentation (AAMI) published in "Water Treatment Equipment for Hemodialysis Applications," ANSI/AAMI RD62:2001.	Avoid codifying dates and values, as these may (will) change prior to changes in the regulations. Suggest "in accordance with current/published/documented standards set forth by…" thus avoiding locking the regulations into outdated dates and values.

Conditions for Coverage Draft Language	ESRD Network #15 Comments
§494.80(b)(1 and 2) Condition: Patient Assessment An initial comprehensive assessment must be conducted within 20 calendar days of the first dialysis treatment..	Suggest changing the language to "assessment must be completed within 30 days of initiation of dialysis in the chronic dialysis setting." Some patients still begin dialysis in the hospital and may not reach the dialysis facility responsible for assessment in a timely manner, or may be admitted to the hospital shortly after beginning dialysis. In either of these cases if any member of the multidisciplinary team has responsibility for a rural facility, this may not allow enough time for a comprehensive assessment.
§ 494.90 Condition: Patient Plan of Care The interdisciplinary team must develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and must include measurable and expected outcomes and estimated timetables to achieve those outcomes. The outcomes specified in the patient plan of care must allow the patient to achieve current evidence-based community-accepted standards.	Change last sentence in this paragraph to: The outcomes specified in the patient plan of care must strive for current evidence-based community-accepted standards, and must also reflect joint decision-making between and the patient and the interdisciplinary team to individualize the optimal goals for that patient.
(a) Standard: Development of patient plan of care (1) Dose of dialysis… (2) Nutritional status… (3) Anemia… (4) Vascular access… (5) Transplantation status… (6) Rehabilitation status…	Suggest substituting values with "per established guidelines or standards"…what if we discover a new measure within a year, or if it is determined that the current values are no longer valid, this language would allow for updates without re-writing the regulations.
	Add (7) Psychosocial Status. The interdisciplinary team must provide the necessary care or **appropriate referral for services** ***(make this language change throughout the document where "provide the necessary care and services" appears. Dialysis facilities may not be able to directly provide the services, but should be capable of referring to the appropriate resource)*** to achieve and sustain an effective psychosocial status.

Conditions for Coverage Draft Language	ESRD Network #15 Comments
§ 494.90 Condition: Personnel Qualifications **Standard:** Water Treatment System Technicians	Qualifications should match Patient Care Dialysis Technician and then add "…must complete a training program…"

Submitter : Ms. Amy Myrtue **Date:** 05/05/2005

Organization : NKF Council on Renal Nutrition

Category : Dietitian/Nutritionist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-3818-P-214-Attach-1.DOC

Attachment #214
DATE May 5, 2005

RE: File Code CMS—3818—P
Medicare Program; Conditions for Coverage for End Stage Renal Disease Facilities

As a renal dietitian with 4 years of experience in renal nutrition , I am writing to comment on the proposed Conditions of Coverage (COC) for End-Stage Renal Disease (ESRD) Facilities.

Regarding "Patients' Rights"

Sec 494.80 lists assessment criteria. I recommend that assessment criteria include specific reference to dialysis adequacy. For example,
(2) Evaluation of appropriateness of the dialysis prescription, **adequacy**, blood pressure and fluid management needs.
Bone disease management should be included in these assessment criteria. This is an extremely important part of ESRD patient care and should be a distinct item in patient assessments. Much research supports the strong link between the biochemical parameters of bone disease and morbidity and mortality.
I support the recommendation for an initial assessment and care plan. I also support a follow-up reassessment within 3 months of the initial assessment.
Monthly reassessments for unstable patients and annual reassessments for stable patients are reasonable. However, the meaning of **Sec 494.80 (d) (2) (iv)** is unclear. Would this regulation require that poor nutrition status, anemia, and inadequate dialysis occur simultaneously in the same patient to present as an unstable patient? It needs to be clear whether the intention here is "and" or "or". In addition, the definition of **poor nutrition status** must be flexible to allow individualized interpretations. One individual with a low albumin, but stable weight, good functional status, acceptable serum cholesterol, phosphorus, and nPCR may not truly be in poor nutritional status.

Regarding "Patient Care Plan"

Sec 494.90—
Among the issues listed to be addressed in the Plan of Care, we believe that bone disease management must be included, for reasons already stated.
I commend including rehabilitation status in patient care plans. It should be very clear in the final document that rehabilitation is broad, as the current language suggests, and that successful rehabilitation will be defined differently for different patients.

Part (b) (3) of this section states that, if expected outcomes are not met after 10 days, the plan of care must be adjusted to achieve specified goals. We believe that this statement should be amended to say "....or there must be clear explanations of why stated goals of treatment are not being met, with a plan to reduce any identified barriers to successful treatment."

Regarding QAPI

I believe it is important for nutrition issues to be included in QAPI and support the language of this section. I would like to see bone disease added to the list of topics to be included in QAPI, for reasons mentioned earlier in comments on the care plan. It is true that the language suggests other topics could be added to those listed, but bone disease is central to measuring dialysis outcomes and should be specified on this list.

Regarding "Personnel Qualifications"

Interdisciplinary team is defined specifically to include a **dietitian**. I encourage that this will be maintained because of the recognized advanced level of expertise that medical nutrition therapy in ESRD requires. I strongly agree with the discussion on pages 6221 and 6222 of the Federal Register, Vol.70, No. 23.

Sec 494.140(c) proposes a definition for dietitian. I suggest that the COC include the definition of dietitian that appears in the Final Rule for the Medicare Part B Medical Nutrition Therapy benefit regulation. That is:
"an individual who:

1) Holds a bachelor's or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics, as accredited by an appropriate national accreditation organization recognized for this purpose;
2) Has completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional; and
3) Is licensed or certified as a dietitian or nutrition professional by the State in which the services are performed..."

We agree that CMS should continue require that ESRD dietitians have a **minimum of 1 year of professional work experience as a registered dietitian**.

Regarding "Governance"

In **Section 494.180 (b) (5),** I would like to see "nutrition and psychosocial needs of ESRD patients" added to the topics covered in the training program. Interdisciplinary awareness of these needs enhances the follow-through on nutrition and social work contributions to patient care plans by all staff members, and this supports improved patient outcomes.

On page 6229 of the Federal Register, Vol 70, No 23, the proposed COC suggest that it has been decided not to propose Federal patient to staff ratios. However, in our opinion, the **final rules must include recommendations for a staffing ratio of 1 qualified registered dietitian per 100 to 125 dialysis patients**. This ratio is necessary to assure adequate medical nutrition therapy for the complex needs of dialysis patients.

A prospective analysis of nutrition status and hospitalization data in dialysis patients in northern California published in 1987showed that those patients with 30 minutes or more of dietitian time per patient per week had fewer hospitalizations ($p<.01$). This would equate to a ratio of 1 registered dietitian per 80 dialysis patients (Kelly, et al. CRN Quarterly. 11: 16-22, 1987).

A realistic assessment of staffing levels in the nation makes it clear that this is a level of staffing not likely to be achieved under current financial constraints. However there is precedent for the level of 100-125 patients per 1 dietitian, established in the NKF K/DOQI Nutrition Guidelines, Appendix IV; and in Title 25 of the Texas Administrative Code, Chapter 117, ESRD Facilities Licensing Rules.

In addition, USRDS (United States Renal Data System) statistics demonstrate that dialysis patients are increasing in complexity based on several factors:

1) The number of elderly dialysis patients is growing

2) The number of patients with other diagnoses (or co-morbidities) is growing. These co-morbidities include primarily diabetes and hypertension, both of which rely on nutrition intervention for optimal control.
3) The number of patients entering dialysis with low serum albumin is growing.

Since the major predictor of poor outcome in end-stage renal disease (ESRD) is low serum albumin; and since low albumin is a factor that intense medical nutrition therapy can improve, adequate dietitian staffing is essential to support a level of intervention to promote improved outcomes. Age and co-morbidities such as diabetes are two other factors linked with poor outcomes and which require more intense nutrition intervention (Lowery, et al. Am J Kid Diseases. 15: 458-82, 1990).

The National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI), Clinical Practice Guidelines for Nutrition in Chronic Renal Failure (American Journal of Kidney Diseases, vol 35, no 6, suppl 2, June 2000) states " ...that an individual dietitian should be responsible for the care of approximately 100 MD (maintenance dialysis) patients but almost certainly no more than 150 patients to provide adequate nutrition services... Because, in many dialysis facilities, the responsibilities of the renal dietitian are expanded beyond the basic care described in these guidelines (e.g. monitoring protocols and continuous quality improvement), these facilities should consider a higher ratio of dietitians to patients."

Thank you for this opportunity to provide input into the proposed administrative rules for outpatient renal dialysis facilities.

Sincerely,

Amy Myrtue, RD, CD
1814 Elliott Avenue NW
Olympia, WA 98502
amyrtue@comcast.net