Submitter : Ms. Twyla Moore

Organization : Arkansas Department of Health

Category : End-Stage Renal Disease Facility

Date: 05/02/2005

Issue Areas/Comments

GENERAL

GENERAL

"see Attachment"

Submitter : **Dr. cheryl gilmartin** **Date: 05/02/2005**

Organization : **Univ of Illinois Hospital and Clinics**

Category : **Pharmacist**

Issue Areas/Comments

Issues 11-20

Personnel Qualifications

attachment

CMS-3818-P-87-Attach-1.DOC

Attachment #87

April 29, 2005

Mark B. McClellan MD, PhD

Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

File Code: CMS-3818-P "Personnel Qualifications"
http://www.cms.hhs.gov/regulations/ecomments

I am writing to offer comments on the proposed revisions to the conditions for Coverage for End Stage Renal Disease facilities. In particular I would like to comment on Proposed 494.10("Personnel Qualifications") as this section addresses the possible role of a pharmacist within the dialysis facility. As a pharmacist, I appreciate that the Proposed Rule acknowledges the contributions pharmacists have made to provide safe and effective use of medications in the dialysis population.

Unfortunately, most dialysis patients do not have access to the professional services that have been documented and pharmacists have been trained to provide. Free-standing facilities are responsible for dialyzing 84% of the dialysis patient population. These facilities do not typically provide pharmaceutical care. For more than 10 years, the outpatient dialysis clinic at the University of Illinois-Chicago (UIC) has provided a dedicated clinical pharmacy staff available for all outpatient dialysis patients. The UIC pharmaceutical services have helped avert numerous drug interactions, helped coordinate medication regimens and therapeutic modifications that occur between the various clinics and the hospital, and provided counseling on the complex drug regimens of dialysis patients. In addition, the staff has provided assistance in obtaining medications for those who don't have prescription coverage. Sadly these services are not universally found within dialysis clinics across the country.

I feel it is necessary to comment on specific issues concerning the recently published federal register document. Under "Personnel Qualifications" it lists and defines each of the responsibilities and training requirements of all of the following: a) medical director, b) nurse, c) dietitian, d) social worker and e) dialysis technician. The Federal Register then proceeds to mention that "there is currently no Federal requirement for a pharmacist to play a role on the multidisciplinary team within the dialysis facility". I propose that there should be such a requirement. CMS has appreciated and requires pharmacist services in long-term facilities. Congress recently has given pharmacists the opportunity to be reimbursed for medication therapy management services (MTMS) beginning January 1, 2006. MTMS is reimbursable under Medicare Part D and provides benefits to Medicare beneficiaries with complex and chronic medical conditions. It is mentioned within the proposed rules of the federal register document that "ESRD is an extremely complex disease requiring highly technical and complex treatment, and patients with this disease have special needs that require highly specialized care that can only be provided by qualified personnel. Clearly dialysis patients should be recipients of pharmacist-provided MTMS and pharmacists should be considered a part of the interdisciplinary dialysis team.

In regards to the proposed elements of patient assessment as mentioned in S494.80 (a), there exists a need for routine reviews of laboratory profiles and medication histories. Additionally, it is

mentioned that a need exists to evaluate factors associated with anemia with corresponding anemia treatment plans and to evaluate factors associated with renal bone disease. At the UIC dialysis unit, clinical pharmacists participate monthly in laboratory profile reviews and manage the medication profiles for the dialysis patients. Based on the multidiscipline evaluations and coupled with a deep understanding each patient's unique array of conditions, medications are adjusted accordingly.

End-stage renal disease (ESRD) patients represent only 0.8% patients covered by Medicare yet utilize an alarming 5.6% of Medicare dollars. In 1998 there were approximately 375,000 ESRD patients for more than 11 billion in total expenditures. The number of ESRD patients is currently projected to increase at about 7.8% per year. The National Institutes of Health projects that over the next 10 years total Medicare ESRD program costs will more than double, reaching total expenditures of $28 billion/year.

There is considerable published research available which highlights the benefits pharmacists have contributed to the health care system. These include: a) the financial benefit of $16.70 for every dollar invested in pharmacists in hospitals and managed care clinics, b) pharmacist reduction in negative therapeutic outcomes across the nation in the ambulatory care setting by 53 to 63%, and c) a reduction in costs spent correcting medication-related problems by 43%.

To truly realize the necessity of pharmaceutical care services in the end-stage renal disease population, we must first consider other significant findings. First of all, the average monthly cost for medications in hemodialysis is $1181. For a hemodialysis unit of 100 patients, approximately $1,417,000 is spent on medications over 1 year. Problems associated with the mismanagement of medications have been estimated to cost $1.33 for every $1 spent on medication. This amounts to $1,884,530 on drug-related problems per 100 dialysis patients. It has been shown that pharmaceutical services can already reduce the total number of medications taken in other non-ESRD ambulatory patient populations by 0.69 per patient. If these services were applied to the ESRD population, it is possible that these services could also reduce the total amount spent on medications by $34,884 per 100 dialysis patients, and $46,342 per 100 dialysis patients on drug-related problems associated with them. Clearly, the benefits of pharmacist participation in a dialysis clinic can be seen.

One of the major concerns affecting our nation as medication usage increases in this country is the simultaneous increase in medication errors. It has been shown that medication errors occur in about 5% of patients admitted to hospitals. Medical institutions which have utilized pharmacists in patient care areas have reduced the risk of errors that adversely affected patient outcomes by an astounding 94%. In the case of end-stage renal disease patients, the potential for medication errors is of particular importance. Dialysis patients frequently see many physicians and receive an average of 10-12 medications, many of which require multiple doses per day. At UIC the pharmacist assists in providing coordination and continuity of care among the various clinics, the hospital and the dialysis unit. Additionally, kidney disease requires patient-specific medication dosing to address the often complex pathophysiology which is typical of these patients. Clinical pharmacists are trained to address those issues as well as the inter- and intradialytic pharmacokinetics of medications.

In conclusion, recognition as well as future promotion of pharmacist services in dialysis clinics may lead to better patient care, fewer adverse outcomes, reduced spending on unnecessary or counterproductive drug treatments, and will provide a solid infrastructure for improved medication use. It is for these reasons why I hope that you will take actions to support comprehensive pharmacist services in dialysis clinics.

Thank you for your consideration

Cheryl Gilmartin PharmD Clinical Assistant Professor University of Illinois-Chicago

Submitter : Mr. christopher decker

Date: 05/02/2005

Organization : Pharmacy Society of Wisconsin

Category : Pharmacist

Issue Areas/Comments

Issues 11-20

Personnel Qualifications

It is critical to ensuring consistent improvement in ESRD medication use that continuity of care be improved. Currently there is insufficient oversight of multiple providers who prescribe and dispense numerous medications to patients treated at ESRD facilities, often without any knowledge of therapies ordered or provided by other practitioners. The change in the Medicare requirements for facilities serving dialysis patients provides a unique opportunity to systematically improve both the quality and cost-effectiveness of medications used by patients with ESRD.

The typical dialysis patient is treated with 12-15 medications. Because of kidney failure, the effects of dialysis and other co-morbidities, patients undergoing dialysis are at high risk for adverse drug events. Coupled with the fact that treatment is routinely provided to ESRD patients by multiple practitioners due to the prevalence of co-morbidity, the complexity of the drug regimes of ESRD patients warrants a regular medication assessment by a pharmacy professional.

The proposed rule calls for a medication history to be completed on each ESRD patient. However, the rule should also require a review to be completed by a pharmacist and that the pharmacist provide recommendations to the Medical Director and other practitioners regarding the patient's therapies. This service will become even more important with upcoming onset of the Medicare Part D prescription drug benefit.

We recommend that CMS develop clinical guidelines and criteria for consultant pharmacists to consider and apply in the conduction of an initial medication review and at least a quarterly review thereafter. Such a review could be similar to that required by CMS of skilled nursing facilities.

The composite rate provided to ESRD facilities should be increased to reflect the incorporation of the clinical pharmacy services. The small increase in cost to be incurred through the addition of this service will be far outweighed by the cost savings associated with improved medication use.

At a minimum, CMS should establish a phased-in program, beginning with one or more ESRD facilities in each state, which could be later expanded to all ESRD facilities. Such an approach would enable the development and application of clinical practice guidelines for the facilities. Pharmacists and medical directors from those facilities could subsequently be used as teaching professionals and consultants for other ESRD facilities in the state as the program requirements are applied to all facilities.

Pharmacists are uniquely qualified to play an important and needed role in the appropriate and safe use of medications in this highly vulnerable group of patients.

Submitter : Connie Anderson **Date:** 05/02/2005

Organization : Northwest Kidney Centers

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-89-Attach-1.DOC

Submitter : Judith Mooberry **Date:** 05/02/2005

Organization : NE Health and Human Services Regulation & Licensur

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

494.40 Water Quality:
- Important to incorporate RD:52:2004
- Support requiring 2 carbon tanks as this will reduce the risk of a chlorine/chloramine breakthrough to patients. In my experience if chorine/chloramine is found at the test port after the first carbon tank it is usually taken care of by the second carbon tank reducing the risk of injury or death to patients. If there is a breakthrough found after the first tank and not the second tank this would also allow the facility to bypass the first tank and continue dialysis using the second tank while troubleshooting the first tank.

494.60 Physical Environment:
- Support the proposal to require facilities to prepare for emergencies including natural disasters. Facilities should be required to have contracts with suppliers for those things that would likely be affected including water, generators, or other facilities to provide dialysis to their patients if possible.
- Support requirement for facilities performing central batch reprocessing to meet the needs of patients with special dialysis solutions as they may not do this if they are not required to.
- Support requirement that all facilities have defibrillators and personnel trained to use them in all facilities including rural facilities. It may take longer for EMS services to reach patients in small rural facilities if the community does not have EMS service and it has to come from a neighboring community. It may also take longer for rural patients to be transported to a regional hospital in a larger community. So immediate life saving measures such as defibrillators are as or are more important in small rural communities as large communities.

494.70 Patient Rights:
- Support the 30 day notice before transfer if other patients and personnel are not at risk.
-Facilities should have policies and procedures to address disruptive or challenging behavior when the behavior first presents. All patients should be aware of the policies and procedures. The policies and procedures should include counselling for the patient and staff taking care of the patient so all are aware of the plan and implement it in a consistent way. The plan should also include the use of contracts, developed with the patient, signed by the patient, in an effort to resolve or reduce behaviors. The Networks have useful information on this.

494.80 Patient Assessment:
- Support the 3 month proposal for the reassessment of the patient. This is a reasonable time frame for patient to show improvement or decline. At this time assessment may show areas for treatment and plan of care changes to improve the patients overall health and outcomes.

494.90 Patient Plan of Care:
-Support method or "necessary actions" for facilities to support patients in process of the work up for a transplant including tracking of required tests etc and copies of progress notes or other communication with transplant coordinators or surgeons.

494.140 Personnel Qualifications:
- Important for charge nurse to be a registered nurse not a licensed practical nurse. Registered nurses have education and training required in this position such as reacting to emergency situations including of provision of IV medications.

Submitter : Mrs. Cathy Henderson

Date: 05/02/2005

Organization : San Mateo Dialysis Center

Category : Dietitian/Nutritionist

Issue Areas/Comments

GENERAL

GENERAL

The proposed shortening of time from 30 days to 20 days for the RD to perform the initial nutritional assessment is not beneficial to the patient for several reasons. During the first month of dialysis, the patient is overwhelmed with information & the patient may still be uremic and not thinking and retaining information well. The patient may still be sick and frequently re-hospitalized and not even be at the out-pt unit for part of the first few weeks or might be at a nursing home where their diet is provided for them and diet asst & teaching may be more beneficial at the time of their discharge from the nursing home. The patient may be relying on nutritional supplements to provide some if not all of the nutritional needs and while RD involvement is vital at this stage, the completion of the initial nutritional asst is not, as the patient is undergoing many changes in nutrition and learning during the first month,in deed thru the first 3 months of dialysis. The proposed 3 month re-asst is repetitive; actually - probably a 3 month initial nutritional asst is right, by then you have had some data of the patient and can determine what the problem areas are and what is improving and what is not. Despite the move to prepare pts for dialysis ahead of time and have fistulas first, may patients still come to out-patient dialysis with catheters and are not getting a great dialysis initially which also affects their appetite or the fistula is placed but needs 3 months to mature so the pt is continuing to change despite an early asst, care plan. If a care plan is needed 10 days after the patient starts, there is not much information available in which to plan and the MD is not always available for every patient's 10 day time frame. The MD does come and has set meeting times but again it may not be in the 10 day time frame required and the Md is not always able to add a meeting time into their already busy schedules. Thank you for reading these comments and please hear my dismay at the shortening of time for an initial nutritional asst, a care plan within a 10 day time frame, and for a repetitive 3 month asst from this renal dietitian.

Cathy Henderson, RD
San Mateo Dialysis Center
2000 S. El Camino Real
San Mateo, CA 94403
650-377-0888
chenderson@peninsulanephrologyinc.com

Submitter : Mrs. Lori Hartwell

Date: 05/03/2005

Organization : Renal Support Network

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

see attached

Submitter : Ms. Maureen McCarthy **Date:** 05/03/2005

Organization : RCG--Pacific NW Renal Services

Category : Dietitian/Nutritionist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-3818-P-99-Attach-1.DOC

Attch #99
May 2, 2005

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

As a renal dietitian with 20 years of experience providing nutrition services in hemodialysis facilities, I am writing to comment on the proposed Conditions of Coverage (COC) for End-Stage Renal Disease (ESRD) Facilities.

Regarding "Infection Control"

Sec 494.30(b) (2) suggests that a registered nurse should be designated as the infection control or safety officer. I recommend freedom to designate other qualified, properly trained staff for this role. At times of nursing shortages it is helpful to have this flexibility.

Regarding "Patients' Rights"

Section 494.70, *Patients' Rights* (a): Patient's Rights

I would like to see this addition to the list of patient rights:
Patients should have access to all qualified facility personnel, including a social worker and renal dietitian, as needed. Social workers and dietitians often have large caseloads, are the only facility personnel who routinely cover multiple clinics, and /or work part-time, and patients often do not know how to contact them when needed. It is not unusual for a patient to see his/her dietitian only once a month. However, there may be a need for nutrition consultation during that month, and patients should be assured that easy access will be available. This means that case loads of renal dietitians must allow time for such added availability

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.
These assessment criteria should also be modified to include **bone disease management**. 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 within 20 days of initiating dialysis, followed by a complete care plan within the next 10 calendar days. 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—I understand that the Patient Plan of Care will include documentation of **transplant status** and that this will replace the current Long-term Program. It is essential that this be a very clear part of the proposed Patient Plan of Care document and that it supports a discussion with the patient about treatment options at intervals of one year.
Among the issues listed to be addressed in the Plan of Care, I 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. I 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..."

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

On page 6224 of the same issue of the Federal Register, comments regarding the role of pharmacists in dialysis units are invited. I think it would be very difficult to add pharmacists to the staffing at the unit level; in today's financial climate, that would present a hardship for facilities. Due to their experience and highly specialized training, nephrology nurses and renal dietitians and certainly the nephrologists themselves are generally able to evaluate pertinent pharmaceutical issues, including drug-nutrient interactions. Nephrologists usually have good access to an appropriate level of pharmacist support in the institutions that provide the acute care setting for patients in their practice.

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 my 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 1987sholld 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 (Lowry, 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,

Maureen McCarthy, MPH, RD, CSR, LD
Renal Dietitian

Submitter : **Date: 05/03/2005**

Organization :

Category : **Physician**

Issue Areas/Comments

Issues 11-20

Personnel Qualifications

I am a physician that works with patients served in an ESRD facility, however, I am not an endocrinologist. I am a GP.

I would like to speak in favor of having a pharmacist added to the ESRD team of professionals responsible for managing dialysis patient therapies. Currently there is little continuity of care managed by pharmacists, yet medication therapies are THE primary mode of treatment for these patients, in addition to dialysis. This shortcoming has led to numerous medical complications and poor medication management. I don't know what other practitioners have prescribed and frankly, neither do most of my patients. Having a pharmacist perform regular review and management of ESRD medication therapies would lead to a significant improvement in the care provided to ESRD patients. If pharmacists are added to the team, they should also be instructed to recommend less costly alternatives whenever possible. Too many of my colleagues prescribe the latest and greatest meds, which may not be greater but they are certainly more costly. Pharmacists know about drug costs and they can make a big difference in managing the cost of the Medicare program if they are incorporated.

Submitter : **Date: 05/03/2005**

Organization :

Category : **Dietitian/Nutritionist**

Issue Areas/Comments

GENERAL

GENERAL

Recommend considering a CMS proposed patient to Dietitian ratio of 100:1 to establish consistent staffing between dialyis facilities.

Issues 1-10

Plan of Care

I recommend extending the timeframe to complete a comprehensive assessment from 20 days to 30 days. As mentioned in the proposed conditions, patients require time to adjust to dialysis and the new aspects of their healthcare. In my practice the assessment is initiated on their first or second day of treatment and completed over the course of the thirty day period. This allows the healthcare provider to focus first on the areas most applicable to an individual patient which will have the most impact on their nutritional status. It allows the practitioner to identify the greatest need for a individual patient and establish a plan of action with that individual to address that need. After addressing the greatest need the practitioner can then focus the education on other areas of the plan of care which are important, however may not be the first priority for a specific patient. The proposed 20 day assessment period will likely cause healthcare providers to condense all information into one or two educational sessions, while overwhelming patients and their families. In reality it would only allow for contact with a patient eight times (for a patient running three days per week) prior to the 20 day deadline. Another area to consider, dialysis facilities often employee part-time dietitians. If a RD is working two days per week (one day for MWF patients and one day for TTHS patients) it would only allow the RD to meet with a patient 3 times prior to the 20 day assessment deadline.

Submitter : Ms. Betty Sullivan **Date:** 05/03/2005

Organization : Trinity Regional Medical Center

Category : End-Stage Renal Disease Facility

Issue Areas/Comments

GENERAL

GENERAL

See attachment

Submitter : **Date: 05/03/2005**

Organization :

Category : **Social Worker**

Issue Areas/Comments

GENERAL

GENERAL

*Regarding patient assessments (p. 79-84), an initial assessment within the first 20 days is a good idea, as long as it is brief and addresses only the immediate needs and issues of the patient. (It should be used as a tool for triaging the patient?s needs.)

*The follow up reassessment within 90 days will be beneficial, as it will allow time to gather information for a more in-depth assessment. Also it will allow patients to feel more comfortable with disclosing personal information, as they will have had more time to form a relationship with the unit social worker.

*Regarding the definition of a qualified social worker (p. 156-157), the MSW degree does provide sufficient training to address various needs of the renal population, however, the LCSW accreditation is invaluable and should not be dismissed. An MSW should still be supervised by an LCSW, as there are clinical issues that an MSW will continue to need guidance on.

Submitter : **Miss. Margaret West** **Date: 05/03/2005**

Organization : **DaVita**

Category : **Dietitian/Nutritionist**

Issue Areas/Comments

Issues 1-10

Plan of Care

Nutrition status:

Adding additional laboratory measures to evaluate nutritional status will help confirm protein energy malnutrition.

Issues 11-20

Personnel Qualifications

Dietitian qualifications:

After completing an extensive four year curriculum, specializing in Human Nutrition at the accredited Winthrop University, I proceeded to complete an intensive, 40 hour + week internship for six months. The accredited internship provided an introduction to the outpatient dialysis facility where I acquired many valuable skills. When I began my first registered dietitian eligible position at an outpatient dialysis, my written nutrition assessments were reviewed and co-signed by another registered dietitian, until I passed my registration exam. Students studying nutrition at accredited programs are well educated and prepared academically, as well as clinically, to work in outpatient dialysis facilities. Adding an additional year of experience as a requirement, will not only discredit the many years of education and clinical experience gained by the internship, but will add additional time, in which, a registered dietitian can not reach the "much needed" dialysis work force. This in turn, may create an already greater demand for experienced registered dietitians in dialysis. From my personal and professional experience, this issue should not be mandated by CMS, but should be addressed with dietetics accreditation board.

Submitter : Mr. Chris Campbell **Date:** 05/03/2005

Organization : Oregon Department of Human Services

Category : State Government

Issue Areas/Comments

Issues 1-10

Water Quality

494.40(a): Water Purity. Rather than incorporating ANSI/AAMI RD62:2001, I would recommend incorporating RD 52. Thank you for your consideration.

Submitter : **Ms. Nancy Poremski** **Date: 05/03/2005**

Organization : **Purity Dialysis - Waukesha**

Category : **Social Worker**

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-3818-P-106-Attach-1.DOC

Attch #106
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,
Nancy E. Poremski, LCSW
Purity Dialysis Centers – Waukesha
721 American Ave. Ste. 204
Waukesha, WI 53188

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 witl* ***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 minimally 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 tre workers are trained to intervene within areas of need that are essential for optimal patien ***References:*** McKinley & Callahan, 1998; Vourlekis & Rivera-Mizzoni, 1997
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	as to the reasons why these behaviors may be harmful to them; it is therefore inappropri 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 with* *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, rehe* *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
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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 e* ***Rationale:*** To ensure patient-centered care, patient functioning and well-being must be c 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 Responsib of the responsibilities of each team member. Responsibilities for social wo comment on "494.140 Condition Personnel qualifications (d) Standard: So 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 & Jo 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 work 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 doctor 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 and 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 ar 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 s 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 fewer 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 : Mrs. Kelli Geronime **Date:** 05/03/2005

Organization : Purity Dialysis-Menomone Falls

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

"see attatched"

CMS-3818-P-107-Attach-1.DOC

Attachment #107
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,
Kelli Geronime, LCSW
Purity Dialysis Centers – Menomonee Falls
W 173 N 9170 St Francis Dr.
Menomonee Falls, WI 53051

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 pati privacy during body exposure. *Patient/family interviews may still take place chairside witl* ***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 c** 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*
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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 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 thc 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 r 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 achi 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 be 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 defini workers are trained to think critically, analyze problems, and intervene with 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 doctor 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 and 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 ar 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 s 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 dialys they found that only 13% of full time dialysis social workers had caseloads of 75 or fewer 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. Madelyn Koontz **Date:** 05/03/2005

Organization : Oregon Council on Renal Nutrition

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-3818-P-108-Attach-1.DOC

Attch #108
May 3, 2005

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

As members of OCRN, a local affiliate of the NKF-CRN, we are writing to comment on the proposed Conditions of Coverage (COC) for End-Stage Renal Disease (ESRD) Facilities.

Regarding "Infection Control"

Sec 494.30(b) (2) suggests that a registered nurse should be designated a the infection control or safety officer. We recommend freedom to designate other qualified, properly trained staff for this role. At times of nursing shortages it is helpful to have this flexibility.

Regarding "Patients' Rights"

Section 494.70, *Patients' Rights* (a): Patient's Rights

We would like to see this addition to the list of patient rights:
Patients should have access to all qualified facility personnel, including a social worker and renal dietitian, as needed. Social workers and dietitians often have large caseloads, are the only facility personnel who routinely cover multiple clinics, and /or work part-time, and patients often do not know how to contact them when needed. It is not unusual for a patient to see his/her dietitian only once a month. However, there may be a need for nutrition consultation during that month, and patients should be assured that easy access will be available. This means that case loads of renal dietitians must allow time for such added availability

Sec 494.80 lists assessment criteria. We 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.
These assessment criteria should also be modified to include **bone disease management**. 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.
We support the recommendation for an initial assessment within 20 days of initiating dialysis, followed by a complete care plan within the next 10 calendar days. We 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—We understand that the Patient Plan of Care will include documentation of **transplant status** and that this will replace the current Long-term Program. It is essential that this be a very clear part of the proposed Patient Plan of Care document and that it supports a discussion with the patient about treatment options at intervals of one year.

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.
We 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

We believe it is important for nutrition issues to be included in QAPI and support the language of this section. We 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**. We encourage that this will be maintained because of the recognized advanced level of expertise that medical nutrition therapy in ESRD requires. We 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. We 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**.

On page 6224 of the same issue of the Federal Register, comments regarding the role of pharmacists in dialysis units are invited. We think it would be very difficult to add pharmacists to the staffing at the unit level; in today's financial climate, that would present a hardship for facilities. Due to their experience and highly specialized training, nephrology nurses and renal dietitians and certainly the nephrologists themselves are generally able to evaluate pertinent pharmaceutical issues, including drug-nutrient interactions. Nephrologists usually have good access to an appropriate level of pharmacist support in the institutions that provide the acute care setting for patients in their practice.

Regarding "Governance"

In **Section 494.180 (b) (5),** we 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,

Submitter : Ms. Madelyn Koontz **Date:** 05/03/2005

Organization : Oregon Council on Renal Nutrition

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-3818-P-109-Attach-1.DOC

Attch #109
May 3, 2005

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

As members of OCRN, a local affiliate of the NKF-CRN, we are writing to comment on the proposed Conditions of Coverage (COC) for End-Stage Renal Disease (ESRD) Facilities.

Regarding "Infection Control"

Sec 494.30(b) (2) suggests that a registered nurse should be designated a the infection control or safety officer. We recommend freedom to designate other qualified, properly trained staff for this role. At times of nursing shortages it is helpful to have this flexibility.

Regarding "Patients' Rights"

Section 494.70, *Patients' Rights* (a): Patient's Rights

We would like to see this addition to the list of patient rights:
Patients should have access to all qualified facility personnel, including a social worker and renal dietitian, as needed. Social workers and dietitians often have large caseloads, are the only facility personnel who routinely cover multiple clinics, and /or work part-time, and patients often do not know how to contact them when needed. It is not unusual for a patient to see his/her dietitian only once a month. However, there may be a need for nutrition consultation during that month, and patients should be assured that easy access will be available. This means that case loads of renal dietitians must allow time for such added availability

Sec 494.80 lists assessment criteria. We 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.
These assessment criteria should also be modified to include **bone disease management**. 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.
We support the recommendation for an initial assessment within 20 days of initiating dialysis, followed by a complete care plan within the next 10 calendar days. We 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—We understand that the Patient Plan of Care will include documentation of **transplant status** and that this will replace the current Long-term Program. It is essential that this be a very clear part of the proposed Patient Plan of Care document and that it supports a discussion with the patient about treatment options at intervals of one year.

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.
We 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

We believe it is important for nutrition issues to be included in QAPI and support the language of this section. We 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**. We encourage that this will be maintained because of the recognized advanced level of expertise that medical nutrition therapy in ESRD requires. We 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. We 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.**

On page 6224 of the same issue of the Federal Register, comments regarding the role of pharmacists in dialysis units are invited. We think it would be very difficult to add pharmacists to the staffing at the unit level; in today's financial climate, that would present a hardship for facilities. Due to their experience and highly specialized training, nephrology nurses and renal dietitians and certainly the nephrologists themselves are generally able to evaluate pertinent pharmaceutical issues, including drug-nutrient interactions. Nephrologists usually have good access to an appropriate level of pharmacist support in the institutions that provide the acute care setting for patients in their practice.

Regarding "Governance"

In **Section 494.180 (b) (5),** we 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,
The Oregon Council on Renal Nutrition

Submitter : Ms. Madelyn Koontz **Date:** 05/03/2005

Organization : Ms. Madelyn Koontz

Category : Dietitian/Nutritionist

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-3818-P-110-Attach-1.DOC

Attachment #110
April 20, 2005

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

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

Regarding "Infection Control"

Sec 30(b) (2): I feel that besides the registered nurse, other qualified, properly trained staff, as the registered dietitian, could fill the position of infection control or safety officer.

Regarding "Patients' Rights"

Sec 494.80: Because research supports the strong link between the biochemical parameters of bone disease and morbidity and mortality, I feel that bone disease management should be included in the assessment criteria. I support the recommendation for an initial assessment within 20 days of initiating dialysis, followed by the complete care plan within the next 10 calendar days. I also support a follow-up reassessment within 3 months of the initial assessment. However,I feel that the definition of stable and non-stable patient status and poor nutrition status used as the criteria for more frequent assessments needs to be more clear and flexible for individualized treatment.

Regarding "Patient Care Plan"

Sec 494.90: I understand that the Patient Plan of Care will replace the current Long-term Program and recommend that the treatment options, including transplant status, be addressed yearly. I also believe that bone disease management must be included in the Plan of Care. If implementing care plans has a 10 day time limit, I recommend that in the event that the expected outcomes are not met, clear explanations are made with a plan to reduce any identified barriers to successful treatment rather than just adjusting the care plan to achieve the goals.

Regarding QAPI

I believe that bone disease management is very important to measuring dialysis outcomes and should be included in the list of nutrition issues.

Regarding "Personnel Qualifications"

Interdisciplinary team: I agree that the dietitian should be included because of the advanced level of expertise that medical nutrition therapy ESRD requires. I recommend that the COC include the definition of dietitian that appears in the Final Rule for Medicare Part B Medical Nutrition Therapy benefit regulation. I also recommend licensure or certification by the State in which the dietitian performs services. I agree with the requirement that ESRD dietitians have a minimum of 1 year of professional work experience as a registered dietitian. In regards to a pharmacist on the team, I feel that it would not be cost effective and other members of the team can deal with the basic pharmaceutical issues (RN, RD, MD); a pharmacist can be contracted if necessary.

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. I also strongly recommend a staffing ratio of 1 dietitian per 100-125 patients to assure adequate medical nutrition therapy for the complex needs of dialysis patients. Most dialysis patients today have significant co-morbidities and many are in the elderly population that need more nutrition intervention for optimal control. Age and diabetes are two 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) recommends that a dietitian be responsible for the care of approximately 100 patients with no more than 150 patients to provide adequate nutrition services. In many facilities, the dietitian has expanded responsibilities that include monitoring protocols and continuous quality improvement.

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

Sincerely.

Madelyn Koontz, RD, LD

Submitter : **Dr. Derrick Latos** **Date: 05/03/2005**

Organization : **Forum of ESRD Networks**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-111-Attach-1.DOC

FORUM OF END STAGE RENAL DISEASE NETWORKS

Attachment #111

May 3, 2005

Mark McClellan, MD, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Attn: CMS-3818-P
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Conditions for Coverage for End Stage Renal Disease Facilities Proposed Rule (CMS-3818-P)

Dear Dr. McClellan:

The Forum of ESRD Networks is the organization that supports and augments the ESRD Networks in promoting and improving the quality of care to patients with renal disease. We appreciate the opportunity to comment on the proposed rule updating the Conditions of Coverage.

We congratulate CMS for emphasizing evidence-based, quality assessment and performance improvement. We also commend CMS for de-emphasizing procedure, and minimizing record keeping requirements. We congratulate CMS for their thoughtful requests for comments. This approach will improve consensus building and minimize unintended consequences.

We believe developing flexible and valid standards, measures and thresholds is the overarching issue in the rule proposal. We address this issue first. Next we comment on specific conditions within the proposal. Finally, we answer relevant requested comments.

The Forum proposes that the rules contain a clear definition of the term "standards." Combining language accompanying the proposed rule and OMB Circular A-119, we propose the following definition of standards. Standards are "current, evidence-based, community-accepted, minimal requirements." We believe each modifier in the definition is important. Standards must be "current" to remain consistent with new scientific evidence. "Evidence" must prove a link between the standard, measure or threshold and a desired outcome. "Community acceptance" of standards includes expert opinion, increases stakeholder consensus, and decreases unintended consequences. The "minimum requirements" term means the lowest allowable performance. The Forum believes codifying performance ceilings will limit continuous quality improvement.

This definition of standards informs many conditions in the proposed rule. If the Conditions codify specific subjects (for example dialysis adequacy), the Conditions cannot respond rapidly to new knowledge and technology. The same is true for

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email: forum@forum.esrd.net • http://www.esrdnetworks.org

codifying numerical standards (for example, hemoglobin of 11) and codifying drugs (for example, erythropoiten). Thus, The Forum proposes a new selection method for patient care elements.

We believe that establishing a "voluntary consensus organization," as defined in OMB Circular A-119, is the best method for developing standards, measures and thresholds. The voluntary consensus organization will recommend current, evidence based standards, measures and thresholds to The Secretary at regular intervals and following sentinel events.

The Forum is equipped to establish and maintain a voluntary consensus organization. The Forum is an ESRD information clearinghouse for CMS and the ESRD community. Forum staff, with specific ESRD Networks, manages The CPM Project and various Technical Expert Panels. ESRD Network Medical Review Boards build local consensus. Network data collection and validation experts are mindful of data collecting burdens.

The Forum respectfully recommends CMS differentiate between standards and guideline statements in The Conditions. All current nephrology guidelines explicitly omit standards and thresholds. The authors of K/DOQI state in the "Disclaimer and Acceptable Use Policy" section, "these guidelines are ...not intended to define a standard of care, and should not be construed as one. Neither should they be interpreted as prescribing an exclusive course of management." In Crossing the Quality Chasm, the Institute of Medicine describes guidelines as facilitating "decision making based on current best evidence", but not intended "to replace patient preferences or clinical experience." Guideline statements are not easily converted to standards, measures and thresholds. Similarly, The Forum respectfully suggests avoidance of standards application to individual beneficiaries, in addition to patient aggregates. Scientific workgroups never intended using guidelines-adapted measures or standards for individual beneficiaries. For example, K/DOQI guideline statements refer always to "dialysis patients," pleural never singular. Therefore, The Forum suggests avoidance of individual-patient-standards as part of the QAPI Program until more is known about unintended consequences and evidence linkage to desired outcomes.

Converting guideline statements into standards, measures and thresholds requires expert input. Experts must assess the strength of evidence linking the statement to a desired outcome. They must determine to whom the outcome is mostly attributed and whether the outcome is actionable by that entity. They must consider the burden of collecting the requisite data. Experts must select statistical methods, including exclusion criteria, to allow comparison among providers. Therefore, The Forum recommends that guidelines, per se, not be used to codify patient care elements.

Specific Comments

General Provisions

1) Definitions (Proposed § 494.10)
   a) The Forum recommends separate definitions for Home Dialysis and Nursing Home/Skilled Nursing Facility Dialysis (Non-acute Care, Institutional Dialysis).

Unlike home dialysis, Institutional Dialysis requires paid professionals often providing treatment to more than one patient per session. Unlike Institutional Dialysis, home dialysis involves family members.

i) "Dialysis Facility" should therefore include reference to a facility that provides Nursing Home or Skilled Nursing Facility dialysis.

b) 494.100.a Self Dialysis

i) The Forum suggests that "self dialysis training" should not require "home training" because "self dialysis" includes facility-based, self treatment. Self dialysis training should included treatment monitoring, machine monitoring, needle procedures, and infection control.

Patient Safety

The Forum commends CMS for associating water treatment, dialyzer reuse, fire prevention, and infection control requirements with the appropriate respective professional organizations' current recommendations. The Forum believes this approach is far superior to and more flexible than codifying procedures. In so doing, the proposed rules can adapt to new technologies and knowledge without rewriting the rules. As noted above, we believe this precedent should be applied to Patient Care also.

1. Infection Control
    a. CMS requested comments regarding adherence to HICPAC guidelines. The Forum wishes to point out a controversy between the HICPAC guideline and SHEA (Society for Healthcare Epidemiology of America) guideline regarding the standard of care for preventing nosocomial transmission of multi-drug resistant Staph aureus and Enterococcus. The Forum suggests whenever evidence based guidelines are in conflict, they should either be reconciled by experts, have both guidelines included, or be omitted from The Conditions.

Patient Care

1. Patient Rights
    a. Advanced Care Directives
        i. The Forum recommends the rules require facilities to honor advanced directives.
2. Comprehensive Patient Assessment and Reassessment.
    a. Initial Assessment
        i. The Forum suggests an increase from 20 days to 30 days for completion of the initial assessment. The increase considers distant facilities. Also, doctors and facilities may need more time when many new patients start dialysis at the same time. The Forum suggests Medical Review Boards examine facilities with large numbers of delayed Initial Assessments for the exceptions noted in the preceding sentences.
        ii. The Forum commends CMS for using the phrases "appropriateness of," and "evaluation of" ... the various assessment elements. The Forum believes these directives improve validity and flexibility compared to codifying specific goals or outcomes. We recommend

the addition of language to allow "the Secretary" to modify or update these elements consistent with new technology and knowledge.

3. Patient Plan of Care
    a. The Forum respectfully reiterates that the K/DOQI clinical practice guidelines statements are not standards. The F orum recommends that a voluntary consensus organization be convened at regular intervals to consider converting a ppropriate g uideline statements to standards based upon supporting evidence linking the statement to a desired outcome. Subsequently, the organization would determine measures and thresholds for the stamdards.
    b. The Forum suggests that numerical standards not be codified (for example, KT/V > 1.2; hemoglobin > 11) because such might prevent or delay inclusion of future advances in technology and knowledge. Following the precedent set in the Patient Safety Subpart, numerical standards should be set by voluntary consensus organizations and approved "by the Secretary" at predetermined intervals.
        i. Standard: Development of patient plan of care.
            1. The Forum appreciates the desire to specify patient care elements that must be addressed in the Plan of Care, such as dialysis adequacy, anemia, etc. However, we believe these inclusions result in rules that are inflexible to future changes and advances. We recommend that The Secretary approve the elements of patient care as recommended by an appropriate voluntary consensus organization.
            2. The Forum suggests that the Secretary approve adequacy, anemia management, nutrition, and vascular access as the currently appropriate elements of care, as recommended by the Clinical Performance Measure Project.
            3. The Forum recommends that language be consistent for each element of care and should include the phrase "must provide the necessary care and services to achieve and sustain an effective ..."
                a. Anemia
                    i. The Forum suggests the above phrase ("necessary care and services") be applied to anemia management. Erythropoietin may not remain the erythropoietic stimulator of choice in the future and standards for hemoglobins or hematocrits may change depending on advances in knowledge and technology. We suggest the reference to erythropoietin and specific numbers be omitted.
                    ii. The Forum agrees the Secretary should approve the hemoglobin and hematocrit

standards as currently included in the rules, subject to future review and updates. But they should not be specified in the rules.

4. Rehabilitation Status
    a. The Forum recommends the addition of "developmental needs" to the phrase concerning "educational needs of pediatric patients." Appreciating a child's developmental status is integral to developing a pediatric rehabilitation program.
    b. The Forum recommends inclusion of functional status (by any vetted tool, such as the Karnofsky Scale), as an important part of a rehabilitation plan.

ii. Implementation
    1. The Forum suggests the statement "Must be signed by the patient or the patient's designee" be amended to allow a patient or designee to refuse to sign, without detriment to the facility or physician, provided the refusal is documented.

4. Quality Assessment and Performance Improvement Program
    a. The Forum recommends that specific elements, such as adequacy of dialysis, be omitted from inclusion in the QAPI program. While the Forum recognizes that these elements of performance are important now, they may not be in the future. Instead, we recommend "The Secretary approve the current, evidence based elements of quality assessment and performance improvement as recommended by an appropriate voluntary consensus organization." The Forum agrees that the elements as listed in the rule are appropriate currently, but they should not be codified.

Administration

1. Medical Director
    a. The Forum recommends the standard for the medical director include, in addition to nephrology training and 12 months experience, participation in a dialysis facility quality assessment and performance improvement program. We hope that this inclusion will stimulate training programs to teach quality assessment and performance improvement.
    b. We suggest rules that empower the medical director to improve substandard performance of attending nephrologists. The rules should include referral to Medical Review Board peer review, State Agency, or State Medical Society. We further recommend a rule requiring the Governing Body to develop specific policy and procedures, including due process, governing medical director oversight of attending nephrologist performance. We believe the benefits and risks of "empowered oversight" justifies written policy and procedures.
2. Governance

a. The Forum suggests a rule requiring the Governing body to "train" the Medical Director, making Medical Director responsibilities explicit.

3. Patient Care Technicians
   a. The Forum suggests replacing "patient sensitivity training and care of difficult patients" with "conflict management and patient centered care."
   b. P 287 (5) (ii) The Forum recommends replacing "interpersonal skills" with "conflict management and patient centered care."
4. Discharge and transfer policies and procedures.
   a. The Forum suggests following the statement "The medical director ensures that no patient is discharged or transferred from the facility unless …" including "The patient requests or initiates transfer" in the list of exceptions.
   b. The Forum recommends adding "by direct contact with the other facility" to the statement "Attempts to place the patient in another facility and documents that effort;"
5. Condition: Relationship with ESRD network.
   a. The Forum suggests expanding requirements beyond Network scope of work, unless the scope of work includes explicit reference to local projects, for example local continuous quality improvement projects.

Response to solicited comments

1 To require minimum threshold values for the patient plan of care
   - The Forum believes requiring minimum values for individual patient care increases the risk of cherry picking and patient-provider conflict. Furthermore, the Forum believes achieving minimal values for individual patients is not entirely actionable by the facility or physician. Absent an electronic medical record, data collection for individual patients would be unduly burdensome. Finally, the Forum suggests minimum values for patient care must be kept current with best evidence and therefore should not be codified.

2 An outcome-based requirement for social services in the patient plan of care.
   - The Forum recommends functional status assessment of individual patients as a desirable outcome. Functional status helps the team develop a realistic rehabilitation program. Changing functional status correlates with survival and hospitalization rates.

3 Comment on the coordination of the transplant process and the method and frequency of communication with the transplantation center.
   - The Forum recommends the coordination requirements be consistent with performance measures developed by Network # 10 and its Technical Expert Panel.

4 Comments on the feasibility of using commonly agreed-upon clinical standards in our requirements and enforcement efforts.
   - As noted above, the Forum emphatically recommends:
     i. Defining the term "standards" as "current, evidence-based, community-accepted minimal requirements."

ii. Avoiding direct extrapolation of standards from existing guideline statements (for example, K/DOQI) until voluntary consensus organizations carefully determine the evidence linking the statement to the desired outcome, the community-accepted minimal standard, and the appropriate threshold for intervention.

5 Comments on methods for using current NKF-K/DOQI clinical practice guidelines as facility-wide measures. For example, comments on the use of the statistically based threshold measures of performance would be especially helpful. Under such an approach, facilities in which a predetermined portion of patients fail to meet the selected clinical standards over some period of time, using a standard deviation, percentile-based, or some other method, need to develop a corrective action plan (CAP).

- The Forum suggests any guideline statements must undergo extensive review by voluntary consensus organizations. These organizations should determine the strength of evidence linking the statement to a desired outcome, community consensus, and derivation of minimal requirements before developing measures and thresholds for intervention.
- The Forum suggests a focused review by the Medical Review Board, prior to a corrective action plan. The Medical Review Board should ascertain the presence or absence of reasonable exceptions (for example, a new center with few patients resulting in a small sample size) for the poor performance. In the absence of reasonable exceptions, the MRB should proceed with a corrective action plan.
- The Forum suggests the threshold for facilities triggering a focused review by the Medical Review Board be consistent with population studies. Population studies use below 2 standard deviations from the mean (for a normal distribution) or less than 2.5% (for an abnormal distribution). These thresholds are less arbitrary and more statistically sound than other percentile thresholds.

6 Comments on how the incentives to "cherry pick" could be minimized.

- We believe The Conditions must remove unintended incentives to "cherry pick" by ensuring a "level playing field" among facilities. These methods include: evidence based case mix adjustment; appropriate exclusion criteria; an adequate sample size; and, accurate attribution for the result. Accurate attribution can be calculated using a linear, generalized hierarchical statistical model.

Again, The Forum expresses its appreciation for the opportunity to express its opinions.

Sincerely,

Derrick Latos, MD, MACP
President, Forum Board of Directors

Submitter : Gyana Bays **Date:** 05/03/2005

Organization : St. Luke?s Hospital

Category : End-Stage Renal Disease Facility

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-3818-P-112-Attach-1.DOC

Attachment #112
May 3, 2005

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

Re: CMS-3818-P; Medicare Program; Conditions for Coverage of End Stage Renal Disease Facilities; Proposed Rule

To Whom It May Concern:

St. Luke's Hospital appreciates the opportunity to comment on the proposed rule regarding conditions for coverage of end stage renal disease (ESRD) facilities. As a safety net hospital for San Francisco, I can attest that the current system for reimbursement for ESRD patients does not meet the need of the population. Patients who are not appropriate for out-patient dialysis, due to other chronic disease or acute disease processes, are not allowed access to out patient centers because their clinical condition is too fragile for that setting. Without allowing bedside dialysis in SNF settings, the chronically ill are discriminated against and hospitals are requested to support a system that denies reimbursement to those who are at greatest risk.

Dialysis of ESRD Patients in Skilled Nursing Facilities
Our primary concern relates to the provisions regarding dialysis in skilled nursing facilities (SNFs). Over one-third of California hospitals operate hospital-based SNFs. These facilities play an important role in helping all hospitals manage their patient population by caring for stable, yet medically fragile, patients. We are seeing an increasing number of patients who have complex medical needs and require dialysis, but are otherwise stable.

These patients could be cared for by nursing facilities. Because of current Medicare coverage interpretations, however, these patients often remain in the hospital intensive care unit (ICU) needlessly. We appreciate the Centers for Medicare and Medicaid Services' (CMS) recognition of this problem as acknowledged in the proposed rule. Allowing SNF residents to access home dialysis, however, does not solve the problem. We urge CMS to revise its position and make it financially feasible for nursing facility patients to receive dialysis at the bedside from a dialysis facility or the SNF.

Data
CHA recently conducted a survey of its members to determine how nursing facilities are currently handling residents who require dialysis. Nearly 25% of California's 170 hospital-based SNFs responded to the survey. Of those responding, 40% had cared for a total of 266 patients who required dialysis over a one-year period. At the same time, an

even greater number of patients were turned away by responding facilities because the patients required dialysis.

Of the dialysis patients who were admitted to SNFs, 50% had a length of stay of 14 days or less. 80% had a length of stay of 30 days or less. 90% were on dialysis prior to admission to the SNF and 86% continued to require dialysis upon discharge. About half of them suffered from end stage renal disease (ESRD).

65% were 65 years and older; 92% were 50 years and older. Over 60% were on Medicare Part A stay in the SNF. Approximately 15% were dually eligible and a mere 5% were insured by Medicaid only.

38% of these patients fell into resource utilization groups (RUGs) RHC and RHB. 17% fell into SE3 and SE2. 19% were evenly spread across RUB, RVB, RMC, RMB, and SSA.

Half of the patients were discharged to home. 20% were discharged to another SNF and 20% were discharged to the hospital. *None of the patients received home dialysis.*

Provision of Home Dialysis to SNF Patients Is Inappropriate

Patients are Too Fragile for Home Dialysis

Nursing home patients who typically require dialysis are extremely fragile. The stability of their health status is precarious; it can change at a second's notice.

The home dialysis benefit, on the other hand, is designed for dialysis patients who are healthier and heartier than the average dialysis patient. Home dialysis is supposed to be self-administered by the dialysis patient.

These nursing home residents, in contrast, often have difficultly simply with sitting up in a dialysis chair for the duration of a treatment. They are in no condition to be engaged in, oversee, or in any way be responsible for their own dialysis treatment.

Dialysis is a complex medical procedure. It involves the cleansing of a person's blood, which is vital to every organ in the person's body. This process puts a person into disequilibrium. If that person's health is compromised in any other manner the dialysis process can trigger complex systems failures that require sophisticated knowledge to reverse. Thus, home dialysis should be reserved only for patients whose health is not otherwise compromised.

Home Dialysis is Problematic for Short Stay Patients

The proposed rule suggests that short-stay patients aren't eligible for home dialysis because the SNF is not their "home." While we believe that a SNF is at all times both a home *and* an institution for all residents – albeit temporary for some – we agree that home dialysis is impractical for short-stay patients.

The vast majority of nursing facility residents who require dialysis receive dialysis services both prior to and after their stay in the SNF. Their stay in the nursing facility is a short break – 30 days or less – in the midst of on-going dialysis treatment. Rarely, if ever, are these patients on home dialysis prior to or after the SNF stay.

As a result, these patients who are typically on chronic dialysis would have to switch to home dialysis and back again to chronic dialysis within a very short and unrealistic time frame. The current system cannot support demands for such quick benefit coverage decisions. Thus, patients' continuity of care would be jeopardized.

Conclusion
For the above-stated reasons, use of home dialysis in nursing homes is inappropriate for the vast majority of nursing home residents.

Bedside Dialysis Services Provided by Dialysis Facility or Nursing Facility Covered by Medicare Statute
Currently, the vast majority of nursing home patients requiring dialysis receive such services at an off-site dialysis clinic. This situation has significant drawbacks. First, it necessitates use of an ambulance – and Medicare resources – to transport the patient to and from the clinic. Second, being transported and sitting up in a dialysis chair are extremely taxing on residents whose health is already seriously compromised. Third, it requires the patient to be out of the nursing facility for a significant amount of time, which as acknowledged in the proposed rule increases the likelihood the patient will miss medication administration, treatment regimens, meals and planned activities. Fourth, because of the resident's medical fragility it is not uncommon for the resident to require accompaniment of a SNF nurse, which pulls resources away from other SNF residents.

We believe that Medicare should cover dialysis provided at the bedside in the nursing facility when provided by a dialysis facility or the nursing facility. Doing so would create a win-win situation. Nursing facility residents requiring dialysis would receive better care. Medicare would save ambulance costs. And many hospitalized dialysis patients would move sooner from the hospital to a lower level of care, thus providing for more effective and efficient use of our nation's limited healthcare resources.

We urge CMS to investigate more thoroughly the possibility of allowing patients to exercise the following options:

- The renal dialysis facility provides the services at the SNF and is paid the composite rate directly;

- The SNF provides the services and receives payment outside the prospective payment system (PPS) for Part A patients (i.e. services are exempt from consolidated billing); and

- The SNF provides the services, without separate ESRD licensure, for those beneficiaries who have exhausted Part A (i.e. develop separate conditions of

coverage requirements that would apply only to SNFs that already meet the SNF conditions of participation).

Not only do we believe these options are the right thing to do, we also believe that they are consistent with existing Medicare law. For residents on a Part A stay, the relevant provisions are Sections 1881(b)(1) and 1888(e)(2)(A)(i)(II).

> Section 1881(b)(1) states that " payments on behalf of such individuals [ESRD beneficiaries] to providers of services and renal dialysis facilities which meet such requirements as the Secretary shall by regulation prescribe for institutional dialysis services and supplies."

This references both providers of services, which SNFs are under the statute, and separately renal dialysis facilities. Thus, it appears that CMS is authorized to pay SNFs the composite rate under Part B. In addition, it seems that CMS has some flexibility under the statute to develop separate requirements for different provider types.

> Section 1888(e)(2)(A)(i)(II) stipulates that "covered skilled nursing facility services" includes: "all items and services (other than items and services described in clause (ii) and (iii)) for which payment may be made under Part B and which are furnished to an individual who is a resident of a skilled nursing facility during the period in which the individual is provided covered post-hospital extended care services".

Dialysis services (at least those that are paid with a "composite rate" – a per-episode capitated amount) are considered Part B services, and since they are not "described in clause (ii) and (iii)," they are not carved out of the SNF PPS bundle.

For residents who are *not* on a Part A stay, the relevant provisions are section 1861(s)(2)(F) and the "on the premises" requirement in the Code of Federal Regulation. Section 1861(s)(2)(F) – where dialysis is excluded from consolidated billing – references "institutional dialysis services" but does not define that term. Rather, the references lead back to Section 1881, which suggests through the separate mention of providers, that SNFs could also be included in the regulatory definition.

Although federal regulation references the requirement that dialysis services be provided "on the premises" of the dialysis provider, this requirement does not appear in statute. Thus, we believe CMS has the flexibility to alter this requirement through regulation as well.

Conclusion

For the above-stated reasons, we urge Medicare to make it financially feasible for SNF residents to receive dialysis services at the SNF, whether under a Part A stay or Non-Part A stay and whether performed by a dialysis provider or by the SNF.

Comments on Home Dialysis Proposed Rules

For the small handful of nursing home residents who might be able to benefit from home dialysis, CHA has the following comments.

Nursing Coverage

The proposed rule would require that a registered nurse (RN) be on the premises whenever in-center patients are being treated. This requirement would take the place of the current requirement that a licensed health professional experienced in rendering ESRD be on duty. We support the approach in the proposed rule. We believe that having an RN on the premises is appropriate with promoting good patient care in the nursing home setting.

Feedback was requested on whether CMS should address patient-to-caregiver ratios in the regulations. CHA is strongly opposed, however, to a one-size-fits-all approach to caregiver coverage. The number of caregivers needed to promote quality care varies with the particular circumstances in any given setting, including, but not limited to, the physical configuration of the facility, the experience and skill level of the particular caregivers involved, and the specific health needs of the patients at issue. It is appropriate for CMS to provide guidance with respect to staffing, but minimum levels or thresholds are inappropriate.

Monitoring

The proposed regulations provide that the ESRD facility should be responsible for the ESRD services provided, including assessing staff competency, reviewing data, monitoring care, monitoring the impact on other nursing home residents, monitoring the premises, monitoring supplies and equipment, maintaining medical records, and assuring residents rights are respected.

CHA supports holding the ESRD provider responsible for matters related to the dialysis treatment. The ESRD provider is the one with the dialysis expertise. Thus, they should be responsible for those matters within their expertise.

Competency

CMS also solicited input on the competency requirements that should be established for caregivers. We believe that competency training and testing should include the problems that can surface both during and after a dialysis treatment. Since these patients are physically compromised, it is critical that caregivers know the signs, symptoms and treatment for complications that could arise during dialysis.

Patient Choice

CHA requests clarification on whether nursing facilities that have residents on home dialysis can limit the dialysis provider or the durable medical equipment (DME) provider the resident uses. Can the SNF prevent the resident from opting Methold II? Can the SNF limit the dialysis providers from which the resident may choose? Can the SNF limit the patient's options to providers with which the nursing facility has a contractual relationship?

Summary
The number of patients who require dialysis, but could otherwise be cared for in a nursing facility, are increasing. Home dialysis is inappropriate for the vast majority of nursing home residents because of their medical fragility. We urge CMS to interpret existing law in such manner as to make it financially feasible for SNF residents to receive dialysis services from dialysis providers or SNFs while at the bedside.

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Sincerely,

Gyana Bays
Director, Case Management
St. Luke's Hospital
3555 Cesar Chavez St.
San Francisco, CA 94110

Submitter : Ms. Jenny Ng **Date:** 05/03/2005

Organization : Sunnybrook & Women's College Health Sciences Centr

Category : End-Stage Renal Disease Facility

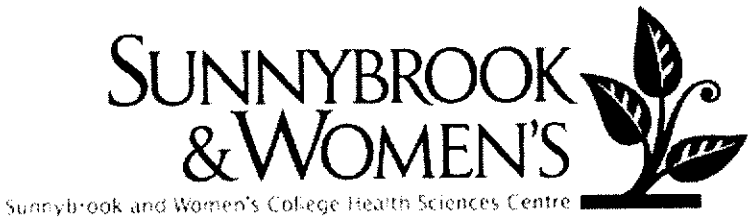
Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-113-Attach-1.DOC



Attachment #113
May 3, 2005

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

Dear Dr. McClellan:

We are writing to offer comments regarding the proposed revisions to the Conditions for Coverage for End Stage Renal Disease Facilities. Specifically we wish to comment on Proposed § 494.140 ("Personnel Qualifications") as this section addresses the possible role of a pharmacist within the dialysis facility. We appreciate that the Proposed Rule acknowledges the well-documented contributions a pharmacist can make to the safe and effective use of medications in vulnerable dialysis patient population.

Our CKD program at Sunnybrook & Women's Health Sciences Centre in Toronto, Canada presently supports 2.5 FTE clinical pharmacists dedicated to the care of our patients. Including clinical pharmacists as part of the multi-disciplinary team has been integral to providing quality care to our CKD patients.

Having a clinical pharmacist within our dialysis program has been **cost-effective** as demonstrated by:

- savings in medication costs of over $140,000 for the dialysis unit
- ensuring early stepdown of high costing IV medications to PO route when applicable
- optimizing medication coverage programs to minimize drug costs for the dialysis unit
- implementation of an influenza vaccination program which has been associated with a decrease in hospitalization
- development of protocols for cost-effective therapy to control drug costs (i.e. individualized heparin dosing program, guidelines for use of phosphate binders)
- individualized patient friendly glucose and blood pressure monitoring program to optimize patient outcomes

Our nephrology pharmacists have also **improved the quality of care** of CKD patients through:

- regular review of medications for patients on hemodialysis
- routine review of bloodwork to ensure efficacy and reduce toxicity of medications
- maintenance of electronic medication records to ensure that multi-disciplinary team has up to date information regarding the patient's medications
- development of an electronic medication schedule to improve adherence to therapy
- facilitating seamless care between inpatient and outpatient programs
- being a medication information resource for both the patient and the multi-disciplinary team

We strongly believe that consultant pharmacists should be included as part of the dialysis facility staff due to the complex nature of drug therapy in dialysis patients, the pharmacokinetic complexity of drugs during dialysis and the need for cost-effective drug therapy.

Specifically, I would like to make the following recommendations:

1. The multidisciplinary dialysis team should include a consultant pharmacist with experience or training in nephrology pharmacy.
2. The routine patient care assessment of dialysis patients should include a medication review by a pharmacist.
3. Pharmacists should participate in the development and implementation of medication-related protocols within dialysis to assure cost-effective drug use.
4. Dialysis facilities should develop and maintain appropriate policies for the safe storage, preparation and administration of medications within the facility. These policies should be developed and maintained in consultation with a pharmacist.

We hope that you will take into consideration our suggestions make you make your review of having a pharmacist in the dialysis unit.

Sincerely Yours,

Matthew Oliver, MHS FRCPC MD
Director of Dialysis

Andrea Fox, BSPhm
Clinical Nephrology Pharmacist

Jenny Ng, BScPhm ACPR
Clinical Nephrology Pharmacist

Submitter : Ms. Theresa Kwechin **Date:** 05/03/2005

Organization : Ms. Theresa Kwechin

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

May 2, 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

Issues 1-10

Compliance with Laws and Regulations

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.

Infection Control

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.

Physical Environment

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.

Water Quality

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.

Patients' Rights

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.

Basis

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.

Plan of Care

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.

Care at Home

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.

Definitions

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.

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Governance

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.

Personnel Qualifications

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.

Responsibilities of the Medical Director

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

ESRD Network

C. Relationship with ESRD Network (494.160)
No comment.

Special Purpose Renal Dialysis Facilities

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.

Laboratory Services

G. Laboratory Services (Proposed 494.130)

I agree to retain the existing requirements.

Medical Records

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.

QAPI

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.

CMS-3818-P-114-Attach-1.DOC

CMS-3818-P-114-Attach-2.DOC

Attachment #114
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.

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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)
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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.

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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.

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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.

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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 : Mrs. Gail Nylin **Date:** 05/03/2005

Organization : DaVita

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

I support the CNSW Comment on Conditions for Coverage for End Stage Renal Disease Facilities File code CMS-3818-P in its entirety.

Submitter : Mr. Jorge Morales **Date:** 05/03/2005

Organization : Mr. Jorge Morales

Category : Social Worker

Issue Areas/Comments

Issues 11-20

Personnel Qualifications

494.180(b)(1) This comment is regarding staffing ratios based on the acuity of patients for social workers employed in outpatient dialysis centers. Please be advised that, social workers in a pediatric dialysis setting often face very unique and time sensitive challenges what other social workers in an adult setting may not face. Some of these challenges include coordination of the plan of care through Child Protective Services (CPS) and the school systems. CPS is not a system that often works well with a medical setting due to the limited understanding of case workers assigned to medically complex and needy pediatric patients. In addition, monitoring the potential burnout of pediatric patients primary caregiver are of vital importance. Pediatric patients cannot afford to lose their primary support. Pediatric social workers must often be the voice for infants and children that are unable to care for themselves or make their needs known. Pediatric dialysis social workers must identify and address caregiver burnout and provide counseling on an ongoing basis to prevent burnout. In addition, extensive family education to ensure a good understanding of a child's disease process as well as training and education of multiple caregivers is also a challenge faced by pediatric social workers.

Home visits are paramount in the investigation of and removing of barriers to good quality dialysis as well as proper and safe care of the pediatric patient. Coordination with school and school RN, education of school staff and peers are very important processes that need to take place in order to facilitate a good adjustment to illness. Coordination of other sources of support such as dialysis and transplant camps and teen support groups, engage children with others like themselves. This is an important endeavor that helps children identify with their disease, observe the outcomes of good self care and must not be overlooked. ESRD is a life long condition for infants and children who have not been given a chance to live. Children would benefit from every supportive resource available to them as well as extensive vocational education. Children must be taught how to incorporate ESRD into their lives. A 100 to 1 ratio of pediatric dialysis patients to social workers is not in the best interest of the children or their future. Acuity ratios, if adopted, must take into consideration the extensive psychosocial, educational and vocational needs of the pediatric patient.

Submitter : Mrs. Shahin Rostami **Date:** 05/03/2005

Organization : St Joseph Hospital Renal Center

Category : Dietitian/Nutritionist

Issue Areas/Comments

GENERAL

GENERAL

The Initial nutrition assessment in 20 calendar days is not practical. I have a new pt who came to dialysis one time and then hospitalized. He has been in hospital for 3 weeks.
I suggest you change the deadline for initial nutrition assessment to within 13 dialysis sessions rather than 20 days.
Respectfuly,
Shahin Rostami, MS,RD,CNSD

Submitter : Mrs. Janice Kendrick, MS, RD **Date:** 05/03/2005

Organization : St. Joseph Hospital Renal Center

Category : Dietitian/Nutritionist

Issue Areas/Comments

Issues 1-10

Compliance with Laws and Regulations

Regarding the proposed condition of coverage for the initial nutrition assessment to be completed within 20 calender days for a dialysis patient, I disagree with this - the time frame is too short. Example: patients are frequently unstable upon initiation of dialysis requiring hospitalization. The patient may be admitted more than 20 days preventing the dietitian from completing the assessment as required. I think the current regulation for Nutrition Assessment to be completed within 30 days or 13 dialysis treatments is more feasible.

Submitter : Mrs. lubna akbany **Date:** 05/03/2005

Organization : St.Joseph Hospital

Category : Dietitian/Nutritionist

Issue Areas/Comments

Issues 1-10

Compliance with Laws and Regulations

This comment is regarding proposed condition of coverage: Nutritional assesment to be completed within 20 calender days.I disagree with this proposal as when the patient is admitted for dialysis often times is unstable requiring multiple hospitalization making it difficult for the dietitian to complete assesments in a timely manner.
It would be beneficial if the current regulation of 30 days or 13 treatements does not change.
Thank You

Submitter : Ms. Enid Myers **Date:** 05/03/2005

Organization : Renal Care Group-Rogers Park

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-3818-P-120-Attach-1.DOC

CMS-3818-P-120-Attach-2.DOC

Attch # 120

Issue Identifier	Enid M. Myers, LCSW
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/05-1622.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 language and communication barriers" ***Rationale***: Healthcare settings are covered entities under the Americans with Disabilities Act. ***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. 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:*** 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 treatments 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 treatment modalities

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	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.

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	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."

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	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

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	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:*** 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.

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	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:*** 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;

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	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

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	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.
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: Transplantation referral tracking	***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 transplant centers and their responsibilities for following up and informing dialysis units of the transplant status of patients referred for transplant.

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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

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	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
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

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	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

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	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: • 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

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	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, 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.

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	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. 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

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	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***: We agree with the preamble that dialysis patients need essential social services

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	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 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

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	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 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

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	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:*** CNSW agrees that all employees must have an opportunity for continuing education and related development activities.
§**494.180 Condition** Governance. (b5) Standard.	***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'

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Adequate number of qualified and trained staff.	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.

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Submitter : **Ms. Andrea Davis** **Date: 05/03/2005**

Organization : **Yorkville dialysis- beth Israel medical Center**

Category : **Dietitian/Nutritionist**

Issue Areas/Comments

GENERAL

GENERAL

494.80

Propose: 1) Initial contact note within 7 days of new admission
2)Comprehensive Nutritition Assessment within 30 days, of which the criteria and the Assessment form is devised and approved by the form commitee of the institution. Strongly disagree with the proposed idea of a 3 month reassement 3)Monthly nutrition notes will address on going issues related to nutritional status, there by eliminating the need for designating a time frame for reassessment.4)It is not clear regarding team approach of comprehensive initial assessment(group form VS currently each discipline has their own initial assessment). 5)CARE PLANS:Recommend initial care plan within a month of new Admission and short term every 6 months, and long term annually.

494.90(a)(2):

Nutritional status:parameters for malnutrition should include low SA, also pre albumin and low cholesterol (<140). Low cholesterol has been often overlooked lately & has been associalted with increased risk of depression, suicide, cancer and well known malnutrtion.

Submitter : **Date: 05/03/2005**

Organization :

Category : **Dietitian/Nutritionist**

Issue Areas/Comments

Issues 1-10

Plan of Care

I am writing in response to the proposed changes for the plan of care of Hemodialysis(HD) patients. I am a Dietitian that covers 3 dialysis units. Two of these units are located opposite directions of each other, both 60 miles from my base unit, also my office. Currently if a new patients initates HD after my last monthly visit, I contact them by phone and complete a portion of their initial assesment (such as usual body wt, diet recall, living and shopping situation, GI problems). I am also able to provide preliminary verbal diet guidelines then mail/fax written guidelines and follow up by phone until I can see them at my next monthly visit.At the next unit visit I am able to complete the comprehensive assessment after assessing them in person using SGA guidlines and current lab results and then 'fine tune' their renal diet guidelines and provide additional written info. I am able to complete the assessments and plan of care within the current 30 day guidelines. By changing the assessments to 20 days of initiation, it will require additional visits to these units, some of these visits would end up being the week prior to the week of lab draw and visits with the rest of the units. This would also mean that writing up the care plan would require an additional visit the week after the visit for lab results. Depending on the initiation date, I would be making a visit to the unit weekly.I don't believe that this proposed change would improve patient care. I believe it will only add additional stress to an already understaffed population(dialysis RNs, PCTs, RDs) leading to less than adequate assessments of needs for new and longstanding HD pts as well as an increase in time for reviewing labs with patients. Both potentially resulting in a decline in nutritional status and management of bone disease(CaxP, PTH). In addition, it would add additional financial strain to cover the cost of mileage and RD time for these frequent visits. Thank you

Submitter : **Mrs. Chhaya Patel** **Date: 05/03/2005**

Organization : **Davita walnut Creek**

Category : **Dietitian/Nutritionist**

Issue Areas/Comments

GENERAL

GENERAL

CMS suggested guidelines for dietitian documentation for Initial assessment with in 20 days and careplan documentation with in 10 days after that is difficult due to doctors scheduling monthly chart reviews on certain weeks of the month. I have 20+ years of experience as Reanl dietitian, and would like to suggest keeping Initial assessment within 30 days or 13 treatments with monthly progress note. This would help to eliminate need for 3 months assessment, since pts are assessed for their diet and labs on monthly basis. Thank you for providing us with comment period on this issue.

I appreciate the recommendation for RD requirement with one year of clinical experience for ESRD.

Submitter : **Ms. Sujata Patel** **Date: 05/03/2005**

Organization : **Yorkville dialysis- Beth Israel Medical Center**

Category : **Dietitian/Nutritionist**

Issue Areas/Comments

GENERAL

GENERAL

494.80
Propose: 1) Initial contact note within 7 days of new admission
2)Comprehensive Nutritition Assessment within 30 days, of which the criteria and the Assessment form is devised and approved by the form commitee of the institution. Strongly disagree with the proposed idea of a 3 month reassement 3)Monthly nutrition notes will address on going issues related to nutritional status, there by eliminating the need for designating a time frame for reassessment.4)It is not clear regarding team approach of comprehensive initial assessment(group form VS currently each discipline has their own initial assessment). 5)CARE PLANS:Recommend initial care plan within a month of new Admission and short term every 6 months, and long term annually.

494.90(a)(2):
Nutritional status:parameters for malnutrition should include low SA, also pre albumin and low cholesterol (<140). Low cholesterol has been often overlooked lately & has been associalted with increased risk of depression, suicide, cancer and well known malnutrtion.

Issues 11-20

Personnel Qualifications

405.2102:
Suggesting clarification for eligibility:
1) Must be RD with atleast one year of clinical experience.

Submitter : Ms. Donna Maynes **Date:** 05/04/2005

Organization : Davita, Inc.

Category : Dietitian/Nutritionist

Issue Areas/Comments

GENERAL

GENERAL

There are times when a new patient starts treatment - and may have only one treatment because they put off dialysis due to fear until they were in a very precarious physical condition - and were then hospitalized after the first treatment for more than a month. I have had patients start treatment and then go on vacation, requesting treatment where they are vacationing and be gone for two months. Both of these conditions happen in units. These situations would make it impossible for a 20 day requirement on an initial assessment to be complied with.

Often patients are so stressed on the first dialysis treatment the only course you have is to introduce yourself, give them reading materials on the renal diet, and plan to talk with them at their second treatment.

A few patients are so angry at the diagnosis of kidney failure and the fact they will need dialysis they don't even want to talk with staff. They may be withdrawn or exhibit behavioral problems. This type of patient may even be verbally abusive to staff. We need, at this point, to only speak of basics related to diet and dialysis and give the patient time to adjust to the diagnosis and need for treatment otherwise we have a very angry, uncooperative patient who won't listen at all, then or later.

There are other situations that arise which prevent a 20 day assessment requirement but most can be accomplished within 30 days. The exception would be hospitalized or vacationing patients,or patients who leave after one treatment believing that they are being lied to by 'the nurses and doctors' and don't need dialysis at all. I have seen patients disappear for more than two months until they are hospitalized because of worsening renal failure, shortness of breath, inability to sleep, and other symptoms that become worse to them than the thought of dialysis.

The point is, that we have to deal with real life situations: with fear, anger, resentment against healthy staff, illness and stress. Many patients do not even remember what we have talked about at the first treatment and it will need to be repeated at a later time. Patients can be so uremic that they 'see' people who aren't there, have problems talking, or may not be able to communicate understandably.

Also, being diagnosed with Chronic Renal Failure and ESRD is a major shock and people react differently in such a situation. A 30 day requirement would be more realistic, however, there should be some allowances for hospitalization and other absences. I have had patients come out of the hospital, have one treatment, and go immediately back into the hospital. There should be some flexibility when you are dealing with human emotions like fear, anger, resentment, and worry or absences from after the first one or two treatments. Thank you for the opportunity to comment.

Submitter : Dr. John Sadler **Date:** 05/04/2005

Organization : Independent Dia;ysis Foundation

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

Submitter : Dr. Loriann DeMartini **Date:** 05/04/2005

Organization : Department of Health Services

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-3818-P-127-Attach-1.DOC

State of California—Health and Human Services Agency
Department of Health Services

California
Department of
Health Services

SANDRA SHEWRY
Director

ARNOLD SCHWARZENEGGER
Governor

Attachment #127
May 3, 2005

Centers for Medicare & Medicaid
Federal Register – February 4, 2005
Notice of Proposed Rule Making
Conditions for Coverage End Stage Renal Disease Facilities
CMS – 3818 – P

To Whom It May Concern:

My comments are directed at the request posed on page 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."

I would strongly recommend that CMS consider adding a Condition of Coverage for Pharmaceutical Services for several reasons

- Average use of medications by ESRD patients if 40% greater than residents in Long Term Care (LTC) Facilities (12 compared to 7 medications/day). Each LTC resident has their drug regimen reviewed by a pharmacist on a monthly basis. The pharmacist is expected to note any and all irregularities and report them to the director of nursing and attending physician (42CFR 483.60 c(1) (2)) with the intent of promoting quality pharmaceutical care

- Use of eight or more medications is associated with 100% chance of an Adverse Drug Reaction and/or drug interaction

- Use of medications in the ESRD patient is further complicated by not only the shear number of medications but also by the complexities associated with drug-dialysis, drug-drug interactions and renal dosing considerations.

Currently the proposal for a medication history on each patient falls short of promoting quality pharmaceutical care as it denies the natural dynamic process of the patient's disease process and changes to medication regimen.

Pharmaceutical Care is defined by American Society of Health-Systems Pharmacist (ASHP) as the direct, responsible provision of medication-related care for the purpose of achieving definite outcomes that improve a patient's quality of life.

Pharmaceutical care involves not only medication therapy (the actual provision of medication) but also decisions about medication use for individual patients. As appropriate, this includes decisions not to use medication therapy as well as judgments about medication selection, dosages, routes and methods of administration, medication therapy monitoring, and the provision of medication-related information and counseling to individual patients.

The pharmacist contributes unique knowledge and skills to ensure optimal outcomes from the use of medications. The pharmacist cooperates directly with other professionals and the patient in designing, implementing, and monitoring a therapeutic plan intended to produce definite therapeutic outcomes.

In addition, the recent release of the Consensus Report, Safe Practices for Better Healthcare: Summary prepared by the National Quality Forum (NQF) supports the following pharmaceutical practices;

- Pharmacists should actively participate in the medication-use process, including, at a minimum, being available for consultation with prescribers on medication ordering, interpretation and review of medications, preparation of medications, dispensing of medications, and administration and monitoring of medications.
- Standardize the methods for labeling, packaging, and storing medications
- Identify all "high alert" drugs
- Dispense medications in unit-dose or, when appropriate, unit of use form, whenever possible.
- Keep workspaces where medications are prepared clean, orderly, well lit, and free of clutter, distraction, and noise.
- Source found at http://www.ahrq.gov/qual/nqfpract.htm

I would encourage CMS to add a Condition of Coverage for Pharmaceutical Services to include but not limited to the following requirements

- Must have pharmaceutical services that meet the needs of the patients. *[Recommend definition to include provision of routine and emergency medications and policies and procedures that assure the accurate ordering, receiving, dispensing, administering, use and monitoring of all medications]*

- The facility is responsible for developing policies and procedures that minimize medication errors and adverse drug reactions.

- The facility must employ a licensed pharmacist who provides consultation on all aspects of the provision of pharmaceutical services in the facility.

- The medication regimen of each patient must be reviewed at least once a month by a licensed pharmacist.

- The pharmacist must report any irregularities and/or medication related problems to the attending physician and director of nursing and these reports must be acted upon.

- In order to provide patient safety, medications must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law

- Medication storage is administered in accordance with accepted standards of practice.

- Current and accurate records must be kept on receipt and disposition of all scheduled medications.

- Outdated, mislabeled, or otherwise unusable medications must not be available for patient use.

An ESRD Condition of Coverage for Pharmaceutical Services is consistent with the expectation of other certified facilities such as hospitals, skilled nursing, ambulatory surgical centers and intermediate care for the mentally retarded. Additionally such a Condition of Coverage will provide a means to promote quality pharmaceutical care and nationally endorsed safe practices.

Thank you for the opportunity to provide input.

Sincerely,

Loriann De Martini, Pharm. D.
Chief Pharmaceutical Consultant
California Department of Health Services
Licensing and Certification Program
916-552-8645
ldemarti@dhs.ca.gov

Submitter : Mrs. Susan Sutter **Date:** 05/04/2005

Organization : Marshland Pharmacies, Inc.

Category : Pharmacist

Issue Areas/Comments

Issues 11-20

Personnel Qualifications

I am writing to comment on the proposed revisions to the Conditions for Coverage for End Stage Renal Disease Facilities, in particular, Personnel Qualifications. This section recognizes the need for a pharmacist within a dialysis facility.

I am the co-owner of two rural community pharmacies in Wisconsin and typically have one or two patients at any one time receiving dialysis services at a dialysis facility in another larger community. As we have tried to work with these dialysis patients, it has become obvious that a pharmacist needs to interact with the patient?s physician and involved nurses at the dialysis facility where the complete medical record is available. Too often as their community pharmacists, we are making educated guesses or not aware at all of the facts necessary to assure appropriate drug therapy.

Medicare has long recognized the value of a consultant pharmacist in skilled care facilities. The dialysis patient usually has a more complicated drug regimen to manage than many of the long-term care patients in a skilled care facility. Pharmacists are uniquely educated and qualified to assure cost-effective drug therapy in these patients while adherence to clinical guidelines and protocols are being met.

The dialysis facility appears to be the one healthcare facility that due to the lack of a pharmacist involvement is at great risk for negative patient outcomes and wasted dollars due to the need for proper storage, preparation, and administration of medications. Again, pharmacists are uniquely educated to develop and maintain the appropriate policies for storage and preparation of medications within the dialysis unit.

As a community pharmacist serving these patients, I firmly believe that the necessity of a consultant pharmacist within a dialysis facility is needed and supported by literature to address the more complex needs of these patients and the facility.

Susan L. Sutter, R.Ph.
Marshland Pharmacies, Inc.
620 Washington Street
Horicon, WI 53032

Submitter : Dr. John Sadler **Date:** 05/04/2005

Organization : Independent Dialysis Foundation

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-3818-P-129-Attach-1.DOC

CMS-3818-P-129-Attach-2.DOC

Attachment #129
Comments on Conditions of Coverage to CMS:

John H. Sadler, M.D.

The Agency is commended for devising new conditions that are derived from prior regulations, not *de novo* criteria. The original conditions statement advised providers as to the standardized characteristics the Medicare program expected of all facilities, and contributed to consistency in establishment and practice. These current regulations will be primarily used as guidance for surveyors, and as such, must be clear and consistent, avoiding subjective statements which are subject to misinterpretation.

The Agency's emphasis on outcomes rather than prescriptive process measures is appreciated, but these conditions are still highly prescriptive. You are urged to reconsider some of the elements that specify how, rather than for what result, the facilities' practice are devised. The desired result is high quality patient care, not specific means of achieving that goal.

Please be aware that current Medicare rates do not cover the cost of dialysis, and any added requirement without additional funding will drive more independent operators to sell to the conglomerates. It is not in CMS best interest to have to deal with one or two sole proprietors of America's dialysis capability.

Specific comments:

405.2102 Definitions.

The "Network Organization" is defined in such a way as to be hard to distinguish from the Governing Body of facilities. Suggest " the liaison body between the federal government and the facilities in its region, functioning to assure quality and accurate reporting."

494.40 Water Quality.

(C) (ii) (D) Reverse osmosis is monitored by both rejection rate and by total dissolved solids or resistivity. All should be indicated as acceptable.

(c) Chloramine/chloramines.

(1) These units are essential where chloramines are used, but represent a needless, purposeless device where chloramines are not in use but water is regularly tested to exclude the possibility of encountering chloramine. Free chlorine is not a threat to dialysis patients. Carbon tanks should not be a blanket requirement.

(2) Testing should be carried out for each shift, but a shift routinely takes more than 4 hours, and there is no reason to test more frequently than before each shift.

494.60: Physical Environment.

(3) Emergency equipment and plans. These requirements are based on an idea, not on data that indicate the necessity for them. Since the defibrillator is another unfunded mandate to underfunded facilities, it should not be required for smaller facilities at least, and the need for them in other facilities treating stable outpatients should be reviewed. Forty years experience in chronic dialysis has not led me to find a need for such equipment. Please review the basis for any such requirement.

(3) (e) Standard: fire safety. Has there ever been a reported fire threatening patients in a dialysis facility? All clinicians want to protect patients and preserve their comfort, but these regulations are not designed for a therapeutic milieu in which a great deal of water circulates continuously and all people and equipment are continuously monitored. One size does not fit all. Application of standard building codes to dialysis facilities is not rational.

494.80 Condition: Patient Assessment.

(b) Frequency of assessment for new patients.

(1) A specified 20 day period for creating a record of assessment is tight. 30 days is reasonable.
(2) the 3 month follow up assessment is of uncertain utility as a general rule. It would be well to reconsider the concept of "short-term care plan" which is useful initially, but probably should be dropped after the initial long term care plan is established. Excess paperwork makes all paperwork less worthy of respect. The object of dialysis care is attending to patients, not creating more documents. Some documents are essential to permit oversight ant to communicate among clinicians, but all others should be limited to avoid wasting the staff time, which is in short supply in today's environment.

494.90 Condition: Patient plan of care.

(b) Implementation of plan of care.

(4) There is no question that patients should be seen by their physician during dialysis at least monthly, but with some remote facilities this is not possible, and some exception should be indicated for such special situations. For routine practice, reimbursement regulations assure contact.

494.140 Personnel Qualifications:

(3) (i) It is comforting to see that you recognize the merit of experienced practical nurses who perform at a high level. They deserve some specifications that protect them as they serve patients and colleagues.

494.170: Medical Records.

(3) (d) No mention is made of electronic medical records, which are increasingly important, even essential. Unless those records are noted in these Conditions, surveyors may not recognize them as satisfactory and secure.

Submitter : Ms. Roberta Lovely **Date:** 05/04/2005

Organization : St. Francis Medical Center

Category : End-Stage Renal Disease Facility

Issue Areas/Comments

Issues 1-10

Physical Environment

The use of AED's is supported but would provide an incentive for this and not assume hospital based units have them automatically. Suction machines should not be a required item as this is rarely needed. Preferance is the AED before a suction machine. Having suction machines also means more maintenance.

Submitter : **Ms. Roberta Lovely** **Date: 05/04/2005**

Organization : **St. Francis Medical Center**

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

Issue Areas/Comments

Issues 1-10

Care at Home

The section on dialysis in nursing facilities is burdensome for both the SNF and dialysis proveder. It lacks any financial incentive for either organization. The basic cost outweighs the fixed reimbursement.

Issues 11-20

Personnel Qualifications

Three months on the job trainig is proposed which would pose undue financial burden on the provider who provider. An 8 to 10 week period would be adequate/safe for this group of personnel. Individuals are hired from the start of training and another two weeks is costly. RN supervision is provided in an ongoing basis.

Submitter : **Date: 05/04/2005**

Organization :

Category : **Individual**

Issue Areas/Comments

Issues 1-10

Infection Control

Infection control should be strictly mandated according to CDC and other sources. Patients frequently get infections, become hospitalized and die.

Patients should be fully informed on how infections are acquired so they can be aware when there are violations by staff and be self-protective.

Submitter : Ms. Marlene S. De Vera **Date:** 05/04/2005

Organization : Ms. Marlene S. De Vera

Category : Individual

Issue Areas/Comments

Issues 1-10

Infection Control

Infection Control 494.30(b)(2) The proposed condition would designate a Registered Nurse to oversee the Infection Control. This would add significant load and responsibility for the nurses who assume more and more responsibilities in this critical time of nursing shortage. Since the Medical Director maintains responsibilities in all of the areas that impact infection control, I would ask that the tracking and trending of infections should remain a function of the QAPI process, under the direction of the Medical Director.

Physical Environment

Emergency Equipment and Plans 494.60 As a nurse, I understand the value of AED in cardiorespiratory arrest. I strongly recommend that there should be no exemption for any healthcare facility from the requirement for an AED.

Water Quality

Water Quality 494.40 (c)(2)I feel that Chloramine testing every four hours (without the addition of a 15-minute window) is adequate and appropriate. If the operational hours for the facility is constant, tracking of water quality should not be that difficult.

Plan of Care

Standard: Frequency of Assessment for New Patients 494.80 (b)(2)The proposed implementation of a second assessment performed on new patients at interval of three months appears to allow for a revision in the patient's plan of care after being stabilized. Depending upon the acuity of the patient's condition and vascular access on admission, three months might not be sufficient time for the patient to be stabilized on maintenance dialysis. I would like to suggest that a definition for stable patient be clearly stated, set and identified by the facility and that the second assessment be performed at that time.

Development of the Plan of Care 494.90(a) I would ask for some flexibility in the way adequacy requirement language is written. Regulatory language should allow for flexibility in the individualized care of patients including those who insist on early termination of treatment despite intervention of the entire multidisciplinary team.
Standard: Implementation of Patient Plan of Care 494.90(b)(4) It is apparent that patient outcomes and satisfaction are improved with regular patient-physician contact. It has, however, been my experience as a nurse and facility administrator that some physicians were unresponsive to the requests. Dialysis facilities should not be held accountable for physician behavior over which they have little or no control.

Patients' Rights

Advance Directives 494.70(a)(5) I applaud the inclusion of the patient's right to complete an advance health care directive in the proposed new set of patients' rights. I would like to recommend that the standard direct any ESRD facility to honor this directive; that if the facility is unable or unwilling to honor a fully executed directive, the facility should be required to notify and assist the patient in a timely referral and transfer of the patient to another facility that is willing to honor the directive.

Issues 11-20

Personnel Qualifications

Standard: Socail Worker 494.140(d) I would like to propose that the definition of a qualified social worker be "Holds a master's degree in social work from a school of social work accredited by the Council on Social Work Education. Please delete section (2) regarding meeting the requirements for social work practice in the state in which he or she is employed. Some states have been reticent to define the quaklifications that would cause the social worker to meet their definition of :Social Worker" as established by the Council on Social Work Education and since CMS has determined that definition to adequately describe a professional who can provide social services in the ESRD community, please delete the state involvement in defining social work qualifications.

Submitter : **Ms. Cynthia Dubansky** **Date: 05/04/2005**

Organization : **Ms. Cynthia Dubansky**

Category : **Social Worker**

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-3818-P-134-Attach-1.DOC

Attachment 134

Issue Identifier	Cynthia Dubansky – Comments on Conditions for Coverage for End Stage Renal Disease Facilities File code CMS–3818–P pg 1
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/05-1622.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 language and communication barriers" ***Rationale***: Healthcare settings are covered entities under the Americans with Disabilities Act. ***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. 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:*** 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 treatments 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 treatment modalities

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."
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."
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 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. ***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.
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: Transplantation referral tracking	***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 transplant centers and their responsibilities for following up and informing dialysis units of the transplant status of patients referred for transplant.

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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." ***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
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:

- 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, 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.

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***: 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 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, 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 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): • 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:*** CNSW agrees that all employees must have an opportunity for continuing education and related development activities.
§**494.180 Condition** Governance. (b5) Standard.	***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'

Issue Identifier	
Adequate number of qualified and trained staff.	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.

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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.

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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 : Karren Crouch **Date:** 05/04/2005

Organization : self

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-135-Attach-1.DOC

CMS-3818-P-135-Attach-2.DOC

Attachment #135
May 3, 2005

RE: CMS-3818-P
494.140 (d)

To Whom It May Concern:

I have been employed in the field of dialysis and kidney transplant since 1979. I have worked as a nephrology social worker for both dialysis and transplantation in a hospital based facility and in a for-profit dialysis facility, as a supervisor of nephrology social workers, as a pre-dialysis patient / family educator for a statewide program and as a nephrology social work consultant, who is currently functioning as a research assistant involved in interviewing dialysis patients about their knowledge and attitudes about transplant. I have been involved regionally, statewide and nationally in a multitude of nephrology related boards, committees and professional organizations, including serving as national president of the Council of Nephrology Social Workers. I have been involved in the development of three national clinical practice guidelines for chronic kidney disease, and I currently serve as editor of a national dialysis patient newspaper. I have presented and published both nationally and internationally over the past several decades. Because of these wide range of experiences, I believe that I am uniquely qualified to comment on the requirements for nephrology social work.

I have a witnessed what I perceive as an alarming change in the practice of not only nephrology social work but also in the entire field over the past 26 years. I do not believe that those on dialysis are receiving the type of care that is mandated by the current Federal register in most areas, although I will focus on my own field, that of nephrology social work. Very few social workers focus on the clinical functions that are mandated by the Federal Register. One only has to review the literature, attend a nephrology social work meeting or talk with most nephrology social workers engaged in the field to ascertain that this is factual. I think there are a variety of reasons for this, including lack of support for engaging in the social work clinical areas of practice by the administrators / headquarters of most dialysis clinics / companies. The typical social worker spends much of his / her time engaged in issues related to transportation and financial matters, both of which can be assumed by individuals with a high school education.

Because of this, I strongly support the proposed requirement for social work qualifications and job functions, 494.140 (d). There is no doubt that those with chronic kidney disease are in need of all of the clinical services outlined in this portion of the proposed regulations, and that those with an MSW are uniquely educated to provide those services. They simply need to be allowed the opportunity to provide them by the administrators of their facilities and freed from being required to deal with issues for which their unique training is not needed. Also, social workers must be allowed caseload ratios that are conducive to them providing the outlined services. If social workers continue to be forced to deal with caseloads that they can not realistically provide

adequate services to, then it is unrealistic to assume they will provide the services that are outlined, regardless of how important they are.

I also strongly support the proposal to eliminate the grandfather clause for those individuals who were practicing as social workers prior to 1976. I know no one to whom that applies, and it has caused continual confusion among providers and surveyors for years.

I also anticipate that there will be many who voice concern over the requirement that an MSW provide care for dialysis and transplant patients. My belief is that these individuals are not attuned to the tremendous impact these individuals face psychologically, socially and financially. Nor are they aware of the unique training that MSWs receive that allow them to provide the full range of services these individuals require. I also believe that many of those who will object are simply focusing on the "bottom line", i.e. the financial interests of dialysis providers, although the MSW makes up very little of a facility's budget, rather than the best interest of dialysis and transplant patients.

Thank you for the consideration of my comments.

Sincerely,

Karren King, MSW, ACSW, LCSW

Submitter : Mr. Douglas Englebert **Date:** 05/04/2005

Organization : State of Wisconsin Dept Health and Family Service

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-136-Attach-1.DOC

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State of Wisconsin

Department of Health and Family Services

Attachment #136
May 4, 2005

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

Dear Dr. McClellan:

I am writing to offer comments regarding the proposed revisions to the Conditions for Coverage for End Stage Renal Disease Facilities. My comments are directed towards the pharmacist role addressed in the proposed section § 494.140 "Personnel Qualifications." I applaud the Centers for Medicare & Medicaid Services in acknowledging the value of a pharmacist in assuring medications for dialysis patients are used safely and effectively.

I am a pharmacist who works for the State of Wisconsin, Department of Health and Family Services, Bureau of Quality Assurance (BQA). The BQA is the State Survey Agency and is responsible for surveying nursing homes, hospitals, end stage renal disease facilities and other types of health care and community facilities. On a daily basis I work with surveyors who evaluate the health care provided to a vulnerable population. Unfortunately all too often we see negative outcomes specifically related to medications that could have been avoided. Based on my observations, I believe it is imperative that consultant pharmacists be included as part of the dialysis facility staff.

I believe the consultant pharmacist has an important role in dialysis facilities for the following reasons:

1) dialysis patients are at a high risk for adverse medication events,
   a) Dialysis patients frequently move from the outpatient dialysis center to the hospital or nursing homes with resultant changes in medication orders. Due to the medically unstable nature of dialysis patients, they experience frequent hospitalization and modification of drug therapy. The movement between the outpatient and inpatient environment is often associated with lack of communication about medication orders leading to a lack of continuity of care.
   b) CMS is currently supporting a patient safety special study to reduce and prevent errors in dialysis units. The contractor for this special study is examining several medication-related

topics for possible inclusion. One such topic is as follows, "Pharmacists should actively participate in the medication-use process, including, at a minimum, being available for consultation with prescribers on medication ordering, interpretation and review of medication orders, preparation of medication, dispensing of medications and administration and monitoring of medications."

2) medication therapy in dialysis patients is very complex requiring clinical and economical considerations,
   a) Dialysis patients frequently see many physicians and receive an average of 10-12 medications, many of which require multiple doses per day. Drug therapy for dialysis patients is complex, requiring many oral and injectable medications. Some medications require multiple doses per day. Non-adherence to therapy is common for various reasons. The inter- and intradialytic pharmacokinetics of medications are complex.
   b) Kidney disease often requires patient-specific medication dosing. Many drugs must be dosed specifically according to patient-specific parameters because the kidney plays such an important role in drug disposition. The effects of various dialysis techniques and dialysis membranes on drug clearance also must be considered when establishing drug therapy regimens.
   c) Most dialysis patients have multiple comorbid conditions that complicate their kidney disease and increase risk for adverse medication-related outcomes. Medication-related problems are well-documented in dialysis populations. Patients who require multiple medications for many comorbid conditions are at increased risk for drug-drug and drug-food interactions and drug toxicity as well as non-adherence. Adverse medication outcomes contribute to patient morbidity and to increased health care costs.

3) medication storage, preparation and administration affects patient outcomes,
   a) Dialysis units stock, prepare and administer medications at the time of dialysis. Many of these medications are considered to be high-alert medications due to the potential for medication error. The requirements of the dialysis process and the need for intravenous medications to be administered at the time of dialysis necessitate dialysis units to stock, prepare and administer medications. Some of these medications, such as heparin, insulin, and intravenous electrolytes (e.g. hypertonic saline and potassium chloride), are well known as high-alert medications. Pharmacists are well-trained for inventory supervision, oversight of medication sterile medication preparation, documentation of medication administration, and reduction of medication errors.
   b) The cost of the ESRD program is increasing and a significant portion of the rising cost can be attributed to the increased use of certain medications (erythropoietin agents, new vitamin D analogs and intravenous iron products). Adequate reimbursement for these medications is important for financial stability of dialysis units. In 2005 under the Medicare Modernization Act, reimbursement for intravenous medications given in dialysis units and dialysis services significantly changed, which will impact the financial status of some dialysis units. Pharmacists are uniquely qualified to promote the cost-effective use of medications within dialysis units through protocol development and utilization. Pharmacists can also assist dialysis programs to ensure that they receive appropriate reimbursement under the new guidelines for medications administered in dialysis units.

4) pharmacists are trained and prepared to serve as consultants to dialysis facilities.

a) CMS is proposing a laboratory profile review as a required component of the dialysis patient's comprehensive patient assessment. Pharmacists are well-prepared to link medication use to laboratory monitoring for response or toxicity. Drug-laboratory and drug-disease interactions are an area of expertise for pharmacists. As such, pharmacists can bring a unique perspective to the proposed laboratory profile review.
b) Pharmacists are in a position to understand the pharmacoeconomics of medication use and comparative drug costs.

For these reasons I am offering the following recommendations:

1) The interdisciplinary team should include a consultant pharmacist with similar training and experience requirements in the area of nephrology as the other members of the team.
2) The routine patient assessment should include a medication review by a pharmacist.
3) Pharmacists should participate in the development and implementation of procedures to assure safe storage, preparation, administration and destruction of medications within the facility.
4) Pharmacists should participate in the development and implementation of practice guidelines or procedures to assure safe, effective and economical use of medications.

To support the following positions I have attached a detailed bibliography for your consideration.

In summary, the Institute of Medicine has fully documented over the past few years the problems that exist with medication use specifically related to adverse medication events. CMS in its wisdom over 30 years ago required a pharmacist review of medications and provision of consultative services to skilled nursing facilities. Recent proposed updates in the Guidance to Surveyors will improve the quality of those services in nursing homes. CMS also recognizes the value of a pharmacist in the Hospital Conditions of Participation as the scope of the pharmacist expected involvement has vastly expanded in the recent update to the guidance for surveyors. Home Health Conditions of Participation also recognize the value of medication regimen review within the requirements. Although the Home Health Conditions of Participation do not require a pharmacist to conduct a review studies conducted in home health agencies verify that a pharmacist conducted medication regimen review improves outcomes and saves money. The evidence is clear that pharmacist involvement as part of the interdisciplinary team positively affects patient outcomes. CMS in its wisdom should take advantage of the opportunity to require the pharmacist to be part of the interdisciplinary team in dialysis facilities to improve patient outcomes and decrease costs.

Sincerely,

Doug Englebert, R.Ph.
Pharmacy Practice Consultant

Bibliography

1. Conrad W, Sczupak, Forman H, et al. Consultant approach to improving drug-related services to chronic hemodialysis patients. Am J Hosp Pharm 1978; 35:558-561.

2. Stoutakis VA, Acchiardo SR, Martinez DR, Lorisch D, Wood GC: Role-effectiveness of the pharmacist in the treatment of hemodialysis patients. Am J Hosp Pharm 1978; 35: 62-65.
   These papers by Conrad and Stoutakis were among the first to demonstrate how pharmacists improved the medication use process within a hemodialysis unit.

3. Anderson RJ. Prescribing medication in dialysis centers. Am J Kidney Dis 1983; 3:104-105.
   Anderson was one of the earliest authors to describe the potential hazards associated with medication use by dialysis patients. He also reported on the large number of medications taken by these patients. This paper contains a call for improved approaches to medication use in the dialysis setting.

4. Mawhinney M, McMullan A, Mulgrew P. Pharmacy and the kidney patient. Health Service J 1989; 99:1006-1008.
   Mawhinney and colleagues described how a pharmacist became involved in a peritoneal dialysis program. These efforts resulted in improved patient care as well as economic savings.

5. St. Peter WL. Clinical pharmacy nephrology consultation and documentation: a comprehensive approach. J Pharm Pract 1993; 6:140-147
   St. Peter described the development of nephrology pharmacy consultative services at Hennepin County Medical Center in Minneapolis. The author discussed the nature of pharmacist activities, documentation of services provided, and issues relating to reimbursement for services within that center.

6. Norwood CE, Pahre SN. Clinical pharmacy nephrology practice in the outpatient dialysis center. J Pharm Pract 1993; 6:133-139.
   These authors describe the justification, origins and nature of a pharmacy nephrology service at St. Joseph Hospital and Health Care Center in Tacoma, WA.

7. Tang I, Vrahnos D, Hatoum H, et al. Effectiveness of clinical pharmacist interventions in a hemodialysis unit. Clin Ther 1993; 15:459-464.
   Tang, et al described how pharmacists provided therapeutic interventions within a hemodialysis unit. These interventions were well accepted and demonstrated their potential value in improving drug therapy.

8. Kaplan B, Mason NA, Shimp LA, et al. Chronic hemodialysis patients. Part 1: Characterization and drug-related problems. Ann Pharmacother 1994; 28:316-319.

9. Kaplan B, Shimp LA, Mason NA, et al. Chronic hemodialysis patients. Part II: Reducing drug-related problems through application of the focused drug therapy review program. Ann Pharmacother 1994; 28:320-324.

Kaplan, et al wrote two papers that describe drug-related problems within a hemodialysis unit. Pharmacists identified the problems and were able to reduce their occurrence by the application of a focused drug therapy review program. (Note: Reference #8 is cited by CMS in the proposed revisions to the Conditions of Coverage.)

10. Veivia AJ, Bailie GR, Eisele G. Hemodialysis patients' knowledge about erythropoietin and iron therapy. Dial Transplant 1995; 24:21-30.

Provision of written information by pharmacists was shown to improve patients' knowledge deficit about their treatment.

11. Grabe DW, Low CL, Bailie GR, et al. Evaluation of drug-related problems in an outpatient hemodialysis unit and the impact of a clinical pharmacist. Clin Nephrol 1997; 47:117-121.

Grabe, et al also documented the occurrence of drug-related problems within a hemodialysis unit. Pharmacist interventions were significant and contributed to improved patient care.

12. Pahre S. Nephrology pharmacy practice in the outpatient dialysis setting. Adv Ren Replace Ther 1997; 4:179-181.

13. Long JM, Kee CC, Graham, MV, et al. Medication compliance and the older hemodialysis patient. ANNA Journal; 1998; 25:43-49

14. Grabe DW, Baile GR, Eisele G, et al. Hemodialysis patients' knowledge about their phosphate binder therapy. J Appl Ther Res 1998; 2:125-132.

This is an early study assessing one aspect of drug-related problems. It indicated that patient understanding of therapy was poor, but that it could be rectified by education.

15. Lau AH, Bailie GR, Matzke GR. The practice of nephrology pharmacy: results of a North American survey. J Appl Ther Res 1998; 2:91-100.

In 1998, only 110 pharmacists were identified as being actively involved with nephrology patients.

16. Curtin RB, Svarstad BL, Keller TH. Hemodialysis patients' noncompliance with oral medications. ANNA Journal 1999; 26:307-316.

The papers by Long, et al and Curtin, et al, document the widespread lack of medication adherence within the hemodialysis population. Older patients are particularly prone to non-adherence. The authors discuss strategies for intervention that may improve medication-taking behaviors.

17. Possidente CJ, Bailie GR, Hood VL. Disruptions in drug therapy in long-term dialysis patients who require hospitalization. Am J Health Syst Pharm 1999; 56:1961-1964.

Possidente, et al discussed an important issue that arises whenever a dialysis patient is admitted to the hospital. Drug orders are commonly disrupted upon admission and

upon discharge. Lack of communication between the chronic dialysis unit and the hospital often may lead to errors in medication use and to less than desirable patient outcomes. A pharmacist who became involved in this problem was a valuable contributor to reducing medication disruptions.

18. Mason NA, St Peter WM, Johnson CA, et al. Trainees' activities and experiences after a clinical pharmacy dialysis traineeship. Am J Health-Syst Pharm 1999; 56:1623-1626.
This report describes the positive effects of a structured training program to prepare pharmacists to provide services to dialysis units.

19. Matzke GR, St Peter WL, Comstock TJ, et al. Nephrology pharmaceutical care preceptorship: a programmatic and clinical outcomes assessment. Ann Pharmacother 2000: 34:593-599.
These authors also report on a structured training program that provided skills to pharmacists in order to serve the needs of dialysis patients and program.

20. Chisholm MA, Vollenweider LJ, Mulloy LL, et al. Direct patient care services provided by a pharmacist on a multidisciplinary renal transplant team. Am J Health-Syst Pharm 2000; 57:1994-1996.

21. Joy MS, Neyhart CD, Dooley MA. A multidisciplinary renal clinic for corticosteroid-induced bone disease. Pharmacotherapy 2000; 20:206-216.

22. Manley HJ, Bailie GR, Neumann MA. Antibiogram development for an outpatient dialysis center. Hospital Pharm 2000; 35: 251-253.
The authors developed an antibiogram and determined the susceptibility of various organisms to cefazolin, gentamicin, and vancomycin. Data indicated that cefazolin alone or in combination was appropriate in this outpatient setting. Local antibiograms may enable limitations in the use of vancomycin.

23. Dahl NV. Herbs and supplements in dialysis patients: Panacea or poison? Semin Dial 2001; 14:186-192.

24. Roehmeld-Hamm B, Dahl NV. Herbs, menopause and dialysis. Semin Dial 2002; 15:53-59.
Natural product therapies are becoming more widely used by dialysis patients. Unfortunately, little is known regarding their efficacy and toxicity, especially when used by patients with kidney disease. Dahl has written these articles to assist nephrology clinicians to understand the value of these therapies.

25. To LL, Stoner CP, Stolley SN, et al. Effectiveness of a pharmacist-implemented anemia management protocol in an outpatient hemodialysis unit. Am J Health-Syst Pharm 2001; 58:2061-2065.
These authors described the results of a study conducted in a Veterans Affairs dialysis unit in which a pharmacist managed the anemia protocol. The results showed that the pharmacist was as effective as the physician in managing anemia.

26. Johnson CA, McCarthy J, Bailie GR, et al. Analysis of renal bone disease treatment in dialysis patients. Am J Kidney Dis 2002; 39:1270-1277.

Johnson and colleagues reported the results of a Network 11 quality improvement activity to improve treatment of renal osteodystrophy. A model treatment protocol was developed and used to evaluate existing dialysis unit-specific protocols from throughout this five-state region. The results indicated much room for improvement in the treatment of this complication of kidney disease.

A second component of the Network 11 project was an assessment of bone disease-related medication use within dialysis units. The authors determined that greater efforts need to be made to manage hyperphosphatemia and hyperparathyroidism.

27. Manley HJ, Carroll CA. The clinical and economic impact of pharmaceutical care in end-stage renal disease patients. Semin Dial 2002; 15:45-49

The clinical and economic impact of pharmaceutical care in end-stage renal disease patients. End-stage renal disease (ESRD) patients are medically complex, require multiple medications for treatments of their various comorbidities, and cost the healthcare system billions of dollars each year. These patients are at risk of drug-related problems (DRPs) that may lead to increased morbidity, mortality, and cost to the healthcare system. Review of the literature demonstrates that pharmaceutical care provided by pharmacists improves ESRD patient care. Pharmacist review of ESRD patients' medication profiles and medical records has shown to be beneficial in identifying and resolving DRPs. Economic analysis suggests that for every $1 spent on pharmaceutical care, the healthcare system saves an estimated $3.98. Provision of pharmaceutical care by pharmacists should be considered for all ESRD patients.

28. Manley HJ, Huke MA, Dykstra MA, et al. Antibiotic prescribing evaluation in an outpatient hemodialysis clinic. J Pharm Technol 2002; 18:128-132.

The authors developed an antibiogram and measured physician prescribing of antibiotics. Data indicated that inappropriate choice of initial antibiotic occurred over 35% of the time. Areas of prescribing improvement were identified to improve antibiotic usage in the hemodialysis population.

29. Manley HJ, McClaran ML, Overbay DK, et al. Factors associated with medication-related problems in ambulatory hemodialysis patients. Am J Kidney Dis 2003; 41:386-393.

In a review of 133 hemodialysis patients' medical records, medication-related problems were identified in 97.7% of patients. A total of 475 medication-related problems were identified, an average of 3.6 per patient. Diabetic patients had more medication-related problems identified than non-diabetic patients.

30. Manley HJ, Drayer DK, McClaran M, et al. Drug record discrepancies in an outpatient electronic medical record: frequency, type, and potential impact on patient care at a hemodialysis center. Pharmacotherapy 2003; 23:231-239.

Medication record discrepancies are a potential source of medication-related problems. In a prospective observational study, a pharmacist conducted a monthly medication interview of hemodialysis patients. During the interview, patient medication use was determined. Over the 5-month period, 215 medication interviews were conducted in 63 patients. One hundred thirteen medication record

discrepancies were identified in 38 (60.3%) patients. The medication record discrepancies placed patients at risk for adverse drug events and medication dosing errors 49.6% and 34.5% of the time, respectively. Incorporation of a pharmacist in patient care may increase the accuracy of the electronic medical records and avoid unnecessary medication-related problems.

31. Manley HJ, Allcock NM. Thiazolidinedione safety and efficacy in ambulatory hemodialysis patients. Pharmacotherapy 2003; 23:861-865.
    The safety and efficacy of rosiglitazone and pioglitazone, two thiazolidinedione hypoglycemic agents used in the treatment of diabetes, were evaluated in 40 hemodialysis patients. The study revealed that these medications were efficacious in improving diabetes control, lowered blood pressure, and did not increase the risk of chronic heart failure exacerbations or increase erythropoietin dose requirements.

32. Elwell RJ, Neumann M, Manley HJ, et al. Hepatitis B vaccination: addressing a drug-related problem in hemodialysis outpatients with a collaborative initiative. Nephrol Nurs J 2003; 30:310-313.
    The uptake of hepatitis B vaccination is suboptimal in dialysis patients. In this initiative between pharmacists and nurses, there was a large increase in vaccination rates and development of acceptable titers.

33. Manley HJ, Drayer DK, Muther RS. Medication-related problem type and appearance rate in ambulatory hemodialysis patients. BMC Nephrol. 2003 Dec 22; 4:10.
    The number, type, and appearance rate of medication-related problems were investigated in randomly selected hemodialysis patients that received monthly pharmaceutical care visits by a pharmacist. At each visit, a pharmacist identified medication-related problems through review of the patients chart, electronic medical record, patient interview, and communications with other health care disciplines. The pharmacist identified at least one medication-related problem for every 15.2 medications reviewed. The most common medication-related problems were medication dosing problems (33.5%), adverse drug reactions (20.7%), and an untreated medical indication (13.5%). The medication-related problem appearance rate was 1.6 per patient per month initially, and then decreased to 0.45 per patient per month after 6 months continuous follow-up. Incorporation of pharmacists in hemodialysis patient care results in avoidance and resolution of medication-related problems.

34. St. Peter WL, Schoolwerth AC, McGowan T, et al. Chronic kidney disease: issues and establishing programs and clinics for improved patient outcomes. Am J Kidney Dis 2003; 41:903-924.
    These authors point out that CKD patients have many comorbidities, including cardiovascular disease, hypertension, diabetes, anemia, nutritional and metabolic derangements, and fluid overload. Unfortunately, evidence shows that current CKD care in the United States is suboptimal. The article reviews several studies suggesting that care provided by multidisciplinary nephrology teams can improve patient outcomes. The authors encourage the development of multidisciplinary teams, including pharmacists, to provide collaborative care to patients with CKD.

35. Drayer DK, Manley HJ. Providing free medications to dialysis patients. A description of a multidisciplinary team medication sampling and patient assistance program. Nephrol News Issues 2004; 18:25-29.

    Many hemodialysis patients are either not insured or are underinsured. These patients require several medications that collectively can cost over $16,000 per year. The authors describe efforts to decrease this burden to some patients through a pharmacist-coordinated multidisciplinary team approach to medication sampling and patient assistance programs at a dialysis facility. Over a 12-month period, 20 patients were provided 3,985 days and $12,751.31 of free medication.

36. Bailie GR. From dialysis outcomes quality initiative to kidney disease outcomes quality initiative: new clinical practice guidelines in nephrology--what the practicing pharmacist needs to know. Pharmacotherapy 2004; 24:551-557

    This paper reviews the processes involved in the development of the K/DOQI clinical practice guidelines, and focuses on those that are potentially important for pharmacy practice.

37. Kimura T, Arai M, Masuda H, et al. Impact of a pharmacist-implemented anemia management in outpatients with end-stage renal disease in Japan. Biol Pharm Bull 2004; 27:1831-1833.

38. Patel HR, Pruchnicki MC, Hall LE. Assessment for chronic kidney disease service in high-risk patients at community health clinics. Ann Pharmacother 2005; 39: 22-27. Epub 2004 Nov 16.

39. Bailie GR, Mason NA, Elwell RJ, Sy FZ. Analysis of medication use in peritoneal dialysis patients in two units. Perit Dial Int (in press).

    The authors described the medication prescription practice patterns of PD patients in a prospective, observational study of patients from two outpatient PD clinics. Patients were prescribed a mean of 9.2 medications and took an additional 2.2 OTC medications/patient. Influenza and pneumococcal vaccines had been given to 81% and 38%, respectively. Most (60%) had received hepatitis vaccine, but about half had received the full course. While most patients (88%) had been prescribed phosphate binders, only 48% were on a vitamin D analogue, and the mean iPTH value was 485 pg/mL. There was a low (22%) use of ACE inhibitors. Only 7% of patients had ever had nasal swabs for *S. aureus* carrier status, and mupirocin was routinely used as prophylaxis by 33% of patients. Despite much emphasis placed on appropriate treatment of hemodialysis patients, this report is suggestive that more attention is needed for PD patients. This study has identified several areas of concern where there is opportunity to improve prescription patterns.

Citations 40-42 represent work arising from the Dialysis Outcomes and Practice Patterns Study (DOPPS) that substantiate the prevalence of medication-related problems within the dialysis population. Pharmacists are among the authors of these papers.

40. Bailie GR, Mason NA, Bragg-Gresham JL. Analgesic prescription patterns among hemodialysis patients in the DOPPS: potential for underprescription. Kidney Int 2004; 65:2419-2425.

These authors demonstrated that 74% of patients in moderate to severe pain were prescribed no analgesics.

41. Mason NA, Bailie GR, Satayathum S, et al. HMG-Coenzyme A reductase inhibitor use is associated with mortality reduction in hemodialysis patients. Am J Kidney Dis 2005; 45:119-126.

Analysis of data from the large DOPPS database showed that there was a large underuse of HMG-Coenzyme A reductase inhibitors (i.e., statins) with documented indications for use. Use of statins was associated with a 31% decrease in the overall relative risk for death and with a 23% lower risk of cardiac mortality.

42. Lopes AA, Albert JM, Young EW, et al. Screening for depression in hemodialysis patients; associations with diagnosis, treatment, and outcomes in the DOPPS. Kidney Int 2004; 66:2047-2053.

This study found that only 35% of patients with physician-diagnosed depression were receiving antidepressant medication. Since patients with depression were found to be at higher risk of death, hospitalization, and dialysis withdrawal, better attention to the appropriate prescribing of antidepressants is warranted.

43. Bootman JL, Harrison DL, Cox E. The health care cost of drug-related morbidity and mortality in nursing facilities. Arch Intern Med 1997; 157:2089-2096.

This is a landmark study documenting the occurrence and economic consequences of medication-related morbidity and mortality in nursing home. However, consultant pharmacists helped reduce these costs by $3.6 billion annually.

Note: Pharmacists have been involved in the Kidney Disease Outcomes Quality Initiative (K/DOQI) process and were authors on the new hypertension guidelines and soon-to-be-released anemia update for CKD patients. A pharmacist also is a co-author of the International Society of Peritoneal Dialysis recommendations for the treatment of peritoneal dialysis-related infections.

Submitter : **Ms. Dori Schatell** **Date: 05/04/2005**

Organization : **Individual comments**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Attachment covers Issues 1-10 AND Issues 11-20.

CMS-3818-P-137-Attach-1.DOC

Attachment #137

Condition	Dori Schatell Comment: CMS-3818-P	Page 1

494.10 Definitions Dialysis facility	**Add**: New # 3: "self-care dialysis," to the listing of what the dialysis facility entity might provide. **Add**: "Teaching a patient to self-cannulate does *not* require certification as a self-care dialysis facility." ***Rationale***: The *Fistula First* effort to promote fistulas includes an emphasis for Medicare beneficiaries on the benefits of learning to self-cannulate; if clinics must become self-care certified to permit this, it will discourage them from encouraging—or even *allowing* patients to learn this important fistula-maintenance self-management skill.
--- *NEW* Staff assisted 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 provided by a trained *patient* and/or a helper. Making these treatments equivalent loses the important differences between them, including the staff training/supervisory needs of nursing home dialysis patients. ***Reference:*** • Tong EM, Nissenson AR. Dialysis in nursing homes. *Semin Dial.* 15(2):103-6, 2002.
494.20. Condition: Compliance with Federal, State, and local laws and regulations	**Add**: "Facilities must accommodate mobility, hearing, vision, or other disabilities or language barriers" ***Rationale***: Healthcare settings are covered entities under the Americans with Disabilities Act. ***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)
494.30 Condition: Infection control	**Add**: The medical director be notified of infection control issues ***Rationale***: The medical director is responsible for medical care in the dialysis setting and was not listed as one of the staff to be notified.
494.50 Condition: Water Quality	**Add**: Require that water purity must meet ANSI/AAMI RD52:2004 standards or most current standards, or preferably require the use of ultrapure dialysate. ***Rationale***: RD52:2004 is the most recent standard for dialysis, but new standards could be

	developed that should take precedence Several studies show a link between ultrapure dialysate and reduced loss of residual kidney function, improved EPO response, reduced inflammatory response, improved nutrition, reduced beta2 microglobulin (amyloidosis), and reduced cardiovascular morbidity. Use of ultrapure dialysate could improve patient quality of life and reduce costs to Medicare. ***References:*** • Arizono K, et al. Use of ultrapure dialysate in reduction of chronic inflammation during hemodialysis. *Blood Purif.*22 Suppl 2:26-9, 2004. • Hsu PY, et al. Ultrapure dialysate improves iron utilization and erythropoietin response in chronic hemodialysis patients - a prospective cross-over study. *J Nephrol.* 17(5):693-700, 2004. • Schiffl H, et al. Ultrapure dialysis fluid slows loss of residual renal function in new dialysis patients. *Nephrol Dial Transplant.* 17(10):1814-8, 2002.
494.60 Condition: Physical Environment. (a) Building	**Add**: (a) Require facilities to be accessible to people with disabilities. ***Rationale***: Americans with Disabilities Act ***Reference:*** • ADA Title III, Part 36, Subpart A, Section 36.304, removal of barriers (http://www.usdoj.gov/crt/ada/reg3a.html#Anchor-91481)
(c) Patient care environment	**Add**: (c) 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:*** • Fact Sheet. *Protecting the Privacy of Patients' Health Information* (http://www.hhs.gov/news/facts/privacy.html)
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 S, et al. Overcoming early learning barriers in hemodialysis patients: the use of screening and educational reinforcement to improve treatment outcomes. *Adv Chronic Kidney Dis.* 11(2):210-216, 2004. • Juhnke J, Curtin RB. New study identifies ESRD patient education needs. *Nephrol News Issues.* 14(6):38-9, 2000. • Kaveh K, Kimmel PL. Compliance in hemodialysis patients: multidimensional measures in search of a gold standard. *Am J Kidney Dis.* 37(2):244-66, 2001. **Add**: (6) Require facilities to inform patients of *all* available treatments (in-center hemo, CAPD, CCPD, conventional home hemo, daily home hemo, nocturnal home hemo, transplant), and to *provide a list of facilities where treatments are offered within 120 miles* if the facility does not offer that treatment. ***Rationale:*** Patients can only do home dialysis (PD or home hemo) if they know these modalities exist, yet the Dialysis Mortality and Morbidity Study Wave 2 found that *fewer than 25% of in-center hemo patients had been told about home hemodialysis or PD.* For patients to truly have choices in their modalities, they must also know *where* the treatments they desire can be obtained. Facilities within 120 miles are roughly a 2-hour drive, which may be a reasonable distance away for home a dialysis facility, since once training is completed, patients only need to visit the clinic for monthly care checks. NOTE: This information is readily and freely available on Home Dialysis Central (www.homedialysis.org). ***References:*** • United States Renal Data System, Chapter 4 USRDS Dialysis Morbidity and Mortality Study (Wave 2), pp. 53-55, 1997. (http://www.med.umich.edu/kidney/usrds/download/1997/ch04.pdf) • Wuerth DB, et al. Patients' descriptions of specific factors leading to modality selection of chronic peritoneal dialysis or hemodialysis. *Perit Dial Int.* 22(2):184-90, 2002. **Add**: (new 17) "Have access to a 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 S, et al. Defining the impact of high patient/staff ratios on dialysis social workers. *Nephrol News Issues* 19(2):55-60, 2005.
- Forum of ESRD Networks. *Designing a Collaborative Action Plan with ESRD Stakeholder,* 2003. (http://www.esrdnetworks.org/DPPCFinalReport.pdf)
- Merighi JR, Ehlebracht K. Workplace resources, patient caseloads, and job satisfaction of renal social workers in the United States. A Survey/Part 1. *Nephrol News Issues.* 18(5):58-60, 62, 64+, 2004.

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, even though paid employment (with insurance) or schooling may be possible for them—particularly if they have access to 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 RB, et al. Differences between employed and nonemployed dialysis patients. *Am J Kidney Dis.* 27(4):533-40, 1996.
- Rasgon SA, et al. Benefits of a multidisciplinary predialysis program in maintaining employment among patients on home dialysis. *Adv Perit Dial.* 12:132-5, 1996.
- Rasgon S, et al. An intervention for employment maintenance among blue-collar workers with end-stage renal disease. *Am J Kidney Dis.* 22(3):403-412, 1993.

Add: (new 19) "Have a work-friendly modality (PD or home hemodialysis) or in-center schedule that accommodates work or school, or referral to a facility that can accommodate their work or school schedules."

Rationale: Same as above for new 18.

References:

Same as above plus:

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

Add: (new 20) "Receive referral for mental health services, physical or occupational therapy,

	and/or vocational rehabilitation as needed" ***Rationale:*** These interventions have been shown to improve patient rehabilitation outcomes. ***References:*** • Beder J. Evaluation research on the effectiveness of social work intervention on dialysis patients: the first three months. *Soc Work Health Care*. 30(1):15-30, 1999. • Dobrof J et al. Dialysis patient characteristics and outcomes: the complexity of social work practice with the end stage renal disease population. *Soc Work Health Care*. 33(3-4):105-28, 2001. • Ericson G, Riordan R. Effects of a psychosocial and vocational intervention on the rehabilitation potential of young adults with end-stage renal disease. *Rehabil Couns Bull.* 37 (1): 25-36, 1993. • Kouidi E, et al. Exercise renal rehabilitation program: psychosocial effects. *Nephron*. 77(2):152-8, 1997. • Levendoglu F et al. A twelve week exercise program improves the psychological status, quality of life and work capacity in hemodialysis patients. J *Nephrol*. 17(6):826-32, 2004. • Painter P, et al. Low-functioning hemodialysis patients improve with exercise training. *Am J Kidney Dis*. 36(3):600-8, 2000. • Painter P, et al. Physical functioning and health-related quality-of-life changes with exercise training in hemodialysis patients. *Am J Kidney Dis*. 35(3):482-92, 2000. • Painter P, Carlson L, Carey S, Paul SM, Myll J. Low-functioning hemodialysis patients improve with exercise training. *Am J Kidney Dis*. 36(3):600-8, 2000. • Schrag W, Witten B. Rehabilitation as an essential social work function: A study of LORAC exemplary practice winners. Life Options Rehabilitation Advisory Council. Part I. *Nephrol News Issues*. 12(10):26-8, 40, 1998. • Schrag W, Witten B. Rehabilitation as an essential social work function: a study of LORAC exemplary practice winners. Life Options Rehabilitation Advisory Council. Part II. *Nephrol News Issues*. 12(11):36-8, 40, 62, 1998. • Witten B, et al. Improving employment outcomes: the renal care team's role. *Nephrol News Issues*. 13(3):46-8, 1999. **Add**: (new 21) "Attend care planning meetings, alone or with representation." ***Rationale:*** Promoting patient participation in care requires that patients have the right to *attend*

	their own care planning meetings if desired, not merely sign off on the documentation. **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." ***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. Even a one-time error by a staff member can cost a patient one of his/her limited access sites. We have heard from many patients over the years that they are terrified of having certain staff members stick them, and right now they have no right to refuse without possibly missing a dialysis treatment. Patients know which staff members are better or worse at cannulating their accesses; who can blame them for wanting that choice? Some patients have expressed a desire to stop dialysis rather than face the day-to-day terror of never knowing what to expect or having any control with which to prevent a potentially poor outcome. 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. Including this requirement in the regulations will help facilities overcome their fear of permitting patients 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 almost entirely *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 (typically $10-15/month), over-the-counter, 4%

	lidocaine gels or ointments are available that will not harm the access and will provide pain relief (e.g., Ela-Max®, Less-n-pain®, or Topicaine®. These products are applied 1-2 hours prior to cannulation, covered by an occlusive dressing, and then washed off thoroughly. Patients who use these products say that they reduce both the pain itself and the fear of the needle pain. All patients should be told that these products exist and where they can obtain them. ***Reference:*** • McLaughlin K, et al. Why patients with ESRD do not select self-care dialysis as a treatment option. *Am J Kidney Dis*. 41(2):380-5, 2003. • Ela-Max - http://www.pdrx.com/elamax.pdf • Less-n-Pain - http://www.sdaproduct.com/Less-N-Pain_Product.htm • Topicaine - http://www.topicaine.com **Add**: (new 26) "Receive a dialysis prescription that is tailored to their individual medical needs." • ***Rationale:*** Some dialysis clinics are giving the *identical dialysis prescription to every patient*, regardless of body size, lab test values, etc. For CMS surveying purposes, it would seem quite simple to verify that that all patients in the clinic are *not* dialyzed for the same length of time, using the same dialyzer. Here is one patient quote to illustrate the problem: "*We have a center here in town, a new one that one of my nephs. bought into that is ridiculous. Some of the rules are : everybody runs 3 hours regardless, no eating, no drinking, no ice, no visitors, one tv (on the wall) for every 3 patients; and each patient is separated from their neighbor by a screen or wall so you can't talk to each other. Sounds more like a prison to me.*"
(b) Standard: Right to be informed regarding the facility's discharge and transfer policies.	**Add**: (1) "Receive counseling and support from the facility 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 urged to first try counseling to resolve difficult situations. **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" ***Rationale:*** The ESRD Networks and the preamble of this proposed *Conditions for Coverage* have both stated that non-compliance should *not* be a basis for involuntary discharge from life-saving 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. Further, competent adult patients have the right to choose not to adhere to their treatment plans, even if this means shortening their lives, and such a decision should not cost them their dialysis care. ***References:*** • Renal Physicians Association and American Society of Nephrology. *Clinical Practice Guideline on Shared Decision Making in the Appropriate Initiation of and Withdrawal from Dialysis* • Forum of ESRD Networks. *Designing a Collaborative Action Plan with ESRD Stakeholders,* 2003. (http://www.esrdnetworks.org/DPPCFinalReport.pdf) • Johnstone S, et al. The use of mediation to manage patient-staff conflict in the dialysis clinic. *Adv Ren Replace Ther.* 4(4):359-71, 1997. • King K, Moss AH. The frequency and significance of the "difficult" patient: The nephrology community's perceptions. *Adv Chronic Kidney Dis.* 11(2):234-9, 2004. • 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.
(c) Standard: Posting of rights.	**Add**: (renumbered 3) Delete or define "reducing...ongoing care." ***Rationale:*** This phrase is unclear. A facility should be able to change days or hours of operation as long as it does not risk employment for working patients, but a facility should not reduce the number or shorten dialysis treatments unless medically justified.
	Add: "Patients' Rights should be written in clear English, at the 7^{th}-9^{th}-grade reading level, and translated into patients' native language, if possible. Facilities that have patients who cannot read

	the patients' rights poster due to illiteracy, visual, or language problems must have an alternate way to inform these patients of their rights which can be verified at survey." ***Rationale***: Americans with Disabilities Act, Civil Rights Act Americans with Disabilities Act Questions and Answers (http://www.usdoj.gov/crt/ada/qandaeng.htm) Office of Civil Rights. *Questions And Answers Regarding The Department Of Health And Human Services Guidance To Federal Financial Assistance Recipients Regarding The Title Vi Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons* (http://www.hhs.gov/ocr/lep/finalproposed.html)
494.80 Condition: Patient assessment (a) Standard: Assessment criteria.	**Add**: (1) "...and functioning and well-being using the SF-36 or other standardized survey (e.g. the SF-8, SF-12, KDQOL, etc.) that minimally permits reporting of or conversion to a physical component summary (PCS) score and mental component summary (MCS) score. If the MCS or mental health domain score is less than 51, assess for major depression using the PHQ-2 or other validated depression survey." ***Rationale***: The preamble to the *Conditions for Coverage* discussed the importance of measuring functioning and well-being (FWB)—but stated that there was "no consensus" about which measure to use. In fact, the literature 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 FWB. Domain scores, when available, provide information that can be useful for patient care planning. 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 interventions, i.e., exercise and cognitive-behavioral therapy. MCS scores less than 51 correlate highly with depression, thus our suggestion for an additional depression screening if the score is below that level. ***References:*** • Rettig RA, et al. Assessing health and quality of life outcomes in dialysis: a report on an Institute of Medicine workshop. *Am J Kidney Dis.*;30(1):140-145, 1997. • Clinical Practice Guidelines for Chronic Kidney Disease: Evaluation Classification and Stratification, *Am J Kidney Dis*, 39(2) Suppl 1:S161-169, 2002.

- DeOreo PB. Hemodialysis patient-assessed functional health status predicts continued survival, hospitalization, and dialysis-attendance compliance. *Am J Kidney Dis*. 30(2):204-212, 1997.
- Kalantar-Zadeh K, et al. Association among SF36 quality-of-life measures and nutrition, hospitalization, and mortality in hemodialysis. *J Am Soc Nephrol* 12:2797-2806, 2001.
- Knight EL, et al. The association between mental health, physical function, and hemodialysis mortality. *Kidney Int*. 63(5):1843-51 2003.
- Kroenke K, et al. The Patient Health Questionnaire-2: validity of a two-item depression screener. *Med Care*. 41(11):1284-92, 2003. Survey at http://www.depression-primarycare.org/clinicians/toolkits/materials/forms/phq9/
- Lowrie EG, et al. 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 DL, et al. Health-related quality of life as a predictor of mortality and hospitalization: the Dialysis Outcomes and Practice Patterns Study (DOPPS). *Kidney Int*. 64(1):339-49, 2003.
- Mapes DL, et al. Health-related quality of life in the Dialysis Outcomes and Practice Patterns Study (DOPPS). *Am J Kidney Dis*. 44(5 Suppl 3):54-60, 2004.

Add: (9)(new i) "The facility must include in its evaluation a report of self-care activities the patient does (e.g. weighing him/herself, cleaning off the access site, guiding the needle site rotation for the technician, reporting symptoms, tracking their lab test values, requesting a certain fluid removal goal, inserting his/her own needles, etc.). 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 to be correlated with higher functioning and well-being, which, in turn, predicts reduced hospitalization and mortality.

References:

- Curtin RB, Mapes DL. Health care management strategies of long-term dialysis survivors. *Nephrol Nurs J*. 28(4):385-394, 2001.
- Curtin RB, et al. Self-management, knowledge, and functioning and well-being of patients on hemodialysis. *Nephrol Nurs J* 31(4):378-387, 2004.

---------- (c) Standard: Assessment of treatment prescription	**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. ---------- **Add:** (v) "Physical debilitation per patient report, staff observation, or physical component summary (PCS) score on a validated measure of functioning and well-being." ***Rationale:*** Low physical functioning in dialysis patients predicts usage of staff time and supplies for emergency needs, more than four times the risk of hospitalizations, and *47 times the risk of mortality*. Low PCS scores (less than 43 on the SF-36) have been shown to predict morbidity and mortality in research among ESRD patients. Patients with PCS scores of less than 34 on the SF-36 were twice as likely to die and 1.5 times more likely to be hospitalized. ***References:*** • Jones KR. Functional status in chronic hemodialysis patients. *Dial Transpl* 19(4):173-178, 1990. • DeOreo PB. Hemodialysis patient-assessed functional health status predicts continued survival, hospitalization, and dialysis-attendance compliance. *Am J Kidney Dis*. 30(2):204-212, 1997. • Lowrie EG, et al. 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 DL, et al. Health-related quality of life as a predictor of mortality and hospitalization: the Dialysis Outcomes and Practice Patterns Study (DOPPS). *Kidney Int*. 64(1):339-49, 2003. • Mapes DL, et al. Health-related quality of life in the Dialysis Outcomes and Practice Patterns Study (DOPPS). *Am J Kidney Dis*. 44(5 Suppl 3):54-60, 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 (less than 34 on the SF-36) predict higher morbidity and mortality in research among ESRD patients. Low MCS scores are also linked to depression and skipping dialysis treatments. Same as above **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 VE, 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. • Kimmel PL, et al Survival in hemodialysis patients: the role of depression. *J Am Soc Nephrol.* 4(1):12-27, 1993. • Kimmel PL, et al. Psychosocial factors, behavioral compliance and survival in urban hemodialysis patients. *Kidney Int.* 54(1):245-54, 1998 • 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. • Wuerth D, et al. The identification and treatment of depression in patients maintained on dialysis. *Semin Dial.* 18(2):142-6, 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 C, et al. Physical function, employment and quality of life in end-stage renal disease. *J Nephrol.* 13(2):142-9, 2000. • Lowrie EG, et al. 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 DL, et al. Health-related quality of life as a predictor of mortality and hospitalization: the Dialysis Outcomes and Practice Patterns Study (DOPPS). *Kidney Int.* 64(1):339-49, 2003. • Mapes DL, et al. Health-related quality of life in the Dialysis Outcomes and Practice Patterns Study (DOPPS). *Am J Kidney Dis.* 44(5 Suppl 3):54-60, 2004.

	• Witten B, et al. Relationship of ESRD working-age patient employment to treatment modality. (Abstract) *J Am Soc Nephrol.* 15:633A, 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**: (1) Dose of dialysis should require facility outcomes to meet or exceed K/DOQI guidelines **Add**: (2) Nutritional status should require outcomes to meet or exceed K/DOQI guidelines **Add**: (3) Anemia should use hemoglobin only (more stable measure) and should require outcomes to meet or exceed K/DOQI guidelines ***Rationale***: Clinical outcome standards must be specified in the *Conditions for Coverage* to provide a basis for CQI efforts, and a floor for quality care. **Add**: (4) "The patient or a caregiver must be trained to care for his/her access, including what problems to report and how to report them. Patients must be informed about self-cannulation and offered training." ***Rationale***: Vascular access represents an enormous cost to the system and potential risk to patients, therefore patients and caregivers must be informed about how to care for the access, report symptoms or problems, avoid access damage, and self-cannulate if possible. ***Reference:*** • Quinn-Cefaro R. Developing a self-cannulation program. *ANNA J.*;26(3):344, 343, 1999. **Add**: (new 5) Home dialysis status. All patients must be informed of *all* home dialysis options, including CAPD, CCPD, 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 7) "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, (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 via a simple equation of: **functioning and well-being + vocational assessment**. Functioning and well-being (measured minimally as PCS and MCS) predict morbidity and mortality. Employment was one basis on which Medicare was extended to people with kidney failure in 1972 when the Medicare ESRD Program was created, therefore job retention, return to work, and educational preparation that can lead to work should remain goals of facility rehabilitation efforts. 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. ***Reference:*** • Hartke RV. Cong. Rec., September 30, 1972, at 30004. ["That is what the pending amendment provides—a chance for thousands of Americans to remain alive and productive. For the $90 to $110 million that this amendment will cost each year is a minor cost to maintain life. And it is a minor cost when compared to the rewards which society will reap from people who can return to

	the workforce rather than wither and die."]
(b) Standard: Implementation of the patient care plan.	**Add**: (3) "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. **Add**: (4) "The dialysis facility must ensure that all in-facility and home dialysis patients are seen by a nephrologist providing the ESRD care at least monthly, as evidenced by a monthly progress note placed in the medical record; one monthly visit should be during an in-facility dialysis session." ***Rationale***: The physician who has the best ability to evaluate the patient's care is the nephrologist and he/she should see the patient on dialysis at least monthly. ***Reference:*** • Plantinga LC, et al. Frequency of sit-down patient care rounds, attainment of clinical performance targets, hospitalization, and mortality in hemodialysis patients. *J Am Soc Nephrol.* 15(12):3144-53, 2004.
(d) Standard: Patient education and training.	**Add**: (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, fluids, and medications (iv) How to read, understand, and use lab tests to track clinic 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. • Curtin RB, et al. Hemodialysis patients' symptom experiences: effects on physical and mental functioning. *Nephrol Nurs J.*;29(6):562, 567-74; discussion 575, 598, 2002. • Curtin RB, et al. Renal rehabilitation and improved patient outcomes in Texas dialysis facilities. Am J Kidney Dis.;40(2):331-8, 2002. • Curtin RB, et al. Self-management, knowledge, and functioning and well-being of patients on hemodialysis. *Nephrol Nurs J* 31(4):378-86, 396; quiz 387, 2004. • Johnstone S, et al. Overcoming early learning barriers in hemodialysis patients: the use of screening and educational reinforcement to improve treatment outcomes. *Adv Chronic Kidney Dis.* 11(2):210-6, 2004..
494.100 Condition: Care at home. (b) Standard: Home dialysis monitoring. --- (c) Standard: Support	**Add**: (2) "Retrieve and review complete self-monitoring data and other information from self-care patients or their designated caregiver(s) at least monthly; and" ***Rationale***: To bill Medicare, a dialysis clinic needs to know what days the home dialysis patient did dialysis. This information is obtained on the dialysis run sheet which would allow the clinic to monitor the patient's treatment. --- **Add**: (i) "Periodic monitoring of the patient's home adaptation, including at minimum an annual

services.	visit to the patient's home by facility personnel (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. **Add**: (B)(vi) "renting" ***Rationale***: Some providers rent dialysis equipment instead of buying. **Add**: (vii) "Identifying a plan and arranging for emergency back-up dialysis services at a location convenient to the patient's home when needed." ***Rationale***: Regional training centers could be hundreds of miles from a patient's home. The plan should provide for patients to dialyze at the closest feasible high-quality center to their homes.
§**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 viii) "Functioning and well-being as measured by physical component summary (PCS) and mental component summary (MCS) scores 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.
494.120 Condition: Special purpose renal dialysis facilities. (d) Physician contact --- (e) Standard: Documentation.	**Add**: Standard: *Nephrologist* contact. (Change from "physician"). ***Rationale***: The patient's *nephrologist* is the one that he/she wants to see. --- **Add**: "All patient care provided in the special purpose facility is documented and forwarded to the

	patient's dialysis facility within *1-working day* of the last scheduled treatment in the special purpose renal dialysis facility." ***Rationale***: If a hospital and transient dialysis clinic must transfer patient care information within 1 day, a special use facility should be required to do so also. Fax machines and/or allowing the patient to hand carry records make this feasible.
494.140 Condition: Personnel qualifications --- (b) Standard: Nursing services. --- (d) Standard: Social worker.	**Add**: Maintain current proposed language for qualifications for the medical director, nurse manager, charge nurse, staff nurse and dietitian. ***Rationale***: This language is okay. --- **Add**: (2) "Self-care *or home training nurse*" ***Rationale***: Specify that self-care nurses can train patients for in-home or in-facility dialysis. --- **Add**: (d) "Social worker must have training in clinical social work." All other sections are appropriate as written. ***Rationale***: All patients, whether urban, suburban, or rural deserve a social worker with a masters degree. MSW training provides two years or post-graduate coursework plus 900 hours of clinical practice in an agency to focus on diagnosis, clinical interventions and building critical evaluation skills that non-MSWs do not receive. There is no logical reason to continue to grandfather non-MSWs in dialysis. In fact, non-MSWs have had 29 years since publication of the original Conditions to complete their MSW degrees. The personnel requirements for social workers are established to protect patients and should not be lowered to protect any non-MSW's job. CNSW provided all clinic administrators with a manual to help them recruit, hire, evaluate, and retain an MSW. Every county has a mental health center with MSWs. If dialysis clinics cannot recruit an MSW they must be recruiting in appropriately, not paying a competitive wage, or defining the social work role in a way that unappealing to MSWs. Finally, clinical social work training is essential to offer counseling to patients for complex issues related to chronic illness, communication, goal-setting, advance care planning, etc. ***References:*** • Forum of ESRD Networks. *Designing a Collaborative Action Plan with ESRD Stakeholders,* 2003. (http://www.esrdnetworks.org/DPPCFinalReport.pdf) • Merighi JR, Ehlebracht K. Polling renal professionals. Changing roles and responsibilities of

	nephrology social workers: are they appropriate? *Nephrol News Issues*. 16(5):59, 74, 2002. • Merighi JR, Ehlebracht K. Issues for renal social workers in dialysis clinics in the United States. A survey/Part II. *Nephrol News Issues*. 18(6):67-8, 71-5, 2004. • Merighi JR, Ehlebracht K. Unit-based patient services and supportive counseling. Provided by renal social workers in the U.S. A survey/Part III. *Nephrol News Issues*. 18(7):55, 59-63, 2004.
(e) Standard: Patient care dialysis technicians	**Add**: (1) "Must be certified by a state or national credentialing program" (technicians) ***Rationale***: Dialysis patients have been asking for some assurance of technician competency for years. Requiring certification would go a long way toward assuring minimal competency. **Add**: (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 who has at least 6 months of experience in providing nursing care in dialysis, and be focused on...and communication and interpersonal skills including customer service, patient sensitivity training, conflict resolution and dealing with difficult situations." ***Rationale***: Patient care technicians often have the least amount of training in dealing with chronically ill and angry people—yet spend the most time with them. Without intending to, they may escalate rather than diffuse situations with their style of communication. Ensuring that patient care technicians are closely supervised by an experienced nurse for 3 months will enable fine-tuning of interpersonal communication skills and modeling of respectful, patient-centered care. ***References:*** • Forum of ESRD Networks. *Designing a Collaborative Action Plan with ESRD Stakeholders*, 2003. (http://www.esrdnetworks.org/DPPCFinalReport.pdf) • Harper G. The time has come for the dialysis industry to support technician certification. Nephrol News Issues. 18(7):25, 29, 2004.
(f) Standard: Water treatment system technicians.	**Add**: "Should have the same educational qualifications as dialysis technicians" ***Rationale***: No-one working in a dialysis facility should have less than a high school diploma or equivalency.
494.150 Condition: Responsibilities of personnel.	**Add**: (c)(2)(iii) Staffing is sufficient to meet the acuity of patients treated by the facility. ***Rationale***: This language was in the preamble but is not currently in the regulations.

A. Standard: Chief executive officer/administrator	***References:*** • Sankarasubbaiyan S, Holley JL. An analysis of the increased demands placed on dialysis health care team members by functionally dependent hemodialysis patients. *Am J Kidney Dis.* 35(6):1061-7, 2000. • Jones KR: Functional status in chronic hemodialysis patients. *Dial & Transplant* 19(4):173-178, 1990.
NEW Standard: Social worker	**Add**: (1) To assess functioning and well-being using a validated survey, to use the mental component summary score to determine which patients need further screening for depression and to screen patients using a validated depression survey. ***Rationale***: Assessment and counseling are skills that master's-prepared social workers learn as part of their clinical training. **Add**: (2) "To recommend a plan of care based on this assessment with the goal to improve the MCS and depression score and to help more patients maintain or attain employment. To implement this plan of care, the social worker should-- (i) inform the nephrologist to evaluate the patient's need for an effective psychotropic medication (ii) offer brief cognitive-behavioral therapy to mildly or moderately depressed patients and their families to instill hope and help them set realistic and achievable goals, (iii) refer severely depressed patients to a psychiatrist or psychologist for in-depth counseling. (iv) help the patients access programs to obtain medications as available and needed; (v) identify work-related problems and help the patient resolve them (vi) refer working age patients to vocational counseling agencies for training and/or help finding a new job" ***Rationale***: Depression is a common response to any chronic illness, including kidney failure. Research has shown that depression increases the likelihood that patients will shorten or skip treatments and inhibits adherence to the patient care plan. Depression is predictive of morbidity and mortality. Identifying and treating depression can improve clinical outcomes. Patients who are employed have improved physical and mental health functioning. They are more likely to have employer group health insurance and a higher income, thus making it easier for them to adhere to the many facets of the renal treatment plan.

	References: • Callahan MB, et al. A model for patient participation in quality of life measurement to improve rehabilitation outcomes. *Nephrol News Issues*. 13(1):33-7, 1999. • DeOreo PB. Hemodialysis patient-assessed functional health status predicts continued survival, hospitalization, and dialysis-attendance compliance. *Am J Kidney Dis.* 30(2):204-12, 1997. • Kimmel PL. Depression in patients with chronic renal disease: what we know and what we need to know. *J Psychosom Res*. 53(4):951-6, 2002. • Kusek JW, et al. Cross-sectional study of health-related quality of life in African Americans with chronic renal insufficiency: the African American Study of Kidney Disease and Hypertension Trial. *Am J Kidney Dis*. 39(3):513-24, 2002. • Witten B, et al. Relationship of ESRD working-age patient employment to treatment modality. (Abstract) *J Am Soc Nephrol.* 15:633A, 2004.
494.170 Condition: Medical records. (b) Standard: Completion of patient records and centralization of clinical information.	**Add**: (2) When medical records are stored electronically, procedures must be in place to protect the private health information of in-facility and home dialysis patients and to back-up data daily. ***Rationale***: HIPAA

§494.180 **Condition**: Governance. (b) Standard. Adequate number of qualified and trained staff.	**Add**: (1) "An adequate number of qualified personnel are present whenever patients are undergoing dialysis so that the patient/staff ratio for all staff is appropriate based on the acuity of patients treated and the level of dialysis care given. Acuity should take into consideration comorbidity, clinical status, functioning and well-being, nutritional and psychosocial needs." ***Rationale***: Software exists to help dialysis clinics establish acuity-based staffing which could improve patient care in a more cost efficient, less stressful manner. **Add**: (5) "There is an approved written training program specific to dialysis technicians that includes-- (iv) Possible symptoms and complications of dialysis; (ix) Potential of patients to live long and active lives on dialysis and how patient care technicians' expectations affect patients' expectations." ***Rationale***: Technicians spend the most time with patients. Research suggests that staff expectations affect patients' expectations (i.e., low expectations yield low expectations). Self-management research has shown that patients who are hopeful and believe that they have some control over their illness and lives are more likely to take better care of themselves than those who feel hopeless and out of control. • Curtin RB, et al. Long-term dialysis survivors: a transformational experience. *Qual Health Res.* 12(5):609-24, 2002.
(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.

Submitter : Ms. Renee Bova-Collis **Date:** 05/04/2005

Organization : Ms. Renee Bova-Collis

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-3818-P-138-Attach-1.DOC

Attachment 138

Issue Identifier	Renée Bova-Collis, MSW, LCSW 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/05-1622.pdf
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:*** It is important that a facility inform patients about all available treatment modalities 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:*** I support the language of a5 and recommend that language also emphasize the right of a patient to participate in the planning of their care and the right to request an interdisciplinary conference with the care team, medical director and/or nephrologists. ***Rationale:*** This is imperative for quality outcome. Not all patients want to be involved in their care, but for those who do it should be an expectation that the facility involve them and include them in decision-making regarding changes in prescription of care. This goes a long way to providing patients with more feeling of control, reduces stress/anxiety, and gives them ownership of their health outcome. ***Comment:*** (a)(13) and (14) I propose including language that would make the facility responsible for reviewing the internal grievance process with patients on a regular basis in such ways as, poster, newsletter, handouts of Patient Rights documents and individual review. ***Rationale:*** Many patients are unaware of their rights to air grievances or not clear the process they should go through.
494.70 Condition	***Add to b1***: "Receive counseling and support from the team to resolve behavioral issues and be informed

Patients' Rights (b) Standard: Right to be informed regarding the facility's discharge and transfer policies.	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:*** I support the language of a8 ***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	***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

(d) Standard: Patient reassessment	eliminate any ambiguity of needs to reassess
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. ***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.
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.
494.100 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
§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. Isupport 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 recommend 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 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). ***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, 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. I 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. As discussed in the preamble for these conditions, I recognize the importance of the professional social worker, and believe there is a need for the requirement that the social worker have a master's degree. 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. 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 I 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	***Add***: (e) Standard: Case aide. Dialysis units that have more than 75 patients per full time social worker

qualifications	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 <u>not</u> 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, <u>End-Stage Renal Disease Workgroup Recommendations to the Field</u>, 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, 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 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): • 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.

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Issue Identifier	CNSW Comment on Conditions for Coverage for End Stage Renal Disease Facilities File code CMS–3818–P pg 1
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/05-1622.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 language and communication barriers" ***Rationale***: Healthcare settings are covered entities under the Americans with Disabilities Act. ***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. 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:*** 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 treatments 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 treatment modalities

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."
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."
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.

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	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:*** 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. ***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.
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: Transplantation referral tracking	***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 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." ***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
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:

- 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, 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.

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: We agree with the preamble that dialysis patients need essential social services

Issue Identifier	CNSW Comment on Conditions for Coverage for End Stage Renal Disease Facilities File
	including transportation, transient arrangements and billing/insurance issu preamble that these tasks should not be handled by the qualified social wo has fewer than 75 patients per full time equivalent social worker), as casel the MSW from participating fully with the interdisciplinary team so that opti achieved. It is imperative that the conditions of coverage identify a new tea social service assistance-the preamble recommends that these clerical tas other than the MSW, but does not specify who that person is-adding this s ambiguity surrounding this issue, and ensure adherence to this recommer that are clerical in nature or involve admissions, billing, and determining in nephrology social workers from performing the clinical tasks central to the Johnstone, 1997). Russo (2002) found that all of the nephrology social wo transportation was not an appropriate task for them, yet 53% of responder transportation arrangements for patients. Russo found that 46% of the nep survey were responsible for making dialysis transient arrangements (whicl patient records to out-of-town units), yet only 20% were able to do patient Excellence in End-of-Life Care's 2002 report, End-Stage Renal Disease W the Field, workgroup members recommended that dialysis units discontinu workers for clerical tasks to ensure that they will have sufficient time to pro patients and their families. Merighi and Ehlebracht (2004b; 2004c; 2005), sampled dialysis social workers in the United States, found that: • 94% of social workers did clerical tasks, and that 87% of thos tasks to be outside the scope of their social work training. • 61% of social workers were solely responsible for arranging p • 57% of social workers were responsible for making travel arra were transient, taking 9% of their time. • 26% of social workers were responsible for initial insurance v • 43% of social workers tracked Medicare coordination periods • 44% of social workers were primarily responsible for complet • 18% of social workers were involved in collecting fees from p this could significantly diminish therapeutic relationships and • Respondents spent 38% of their time on insurance, billing an time spent counseling and assessing patients. • Only 34% of the social workers thought that they had enough patient psychosocial needs. This evidence clearly demonstrates that there needs to be another team m clerical social service needs. This position would be cost-effective, as the

	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 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): • 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:*** CNSW agrees that all employees must have an opportunity for continuing education and related development activities.
§**494.180 Condition** Governance. (b5) Standard.	***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'

Adequate number of qualified and trained staff.	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.

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Submitter : Ms. Kris Robinson **Date:** 05/04/2005

Organization : Executive Director

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-139-Attach-1.PDF

Attch 139

aakp

The Voice of All Kidney Patients

BY FEDEX AND ELECTRONIC SUBMISSION

May 4, 2005

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:

On behalf of the American Association of Kidney Patients ("AAKP"), I am writing to comment on the proposed rule for end-stage renal disease (dialysis) facilities (CMS-3818-P), published in the *Federal Register* on February 4, 2005. Below, we briefly describe AAKP, and then provide AAKP's comments.

- **About the American Association of Kidney Patients (AAKP)**

Background. The American Association of Kidney Patients (AAKP) (www.aakp.org) was founded in 1969, and is the nation's only education and advocacy organization for people with kidney disease both patient-led and managed. Each year, AAKP serves over 12,000 members and, through its programs, hundreds of thousands of other Americans who have either lost kidney function (and live with dialysis or transplant) or have chronic kidney disease (CKD). The *average* life expectancy for individuals following initiation of dialysis therapy is short, about 5 years. But AAKP's membership includes many long-term dialysis survivors, who live full and productive lives through aggressive attention to their health care, a core mission of AAKP. Indeed, most kidney patients face not only the challenge of kidney disease, but other medical conditions as well, such as diabetes and hypertension.

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AAKP's General Principles in Evaluating Public Policies. AAKP reviews proposed government policies with respect to several core principles: Will the proposed policy improve access, quality and outcomes, and affordability of care to America's kidney patients, and does the proposed policy respect the principle that *the physician and patient make a joint determination of the care plan best suited for that patient*?

- **AAKP's Comments on the Proposed Dialysis Facility Conditions of Coverage (CoC)**

AAKP first provides general comments on the proposed rule, followed by comments on specific provisions.

1. General Comments on Proposed Rule.

AAKP commends the Centers for Medicare and Medicaid Services ("CMS") for undertaking comprehensive revision of the dialysis facility conditions of coverage (CoC), which have not been fully revised since their initial publication in June 1976 – 29 years ago. AAKP notes that under the Medicare statute CMS has *broad plenary authority* to prescribe regulations that providers of dialysis services must meet in order to qualify for Medicare payment.[1]

Nine points:

First, AAKP believes that revising the dialysis facility CoC should occur more frequently than every 29 years. **At a minimum, AAKP recommends CMS publish in the *Federal Register* a notice requesting public comment on the need to revisit the dialysis facility CoC every three years – in addition, of course, to using voluntary consensus bodies to establish or update clinical performance measures and technical expert panels to address important issues; and the formal and informal advice CMS receives from kidney community stakeholders on an ongoing basis.**

Second, AAKP encourages CMS to issue the final rule on the updated CoC as soon as possible. Although the Medicare Modernization Act apparently only requires final rules be published within 3 years of the proposed rule, CMS can and should act more quickly – perhaps within the minimum required 60 days.

Third, AAKP recommends CMS solicit the help of patients and kidney health professionals – physicians, pharmacists, nurses, technicians, social workers, and administrators – in drafting the interpretative guidelines, which "operationalize" the rule and are used by State survey and certification in determining compliance.

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[1] See Section 1881(b)(1) of the Social Security Act for general authority, and 1881(f)(7) for specific authority related to reuse of dialyzers. Sections 1881(b)(5)(B) through (D) provide CMS with broad authority to obtain data from dialysis providers. Section 1881(c) establishes ESRD network organizations to assure that dialysis patients are provided appropriate care.

Fourth, AAKP supports CMS's move to CoC that are patient-centered, evidence-based, and outcomes-oriented, with clear expectations for dialysis facility accountability and a facility process for quality improvement. AAKP is encouraged that patient participation in care planning and implementation is strongly encouraged by the proposed rule[2], with a focus on both medical care and rehabilitation. AAKP also describes below the importance of psychological services.

In this regard, CMS describes the rulemaking as a "fundamental shift in our regulatory approach," from one that is highly prescriptive to one focused on outcomes.[3]

Among other advantages, this approach can provide dialysis facilities with the flexibility to innovate. AAKP recommends that CMS develop a process to identify dialysis facility innovations that improve care, and to publicly recognize and encourage dialysis facilities to share innovative "best practices."

Of course, any shift to outcomes depends on measures and standards. An important initiative in this regard is the updating, revising, expanding, and reporting of clinical performance measures (CPM).[4] Currently, CMS has identified three CPMs – dialysis adequacy, anemia management, and vascular access[5] – which are reported for a 5-percent sample.[6] CMS states its intention in the proposed rule "to propose ESRD performance standards that dialysis facilities would be *required* to meet *as well as* propose a method to recognize updates in existing consensus-based patient-specific performance measures"[7] (italics added).

AAKP endorses CMS's commitment to CPM requirements and to expand the minimum performance standards for dialysis facilities.[8] CMS apparently intends to identify a "voluntary consensus body" (or bodies) to develop additional measures and standards. Any new performance measures would be evaluated by CMS, and those standards that meet CMS's "needs for the effective administration of the ESRD program" would be adopted through additional rulemaking.[9] AAKP recommends that CMS be proactive in this process and that CMS fund the work of any voluntary consensus body. In 1994, CMS's initiative was essential to prompting development of the current CPMs (originally the ESRD Core Indicators Project).

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2 See, e.g., § 494.70
3 6187.
4 CMS's interest in clinical performance measures is discussed at 6188-6190, and 6231-6232.
5 Link: www.cms.hhs.gov/esrd/1d.pdf
6 See 6189
7 6190
8 6232
9 6190

CMS is concerned, however, that performance standards could encourage "cherry picking" and discourage facilities from accepting resource-intensive patients. CMS should examine which factors or patient characteristics require more resources, including staff time, and consider facility-based adjusters, in addition to or as an alternative to case-mix adjusters.[10]

Fifth, AAKP believes that conditions, standards, and measures are only as effective as surveillance and enforcement. In 2003, Senator Charles Grassley[11] and the General Accounting Office[12] advised CMS on deficiencies in State survey and certification for dialysis facilities – and AAKP asks how much progress CMS is making in addressing those concerns. **AAKP endorses prompt implementation of planned improvements in the CMS ESRD information systems over the next 2 to 3 years, as described in the proposed rule, which will allow better monitoring of the quality of care.**[13]

Sixth, AAKP wishes to emphasize that there can be no quality dialysis care without access to dialysis. As noted below ("Definitions" and "Condition: Care at Home"), access has been an issue for dialysis patients requiring nursing home care. Although outside the scope of the proposed rule, AAKP is deeply concerned about the lack of data about access in rural and inner city areas, and encourages CMS to contract with a network organization or other appropriate entity to examine this issue and draft recommendations on geographic access standards. Such information might be very useful to Congress, which has, for example, addressed the issue of access to hospital care in rural areas by enacting the Medicare critical access hospital program.

Seventh, CMS should also develop cost estimates and reimburse dialysis facilities for any additional services required by kidney patients identified in this rule. **For example, in our comments below, AAKP recommends improved infection control, the use of consultant pharmacists, a shift to ultrapure dialysate, and the elimination of dialyzer reuse.**

Eighth, although outside the scope of the proposed rule, AAKP endorses the concept of "pay for performance" (P4P), under which reimbursement for health and rehabilitation services for kidney patients – including dialysis -- is linked to quality of care. As AAKP President Brenda Dyson noted in a recent article, "Just like every other American, [AAKP's] members expect accountability and quality in any purchase

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10 6232

11 Grassley letter to HHS Secretary Tommy Thompson, November 6, 2003, Link: http://finance.senate.gov/press/Gpress/2003/prg110603.pdf

12 General Accounting Office, "Dialysis Facilities: Problems Remain in Ensuring Compliance with Medicare Quality Standards"; Washington, DC, October 2003. Link: www.gao.gov/new.items/d0463.pdf

13 6198-6190, 6231-6232

decision, including their health care services. Isn't that just common sense?"[14] **Moreover, P4P can provide incentives for quality, and is a more sophisticated tool than the sanctions permitted under current law for dialysis facilities who are not in compliance with regulations.**[15]

Lastly, AAKP again raises the call for a "National Commission on Improved Kidney Patient Outcomes." Mortality rates in ESRD are unacceptably high, and there is substantial evidence that patients do not receive all needed medical care. Although dialysis treatment is an essential element in the care plans of the nation's ESRD patients, quality medical care requires broad multidisciplinary coordination of medical care (given that many patient's have multiple medical conditions, which often are not fully treated). There are also many other opportunities to improve care and reduce costs to Medicare, including slowing the progression to ESRD among chronic kidney disease patients (CKD), better chronic disease management, advances in new technology and biomedical solutions, more transplantation, and improved patient education.

2. Comments on Specific Provisions of the Proposed Rule.

I. General Provisions (Part 494—Subpart A)

A. Definitions (§ 494.10)

Definition of "Home Dialysis" in an Institutional Setting. At 6191, CMS requests comment on whether the definition of "home" for "home dialysis" should also include institutional settings such as nursing homes. In AAKP's view, the term "home dialysis" is properly reserved for dialysis care in a personal home – although as described below, following additional research, CMS may wish to craft a new definition for "institutional home dialysis."

Typically, home dialysis patients are highly motivated and assume direction for their care; in addition, a home patient is typically the only person receiving dialysis in the "home".

Nursing home patients are simply a different group of patients. Indeed, CMS makes this point under the preamble section entitled "Dialysis of ESRD Patients in Nursing Facilities and Skilled Nursing Facilities" (pp. 6212 et seq.):

> In the current ESRD regulations, the home dialysis training requirement presents a significant barrier in providing home dialysis to NF or SNF residents as the

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[14] Brenda Dyson, "The quality imperative: Why the kidney community must take charge", *Nephrology News and Issues*, October 2003, 98-99.

[15] For current sanctions for noncompliant facilities, see Section 1881(g) of the Social Security Act. See also proposed rule, "Subpart H—Termination of Medicare Coverage and Alternative Sanctions for End State Renal Disease (ESRD) Facilities", at 6245-6246

> patient may be untrainable and may not have a ready caregiver who could be co-trained to assist the resident in performing dialysis. ... We have received correspondence requesting that the home-dialysis training requirement be waived for NF or SNF residents. It has been our longstanding policy to encourage home dialysis. We are also aware of the current limitations relative to severely debilitated patients who are ineligible for home dialysis based on the training requirement. Given the relative acuity of nursing home patients, there are safety concerns associated with allowing patients in nursing homes to be home dialysis patients. These patients may be less able to voice symptoms/problems than the typical ESRD home patient. In addition, the dialysis care of a patient who requires nursing home services may be more complex than the dialysis care of an independent home dialysis patient, and given their frailty, these patients may be more vulnerable than an independent home dialysis patient. Because of this, we have significant safety concerns about encouraging home dialysis, provided by multiple caregivers, who may not have any dialysis experience, in this setting.

Nonetheless, as we discuss more fully below, under "Condition: Care at Home (Proposed § 494.100)" there may be valid reasons for providing "home dialysis" at an "institutional home." From a plain reading of the statute, CMS has broad authority to provide a higher payment for home dialysis – e.g., which includes equipment purchase.[16] Higher payment may be appropriate because nursing home patients may be more expensive, both because of the small numbers per facility and also because such patients may require more intense services to successfully dialyze. Indeed, higher payment might improve access to nursing homes for ESRD patients, which has been a persistent problem, according to the Inspector General of the U.S. Department of Health and Human Services.[17]

AAKP's concern is that "home dialysis" should not be a pretext for a lesser standard of dialysis treatment for ESRD patients living in an institutional home. AAKP's notes that crafting an informed "institutional home dialysis policy" requires better data about the number (and future number) of patients in nursing homes (and other institutions such as assisted living or rehabilitation centers) who need dialysis – and under what arrangements dialysis is provided today. For example, some nursing facilities have established cooperative ventures with a local dialysis provider, serving as "landlord" to a program established on-site.[18]

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[16] See Sec. 1881(f) of the Social Security Act.

[17] Office of Inspector General, U.S. Department of Health and Human Services, "Medicare Beneficiary Access to Skilled Nursing Facilities: 2000"; Washington, DC, 2000. Link: http://oig.hhs.gov/oei/reports/oei-02-00-00330.pdf

[18] See, e.g., Robert MacKreth, "Developing an On-Site Dialysis Treatment Center" (Adapted from the submission by the Glengariff Health Care Center, Glen Cove, NY), 2001. Link: www.nursinghomesmagazine.com/Past_Issues.htm?ID=393

AAKP recommends that CMS should contract with a network organization to convene a technical expert panel (TEP) to revisit CMS's interim guidance[19] and survey this matter. The TEP may wish to consider drafting a new definition and provide recommendations regarding "institutional home dialysis" that address both the quality and payment issues discussed above.

AAKP revisits these comments below under the section "Condition: Care at Home (§ 494.100), below.

B. Compliance With Federal, State, and Local Laws and Regulations (§ 494.20)

1. **Comment.** AAKP supports the requirement that dialysis facilities be in compliance with all Federal, State, and local laws and regulations, including, of course, participation in the quality improvement activities of the ESRD networks.[20]

2. **Off-Label Drug" Use.** CMS is "proposing that dialysis facilities must be in compliance with the appropriate Federal, State, and local laws and regulations regarding drug and medical device usage."[21] AAKP asks that this provision be clarified to ensure that physicians are not restricted from appropriately prescribing Part B covered drugs in a dialysis facility, including "off label" use of such drugs.

II. Patient Safety (Proposed Part 494—Subpart B)

A. Condition: Infection Control (§ 494.30)

1. **Proposal for Infection Standard and Reporting.** Effective infection control is essential to patient well-being, but infection is a serious problem among kidney patients, according to United States Renal Data System.[22] **AAKP recommends improved infection surveillance – specifically: (1) data elements regarding septicemia and infection specified in the core data set should be implemented forthwith; (2) that CMS should consider establishing an appropriate clinical performance measure or standard; and (3) public reporting of facility infection rates on Dialysis Facility Compare.**

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19 "Clarification of Certification Requirements and Coordination of Care for Residents of Long-Term Care (LTC) Facilities Who Receive End Stage Renal Disease (ESRD) Services" (March 19, 2004). Link: www.cms.hhs.gov/medicaid/survey-cert/sc0424.pdf

20 See Sec. 1881(c) of the Act regarding the authority of ESRD networks to conduct quality improvement initiatives.

21 6191

22 See United States Renal Data System, "Chapter 6—"Outcomes: hospitalization & mortality," *2004 USRDS Annual Data Report (ADR) Atlas*. Link: www.usrds.org.

2. Hepatitis C (§ 494.30(a)(1)). AAKP recommends the final regulations follow the CDC recommendations for testing dialysis patients for hepatitis C. Medicare should reimburse for routine testing of hepatitis C.

3. Designation of Responsibility for Infection Control Program (§ 494.30(b)(2)). Given scope of the medical director responsibilities provided elsewhere in the proposed rule,[23] AAKP believes the medical director should be responsible for the infection control program. The medical director may delegate specific duties to a registered nurse or other qualified individual, but the medical director should be the accountable individual.

B. Condition: Water Quality (§ 494.40)

1. Water Quality Standard. AAKP strongly supports adding a new condition for water quality to the conditions of coverage.

2. AAMI Water Quality Standards. CMS incorporates by reference certain water quality and equipment standards of the Association for the Advancement of Medical Instrumentation (AAMI) in the proposed conditions of coverage. As a general matter, AAKP believes dialysis facilities should meet the most current AAMI standards, and new or updated standards should be promptly adopted. AAKP recommends that CMS incorporate by reference any future updates or revisions of the applicable AAMI standards.

3. Ultrapure Dialysate. CMS invites comments on ultrapure dialysate (at 6195). AAKP notes that a substantial literature implicates non-ultrapure dialysate in chronic inflammation among hemodialysis patients; that European standards for dialysate contaminants more stringent than in the United States, which may be one factor accounting for lower mortality among European dialysis patients compared to U.S. patients; and at least one large dialysis organization offers a dialysis treatment protocol based on single-use dialyzers with ultrapure dialysate.

AAKP strongly recommends prompt adoption of an ultrapure dialysate standard. In addition, CMS should estimate the costs of adopting ultrapure dialysate and commensurate water quality standards, and if there are substantial costs in a changeover, compensate appropriately.

C. Condition: Reuse of Hemodialyzers and Bloodlines (§ 494.50)

AAKP opposes reuse of dialyzers, and as noted above at least one large dialysis organization has moved to single use of dialyzers. AAKP believes at best the proposed condition provides the minimum acceptable standards for reuse. Among other issues,

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[23] See § 494.150

AAKP is concerned with reports that dialyzers may be routinely used 30 or more times. AAKP strongly recommends CMS contract for a technical expert panel to examine all facets of reuse and make recommendations to improve current practice.

D. Condition: Physical Environment (§ 494.60)

1. Facility Temperature. As the preamble notes, temperature complaints are common in dialysis facilities. AAKP supports both setting temperature at a consensus patient level, and encouraging facilities to make reasonable accommodations. CMS should also consider including the costs of purchase and laundry of blankets in facility reimbursement.

2. Automatic External Defibrillator (AED). AAKP strongly supports a requirement that all dialysis facilities have an AED, including small, rural facilities, where the proposed rule only requires access to a defibrillator. ESRD patients are at high risk for cardiac events, and an AED provides the most robust technology for quick intervention.

CMS requests comment on whether small, rural facilities should receive a waiver on the defibrillator requirement. AAKP supports an AED requirement for such facilities. Medical care may be less available in a rural area, and in any case would establish a lower standard of care for rural facilities. As noted in "General Comments" (above), AAKP is very concerned about the financial viability of rural and inner city facilities, but believes this matter should be addressed with a new payment system for critical access dialysis facilities. Lastly, from a brief internet survey, the retail prices of AEDs are sharply lower than the prices estimated in the proposed rule, and even greater discounts may be available when bought through a group purchasing organization.

III. Proposed Part 494—Subpart C (Patient Care)

A. Condition: Patients' Rights (§ 494.70)

1. General Comment. AAKP strongly supports modification of the existing condition that a patient (or their representative) must be informed of his or her rights and responsibilities at the beginning of treatment at a facility. AAKP supports expansions or additions to the existing condition for "Patient Rights" – including (1) references to privacy and confidentiality; (2) the right to establish an advance directive, (3) the right to be informed about all treatment modalities; (4) the right to be informed about the internal grievance process, (5) the posting of phone numbers for the ESRD network and State survey and certification organizations, and (6) 30 days' prior notice of involuntary discharge.

2. Information a Patient Can Understand (§ 494.70(a)(2)). AAKP recommends that facilities document that patients have demonstrated their understanding of information.

3. Right to Participate in Care (§ 494.70(a)(5)). **AAKP strongly supports element (5), which replaces text in the current rule, "due consideration is given to the [patient's] preferences," with the patient right to participate in all aspects of his or her care.** Element (5) reads, "(5) Be informed about and participate, if desired, in all aspects of his or her care, including advance directives, and be informed of the right to refuse treatment and to refuse to participate in experimental research."[24]

4. Treatment Modalities (§ 494.70(a)(6)). **In addition to informing patients of all available modalities, AAKP recommends that facilities must inform patients where other treatment modalities are offered if the facility does not offer a modality (e.g., home dialysis).**

5. Access to Social Workers and Dietitians (§ 494.70(a)(10)). AAKP recommends this standard be modified to ensure patients are specifically informed about availability of social worker and dietitian services.

6. Involuntary Discharge (§ 494.70(b)). **AAKP recommends that patients should not be discharged for "non-compliance" with the medical regimen. AAKP also recommends CMS review and adopt recommendations of the report, "Decreasing Dialysis Patient-Provider Conflict: National Task Force Position Statement on Involuntary Discharge" (April 2005).** This report was drafted by the "Decreasing Dialysis Patient-Provider Conflict Project" (DPC), sponsored by the Forum of ESRD Networks. AAKP also recommends CMS should examine relevant State patient abandonment laws. AAKP comments further on discharge policy below under "Condition: Governance."

7. Posting of Rights (§ 494.70(c)). **In addition to posting State agency and ESRD network complaint numbers, AAKP recommends posting the telephone number and other contact information of the Medicare Ombudsman.**[25]

B. Condition: Patient Assessment (§ 494.80)

1. Comment. **AAKP strongly supports the addition of the new condition for patient assessment – with a prompt initial evaluation (20 days) and follow-up evaluation at three months (which includes an assessment of how a new patient is adjusting to his or her treatment plan).**

2. Bone Disease (§ 494.80(a)(5)). **AAKP recommends rewording element, "(5) Evaluation of factors associated with renal bone disease," to read, "(5) Evaluation of**

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[24] 6249

[25] See "CMS Hires Medicare Ombudsman Dan Schreiner To Be 'Voice' For Medicare Beneficiaries" (3/22/05). Link: www.cms.hhs.gov/media/press/release.asp?Counter=1393

factors associated with mineral metabolism and renal bone disease," to reflect current terminology.

3. Psychosocial Evaluation (§ 494.80(a)(7)). **AAKP recommends element, "(7) Evaluation of psychosocial needs," be modified to read, "(7) Cognitive and behavioral assessment, and evaluation of psychosocial needs."** The facility should be aware of a patient's cognitive abilities to effectively engage a patient in his or her care planning (see § 494.70(a)(2)), and given the ongoing attention to "difficult" or "non-compliant" patients, a behavioral assessment should be part of the problem-solving process. AAKP also notes that psychological conditions such as depression are associated with higher use of health care resources and poorer health outcomes generally, and recognition and treatment of such conditions is very important.

4. Consultant Pharmacist. **AAKP recommends a consultant pharmacist should be included as part of the facility's interdisciplinary team.** ESRD patients have special vulnerability to drugs because patients typically take multiple medications, not only to manage kidney failure, but other medical conditions, such as diabetes and hypertension. In addition, with the new Medicare drug benefit slated to begin January 1, 2006, prescription drug plan formulary considerations will be an important new factor in the successful assessment and care of ESRD patients.

C. Condition: Patient Plan of Care (§ 494.90)

1. Outcomes and Timetables. **AAKP strongly supports the proposed text that a plan of care "must include measurable and expected outcomes and estimated timetables to achieve these outcomes."** AAKP recommends that CMS establish a project with a network organization to examine how dialysis facilities draft and execute measurable outcomes and timetables, with the goal of identifying "best practices."

2. Clarification of "Community Accepted Standards". The proposed regulation states, "The outcomes specified in the patient plan of care must allow the patient to achieve current evidence-based community-accepted standards." AAKP notes the term "community-accepted standards" is not included under definitions (§ 494.10) and is unacceptably vague. Read literally, the minimum standard of acceptable dialysis care could vary by zip code. If CMS means by "community-accepted standards," the product of a voluntary consensus body (as discussed in the preamble), that should be so stated.

3. Referrals. **AAKP recommends that a plan of care should include appropriate referrals for all needed physical or psychological care and rehabilitation services not otherwise provided at the facility, by the patient's physician(s), or by other health care professionals.** Such referrals may also include referral to the new CMS Chronic Care Improvement Program (CCIP), a pilot program

focusing on diabetes and chronic heart failure management[26], and public vocational rehabilitation and employment assistance services.

4. Minimum Threshold Values. **AAKP recommends inclusion of minimum threshold values in the patient plan of care if such values would improve patient care.** However, AAKP raises the concern if including values in regulation might make future changes to the minimum values – as clinical practice evolves – difficult,[27] because changes would require formal rulemaking. AAKP asks whether such values might be included with same effect in subregulatory guidance.

5. Mineral Metabolism and Bone Disease. **AAKP recommends the plan of care include an element for "Mineral metabolism and bone disease."** Treatment of mineral metabolism disorders (hyperphosphatemia, hypercalcemia, and secondary hyperparathyroidism) and bone disease is fundamental to patient well-being and is treatable.[28] The proposed rule also cites the importance of "active Vitamin D" as an "important breakthrough in quality-of-life."[29] AAKP notes that a technical expert panel convened by Network and is completing its report (expected to be delivered to CMS in June 2005).[30]

Although outside the scope of the proposed rule, AAKP recommends that Medicare provide a dental benefit to ESRD patients. Bone disease among kidney patients is universal, and reimbursed medical care should include treatment of bones supporting the teeth and damage and loss of teeth due to deterioration of supporting bones.

6. Medication Therapy Management. **AAKP recommends that the plan of care include medication therapy management.** The goals of medication therapy management are to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events, including adverse drug interactions. Medication therapy management is a key element of the new Medicare prescription drug benefit, and dialysis facilities should consider obtaining resources available under that program.

7. Transplant Surgeon (§ 494.90(a)(5)). **AAKP opposes the elimination of the transplant surgeon as a member of the interdisciplinary team. AAKP recommends that the requirement be retained that a transplant surgeon sign every plan of care.** Transplantation is a highly desirable treatment for end-stage renal disease, and removal of the transplant surgeon from the interdisciplinary team guarantees that patients will not

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[26] More information on CCIP at www.cms.hhs.gov/medicarereform/ccip

[27] CMS acknowledges this issue elsewhere in the proposed rule, at 6218.

[28] See, e.g., Block, G.A., et al., "Mineral Metabolism, Mortality, and Morbidity in Maintenance Hemodialysis"; J Am Soc Nephrol 15:2208-2218, 2004. Abstract link: www.jasn.org/cgi/content/abstract/15/8/2208

[29] 6207

[30] See slide show, "Bone Disease Clinical Performance Measures for Patients with Kidney Failure," at www.cms.hhs.gov/quality/esrd/BoneDisease.pdf

be exposed to the most current thoughts/state-of-the-art consensus about suitability for transplantation.

8. **Monthly Physician Visit (§ 494.90(b)(4)). AAKP recommends a dialysis facility ensure that all "healthy" dialysis patients are seen by the physician who provides their ESRD care at least twice a month at the facility, as evidenced by a progress notes placed in the facility's medical records. Unstable or unwell patients may require more physician visits per month at the center.**

9. **Patient Education and Training (§ 494.90(d)). AAKP strongly endorses the inclusion for the first time of a standard in the conditions of coverage for patient and family education/training as an element in plan of care. AAKP would modify the language of Standard 494.90 with the words in italics, "The patient care plan must include, as applicable, education and training, *including peer education*, for patients ... ."** In AAKP's view, ESRD patients can only be active partners in their care when well informed about the medical and non-medical aspects of their care, and patients who are active partners are more likely to survive and thrive. AAKP strongly agrees with the statement in the preamble to the proposed rule, "Educating and training patients and their families is key to a successful transition to a life with dialysis."[31]

10. **Pre/Post Dialysis Session Assessments.** AAKP recommends systematic, standard elements to assess a patient's condition pre- and post-dialysis be listed in the regulation, rather than solely in the interpretive guidance. Such elements may include patient report, examination of access site, heart rate/rhythm, GI status, and signs of fluid overload.

D. Condition: Care at Home (§ 494.100)

"Home Dialysis" in an Institutional Setting. AAKP discusses this issue above under "Definitions" (§ 494.10)) and repeats that recommendation: CMS should contract with a network organization to convene a technical expert panel (TEP) to revisit CMS's interim guidance,[32] survey this matter, and make recommendations. The TEP may wish to consider drafting a new definition and recommendations regarding "institutional home dialysis" that both address the quality and payment issues discussed above.

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

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32 "Clarification of Certification Requirements and Coordination of Care for Residents of Long-Term Care (LTC) Facilities Who Receive End Stage Renal Disease (ESRD) Services." (March 19, 2004). Link: www.cms.hhs.gov/medicaid/survey-cert/sc0424.pdf

1. Comment. AAKP strongly supports the addition of a new condition for quality assessment and improvement. There is no way we are doing the best job possible, and every day there are new ways to improve care.

2. Patient Participation in QAPI. AAKP recommends that the QAPI condition include a requirement that facility patients be solicited for suggestions to improve the quality and safety of care provided at the facility – in addition to the element of the program scope, "patient satisfaction and grievances" (§ 494.110(a)(2)(vii)).

3. Program Scope (§ 494.110(a)). AAKP recommends that program scope be expanded to include infection control, mineral metabolism and bone disease, staff education, and transplant referral. Regarding "staff education," AAKP recommends adding this element to program scope in response to patient complaints that staff are unable to explain the treatment process, important aspects of clinical care, or operational policies, or are uninformed about patient rights. We have discussed above the reasons above for adding infection control and mineral metabolism.

4. Common Survey Instrument of Patient Satisfaction. In response to CMS's request for comment on the value of utilizing a common instrument for assessing patient' experience of care,[33] AAKP recommends this approach, at a minimum, to provide comparable information across facilities. Facilities would be free, of course, to supplement the common survey with its own measures. AAKP further recommends that such instrument be administered by an independent third party when patients are not on dialysis. AAKP notes that CMS has made a substantial investment in ESRD Consumer Assessment of Health Plan Survey (CAPHS), and that this instrument is well designed and tested. In addition, there are other well-established instruments that assess physical, mental, and clinical outcomes that might also be administered on a periodic basis.

5. Facility Specific Standards for Enforcement. In response to CMS's request for comment,[34] AAKP endorses the use of commonly agreed upon clinical standards as requirements subject to enforcement. AAKP also endorses CMS's proposed text for "Condition: Clinical Standards" and "Standard: Performance Expectations."[35] As AAKP notes above (§ 494.90), we share CMS's concern[36] that including clinical values in regulation might make future changes to the minimum values – as clinical practice evolves – difficult,[37] because changes would require formal rulemaking. AAKP asks whether such values might be included with same effect in subregulatory guidance.

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37 CMS acknowledges this issue elsewhere in the proposed rule, at 6218.

IV. Administration (Proposed Subpart D—Administration)

A. Condition: Personnel Qualifications (§ 494.140).

1. Medical Director Qualifications (§ 494.140(a)). AAKP recommends that CMS retain the requirement that a medical director be board certified or board eligible, pending a better explanation of why this requirement should be discontinued.

2. Dialysis Technician Qualifications (§ 494.140(e)). AAKP believes that a 3-month on-the-job training program is not sufficient for employment as a dialysis technician. AAKP recommends that this job training should follow (or be contemporary with) successful completion of a national technician certification program. AAKP does not believe this recommendation is controversial. As CMS notes elsewhere in the proposed rule, "dialysis technicians are now the primary caregivers in many dialysis units."[38] At least 5 states, including Texas, California, Arizona, Ohio, and Oregon, already recognize a national standardized examination to qualify as a dialysis technician. Dialysis industry legislation now before Congress would require that a dialysis technician: (A) has completed a training program in the care and treatment of an individual with chronic kidney failure who is undergoing dialysis treatment; (B) has been certified by a nationally recognized certification entity for dialysis technicians; and `(C) is competent to provide dialysis-related services.[39]

3. Consultant Pharmacist. AAKP recommends a consultant pharmacist should be included as part of the facility's interdisciplinary team (identical recommendation made above at § 494.80).

B. Condition: Medical Director (§ 494.150)

AAKP endorses CMS's proposals to strengthen the role of the facility medical director, including responsibility for the quality assessment and performance improvement program (QAPI) (§ 494.110), development and approval of patient care policies and procedures manual, and compliance with the facility's discharge and transfer policies and procedures. As noted above, AAKP also recommends the medical director be responsible for the infection control program (§ 494.30).

C. Condition: Relationship with ESRD Network (§ 494.160)

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[39] See S. 635, the "Kidney Care Quality and Improvement Act of 2005".

As AAKP comments above (§ 494.20), participation in the quality improvement activities of the ESRD networks is a legal responsibility of dialysis facilities. AAKP also believes participation is a moral responsibility.

D. Condition: Governance (§ 494.180)

1. Governing Body. AAKP recommends that facilities solicit nominations from among facility patients for an individual to be included in the governing body as an advisor.

2. Qualified and Trained Staff (§ 494.180(b)). Given the large percentage of dialysis patients whose care is reimbursed by Medicare, from an "active purchaser perspective" Medicare has a special responsibility to devise and enforce standards, including standards for staff. AAKP makes two recommendations:

First, AAKP would modify CMS's proposal (§ 494.180(b)(2)) that a registered nurse "must be present in the facility at all times that patients are being treated,"[40] to "present and available".

Second, AAKP recommends CMS revisit what constitutes "adequate number of qualified and trained staff". Specifically, AAKP recommends CMS delineate the responsibilities of all staff – including nurses, dialysis technicians, social workers, and dieticians – in a manner comparable to the responsibilities of the medical director (§ 494.150).

In addition, although "acuity based staffing plan" may be desirable, clearer, more detailed specifications are needed to evaluate this proposal. Moreover, unless there is some staff-to-patient ratio, facilities may vary widely in the level of service to patients, in effect providing a different level of benefit (or "bundle") for the same reimbursement. AAKP believes a technical expert panel could promptly address this issue.

3. Training Program for Dialysis Technicians (§ 494.180(b)(5)). AAKP supports the "requirement for a written approved training program ... that is specific to dialysis technicians." However, as noted above (494.140), AAKP recommends successful completion of a national technician certification program as well.

4. Internal Grievance Process (§ 494.180(e)). AAKP strongly supports a requirement for an internal grievance process. AAKP recommends patient involvement in the design and administration of the internal grievance process, and routine reporting to the network organization of the number and topic of

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complaints. AAKP concurs with the CMS statement, "We believe a good internal grievance process is an invaluable tool in resolving patient grievances in a positive and expeditious manner for both the patient and the facility."[41]

5. **Discharge and Transfer Policies and Procedures (§ 494.180(f)). AAKP supports the proposal to hold the dialysis facility accountable for adherence to the facility's patient discharge and transfer policies and procedures. As noted above (§ 494.70), AAKP recommends CMS review and adopt recommendations of the report, "Decreasing Dialysis Patient-Provider Conflict: National Task Force Position Statement on Involuntary Discharge" (April 2005).**

6. **Furnishing Data and Information for ESRD Program Administration (§ 494.180(h)). As we note in "General Comments" at the beginning of this letter, AAKP believes that conditions, standards, and measures are only as effective as surveillance and enforcement. Full participation in reporting existing CPMs would be an important part of this effort, as well as full implementation of the VISION system. We also incorporate by reference our comments regarding minimum performance standards for dialysis facilities, and remedies for cherry picking" and factors that might discourage facilities from accepting resource-intensive patients.**

7. **Disclosure of Ownership (§ 494.180(i)). AAKP recommends that ownership information of a dialysis facility be available to any member of the public upon request.**

In closing, AAKP appreciates the hard work and dedication of the CMS staff in revising the dialysis facility conditions of coverage. Once again, CMS is making a positive difference in the lives of kidney patients. If AAKP can otherwise be helpful on this matter, please do not hesitate to contact me or Kris Robinson, AAKP's Executive Director, at (800) 749-2257 or krobinson@aakp.org.

Sincerely,

Brenda Dyson
President

cc: Barry Straube, M.D.

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Submitter : **Date: 05/04/2005**

Organization :

Category : **Dietitian/Nutritionist**

Issue Areas/Comments

Issues 1-10

Plan of Care

Recommend the time allowed to complete an initial assessment be 30 days from the start of treatment. The recommended 20 days does not allow enough time to provide thorough education and follow up without overwhelming the patient and the patients family.

Issues 11-20

Personnel Qualifications

Consider adequate a standardized staffing ratio for # of patients per Dietitian. Previously recommended was 100:1, however it varies per company. Some companies have a ratio of 150:1 Which makes it difficult to provide comprehensive quality care to all 150 patients.