CMS-3818-P-1

Submitter : Dr. Glenn Goldstein **Date & Time:** 01/24/2005

Organization : Dermatology & Skin Cancer Specialists

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attached

Submitter : **Dr. Curtis Johnson** **Date: 03/10/2005**

Organization : **Dr. Curtis Johnson**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

Submitter : Dr. Alvin Moss **Date:** 03/14/2005

Organization : West Virginia University School of Medicine

Category : Physician

Issue Areas/Comments

Issues 1-10

Patients' Rights

I have two comments:
1) The current wording with regard to advance directives in the section on Patients' Rights is weak. It reads on page 6201 in column three, 'Proposed 494.70(a)(5) would also require the facility to inform patients of the right to establish an advance directive.' On page 6202 in the first column, it reads, 'After taking these factors into account, we believe it is prudent to consider adding advance directives as a requirement in the patients' rights condition of this proposed rule.' At a minimum, dialysis units should be required to provide an advance care planning process in which patients are encouraged to 1) identify their preferred surrogate decision-maker in the event of incapacity, 2) complete an advance directive (called a medical power of attorney or durable power of attorney for health care or health care proxy) in which they name their preferred decision-maker, and 3) state how much leeway they want to give this decision-maker. This process preserves patient autonomy and helps nephrologists and dialysis units know with whom to make decisions if the patient loses capacity, a not infrequent occurrence for dialysis patients. In this advance care planning process, the dialysis unit should also identify if there are health states in which the patient would not want to be kept alive with dialysis or other forms of life support. The research shows that three-quarters or more of dialysis patients would not want to be kept alive if they had severe dementia or were in permanent coma (Singer PA, Thiel EC, Naylor CD, Richardson RM, Llewellyn-Thomas H, Goldstein M, Saiphoo C, Uldall PR, Kim D, Mendelssohn DC. Life-sustaining treatment preferences of hemodialysis patients: Implications for advance directives. J Am Soc Nephrol 1995 Nov;6(5):1410-7).

2)An informed patient's wish not to be resuscitated should be honored in the dialysis unit. Current research indicates that between 15-30% of dialysis units perform CPR on all patients regardless of whether they want it or not. The Renal Physicians Association and American Society of Nephrology Position on Quality Care at the End of Life reads: 'To respect the wishes of patients who prefer not to undergo cardiopulmonary resuscitation, nephrologists shall issue do-not-resuscitate orders for their patients who request them. These orders shall be issued in the dialysis unit in a manner that respects patient confidentiality and yet ensures that those treating the patient are aware of them. Physicians are legally required to honor competent patients' treatment decisions. To do otherwise, ie, to perform unwanted cardiopulmonary resuscitation on a competent patient, constitutes medical battery. It is important to note, however, that a do-not resuscitate order does not preclude other standard measures in dialysis treatment such as fluid resuscitation for intradialytic hypotension. A do-not-resuscitate order only becomes effective when the patient has experienced a cardiac or respiratory arrest
(http://www.renalmd.org/members_online/members/downloads/RPAASN_PositiononQualityCareattheEndofLiferevised.pdf).'

Also we know now from research that 90% of dialysis patients believe that a patient's wish not to be resuscitated should be respected in the dialysis unit (Moss AH, Hozayen O, King K, Holley JL, Schmidt RJ. Attitudes of patients toward cardiopulmonary resuscitation in the dialysis unit. Am J Kidney Dis 2001;38:847-852). I would like to see the Conditions of Coverage under the Patients' Rights section include that dialysis units are required to honor informed patients' wishes not to be resuscitated.

Both suggestions are made to improve the quality of end-of-life care for dialysis patients by respecting patients' rights. Research has shown that dialysis patients consider having control over the treatment they receive at the end of life as extremely important (Singer PA, et al. Quality end-of-life care: patients' perspectives. JAMA 1999 Jan 13;281(2):163-8).

Submitter : **Ms. juanita valentine** **Date: 03/15/2005**

Organization : **sharp memorial hospital**

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

Issue Areas/Comments

GENERAL

GENERAL

Regarding extension of nutritional consult for live kidney donors.
Potential donors are selected because they are in good health and will not be undergoing an event that will alter their general health. Also there would be additional costs to the transplant centers associated with nutritional consult for live donors. I would rather see our efforts to ensure live donors are aware of the alternatives of donation and udnergo screening that is consistent with all centers.

Submitter : **Catherine Turner-Raborn** **Date: 03/16/2005**

Organization : **Maricopa Integrated Health System**

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

Issue Areas/Comments

GENERAL

GENERAL

re: QAPI - In regards to setting a numerical target value to hemodialysis adequacy, anemia and albumin and using this to determine performance of a facility would greatly disadvantage units similar to ours. We are an inner city unit with a very low income patient population. This population also includes due to our contracts, prison facilities and chronic and acute psychiatric facilities. We also care for nursing home patients many who are so debilitated they arrive by stretcher. While we make every effort to reach current NKF-K/DOQI clinical practice guidelines we often have very little control over these patients diets or lifestyle outside of the unit. Our population also includes undocumented patients who live at poverty level. While we are often able to obtain food boxes or supplements for them, we do not know if they are utilizing them or if they are selling them. Our case mix provides us with many challenging situations and it is often difficult to meet NKF-K/DOQI guidelines especially in regards to albumin. Using minimum numerical target guidelines as a measure of a facilities performance would be disadvantaging facilities such as ours.

Submitter : Mr. Robert Daly **Date:** 03/18/2005

Organization : CMS

Category : Federal Government

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-6-Attach-1.DOC

CMS-3818-P-6-Attach-2.DOC

Attachment #6

COMMENTS ON CONDITIONS FOR COVERAGE FOR END STAGE RENAL DISEASE FACILITIES; PROPOSED RULE

PART 488

The proposed rule would recodify existing regulations on alternative sanctions at new 42 CFR Parts 488.606, 488.608, and 488.610. The existing and proposed rules provide for an informal hearing before CMS imposes an alternative sanction for failure to participate in ESRD network goals and objectives. Neither the existing nor the proposed rule are clear on whether CMS intended to allow the ESRD supplier the opportunity for two hearings on alternative sanctions—an informal hearing pursuant to 42 CFR Part 488.610 and a formal hearing pursuant to 42 CFR part 488.608.

CMS Region V is currently conducting an informal hearing on a proposal to impose an alternative sanction pursuant to the existing regulation at 42 CFR Part 405.2184. Our review of existing legislation and regulation, including the legislative and regulatory history, found that it is unclear whether the supplier must be afforded a right to both the informal and the formal hearing on the proposal to impose an alternative sanction. We have decided to err on the side of caution and, after the informal hearing is completed, allow the supplier the opportunity for a formal hearing pursuant to 42 CFR Part 498. This imposes a heavy burden on the agency and in essence leads to two administrative hearings on the same issue.

I recommend that the proposed rule at 488.610 clarify that the supplier is entitled only to an informal hearing on a proposal to impose an alternative sanction. The right to a formal hearing under Part 498 should be limited to a proposal to terminate the ESRD supplier's participation in Medicare.

Robert P. Daly, Manager
Non Long Term Care Branch
CMS Region V

312-886-5344

rdaly@cms.hhs.gov

Submitter : **Ms. joanne harris** **Date: 03/18/2005**

Organization : **ghc**

Category : **Social Worker**

Issue Areas/Comments

GENERAL

GENERAL

I am responding to file code CMS-3818-P Social Worker PROPOSED 494.140[D] REGARDING THE GRAND-FATHER CLAUSE. There are quite a few social wokers that have many years experience but do not have their MSW's. Many handle two clinics and do not have any problems at all. Maybe there should be more supervision required from a MSW like they have in long term care facilities and transplant centers. Transplant patients have complex issues just like dialysis patients and sometimes they require more care. We feel that this would be a loss to the dialysis community if we had to leave after 30 years of caring for renal patients. Please consider in keeping the social workers that are already employed in dialysis centers with strict supervision and not hiring any non msw fom this date on. Thnak You for your consideration for a caring group of employees.

Submitter : Mr. Robert Arbuckle **Date:** 03/24/2005

Organization : Mr. Robert Arbuckle

Category : Individual

Issue Areas/Comments

Issues 11-20

Governance

There must be language in the changes that makes it a law rather than a guideline for dialysis providers to follow the guidelines and when there are laxes or infractions, penalties follow, not just reports as to what they've done to remedy the problem but financial penalties. No corporation will be self governing without ramifications and the dialysis corporations are no different. They should not be able to drop a patient for being late, or missing treatments or complaining about the level of care they are getting as they use these real and emplied threats to keep patients from protecting their rights.

As a dialyis patient, I have seen hundreds of non-sterile things done in the clinics and when asked, it becomes immediately clear that no training has been provided in these areas or at least a lack of training and with staff in short supply, no one worries about the ramifications of not following sterile guidelines.

In summary, we need teeth in CMS guidelines and in all Fed regulations via laws rather than calling them guidelines .. laws that bear financial consequences for non-compliance.

Submitter : Mr. Theodis Hayslett **Date:** 03/25/2005

Organization : Mr. Theodis Hayslett

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I am a person with ESRD. Currently I do hemodialysis at the clinic but previously I did CAPD at home. I much prefer the peritoneal dialysis and the freedom it brings to be in charge of where, and at what time I would do my daily dialysis. I hope to soon return to CAPD when my heart heals. I had open heart surgery this month. I found the care that my CAPD nurse gave me helpful and considerate. I soon realized that I would NOT receive the same level of attention from an overworked staff at the hemo side of the same clinic. The difference is very disappointing to me. I can tell that the staff is overworked because now when I call to speak to the nurse, I am always told she is too busy to come to the phone. I get brushed off, and some important issues were not addressed in a timely manner lead to my ending up in the hospital. The waiting room lobby is small and the chairs uncomfortable. The T.V. is always on a Spanish speaking channel. I think the waitng area could be more comfortable. The parking is very good with plenty of parking close to the building.

I have been very happy with the advice given me by the dieticain. I can't figure out why the keep the social worker as she does nothing and has no anwswers for any questions I ask her. I can find out what I need from her faster on the internet. The doctors are ok. Since several have started and finished their fellowship over the years, I have a pool of doctors that I know. I currently have a new fellow and I don't like him so much. He is brisk and doesn't listen to me. I don't know if it is because now that I am a hemo patient it is differnet but I know the doctors did act different when I was doing CAPD. Could it be because doctors KNOW that if you are doing CAPD you are more informed about your treatment choices? I don't know but I do know I have been treated differently since I had to switch. (Switche against my will as I had a serious yeast infection the really made me sick. I do want to mention one more thing. The emotions that a patient has should be taken into account. I felt that changing to hemo would kill me and it almost did. I was encouraged to consider changing ealy last year and got a access put in. It was a problem and I tried to tell the doctor but nobody listened to me. I ended up in the hospital with peritious. Then the doctor tried to use my access because my CAPD cathather had to come out. That's when they found the blockage. They put a temp neck cath in and gave me dialysis in the hospital. Then I was sent home. The next day I was to report for my first in clinic hemodialysis treatment. I was very scared. I was made to wait TWO hours to get on the machine. One hour later I had a really bad heart attack. I think if I hadn't had to sit there and wait for two extra hours(someone told me the wrong time to come) I might not have had the heart attack. Who knows? Anyway, I lived and just this past month I had open heart surgery. I feel better but I wanted to share my experience with you.

Submitter : **Dr. Janice Perry** **Date: 03/28/2005**

Organization : **Medication Management Service**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

The VA is getting into Epogen Clinics with Clinical Pharmacist involvement with great success. They are having positive provider feedback and substantial cost avoidance while providing better patient care.
Interestingly enough the patient safety officer was instrumental in obtaining buy-in from one VA's administration. Through Root Cause Analysis (RCA) the Renal Clinic was identified as an opportunity for improvement for patient care.
These clinical pharmacist all have clinical privileges (collaborative practice agreements) to assist in their duties, ordering labs. and denying prescriptions as well as reviewing consult request for medications. They provide in-service training to nurses and providers in the clinic.
If clinical pharmacist involvement is being looked at and instituted by the largest managed healthcare system in the country, should it not be looked at and given the same opportunity in the private sector?

Submitter : **Ms. Judith Filangeri** **Date: 03/29/2005**

Organization : **Univ of California, San Diego**

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

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-3818-P-11-Attach-1.DOC

Medicare Program; Conditions for Coverage for End Stage Renal Disease Facilities.
Comments on Proposed Rule
CMS-3818-P

Attachment #11
Submitted by:
Judith A. Filangeri
Administrative Director/Nephrology Programs
University of California, San Diego Dialysis Program
200 West Arbor Drive
San Diego, CA 92103-8781

In re:
Federal Register/Volume 70, No. 23/Friday, February 4, 2005/Proposed Rules
Department of Health and Human Services
42 CFR, Parts 400, 405, 410, 412, 413, 414, 488, and 494
CMS-3818-P

Water Quality:
Proposed § 494.40 Condition: Water quality (c) Standard: Chlorine/chloramines (2)
Problem: "before each patient shift or every 4 hours, whichever is shorter,...."
Comment: There are situations where "every 4 hours" will force testing right in the middle of a treatment, which is not ideal.
Recommend deletion: "*every 4 hours*"

(2) (ii) (A) If the test results are greater than 0.10 mg/L for chloramines as specified in paragraph (c)(2)(i), To immediately terminate dialysis is not the only way to protect patients in our view. Some facilities use the addition of ascorbic acid to their acid concentrate to accommodate the removal of chlorine/chloramines from the water should the primary and secondary carbon tanks become exhausted.
Recommendation: Change the wording to state: (A) Immediately terminate dialysis treatment to protect patients from exposure to chlorine/chloramines, OR, for facilities that add ascorbic acid to their acid concentrates and use a central acid concentrate delivery system, should there be breakthrough exceeding the limit of 0.1 mg/L of chlorine or chloramine at the secondary carbon tanks the dialysate from each acid bath in use should be tested for the concentration of chlorine/chloramines. If the level of this test exceeds the limit of 0.1 mg/L then immediately terminate dialysis treatment.

Additionally the section should state that, for facilities that add ascorbic acid to their acid concentrates and use individual acid containers for their acid concentrate delivery system, should there be breakthrough exceeding the limit of 0.1 mg/L of chlorine or chloramine at the secondary carbon tanks, the dialysate from each dialysis machine in use should be tested for the concentration of chlorine/chloramines. If the level of this test exceeds the limit of 0.1 mg/L then proceed to the actions beginning with paragraph (A) of this section.

Physical Environment:
Proposed § 494.60 (c) Standard: Patient care environment
(2)(i), The regulation as stated is vague and subjective.
Recommendation: there should be a specific temperature range cited.

Patients' Rights
Proposed § 494.70 Condition: Patients' Rights. (a) Standard: Patients' rights
(2) "Receive all information in a way that he or she can understand"

Comment: While we are all sensitive to the importance of providing information to patients, to mandate that the dialysis unit provide *all information* regardless of language barriers is a set up for failure, even if how the information is provided is left to the dialysis unit.
Possible language: "to have the dialysis facility make a clear and documented effort to assure that every patient receives all information in a way that he or she can understand"
(9) Comment: It should not be the responsibility of the dialysis unit to make sure the physician does as part of the physician's medical practice and assuring that the physician has informed the patient of "his or her medical status" falls in that realm.
Recommend deletion.

Patient Assessment:
Proposed § 494.80 Condition: Patient assessment:
(a) Standard: Assessment criteria
(4) Comment: Although specifying erythropoietin in the Conditions of Coverage is not new, it has always seemed to me that to specify a particular medication is to build in obsolescence.
Possible language: "...including administration of medications, for example, erythropoietin."

(b) Standard: Frequency of assessment for new patients
(1) Comment: This Condition needs to clearly differentiate between "first dialysis treatment" and "first dialysis treatment in an outpatient facility." Otherwise the clock starts ticking before the facility gets the patient. Also, 20 calendar days is unrealistic. Since elsewhere in this document CMS accepts once a month as the minimum number of times for a physician to round on patients and since it is possible that the physician would only visit an outlying rural unit once a month, then less than 30 calendar days does not make sense. In addition, patients starting dialysis are frequently unstable and require hospitalization. To make every effort to include the patient in their own assessment and care planning, on some occasions initial assessment and plan might exceed 30 days.
Possible language: An initial comprehensive assessment must be conducted within 30 calendar days after the first chronic outpatient dialysis treatment at the facility unless there is documented medical justification why this could not occur.

(d)Standard: Standard: Patient reassessment
(2) (i-iv) Comment: The definition for "unstable" is so vague that every patient could easily be determined to be unstable. I'm uncomfortable with really vague terms like "extended" or "frequent" or "marked" or "significant." If the expectation is that the facility will define these, which is what I would hope is the case, then perhaps the regulations need to so state.
Possible language somewhere: Each facility must address the definition of "unstable patient," using community guidelines.

Patient Plan of Care:
Proposed § 494.90 Condition: Patient plan of care (a) Standard: Development of patient plan of care (1-3)
Comment: The problem here is the on-going one of patient willingness and ability to comply with an agreed-upon treatment plan. Although the interdisciplinary team includes the patient, the true control is almost entirely in the hands of the patient. If the patient chooses to skip dialysis, cuts treatments short, refuses to follow dietary recommendations, refuses to follow up on psychiatric consults, refuses or fail to take meds, etc., anything that will result in the plan not being met, then ultimately the language here forces the facility to seek to discharge the patient from the care of the facility or face sanction under this Condition.
Possible language: "The outcomes specified in the patient plan of care must allow the patient to achieve current evidence-based community-accepted standards *or document interdisciplinary team efforts to achieve such standards and the reason(s) why the specific outcomes could not be achieved.*"

(6)Rehabilitation status
Comment: To require the dialysis facility to provide resources outside of educational material and community resources available is an unfunded mandate. This is especially true for pediatric patients in a non-pediatric unit where the alternative is to refuse to take the pediatric patient (even when no pediatric alternative exists) rather than provide the level of support requested in this Condition.
Possible language: *The interdisciplinary team should assist the patient in identifying a level of productive activity, including vocational, desired by the patient, and assist the patient in achieving that level through referral to appropriate educational material and community resources.*

(b) Standard: Implementation of the patient plan of care
(3) Comment: Since it is already identified in section 494.80 (b) (2) that a follow up assessment must occur within 3 months. Why is this necessary?
Recommend deletion.

(c) Standard: Transplantation referral tracking.
Comment: I'd like a clearer explanation of what tracking the results of referral means. Does this mean, for instance, that if a patient's listing is on medical hold pending a cardiac evaluation that the dialysis unit is expected to follow up and schedule that evaluation?
Recommendation: *The interdisciplinary team must have a record of the status of each kidney transplant center referral....*

Care at Home
Proposed § 494.100 Condition: Care at Home
(b) Standard: Home dialysis
(2) Comment: Home patients are very independent and although it is reasonable to expect that self-monitoring data should be reviewed every 2 months, if this is a Condition, then an uncooperative patient who refuses to bring data in timely jeopardizes the facility's certification, giving the facility no choice but to ask the patient to seek care elsewhere. This, even though the physician and facility may well have adequate documentation of patient status from other sources (lab work, physical assessment, etc.).
Recommendation: Either include language allowing for documentation on the part of the facility of a good-faith effort to obtain this documentation or delete the requirement.

Personnel Qualifications
Proposed § 494.140 Condition: Personnel qualifications
(b) Standard: Nursing services
(1) Nurse manager (i) "full time employee"
Comment: Many smaller dialysis facilities share a nurse manager. With the availability of cell phones and email, a full time nurse manager in every facility is unnecessary.
Recommended language: delete "full time employee"

(3) Charge nurse
Comment: Not all facilities have a charge nurse position. Some facilities delegate the tasks of the charge nurse.
Recommended language: delete "charge"

(c and d) Standards : Dietitian and Social Worker
Comment: "The facility must have..." What does "must have" mean? Does that mean employed or available?

(d) Social worker
Comment: I see no mention of "licensed." In the past, the surveyors have interpreted "licensed" to mean that the social worker must be not only an MSW but also certified or licensed if the state licenses or certified. Does this mean that MSW is adequate or that does this section still require licensure/certification? What does "Meets the practice requirements for social work practice in the State...." Mean? Does this mean able to bill Medicare independently in a private setting?
Recommended language: cannot draft since I am unclear on the legal meaning of the language currently in place, but STRONGLY suggest that language make it clear that a master's degree in social work is all that is required.

Governance
Proposed § 494.180 Condition: Governance
(b) Standard: Adequate number of qualified and trained staff
(4) Comment: While one would certainly hope that all employees have an opportunity to grow professionally, this should be a personal responsibility, not a facility obligation since no funding is provided for continuing education or related development activities.
Recommend delete.

(5) Comment: Does there need to be "an approved written training program" in a facility that does not do its own training or is this in addition to the formal training programs?
Recommend added language as follows (addition in italics): There is an approved written training program specific to dialysis technicians *in those facilities that provide technician training* that includes....

(f) Standard: Discharge and transfer policies and procedures
Comment: Given the fact that the patient is such a key element in the success of the patient care plan, and given that treatment outcome measures are increasingly being used to evaluation the facility's compliance with conditions of coverage, then perhaps a reason for discharge needs to be added to allow a facility to discharge/transfer a patient whose behavior interferes with his or her plan of care in any way, including willful non-compliance to agreed upon treatment goals.
Recommended: "The medical director ensures that no patient is discharged or transferred from the facility unless – (X #) *the patient's behavior interferes with the operation of the dialysis facility or poses a threat to the patient or to others.*

(4) "The facility has reassessed the patient and determined that the patient's behavior is disruptive and abusive...."
Comment: It is more than possible for a patient's behavior to be highly disruptive without being abusive.
Recommended: "disruptive and/or abusive."

(4)(ii) Signature by both the medical director and the patient's attending physician.
Comment: Making physician behavior part of the facility's obligation is always problematic. If the dialysis facility has a policy outlining the steps the facility needs to go through to make every effort to resolve the problem, and if the medical director concurs that this policy has been followed and that the patient needs to be discharged or transferred, it should not <u>also</u> be a requirement that the attending physician sign an order to this effect. Physicians should follow the policies of the unit in which they are privileged to practice, but in practical fact from time to time they do not. It is not always possible to require discontinuation of a physician's privileges when he/she fails to follow policies.
Recommended: replace "both the medical director and the patient's attending physician" with, "Either the medical director or the patient's attending physician."

Submitter : **Dr. CHRISTOPHER HOY** **Date: 03/29/2005**

Organization : **RUBIN DIALYSIS CENTER**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT

CMS-3818-P-12-Attach-1.DOC

Attachment#12

Comments on
Proposed Revisions to Conditions for Coverage for
End Stage Renal Disease Facilities

March 29, 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. Specifically I wish to comment on Proposed § 494.140 ("Personnel Qualifications") as this section addresses the possible role of a pharmacist within the dialysis facility. I 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.

I am the assistant medical director of a small not-for profit independent dialysis provider with 3 dialysis units in upstate New York. I am also in private practice in Nephrology, caring for almost 100 ESRD patients receiving incenter hemodialysis, home peritoneal dialysis, and nocturnal home hemodialysis. Our incenter and PD patients are on an average of 10 oral medications and 2 parenteral medications. They are variously being treated for kidney failure, hypertension, coronary artery disease, congestive heart failure, diabetes, HIV, hyperlipidemia, COPD, peripheral vascular disease, anemia, and malignancies. The extraordinary complexity of their medical problems, the altered metabolism of medications in renal failure, and the high potential for interactions of their medications all make the care of these patients much more difficult.

I believe that consultant pharmacists in the dialysis unit would improve the safety and quality of care that my patients receive. They should be included as part of the dialysis facility staff for the following reasons:

- the complex nature of drug therapy in dialysis patients,
- the pharmacokinetic complexity of drugs during dialysis

- the vulnerability of these patients for adverse medication-related outcomes,
- the need for storage, preparation, and administration of medications within the dialysis unit,
- the need for cost effective drug therapy,
- the changing nature of drug therapy that will arise due to the MMA, and
- the training of pharmacists that prepares them to serve as consultants to dialysis facilities.

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. Medication reviews should be conducted at least monthly. This frequency is consistent with what is required in skilled nursing and intermediate care facilities.
4. Pharmacists should participate in the development and implementation of medication-related protocols within dialysis to assure cost-effective drug use.
5. 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.

There is obviously the issue of how the pharmacist would be paid. I would posit that the savings from unnecessary medication orders, avoidable medication interactions, and a decrease in hospitalizations from medication complications would result in decreased overall non-dialysis health care expenditures for these patients, more than compensating for the the cost of a pharmacist. I would also suggest that patient mortality might be improved. It would not be unreasonable to test these hypotheses in a trial of different dialysis units, an investigation we would be happy to participate in.

Thank you for your consideration.

Sincerely yours,

Christopher D. Hoy, MD

Submitter : **Janice Mitchell** **Date: 03/29/2005**

Organization : **DaVita, Inc**

Category : **Dietitian/Nutritionist**

Issue Areas/Comments

GENERAL

GENERAL

Regarding "Plan of Care" and the team having 20 days from initiation of dialysis treatment to complete comprehensive assessment: In an ideal setting, this should not be difficult. However, in the Midwest, we cover large geographic areas and it may not be physically possible to see a new patient within 20 days. Example, one of my colleagues has a 4 hour drive to reach the dialysis unit and is only able to make the trip once a month.

Submitter : **Date: 03/30/2005**

Organization :

Category : **Dietitian/Nutritionist**

Issue Areas/Comments

GENERAL

GENERAL

I am a dietitian working per diem in a small dialysis unit (~30 patients). I travel 3 hours round trip to the unit. I am at the unit the third week of the month for 2 days. My concern is the 20-day timeframe for completing the comprehensive assessment. I agree that the assessment needs to be completed before the Plan of Care is completed, however splitting the current 30-day timeframe into 20 days for the assessment and 10 days for the Plan of Care will present a problem for units like the one I work in. There are times that a new patient starts a day or two after I have been at the unit. It is not practical for me to return to the unit until the next month's visit. I do contact new patients by telephone shortly after they start at the unit. I am able to find out about their specific situations and answer their immediate questions, but I feel that a comprehensive assessment needs to be done in person. In our area there are a number of units like this. I think that a practical Condition of Coverage would be: The team must complete a comprehensive assessment and a Plan of Care within 30 days from initiation of dialysis treatment. The comprehensive assessment must be completed prior to the completion of the Plan of Care. Thank you.

Submitter : Mr. Charles Shaffer **Date:** 03/30/2005

Organization : PA Dept. of Health

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

I recently attended the annual update in Florida. I was glad to hear about the updates to the regs. Staff from my field office participatred in the STAR program. The reports were very good. I look forward to that system going forward. Knowing that the ESRD regs. may not be a reality for 2 years really makes me want to see what actually is in print. I look forward to a more comprehensive comment opportunity than. I like what I see so far.

Thank you,

Submitter : **Mr. John Pilmer** **Date: 04/01/2005**

Organization : **individual**

Category : **Nurse**

Issue Areas/Comments

Issues 1-10

Infection Control

494.30 Infection Control
Creating an Infection control condition is an excellent proposal. The entire CDC MMWR April 27, 2001 should be incorporated by reference along with the CDC guidelines for multiple entries of single use vials. By incorporating only the At a Glance section you are implying that facilities do not have to follow these CDC recommendations.

Water Quality

By incorporating only sections of AAMI RD52 the dialysate requirements are weak. All of RD 52 should be incorporated by reference. The issue of testing the final dialysate pH with an independent meter and an acceptable pH range should be addressed. This is becoming a big controversy. There are components of RD61 that might also merit incorporation to strengthen the dialysate safety requirements. This is an area of great concern that has caused adverse patient outcomes.

Physical Environment

I like the Life Safety Code requirement.

Plan of Care

What happened to Patient assessment? Here are my comments on that condition.What about outcome measurements? These are well documented as standard of practice in the K/DOQI guidelines. Measurements of Kt/V and albumin are required to be measured but minimums are not addressed. A facility could decide a Kt/V of 1.0 was a reasonable goal. This was not uncommon a few years ago.

Vascular Access: ?The patient?s vascular access must be monitored to prevent access failure, including monitoring of ateriovenous (misspelled) grafts and fistulae for stenosis.? What does this mean - Transonics or listening with a stethoscope occasionally?

Care at Home

494.100 Care at Home: ?For self-care, must be conducted by a registered nurse.? I would agree that most of the training should be provided by an RN, but a technician might be able to provide some help such as a lecture on the hemodialysis machine. This appears to imply this is not acceptable.

?including visits to a patient?s home? Does this mean facility personnel would need to periodically visit every patient?s home? This could use some clarification.

The issue of dialysis in nursing homes needs to be addressed and clarified. The guidance on this is vague and should be clarified by regulation. Peritoneal dialysis in nursing homes should not have additional requirements as this could create a hardship for patient access. Previous guidance has indicated a nurse experienced in providing dialysis care must be on duty whenever a patient is undergoing dialysis. For CAPD patients this would be 24/7 and may create a hardship. For hemodialysis in nursing homes it seems prudent to have such a nurse on duty.

Issues 11-20

Personnel Qualifications

494.140 Personnel qualifications: Requiring a technician to be under ?the direct supervision of a registered nurse? for three months following training could create a hardship. Many facilities have only one RN on duty and s/he has many duties that might preclude ?direct? supervision. This would imply that the nurse would have to be with the technician when s/he was performing tasks for the entire three month period. This might make it difficult for the nurse to complete other tasks.

Medical Records

494.170 Medical Records: How about ?Patients must have physician orders for all treatment parameters and these orders must be followed.? I don?t see anywhere in these proposed regulations that would require facilities to have medical orders and follow them.

Submitter : Dr. Curtis Johnson **Date:** 04/01/2005

Organization : Wisconsin Dialysis Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-3818-P-17-Attach-1.DOC

Attachment# 17
March 8, 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 Proposed § 494.140 ("Personnel Qualifications") within the proposed revisions to the Conditions for Coverage for End Stage Renal Disease Facilities. Within this document, CMS has invited comment regarding the role of the pharmacist within a dialysis clinic, and I am eager to offer my thoughts.

I have practiced nephrology pharmacy for 27 years. During that time, I have had first-hand experience in providing pharmacy services to dialysis patients. At the present time, I serve as a consultant pharmacist to Wisconsin Dialysis, Inc., a free-standing dialysis facility in Madison, WI. I am routinely providing those pharmacist services that I feel are so desperately needed by dialysis patients and dialysis facilities.

Within our facility, I participate regularly in patient care planning. My contribution is the review of the multiple medications prescribed for our dialysis patients. Almost without fail, I identify some actual or potential medication-related problems for every patient we serve. As is common across the United States, our patients are prescribed many medications to treat their multiple medical problems, ranging from those that are rather specific to kidney disease (e.g., anemia, bone and mineral abnormalities) to those that are related to other comorbid conditions (e.g., hypertension, lipid disorders, diabetes, cardiac disease, infections, depression, hypothyroidism, and nutritional disorders). Patients are overwhelmed with the medication burden they are prescribed. I can and do contribute to simplifying this burden and ensuring that medications are being used wisely, safely, and effectively.

I also serve as a ready resource to the medical, nursing, and technician staff within the dialysis facility. I am routinely sought out as a source of information regarding medications prescribed or administered within the facility. Another of my major activities is the provision of medication-related in-service programs that deal with new drug therapies or new medication-related clinical practice guidelines such as those advanced by the National Kidney Foundation.

I assist our medical director in the development of protocols for medication use within the dialysis facility. For example, I have assisted in the development of our anemia

protocol and our bone and mineral protocol. I have been the person given responsibility for the day-to-day implementation of the anemia protocol. I also am a member of our facility's quality assessment committees for hemodialysis and peritoneal dialysis.

Because of the high volume of medications administered within our dialysis facility, I have been given the responsibility of oversight of our drug procurement, storage, and administration. These responsibilities are routinely assigned to pharmacists in other settings, and we believe that they should rest with a pharmacist within our dialysis program.

My knowledge of drug therapy and drug distribution gives me an important perspective on issues relating to patient safety within a dialysis unit. Medications and drug prescribing are important contributors to adverse events. CMS and others are committed to improving patient safety, and I believe a pharmacist can make an extremely valuable contribution to those efforts within dialysis facilities.

Finally, I am viewed as an important resource regarding the cost of medications used within our dialysis unit. I bring a perspective on drug pricing and reimbursement that is helpful to our administrative team faced with the financial management of the organization. This responsibility will grow even more important within the environment of the MMA.

Why have I been asked to perform these services within our dialysis program? I think the answer is straightforward. As a pharmacist, I possess certain skills that do not rest with other individuals within our program. My focus is drug therapy. I understand the complex nature of kidney disease and its related complication as well as the nuances of safe and effective drug therapy in patients with many risk factors for adverse outcomes. Medications are absolutely essential to the care of dialysis patients. These patients deserve the benefit of someone with a high degree of knowledge about drug therapy. But the skills of a pharmacist go beyond knowledge of drug therapy. Pharmacists also understand the principles of patient safety and proper medication distribution systems. We also understand drug prices and the cost effective use of drugs within such a complex patient population.

I can say from personal experience that consultant pharmacists absolutely should be a part of the multidisciplinary team within dialysis facilities. Dialysis patients deserve the services of these uniquely trained professionals.

Sincerely,

Curtis A. Johnson, Pharm.D.
Professor (Emeritus) of Pharmacy and Medicine
University of Wisconsin
Senior Clinical Pharmacist
Wisconsin Dialysis, Inc.

Submitter : Dr. Harold Manley **Date:** 04/04/2005

Organization : Albany College of Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-18-Attach-1.DOC

Attachment #18

March 28, 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 Proposed § 494.140 ("Personnel Qualifications") within the proposed revisions to the Conditions for Coverage for End Stage Renal Disease Facilities. Within this document, CMS has invited comment regarding the role of the pharmacist within a dialysis clinic. I am pleased to have the opportunity to voice my support for this concept.

I have been involved in nephrology pharmacy for 8 years as a clinician, researcher and educator, and have developed a variety of skills and gained many experiences in that time. Currently, I am a full-time faculty member with responsibilities for the provision of didactic and clinical experiences for students and research in dialysis patients. In addition to care of individual patients, my experience has been requested to aid the production of guidelines that influence dialysis patients in a global setting. I am a member of a Technical Expert Panel for a CMS sponsored project conducted by ESRD Network 8, Inc. and the University of Mississippi School of Pharmacy entitled: End Stage Renal Disease Outpatient Medications Project. The outcomes of this project are to provide a list and classification scheme for medications used in ESRD patients and to propose criteria that can be used for future development of an ESRD-specific drug utilization review protocol. I am also an editorial board member of the National Kidney Foundation's (NKF) Kidney Learning System. The purpose of the NKF Kidney Learning System in to increase awareness of the various Kidney Disease Outcome Quality Initiative (K/DOQI) guidelines among various health care disciplines.

Since 1997, I have devoted my professional career to the identification and resolution of medication-related problems (MRPs) in dialysis patients. The clinical research investigating MRPs in dialysis patients I have conducted utilized pharmacist implemented medication therapy management (MTM) processes.

In the dialysis population, MRPs are divided into nine categories: indication without drug therapy (IWD-patient has a medical problem requiring medication therapy, but is not receiving medication), drug without indication (DWI-patient is taking a medication for which no medically valid indication can be found), improper drug selection (IDS-patient has a medication indication,

but is taking the wrong drug), sub-therapeutic dosage (UD-patient has a medical problem being treated with too little medication), overdosage (OD-patient has a medical problem being treated with too much medication), adverse drug reaction (ADR-patient has a medical problem that is the result of an adverse effect), drug interaction (DI-patient has a medical problem that is the result of a medication-medication, medication-laboratory, or medication-food interaction), failure to receive drug (FRD-patient has a medical problem that is the result of not receiving medication), and inappropriate laboratory monitoring (LAB - patient requires laboratory test(s) to either adequately monitor medication therapy, ensure that common comorbid conditions are adequately identified and treated, or ensure that existing comorbid conditions are adequately treated)

Risk factors for the presence of MRPs in dialysis patients include: $\geq$ 3 concurrent disease states; medication regimen changed $\geq$ 4 times during the past 12 months; taking $\geq$ 5 medications or $\geq$ 12 doses per day; noncompliance history; drugs that require therapeutic monitoring; and presence of kidney disease or diabetes as a chronic condition. Virtually all dialysis patients have multiple risk factors for MRPs. Application of the concept of MRPs permits identification and resolution of problems of drug over- and underdosing, drug interactions, adverse event monitoring and reaching outcome goals, while at the same time ensuring the most cost-effective approach.

Under the Medicare Modernization Act, prescription drug plans and Medicare Advantage plans will be required to have continuous quality improvement programs such as MTM programs to optimize use of prescription drugs, improve outcomes and reduce adverse drug interactions in the Medicare patients signed up in their plan. Not all dialysis patients will enroll in these medication plans. However, all dialysis patients will need this service as they are at increased risk for MRP. Compilation of published reports suggests that in the U.S. HD population, 1,052,406 MRPs can be identified at first MTM review and 165,477 MRP per month after 6 months continuous pharmacist MTM follow-up. Provision of MTM at the dialysis clinic will improve patient care and will result in considerable cost savings. A review of published reports demonstrated that for every $1 spent on pharmaceutical care (i.e., MTM) in ESRD patients, the healthcare system (i.e., CMS) will save approximately $4.

Pharmacists possess a unique skill set that can be of profound use for patients on dialysis. Pharmacists are uniquely qualified as we are specifically trained for medication review and assessment. The focus of nephrology pharmacists encompasses pharmacotherapy, pharmacokinetics and pharmacoeconomics. Pharmacists are ideally trained to understand the complexities of variations in drug disposition during dialysis and between dialysis sessions. Pharmacists are often the most appropriately placed to ensure compliance with many of the medication-related clinical practice guidelines. In the dialysis patient population, pharmacists also demonstrated to be better than nurses and physicians in obtaining medication use information.

Residents of long-term care facilities, who share many of the characteristics of dialysis patients in terms of multiple comorbidities and complex therapeutic regimens, enjoy review of their medication regimens at least once per month. There are compelling data demonstrating that pharmacists within dialysis units can identify potential MRPs and are typically successful in having the medication orders appropriately altered. Unfortunately, only a small proportion of

dialysis facilities within the United States use the services of a suitably-trained nephrology pharmacist.

Specifically, I would like to make the following recommendations:

1. The multidisciplinary dialysis team should include a consultant pharmacist
2. The routine patient care assessment of dialysis patients should include a medication review by a pharmacist.
3. Medication reviews should be conducted at least monthly. This frequency is consistent with what is required in skilled nursing and intermediate care facilities.
4. Pharmacists should participate in the development and implementation of medication-related protocols within dialysis to assure cost-effective drug use.
5. 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.

In summary, I feel that dialysis patients are currently disadvantaged in not having the routine services of pharmacists. Because of our unique training and skills, I suggest that pharmacists should become a routine part of the multidisciplinary team that cares for these individuals. There follows a brief bibliography that documents some of the activities of pharmacists in the dialysis setting.

Sincerely,

Harold J. Manley, Pharm.D., BCPS
Associate Professor of Pharmacy

Annotated Bibliography

1. Manley HJ, Carroll C. The clinical and economic impact of pharmaceutical care in end-stage renal disease patients. Semin Dial. 2002 ;15(1): 45-9.

   A review of published reports demonstrated that for every $1 spent on pharmaceutical care (i.e., MTM) in ESRD patients, the healthcare system (i.e., CMS) will save approximately $4.

2. Manley HJ, Cannella CL, Bailie GR, St. Peter WL. Medication –related problems in hemodialysis patients: a pooled analysis of published reports. Submitted: American Journal of Kidney Diseases March 2005

   Compilation of published reports suggests that in the U.S. HD population, 1,052,406 medication related problems can be identified at first medication therapy management (MTM) review and 165,477 MRP per month after 6 months continuous pharmacist MTM follow-up

2. 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.

3. 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.

4. 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.

5. 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.

6. 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.

7. 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.

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.

10. 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.

Submitter : **Mrs. Linda Beisch** **Date: 04/04/2005**

Organization : **Virgina Beach Dialysis**

Category : **Nurse**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-3818-P-19-Attach-1.DOC

Attachment #19

As a certified hemodialysis nurse (RN) who has worked in dialysis since 1972, I have the following general comments regarding the proposals:

1. The RN shortage is projected to worsen when the baby-boomers retire. I will be retired when these regulations are published/finalized.

2. As an RN in 1972, my salary was $3.56/hr. Today I cannot hire nurses for less than $20/hr and have a severe shortage of RN's in my unit.

3. The LPN's at this unit have far more dialysis experience than most of my RN's.

Specific Comments:

494.140 (b) (2)

There is no need that self-care training be conducted by an RN. Many LPN's are well able to perform this function and have done so for many years.

494.140 (b) (3)

An LPN is well able to function as a charge nurse – without supervision by an RN on site.

494.180 (b) (2)

I don't believe it is necessary for an RN to be present in the facility at all times. A physician is available at all times by phone. In true emergencies, we call 911 and they transport patients to the ER. All staff are trained in emergency procedures and hold CPR certification.

494.140 (e) (3)

LPN's are very capable of supervising dialysis technicians. Home patients and partners are trained for dialysis and do dialysis at home without any direct supervision after 4-6 weeks.

I have been working with dialysis technicians since 1972. The technology today is excellent, enabling staff to care for more patients.

It is not necessary for a dialysis technician to have direct supervision for a period of 3 months. Staff training is individualized and no one requires direct supervision for 3 months. Nurses, whether RN or LPN's, are always present and in charge of the care of patients and supervision of all staff.

LPN's and RN's are trained in dialysis exactly like technicians are trained.

494.60 (c) (2)

Facilities need to look to all use groups in ascertaining comfortable building temperatures. Most dialysis patients are cold by virtue of their anemia and the blood being circumvented to the dialysis machine. Staff are moving about, usually at a rapid pace, and have additional PPE (clothing to prevent accidental blood exposure). Patients can add clothing/blankets when cool, but staff cannot take off their clothing.

Linda S. Beisch, RN, CNN
4780 Open Greens Dr.
Virginia Beach, VA 23462

Submitter : **Ms. Mary Jane Helenek MS RPh MBA** **Date: 04/06/2005**

Organization : **American Regent, Inc.**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-3818-P-20-Attach-1.PDF

Attach #20

AMERICAN REGENT
LABORATORIES, INC.

One Luitpold New York
(631) 924-4000 • (800) 645-1706 •

April 1, 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:

This letter is in regard to the proposed revisions to § 494.140 ("Personnel Qualifications") of the Conditions for Coverage for End Stage Renal Disease Facilities published in the Federal Register on February 4, 2005. I would like to take this opportunity to submit my comments to the Centers for Medicare and Medicaid Services ("CMS") regarding the role of the pharmacist within a dialysis clinic. 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. CMS should be commended for soliciting public comment on this issue.

I have been a pharmacist for 23 years as a clinician, consultant and administrator. I am currently the President and CEO of Luitpold Pharmaceuticals, Inc. Luitpold Pharmaceuticals and its American Regent division are industry leaders in the development, manufacture, and distribution of more than 130 injectable products, including Venofer® (iron sucrose injection, USP) and Dexferrum® (iron dextran injection, USP) used for the treatment of iron deficiency anemia. We are active in several nephrology associations, including the American Society of Nephrology and the National Kidney Foundation. I have had the opportunity to work with The National Kidney Foundation Dialysis Outcomes Quality Initiative (K/DOQI) work group, in the development of guidelines for anemia management. The dedicated professional staff of nephrology nurses and pharmacists at American Regent works closely with dialysis providers to help provide optimal anemia management for dialysis patients. This gives us a unique perspective on medication usage in this difficult patient population.

Chronic kidney disease patients, especially dialysis patients have complicated and extensive medication regimens. Pharmacists are ideally trained to understand the complexities of variations in drug disposition in the dialysis patient. Dialysis patients frequently see many physicians and receive an average of 10-12 medications, many of which require multiple doses per day. Because the kidney plays such an important role in drug disposition, many drugs must be dosed specifically according to patient-specific parameters. The effects of various dialysis techniques and dialysis membranes on drug clearance also must be considered when establishing drug therapy regimens. Most dialysis patients have multiple co morbid 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 co morbid conditions are at increased risk for drug-drug and drug-food interactions and drug toxicity as well as non-compliance. Adverse medication outcomes contribute to patient morbidity and to increased health care cost. These factors clearly outline the need for pharmaceutical care for dialysis patients. Because of the lack of a requirement for pharmacists to participate in the activities of a dialysis unit, most dialysis patients do not receive the benefit of medication review conducted by a pharmacy professional that is specifically trained to detect and address medication-related problems.

The clinical and economic value of pharmacist-related interventions has been well documented in various disease states, including chronic kidney disease. A study published in the September 22, 2003 issue of the Archives of Internal Medicine found that preventable adverse drug events were reduced by 78% when pharmacists participated in general medicine rounds.[1] Grabe et al documented the occurrence of drug-related problems within a dialysis unit. Pharmacist interventions were significant, and contributed to improved patient care.[2] In 2004; Hilleman et al published a study showing the cost-savings of pharmacist-directed interventions in the treatment of hypercholesterolemia.[3]

Residents of long-term care facilities, who share many of the characteristics of dialysis patients in terms of multiple co-morbidities and complex therapeutic regimens, are required to have a pharmacist review of their medication regimens at least once per month. There are compelling data demonstrating that pharmacists within dialysis units can identify potential drug-related problems and are typically successful in having the medication orders appropriately altered. Unfortunately, only a small proportion of dialysis facilities within the United States use the services of a suitably-trained nephrology pharmacist.

In conclusion, I feel that dialysis patients are disadvantaged in not having the routine services of pharmacists. Pharmacists should become a part of the multidisciplinary team providing care for these patients. Implementation of § 494.140 ("Personnel Qualifications") of the Conditions for Coverage for End Stage Renal Disease Facilities would result in the improved clinical outcomes and cost-effectiveness seen in other disease states and settings. The routine patient care assessment of dialysis patients should include a monthly medication review by a pharmacist.

Thank you for the opportunity to comment on these proposed Conditions for Coverage.

Sincerely;

Mary Jane Helenek

Mary Jane Helenek, M.S. R.Ph. M.B.A
President and CEO
Luitpold Pharmaceuticals, Inc.

References

1. Kucukarslan S, Peters M, Mlynarek M, Nafziger D, Pharmacists on Rounding Teams Reduce Preventable Adverse Drug Events in Hospital General Medicine Units *Arch Intern Med.* 2003;163:2014-2018.
2. 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.
3. Hilleman DE, Faulkner MA, Monaghan MS. Cost of a pharmacist-directed intervention to increase treatment of hypercholesterolemia. *Pharmacotherapy* 2004; 24(8):1077-83.

Submitter : Mrs. Jennifer Harris **Date:** 04/06/2005

Organization : DaVita

Category : Dietitian/Nutritionist

Issue Areas/Comments

GENERAL

GENERAL

-The proposed idea of having a Care Plan due 10 days following the initial Dietitian assessment is almost impossible. Doctors plan for their monthly care plan meetings months in advance and adjusting those for new patients won't be done by the doctors.
-Also, shortening the time initial Dietitian assessments are to be done (from 30 days to 20 days) doesn't give us as Dietitians enough time to fully assess these patients. The assessment would be incomplete and not a true assessment of how the patient is adjusting.
-Thirdly, having a comprehensive re-assessment by Dietitians after 3 months is repetitive. We do monthly comprehensive care plan notes on all of our patients anyway and by having to rewrite that information on another form is a waste of time.
-Please consider leaving the nutrition assessment guideline where it is at 30 days and having the Care Plan done within that first month the patient is with us. Also, please consider not adding a repetitive step for us in the 3 month re-assessment.

Submitter : Ms. Laura Whitmore **Date:** 04/06/2005

Organization : Davita, Inc.

Category : Dietitian/Nutritionist

Issue Areas/Comments

GENERAL

GENERAL

-The proposal to have the Care Plan due 10 days after the initial Dietitian assessment is almost impossible to accomodate. The doctors usually have a set schedule for when they do monthly care plan meetings; or they plan for their monthly care plan meetings months in advance. Adjusting care plan meetings to meet those deadlines when we admit new patients wont be done by the doctors because they dont have the flexibility in their schedules to accomodate this.

-Shortening the timeframe for initial nutrition assessments to be completed in (from 30 days to 20 days) doesn't give us as Dietitians enough time to fully assess these patients. A shorter timeframe will lead to incomplete assessment and it will also be difficult to assess how the patient is adjusting.

-Lastly, having a comprehensive re-assessment by Dietitians after 3 months is redundant. We do monthly comprehensive care plan notes on all of our patients anyway and a 3-month follow up would just be a duplication of documentation.

Submitter : **Dr. David Taber** **Date: 04/07/2005**

Organization : **Wingate University School of Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Issues 11-20

Personnel Qualifications

I would like to offer my suggestions on whether you should require a pharmacist be involved with patients with ESRD in order to have access to Medicare funding. Obviously, you are well aware of the overall benefits that patients obtain by receiving care from a clinical pharmacist. Having a pharmacist review medications, make recommendations, perform medication histories, and provide education is essential to the care of a patient with ESRD. I know this first hand. I have provided care as a clinical pharmacist to patients with renal disease and ESRD for over 4 years. As pharmacists, we have a unique knowledge base and set of skills that clearly benefit patient care. Additionally, studies have demonstrated that the addition of a pharmacist to the helath care team significantly decreases costs by both preventing adverse drug events and maximizing medication usage. given the rapidly rising costs of caring for patients with ESRD, this is a significant finding. Please consider requiring a pharmacist with advanced training to review medications on patients with ESRD in order to recieve Medicare funding. If logistics are a concern, just look at how this has impacted long-term care facilities and Medicare funding. Bottom line, you can't afford NOT to require this change!! Thank you for your time.

Sincerely,

David J. Taber, Pharm.D., BCPS

Submitter : **Ms. Maria Ashton** **Date: 04/07/2005**

Organization : **American Regent, Inc**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-24-Attach-1.DOC

AMERICAN REGENT

One Luitpold Drive, Shirley, New York 11967
(631) 924-4000 • (800) 645-1706 • Fax (631) 924-1731

Attachment #24
April 1, 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:

This letter is in response to proposed revisions to § 494.140 ("Personnel Qualifications") of the Conditions for Coverage for End Stage Renal Disease Facilities published in the Federal Register on February 4, 2005. I would like to take this opportunity to submit my comments to the Centers for Medicare and Medicaid Services ("CMS") regarding the role of the pharmacist within a dialysis clinic. 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. CMS should be commended for soliciting public comment on this issue.

I have been a pharmacist for 17 years as a clinician and consultant. I am currently the Manager of Professional Services at American Regent, Inc. American Regent manufactures, and distributes more than 130 injectable products, including Venofer® (iron sucrose injection, USP) and Dexferrum® (iron dextran injection, USP) used for the treatment of iron deficiency anemia. I work closely with national thought leaders and dialysis providers to help provide optimal anemia management for dialysis patients. I help provide education to renal healthcare professionals on anemia management. This gives me a unique perspective on medication usage in this difficult patient population.

The clinical and economic value of pharmacist-related interventions has been well documented in various disease states, including chronic kidney disease. A study published in the September 22, 2003 issue of the Archives of Internal Medicine found that preventable adverse drug events were reduced by 78% when pharmacists participated in general medicine rounds.[1] Grabe et al documented the occurrence of drug-related problems within a dialysis unit. Pharmacist interventions were significant, and contributed to improved patient care.[2] In 2004; Hilleman et al published a study showing the cost-savings of pharmacist-directed interventions in the treatment of hypercholesterolemia.[3]

Residents of long-term care facilities, who share many of the characteristics of dialysis patients in terms of multiple co-morbidities and complex therapeutic regimens, are required to have a pharmacist review of their medication regimens at least once per month. There are compelling data demonstrating that pharmacists within dialysis units can identify potential drug-related

problems and are typically successful in having the medication orders appropriately altered. Unfortunately, only a small proportion of dialysis facilities within the United States use the services of a suitably-trained nephrology pharmacist.

Chronic kidney disease patients, especially dialysis patients have complicated and extensive medication regimens. Pharmacists are ideally trained to understand the complexities of variations in drug disposition in the dialysis patient. Dialysis patients frequently see many physicians and receive an average of 10-12 medications, many of which require multiple doses per day. Because the kidney plays such an important role in drug disposition, many drugs must be dosed specifically according to patient-specific parameters. The effects of various dialysis techniques and dialysis membranes on drug clearance also must be considered when establishing drug therapy regimens. Most dialysis patients have multiple co morbid 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 co morbid conditions are at increased risk for drug-drug and drug-food interactions and drug toxicity as well as non-compliance. Adverse medication outcomes contribute to patient morbidity and to increased health care cost. These factors clearly outline the need for pharmaceutical care for dialysis patients. Because of the lack of a requirement for pharmacists to participate in the activities of a dialysis unit, most dialysis patients do not receive the benefit of medication review conducted by a pharmacy professional that is specifically trained to detect and address medication-related problems.

In conclusion, I feel that dialysis patients are disadvantaged in not having the routine services of pharmacists. Pharmacists should become a part of the multidisciplinary team providing care for these patients. Implementation of § 494.140 ("Personnel Qualifications") of the Conditions for Coverage for End Stage Renal Disease Facilities would result in the improved clinical outcomes and cost-effectiveness seen in other disease states and settings. The routine patient care assessment of dialysis patients should include a monthly medication review by a pharmacist.

Thank you for the opportunity to comment on these proposed Conditions for Coverage.

Sincerely;

Maria Ashton M.S. R.Ph.
Manager of Professional Services
American Regent, Inc.

References

1. Kucukarslan S, Peters M, Mlynarek M, Nafziger D, Pharmacists on Rounding Teams Reduce Preventable Adverse Drug Events in Hospital General Medicine Units *Arch Intern Med.* 2003;163:2014-2018.
2. 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.
3. Hilleman DE, Faulkner MA, Monaghan MS. Cost of a pharmacist-directed intervention to increase treatment of hypercholesterolemia. *Pharmacotherapy* 2004; 24(8):1077-83.

Submitter : Mrs. Brenda Highfill

Organization : Arkansas Renal System

Category : End-Stage Renal Disease Facility

Date: 04/12/2005

Issue Areas/Comments

GENERAL

GENERAL

see attachment

Issues 1-10

Basis

I would like to address the proposed regulation that addresses performance improvement for anemia management. If all hemodialysis patients are to maintain a hct of 33% for a criteria standard, it is imparative insurance companies like BC/BS(I am farmiliar with state of Ark) give pre ESRD patients approval to start epogen/procrit if hct<33%,NOT 30%. CMS is advocating a higher hct than can be attained for new dialysis patients prior to start on dialysis. Also for proper quality improvement new patients to dialysis SHOULD not be counted in statistics until 3 months,in my opinion. Amgen advocates no change in epogen for 4 weeks once a dose is prescribed and CMS requires dialysis units to count the patient in our anemia statistics the day they initiate dialysis. Dialysis staff can not be held accountable for quality outcomes when they haven't even cared for the patient.

Submitter : Dr. Page Dunlap

Organization : Tennessee Pharmacists Association

Category : Pharmacist

Date: 04/14/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Submitter : **Dr. Page Dunlap**

Organization : **Tennessee Pharmacists Association**

Category : **Pharmacist**

Date: 04/14/2005

Issue Areas/Comments

GENERAL

GENERAL

I am writing to offer comments regarding the proposed revisions to the Conditions for Coverage for End Stage Renal Disease Facilities. I would specifically like to address the possible role of a pharmacist within the dialysis facility as proposed in section #494.140 (?Personnel Qualifications?). I appreciate that the Proposed Rule acknowledges the well-documented contributions a pharmacist can make to the safe and effective use of medications in the vulnerable dialysis patient population.

I am a pharmacist working with the Tennessee Pharmacists Association. My organization represents pharmacists who serve in a consulting capacity to ESRD facilities.

Consultant pharmacists should be included as part of the dialysis facility staff for several reasons. Dialysis patients are generally on multiple medications, sometimes more than 8-12 drugs. These medications are complex in nature and may require special monitoring based of the pharmacokinetic nature of these drugs during dialysis. Many of these drugs may need to be readministered due to the elimination of the drug during the dialysis process. Dialysis patients, like the elderly, are extremely susceptible to adverse medication-related outcomes. Who best to monitor these patients for possible adverse events and medication regulation than the drug expert, the pharmacist?

The pharmacist is expertly trained in the storage, preparation and administration of medications that may be used within the dialysis unit. The pharmacist is trained to look for the most cost-effective approach to drug therapy. The pharmacist is aware of the changing nature of drug therapy that will arise due to MMA. Pharmacists receive exceptional training that prepares them to serve as consultants, including consultants to dialysis facilities.

I would like to make the following recommendations:

1. The multidisciplinary dialysis team should include a consultant pharmacist, preferably with experience or training in nephrology pharmacy. (This may not always be possible for ESRD facilities in smaller towns. However, pharmacists are trained in this area during their professional education and may receive additional education outside the classroom.)
2. The routine patient care assessment of dialysis patients should include a medication review by a pharmacist.
3. Medication reviews should be done on a monthly basis. This is consistent with what is required in skilled nursing facilities and intermediate care facilities.
4. Pharmacists should participate in the development and implementation of medication related protocols within the dialysis facility to ensure cost-effective drug use.
5. Pharmacists should be involved in the development and maintenance of dialysis facility policies for the safe storage, preparation and administration of medications within the facility.

As you are aware, the pharmacist can be a great contributor to the health and well being of dialysis patients. Certain medications need to be dose adjusted or supplemental doses may be needed post dialysis based on the filter size and the medication being filtered. The pharmacist has the knowledge to make the necessary adjustments and would be of much assistance to the multidisciplinary team. Pharmacists may also provide excellent patient education for staff development and for patients to promote better understanding of the medications used in these patients both during and after dialysis.

Please consider making the pharmacist a part of the multidisciplinary team within the dialysis facility. Not only will the patient benefit from the expertise of the pharmacist, so will the facility.

Thank you for your consideration.

Sincerely,

Page Dunlap, Pharm.D.
Associate Executive Director
Tennessee Pharmacists Association

Mary-Ellen Upton
Pharm.D. Cadidate-2005
University of TN
College of Pharmacy

Submitter : Dr. Page Dunlap

Organization : Tennessee Pharmacists Association

Category : Pharmacist

Date: 04/14/2005

Issue Areas/Comments

GENERAL

GENERAL

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3. Medication reviews should be done on a monthly basis. This is consistent with what is required in skilled nursing facilities and intermediate care facilities.
4. Pharmacists should participate in the development and implementation of medication related protocols within the dialysis facility to ensure cost-effective drug use.
5. Pharmacists should be involved in the development and maintenance of dialysis facility policies for the safe storage, preparation and administration of medications within the facility.

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Please consider making the pharmacist a part of the multidisciplinary team within the dialysis facility. Not only will the patient benefit from the expertise of the pharmacist, so will the facility.

Thank you for your consideration.

Sincerely,

Page Dunlap, Pharm.D.
Associate Executive Director
Tennessee Pharmacists Association

Mary-Ellen Upton
Pharm.D. Cadidate-2005
University of TN
College of Pharmacy

Submitter :

Date: 04/14/2005

Organization :

Category : **State Government**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-29-Attach-1.DOC

Attachment #29
April 13, 2005

The State of Wyoming survey agency would like to submit the following comments regarding the proposed federal regulations for ESRD facilities:

Comments concerning: **Definitions**

1. We feel that the term "home dialysis" should address or further define dialysis treatments given in other facilities such as long term care (LTC) facilities. In addition, we would like to see specific regulations for dialysis in LTC and/or other facilities. This would be more helpful then the S & C 04-24 letter written for guidance.

Comments concerning: **Water Quality**

1. We would like to see the adoption of the entire RD-52 AAMI guidelines. We feel these guidelines give specific water and dialysate standards. The water quality standards within these guidelines reduce the possibility of chemical and bacteriological encounters for each dialysis patient. Having sections of AAMI guidelines from RD-62 and RD-52 becomes confusing for both the ESRD facility and the surveyor.

Comments concerning: **Reuse of hemodialyzers and bloodlines**

1. During the survey process, how would this section ensure the wishes of patients who choose not to "reuse" their dialyzer? Would the surveyor still expect to see a consent for reuse?

2. Is it assumed the facility would have policies and procedures for reuse? Would survey issues related to reuse come under infection control and patient safety?

Comments concerning: **Patient's rights**

1. We were encouraged to see the requirement for the "posting" of the patient's rights. We would like to see that the regulation also include a 'second' source of contacting either the Network or state agency. As it is written, the regulation would only require a phone number. The posting of the address for each, the Network and state agency, would provide a second method of access to patients without a phone, and who wish to contact an outside source.

2. We would like to see a requirement for the posting of the facility's grievance process. We feel this would make the process accessible to all patients.

Comments concerning: **Patient plan of care - - -Implementation of the patient care plan**

1. Regarding: "(4) The dialysis facility must ensure that all dialysis patients are seen by a physician...periodically, while the hemodialysis patient is receiving in-facility dialysis." Could the regulation make an exception or waiver for rural areas when the service is provided, but the ESRD physician does not see the patient except in the office, which is located in another state/city?

Comments concerning: **Internal grievance process**

1. We would like to see the requirement that the facility must post its grievance process and the facility must accept a grievance in any form in which it is presented, verbal or written.

Comments concerning: **Emergency Coverage**

1. Why does a facility need to have an agreement with a hospital that it, the hospital, can provide inpatient care? Hospitals view these agreements as "contracts". The hospitals (and their lawyers) are hesitant to enter into these agreements, and hospital regulations do NOT require hospitals to enter into these agreements. Please explain the purpose of the agreement and how the agreement can be 'enforced' on the hospital side to have such agreements. Rural clinics are usually overseen by the ONLY nephrologist who already has admitting privileges at the ONLY hospital which is capable of in-patient dialysis.

Submitter : Ms. Jean Muller

Organization : Davita Oceanside

Category : Dietitian/Nutritionist

Date: 04/14/2005

Issue Areas/Comments

GENERAL

GENERAL

I'm a dietitian at a dialysis unit. The proposed condidtion of coverage that a dietitian must comple nutrition assessment in 20 days is often not possible. Often a new dialysis patient will come for a treatment and then is hospitalized for a time. It is better to word the condition of coverage in terms of number of dialysis treatments. For example, assessment done within first 13 treatments.

Submitter : Ms. Connie Schagunn **Date:** 04/17/2005

Organization : Ms. Connie Schagunn

Category : End-Stage Renal Disease Facility

Issue Areas/Comments

GENERAL

GENERAL

see attachement

CMS-3818-P-31-Attach-1.DOC

Attachment #31

Comments on Proposed ESRD regulations
File code CMS-3818-P

"Compliance with Laws and Regulations"- The preamble discussion indicates that the regulations would require facilities to adhere to medical device manufacturer's instructions for use, but the regulation, as written is vague in that area .The regulation should specifically state this requirement. Many dialysis providers have, because of financial or time issues, developed "more efficient" procedures for medical device use, which do not reflect the manufacturer's instructions, and without performing studies demonstrating that the "more efficient" method was safe for the patients.

"Infection control"- It is very good that the regulations specifically state adoption of the CDC guidelines. Appointing an RN Infection Control Officer is an excellent addition-this was a practice common in ESRD facilities 20 years ago and was very effective. Requiring facilities to provide each patient with a separate non-disposable blood pressure cuff would incur an additional cost, as the current practice is to wipe the cuffs with disinfectant between uses on multiple patients. The additions of the requirements for infection tracking and reporting are especially good and vital for patient and public safety.
This regulation (via the CDC guidelines) would require that all new facilities have a separate isolation room, but what about the existing facilities which don't have this? They should be required to, at a minimum, provide a designated patient station, as removed from the other patients and public as possible, with a hand washing sink readily available. The CDC guidelines (April 27, 2001 Vol 50/No, RR -5 page 27) states "Isolation Room" which implies separate ventilation system for air born transmission. The purpose of the isolation room in dialysis centers is for treatment of patients with blood born pathogens; this should be clarified either in regulation or by the CDC.

"Water Quality"- Since there is such a lengthy period between revisions to regulations, it is imperative that the **MOST CURRENT** standards be adopted. This is especially vital in ESRD, where a multitude of medical devices are used and adequate water quality directly correlates to patient safety. Although the regulation adopts the "ANSI/AAMI RD 61 and 62", these are NOT the most current or comprehensive AAMI standards for dialysis devices. **The 2004 "ANSI/AAMI RD 52"** addresses the equipment standards for water treatment as well as the standards for dialysate. In the past few years, in an effort to economize, the practice of mixing dialysate on-site has become commonplace. Without adequate oversight, this practice has the potential to cause serious harm to many patients. **"RD 52"** addresses the equipment and safety requirements for dialysate mixing and distribution and should be adopted into the regulations.

"Reuse"- It is appropriate to condense the reuse regulations and to adopt the most current AAMI standard, "RD 47". Refrigeration of used (bloody) dialyzers (in lieu of reprocessing within a 2 hour period) has been associated with bacterial and fungal growth in some infection outbreaks in ESRD facilities. The provision of refrigerating dialyzers should be scrutinized more closely by AAMI and CMS with detailed recommendations regarding this alterative.

"Physical Environment"- The adoption of the LSC in the ESRD facilities is very appropriate and necessary. These patients are connected to machines; many are non-ambulatory and unable to easily evacuate a building in an emergency. The average staff-to-patient ratio is 4:1. Many of the facilities are in strip malls without

medical facility fire clearances. These clinics do not have sprinkler systems or fire wall separations from the other occupants of the building. This places the patients at an increase risk during an emergency.

The requirement of emergency equipment, including an AED and emergency medications, is excellent. Most of the facilities have eliminated the emergency drugs, cardiac monitors and defibrillators, and educating their staff in emergencies. Many clinics now simply respond to patient emergencies by call 9-1-1 and do not provide emergency/supportive care. ESRD patients have many co-morbid conditions and cardiac arrests are not uncommon during dialysis, with up to 15 minute EMS response times. More immediate initiation of advanced cardiac life support has demonstrated a reduction in mortality with sudden cardiac arrest.

Elimination of the requirement for visual surveillance of patients is not appropriate. Some facilities are still laid out with separate rooms for patient stations, not visible from any central nurses' station. The reduction of staff in the ESRD setting has created the situation where patients are not in visual surveillance of staff for periods up to 30-60 minutes between blood pressure checks. At blood flow rates of 400 ml/min, it takes less than 5 minutes for a patient to exsanguinate. Constant visual surveillance during hemodialysis is imperative.

"Patients' Rights"- As in the long term care regulations, all staff of an ESRD facility should be required to receive mandatory education in the patients' rights. These regulations do address staff education. The environment of an ESRD promotes familiarity between staff and patients, with the line of professionalism often crossed. There have been numerous allegations of staff verbally abusing patients, in the absence of any requirement for staff education in patients' rights.
Clear guidelines for involuntary discharge are sorely needed in the ESRD, as there are many "problem" patients who end up dialyzing in the ED (at additional cost to CMS) because they were kicked out of a facility prior to active interventions or attempts to resolve staff/patient issues.

There is no longer a statement that the patient has the right to be involved in the planning of their care, only to be informed. This should not be deleted form the regs, as it is an important patients' right.

"Patient Assessment"- It is a good concept to perform an initial comprehensive patient assessment and a follow up assessment within 90 days of the first, however, only an annual reassessment thereafter for stable patients is too long. The dialysis patient has many co-morbid conditions, which even in the stable dialysis these factors needs to be addressed by the health care team more frequently than every 12 months.

Facilities have developed their own definitions of "unstable" patients, but have loosened the definitions to incorporate very few patients. If this were to continue and only an annual reassessment required, many patients' issues would be overlooked and not addressed by the IDT, likely leading to negative outcome.

These regulations do not mention any requirement for the IDT to conduct meetings for discussion of the patients. Facilities should be required to conduct periodic "Patient Care Conferences", and include the patients and/or their families. Clearly, face-to-face discussions by the IDT and patients, of patients' individual issues utilize the knowledge of each discipline, and enhance everyone's understanding of that patient's status and the plan for their care. The elimination of this requirement (V174) would be detrimental to the quality and individuality of patient care. Facilities would then simply "pass around paper" amongst the IDT members, each filling in their portions, then show it to the patient, simply to meet the requirement. There would be no collaborative exchange to maximize the patient's quality of care and life.

"Plan of Care"- Listing the various specific areas to be addressed in the plan of care is very good. This gives facilities a clear framework for care plan development. It is also good that transplantation status and patient education are addressed.
These regulations do not specify that the patient (or designee) is to be involved in the development of the plan of care, only that they sign the document when completed. As stated in the "patient assessment" comments, without such a requirement, the intent of a plan of care which truly addresses each patient's individual needs and utilizes the strengths of each member of the IDT will not be met. Only paper compliance will be achieved.

Realizing that a requirement for patient involvement is discussed in the preamble, it is important to note that, during most of the ESRD surveys, the Administrative staff frequently argues that they can not be required to comply with something that is not written in the regulations. The regulations, as written, do not include the requirements for patient involvement in care planning and for an actual IDT patient care conference, making enforcement of such requirements difficult.

"Care at Home"- Will a home visit be required at the onset of home-training, and periodically thereafter? The way the reg is written (494.100 (c)(1) (i)), any home visits are dependent on the patient care plan. What if a facility decides a patient's care plan does not require a home visit? Surely the regs should specifically state a requirement for home visits on ALL home patients. The home environment and support can not truly be evaluated through the interview process only.

Although these regs do address the care of patients on home hemodialysis and peritoneal dialysis, they do not address the care of the institutionalized patient. With the increase in dialysis patients in the long term care settings, the new regs need to reflect CMS's letter of July, 2004, addressing dialysis in the nursing homes.

"QAPI"- Excellent! A clear requirement for a defined QA program is necessary in the ESRD setting. Although there are already ESRD "standards" for lab outcomes, as described by K/DOQI, the discussion in the preamble about publishing numerical "standards" in the Federal Register is well taken. The more specific information the suppliers of ESRD have, the more likely they will be to conform to the expectations.

The list under 494.110 (a)(2)(i-vi) should be more inclusive of things such as hospitalizations, infections (also required in the "Infection Control" condition), incidents and accidents, and mortality and morbidity review.

"Personnel Qualifications"- Hemodialysis is an extremely invasive procedure, requiring extensive technical knowledge by all levels of patient care staff. The team's personal experience and practice, that it takes at least 6 months to one year, working with the dialysis machines and the different circumstances which come up with patient emergencies, to acquire an adequate knowledge base. The Charge Nurse at a facility may likely be working in the absence of any other administrative or licensed personnel, in the early morning or after hours. During those times, the Charge Nurse would be expected to have enough knowledge to make critical decisions affecting the health and safety of the patients. Requiring only 3 months of dialysis experience is wholly inadequate, and would risk the patients' safety. In California there are no training guidelines or certification for RNs in dialysis (as with PCTs). This would allow for facilities to hire RNs, inexperienced in dialysis, train them quickly and place them in charge within a 3 month period! A VERY unsafe situation!

The requirement for the Charge Nurses should include at least 6 months in a dialysis setting AFTER training is completed and basic competency verified.

The stated requirements for the PCTS and Water Technicians are great. Currently many facilities leave the Reuse Technicians in charge of the water systems, without adequate education.

"Medical Records"- This condition was reduced too much, as the documentation in the medical records of ESRD patients is often incomplete, inaccurate and not in accordance with identified medical records standards. Dialysis treatment records must include information about the dialysis machine settings and safety checks, information regarding assessment of the patient before, during and after dialysis, any medications and treatments delivered, and any unusual events occurring during the treatment. Often, the treatment records do not include this information, making it impossible to determine what happened during the patient's treatment. This is only one example of how incomplete many of the ESRD patients' medical records are.

The new regs should at least include a statement regarding the adherence to medical records standards; the old V246 was a good tag!

"Governance"- Regarding the discussion in the preamble about staffing ratios, California does not have any for dialysis facilities. We have seen as much as I RN for 21 patients in facilities by one corporate provider. It is very difficult to assess negative patient outcomes related to poor staffing in dialysis, as tracking mortality is difficult and nebulous. When no actual demonstrated outcome could be cited, the above-mentioned corporate facility's response to the citation for poor staffing was that the staffing was at the level identified by the corporation and was, in fact, sufficient, as the only stated requirement was one RN in the building.
To assure the safety of the patients, minimum staffing ratios are necessary, and should be included in the CMS regs.

The outline about involuntary discharge is very good, and needed!

Submitter : **Mr. Richard Goodenbour** **Date: 04/18/2005**

Organization : **Mr. Richard Goodenbour**

Category : **Individual**

Issue Areas/Comments

Issues 1-10

Plan of Care

Plan of Care 494.90

There is an annual and a monthly a care plan prepared but the extent of the patient involvement is a signature possibly a month or more after the care plan is already in effect. The patient while being dialyzed, the charge nurse orders the patient to sign the care plan. If the patient attempts to read the care plan the RN seems very offended. The RN repeatedly interrupts the patient while they attempt to read the care plan, insisting that the patient sign the plan. The RN can be very intimidating. While the patient is dialyzing they are in a very compromised position and many can be intimidated into just signing because they are in fear of retaliation.

When the comprehensive care plan is developed and the selected modality and setting of the treatment is discussed and determined the patient should be given accurate data to determine whether to reuse the dialyzer or receive a new one each treatment. The patient should be informed that they do have this choice. For example, once again while the patient is being dialyzed the RN or the unit Director place a paper in front of the patient and tell them to sign here and say something to the patient like ??allow us to reuse your dialyzer and only you will ever use this dialyzer . Because of the presentation the patient gets the impression that if they did not sign they might get a dialyzer that someone else had used before but if they sign they will always get their own dialyzer. Part of this is people have always been conditioned to always trust the medical profession and not to question something that they tell you.
No options are explained and the risks of reusing the diaylizer is not explained. The patient is not informed that recent scientific studies have determined that you receive better treatment/results using a new dialyzer each treatment. In 2003 At the American Society of Nephrology (ASN) Conference, one of the major renal conferences, which was held in San Diego on November 14 ? 17, a scientific study was presented regarding the improvements in medical outcomes of single-use dialyzers compared to re-use dialyzers. This retrospective study found a survival advantage in patients using new synthetic membrane dialyzers with each treatment compared to patients using dialyzers that had been clinically reprocessed (reused).

It should be noted that just because the patient has signed the care plan does not mean that they have had any involvement in it or that they have even read it. There should be a space after the place for the patient to sign the care plan where the patient must date it the date they are signing the care plan. Presently this might be a month or two after the care plan took effect.

Rehabilitation Status (Proposed 494.90(a)(6))

Successful rehabilitation should be to return the patient to the same level of employment that they were employed at before beginning dialysis, and at the same income level. Not just returning to any level of gainful employment. It should be clarified who would be doing this rehabilitation. Would this be done by the Social Security Vocational Rehabilitation?

A concern with 411 subpart F is how quickly the patient will reach the lifetime benefit of the health insurance through their employment and what would be required to re-acquire Medicare once the lifetime benefit of the other health insurance was reached.

Patients' Rights

V. Proposed Part 494 Subpart c(Patient Care)

Section 494.80 B.Patient Assessment

It is very important that the patient be included as part of the team if the patient chooses to be. This is a positive change and one that is needed. The team concept is always talked about and sounds good but in reality the patient is left out of the team and has no voice. If the patient questions anything they are told that if they are not satisfied they are welcome to get treatment elsewhere if they don?t like the way things are done. Again reality offers patients no choice in treatment providers unless they relocate.
Involving the family members is also a positive change, for example, my wife was never spoken to by anyone in the unit until I was hospitalized. Some communication and education of family members may take place initially when a patient begins dialysis but if the patient?s family composition changes. There is no contact or education with the 'new? family member. In fact, the unit personnel know so little about patients, they don?t even know there was a change

The evaluation of the patient?s ability, interest, preferences and goals, including level of participation in the dialysis care process is a positive change and should be confirmed and or reevaluated at least annually. Presently, the patients are treated as incapable and non- functioning adults. For example, the process of weighing yourself when you arrive and after treatment involves stepping onto an electronic scale with a digital read out and recording this number on a piece of paper. The patients are not allowed to do this without a person from the unit, genererally an RN observing. Even if the patient is one whose functioning and whose current activity level is quite adequate the patient is not allowed to walk back to the treatment chair or leave the treatment chair without being accompanied by an RN.

Evaluation of the current physical activity level or desire to improve the levels will be a positive change.

Evaluation of the patient?s current vocational status and whether education is required to return to the same level of employment they were at before beginning dialysis is necessary? In some cases to returning to the same level of employment might require more education. For example a person may have worked there way

up to a management position in a company with out having a BA, the person?s previous position may have been filled by the time they are capable of returning to employment. To return to the workforce into a management position at a different company might require that they earn a BA.

As proposed in section 494.80(d)(1) an annual reassessment should be adequate for a stable patient.

In section 494.80(d)(2)(i) through(d)(2)(iv) significant changes in psychosocial needs is mentioned. The only time the social worker sees the patients is while they are undergoing treatment. There is no privacy in this environment and many patients will not discuss their needs without privacy, so how is this determined? The Social worker needs to take a more active role and meet with the patient and the patient?s family in a confidential setting.

Submitter : **Ms. Aaron Battle** **Date: 04/18/2005**

Organization : **End Stage Renal Disease Network of New York**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

"See Attached"

CMS-3818-P-33-Attach-1.DOC

Attachment #33

Comments on CMS- 3818 - P

Dose of Dialysis

Although performance measures are most important (Kt/V values, hematocrit), there should be some way to determine dry weight, when there are no visible or other signs of fluid gain. It seems that at present it is a guessing game, which causes problems with blood pressure as well as dehydration in some patients.

Vascular Access

Very important. Patients should be made aware of any risk factors involved with co-morbid factors as well as education regarding their access (i.e. available treatments, preventative care).

Medical Records

Patient records should be updated with any changes, corrections or problems 2-4 days after the event. Because dialysis patients are seen 3 times a week, it is important that information is corrected and updated, if not by the next treatment, then before the treatment after. Because there are changes from treatment to treatment, all assessments made by physicians or nursing staff, after or during treatments, should be place at the front of the chart. Also, because there are staff changes (i.e. sick call), this information should be available.

Requirement at existing 405.2139 (c) that the facility designate a staff member to serve as the medical records supervisor to facilitate the record keeping process. **This requirement should remain because of the frequency of treatments and to make sure that information is updated and documented as soon as possible.**

Personnel Qualifications

Dialysis Technicians - Since dialysis technicians provide most of the care to patients during treatments, there should be uniform training and certification for dialysis technicians. It is important for technicians to be competent in patient care as well as medical emergencies. Three months is an adequate time when there is supervision by a qualified nurse, but in many cases the nurses duties impede them from closely monitoring technicians. So, after the 3 month period there should be an assessment to verify that technicians are competent in patient care including access care and maintenance education, patient privacy and confidentiality, good interpersonal skills, recognizing and reporting medical errors, and dealing with emergencies.

Submitter : Ms. Arlene Sukolsky **Date:** 04/18/2005

Organization : TransPacific Renal Network

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

"see attachment"

Submitter : **Dr. Carol DiRaimondo** **Date: 04/18/2005**

Organization : **TransPacific Renal Network Medical Review Board**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

"see attachment"

CMS-3818-P-35-Attach-1.DOC

CMS-3818-P-35-Attach-2.DOC

TRANSPACIFIC RENAL NETWORK

April 18, 2005

Attachment #35
Centers for Medicare & Medicaid Services
Department of Health Services
PO Box 8012
Baltimore, Maryland

Re: FILE CODE CMS 3818p

To Whom It May Concern:

The following comments represent the consensus of the Medical Review Board and the Board of Directors of the TransPacific Renal Network regarding the proposed Conditions of Participation.

Patient Safety: The Board supports the proposal that new facilities must have an isolation room. We further recommend consideration of required testing for Hepatitis C upon admission to a dialysis facility and periodically thereafter. We further recommend that existing laws regarding reimbursement for this procedure must be changed, and that CDC Guidelines must be followed, including reimbursement for testing for Hepatitis C. The Board also supports the recommendation of a Hepatitis B positive separate area in existing facilities, unless the facility is so small that a separate area is not feasible.

Water Quality: There are no data available to support the proposed requirement for ultra pure dialysate, and this also adds significant costs to the facility.

Physical Environment: The Board supports all of the recommendations for emergency preparedness and feels there should be no exemptions for defibrillators in rural facilities. Personnel should be certified in CPR and AED.

Patient Assessment: The Board feels that 30 days AFTER ADMISSION to a dialysis facility is more appropriate for patient assessment, followed by a 6-month comprehensive review. The Board also supports the elimination of the long term care program and signature of a transplant surgeon. The requirement for seeing patients on a monthly basis may be unduly burdensome for geographically-isolated facilities or those with severe nephrologist shortages. The Board questions the reasonableness of holding the facilities responsible for assuring that physicians would be required to see patients while on dialysis.

Patients Rights: We seek clarification of "appropriateness of discharge". The Board supports the concept that patients may not be discharged for not following staff recommendations. The Board is pleased to see a requirement that patients be informed of their right to complete an advance health care directive.

4470 Redwood Highway, Suite 102, San Rafael CA 94903 • Tel (415) 472-8590
Fax—Data Dept (415) 472-8594 • Fax—QI, Patient Services, Administration (415) 472-8596
www.network17.org

TRANSPACIFIC RENAL NETWORK

Dialysis in skilled nursing facilities: There is no financial incentive for these facilities to undertake dialysis unless changes are effected in licensure. SNFs should not have to be responsible for equipment, staffing, and transportation. We have concerns about quality, safety, and accountability.

Priority of Improvement Activities: The Clinical Performance Measures initiative should provide the data necessary to guide facility quality improvement. Billing data, usually submitted by clerical staff, would be questionable as to accuracy. We question the use of minimum standards, since standards change over time. Minimum standards might actually restrict patients to accessing care if the patients are labeled as unacceptable.

Medical Director Qualifications: We object to the lowering of standards for this important position, except on a case-by-case basis.

Social Worker Qualifications: We strongly support the recommendation that social workers should be freed of clinical tasks, and advocate that a masters level should be the community standard, and licensing required.

Dialysis Technicians: The Board supports this language.

Adequate number of trained staff: The minimum requirement for one registered nurse per shift does not take into consideration the large number of patients in a given facility and makes for questionable patient safety.

Discharge and Transfer Policies: The Board supports the proposed language.

Respectfully submitted by the Medical Review Board of the TransPacific Renal Network:

Russell Branco, CHT
John Brennan, Consumer
Evelyn Butera, RN
Rickey Creet, CHT
Carol DiRaimondo, MD
Karen Dyer, RD, MS
Ted Lynch, MD
Patricia McCarley, RN, CNP
Thomas Paukert, MD, PhD
James Robertson, MD
Cathy Rosaia, RN
Lawrence Spergel, MD
Jared Sugihara, MD
Stephen Tomlanovich, MD
Edwina Whitacre, RN
Sandy Wallace, RD
Roberta Wilson, RN
Elizabeth Wong, LCSW

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www.network17.org

Submitter :

Organization :

Date: 04/18/2005

Category : **Nurse**

Issue Areas/Comments

GENERAL

GENERAL

Test

Submitter : Dr. Wendy St. Peter **Date:** 04/19/2005

Organization : University of Minnesota

Category : Pharmacist

Issue Areas/Comments

Issues 11-20

Personnel Qualifications

See Attachment

CMS-3818-P-37-Attach-1.DOC

ATTACHMENT #37

UNIVERSITY OF MINNESOTA

College of Pharmacy
Department of Pharmaceutical Care
& Health Systems

Wendy L. St. Peter, Pharm.D. FCCP, BCPS
Associate Professor

Hennepin County Medical Center
914 South 8th Street
Suite D-206
Minneapolis, MN 55404

Tele: (612) 347-7752
FAX: (612) 347-5878
Email: stpet002@umn.edu

April 19, 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 would like to offer my insight regarding Proposed § 494.140 ("Personnel Qualifications") within the proposed revisions to the Conditions for Coverage for End Stage Renal Disease Facilities.

I have been a nephrology pharmacy practitioner for 17 years at Hennepin County Medical Center (HCMC) in Minneapolis. During that time, I have provided medication therapy management services to both hospitalized and outpatient dialysis patients. Thus, I have routinely provided pharmacy services to a patient population that I believe greatly needs pharmacy care. I'm currently conducting epidemiologic research in chronic kidney disease (CKD) patients with the United States Renal Data System (USRDS).

HCMC has employed pharmacists with specialized knowledge in patients with CKD, end-stage renal disease (ESRD) and kidney transplantation since the 1970's. Currently, our 350 bed hospital has one pharmacist practicing in the area of CKD and ESRD, another practicing in kidney transplantation and a pharmacy resident in training for both of these areas. HCMC hospital and pharmacy administrators have maintained this level of pharmacy care for these specific patient populations because they are medically and pharmaceutically complex and they believe that pharmacists not only improve patient outcomes in patients with ESRD, but provide cost-effective care.

ESRD patients are prescribed, on average, 10-12 medications (not including botanical products). I've routinely taken care of patients who have been prescribed >20 medications at one time for common kidney-related comorbidities including anemia, infections and bone and mineral disorders as well as common general conditions that are seen in ESRD patients such as hypertension, hyperlipidemia, diabetes, cardiovascular disease, depression and nutritional disorders. My experience is that patients generally feel overwhelmed with the shear number of medications and the number of times a day they need to take their medications. With the number of medications on the market today, other dialysis team members (physicians, nurses, dieticians and social workers) often do not have the necessary background and expertise to conduct a thorough medication review, looking for drug-related problems (drug interactions, underdosing, overdosing, appropriate drug for indication, etc...). There is also the additional complexity of the dialysis procedure. Dialysis patients may be treated by hemodialysis (HD) or peritoneal dialysis (PD). There are many different HD membranes and several different HD and PD procedures that are used today. The extent of drug removal varies depending on the membrane and technique.

Pharmacists who are trained in nephrology can provide the necessary expertise to design rational dosage regimens taking each patient's medical conditions, and dialysis therapy into consideration.

As a nephrology pharmacy clinician at HCMC, I reviewed ESRD patient's medication records and made recommendations when I encountered drug-related problems. On average, I detected and made recommendations on 4.5 drug-therapy problems per patient. Ninety-five percent of recommendations were accepted by and implemented by physicians. I documented these activities in the following article: St. Peter WL Clinical pharmacy nephrology consultation and documentations: a comprehensive approach. Journal of Pharmacy Practice, 1993;6:140.

Drug-related problems need to be detected, evaluated and addressed in all U.S. patients with ESRD, not just selected patients in specific programs that are fortunate to have nephrology pharmacy services. HCMC hospital and pharmacy administrators have continued to invest in nephrology pharmacy practitioners because pharmacists possess a background and skill set that other healthcare practitioners do not have. Pharmacists that have been trained in nephrology understand the complex nature of kidney disease, its related complications, the additive complexity of dialysis therapies and the nuances of safe and cost-effective medication management in a population of patients at enormous risk for complications, poor outcomes and increased health care costs.

USRDS research shows that Medicare spends almost 7% of its budget on ESRD patients that constitute only 0.6% of the Medicare population. About half the costs can be attributed to hospitalizations. Pharmacists who provide services to dialysis units have the potential to improve patient outcomes and reduce hospitalizations through optimal medication therapy management.

At a minimum, a pharmacist's role in the dialysis unit should include:

- Monthly medication and medical chart review for detection and evaluation of drug-related problems
- Provision of medication therapy management services to individual patients
- Involvement in development of medication therapy protocols and algorithms

In closing, dialysis patients desperately need routine medication therapy management services for optimal health outcomes. Pharmacists are uniquely qualified to provide these services in outpatient dialysis settings.

Sincerely,

Wendy L. St. Peter, Pharm.D., FCCP, BCPS
Associate Professor, University of Minnesota College of Pharmacy
and
Co-investigator, United States Renal Data System

Submitter : **Date: 04/19/2005**

Organization : **Davita Dialysis**

Category : **Dietitian/Nutritionist**

Issue Areas/Comments

Issues 1-10

Plan of Care

The proposal to perform initial nutrition assessment in 20 calender days for a new patient, does not take into account that a lot of times, the patient is admitted back to the hospital for any complication and can stay there for greater than 20 days. Hence, the current practice of completing the initial nutrition assessment should stay at 30days after admission.

Also, the proposed comprehensive nutrition re-assessment in 3 months is quite redundant. Currently, our clinics do monthly multidisciplinary care plans on each and every patient, and address any current nutritional complication or problem for that patient, on that month; rather than waiting for 3 months. Presently, all new patients are considered unstable patients for atleast 3 months and have a comprehensive evaluation by the multidisciplinary team on a monthly basis. Besides, there is an annual comprehensive re-assessments that are performed on all the patients.

I strongly feel that the proposed conditions by CMS for nutrition assessments/re-assessments are just increasing the paper-work load of the dietitians without improving patients quality of care and outcomes. Outcomes can be formulated to look great on paper, but that does not imply that they improve quality of care.

Submitter : **Date: 04/19/2005**

Organization : **AOPHA**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-3818-P-39-Attach-1.DOC

Attachment #39
MEMORANDUM

TO: CMS

FROM: AOPHA - The Advocate Of Not-For-Profit Services for Older Ohioans

DATE: April 19, 2005

SUBJECT: CMS -33818-P
(Proposed rulemaking for the coverage and provision of home dialysis services when a beneficiary is a resident of a Medicare or Medicaid certified skilled nursing facility.)

1) Clarification is needed regarding the issue below:

Under the Medicare home dialysis regulations, a beneficiary with end stage renal disease may elect to receive dialysis services at home. CMS has opined that it is permissible for a nursing facility resident to elect to receive home dialysis in a nursing facility ("NF") or a skilled nursing facility ("SNF") as the patient's home. In order to do so, the beneficiary contracts with a dialysis facility or a durable medical equipment supplier to provide the equipment, training and monitoring services required by the beneficiary. The law further contemplates that "Caregiver" services (i.e., the help and assistance necessary for a dialysis patient to self-dialyze from non-professionals) are to be provided by a family member or friend of the patient, or the patient himself, and no additional reimbursement is provided to pay for these services. This is because home dialysis was originally contemplated to occur in the patient's home, where a spouse, friend or other family member living with the patient would be available to assist the patient in self-dialyzing. Thus, the Medicare program provides coverage for training of Caregivers and patients in home dialysis, but does not pay Caregivers for their services.

Thus, while CMS has made it clear under its proposed rulemaking that it wishes to permit residents living in a NF or SNF to receive home dialysis in the facility, and that the facility should be considered the resident's "home" for the purposes of Medicare coverage for home dialysis, CMS has not clarified who should be responsible for arranging and paying for the services of a Caregiver. When home dialysis is made available to residents living in a NF or SNF, it is virtually impossible to ensure that a friend or relative can be available to provide Caregiver services. Further, it raises liability issues for the NF or SNF to permit an outside person to perform such monitoring services.

Generally, the end stage renal disease centers and durable medical equipment providers that provide the equipment and support services to the beneficiaries have taken the position that their reimbursement rate does not cover Caregiver services, and have demanded that the facility pick up this cost. Further, some end stage renal disease centers and durable medical equipment providers have taken the position that they are prohibited from providing this service free of charge by the applicable fraud and abuse laws. As a result, NFs and SNFs, at the demand of these providers, have arranged for the services of Caregivers by contracting or employing qualified individuals to provide the service to residents.

However, if it is indeed a resident's obligation to arrange (and consequently to pay for) Caregiver services under the Medicare home dialysis program there could also be fraud and abuse issues with the NF or SNF providing such services to the resident at no additional cost. Among other things, the provision of free services to a federal healthcare beneficiary intending to induce the beneficiary to receive services from the facility may constitute a violation of the federal anti-kickback statute (42 USC 1320a-7a(a)(5); 42 CFR 1003.102(a)(13). This is exacerbated by the fact that when a resident is a recipient of the Medicaid program, it would be impossible for the resident to personally cover the costs of Caregiver services, as all of the resident's income goes to the facility to

cover the cost of nursing facility care, with the exception of the monthly resident's personal allowance which the resident needs for incidental expenses.

For all of the above reasons, we think that CMS should clarify who is to be responsible for arranging for and paying for the services of a Caregiver. If it is the NF or SNF's responsibility, will the resident be responsible for paying for this service? If the resident does not or cannot pay for the service, would the facility providing a Caregiver expose itself to risk of violation of the fraud and abuse laws? Answers to these questions would be very helpful to the provider community.

2) AOPHA membership has the following general comments:

- Hemodialysis is very complex and requires direct supervision, where peritoneal dialysis does not.
- We do not support the idea of nursing home residents providing self hemodialysis.
- We are concerned over the shift of liability to the nursing home.

Thank you for the opportunity to comment. If you need further information, please contact:

Paulette Luneborg, BSN, RN
Director of Regulatory Relations
AOPHA
855 S. Wall Street
Columbus, Ohio 45133
E-mail: pluneborg@aopha.org
Phone: 614-444-2882 (ext. 20)
Fax: 614-444-2974

Submitter : Mrs. Jennifer Hedges **Date:** 04/20/2005

Organization : Sharp Memorial Kidney Transplant Center

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

I'm a transplant social worker and have reviewed the proposed "Patient plan of care" section of the conditions for coverage of dialysis. I believe it's important that the interdisciplinary team develop plans for pursuing transplantation with each patient. I especially agree that there needs to be a transplantation referral tracking device. This includes that the team communicate with the transplant center regarding patient transplant status at least quarterly. This way patients will be less likely to fall through the cracks. Patients often think they're listed when they still have workup pending, or they're ready for a transplant but have psychosocial issues with Dialysis.

Submitter : Mr. Scott Vivona **Date:** 04/21/2005

Organization : Calif. Dept. of Health Services -- L

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

The outline about involuntary discharge is very good, and needed!

Issues 1-10

Water Quality

"Reuse"- It is appropriate to condense the reuse regulations and to adopt the most current AAMI standard, "RD 47". Refrigeration of used (bloody) dialyzers (in lieu of reprocessing within a 2 hour period) has been associated with bacterial and fungal growth in some infection outbreaks in ESRD facilities. The provision of refrigerating dialyzers should be scrutinized more closely by AAMI and CMS with detailed recommendations regarding this alterative.

Physical Environment

"Physical Environment"- The adoption of the LSC in the ESRD facilities is very appropriate and necessary. These patients are connected to machines; many are non-ambulatory and unable to easily evacuate a building in an emergency. The average staff-to-patient ratio is 4:1. Many of the facilities are in strip malls without medical facility fire clearances. These clinics do not have smoke detectors, sprinkler systems or fire wall separations from the other occupants of the building. This places the patients at an increase risk during an emergency.

The requirement of emergency equipment, including an AED and emergency medications, is excellent. Most of the facilities have eliminated the emergency drugs, cardiac monitors and defibrillators, and educating their staff in emergencies. Many clinics now simply respond to patient emergencies by call 9-1-1 and do not provide emergency/supportive care. ESRD patients have many co-morbid conditions and cardiac arrests are not uncommon during dialysis, with up to 15 minute EMS response times. More immediate initiation of advanced cardiac life support has demonstrated a reduction in mortality with sudden cardiac arrest.

Elimination of the requirement for visual surveillance of patients is not appropriate. Some facilities are still laid out with separate rooms for patient stations, not visible from any central nurses? station. The reduction of staff in the ESRD setting has created the situation where patients are not in visual surveillance of staff for periods up to 30-60 minutes between blood pressure checks. At blood flow rates of 400 ml/min, it takes less than 5 minutes for a patient to exsanguinate. Constant visual surveillance during hemodialysis is imperative.

"Patients' Rights"- As in the long term care regulations, all staff of an ESRD facility should be required to receive mandatory education in the patients' rights. These regulations do address staff education. The environment of an ESRD promotes familiarity between staff and patients, with the line of professionalism often crossed. There have been numerous allegations of staff verbally abusing patients, in the absence of any requirement for staff education in patients' rights. Clear guidelines for involuntary discharge are sorely needed in the ESRD, as there are many "problem" patients who end up dialyzing in the ED (at additional cost to CMS) because they were kicked out of a facility prior to active interventions or attempts to resolve staff/patient issues.

There is no longer a statement that the patient has the right to be involved in the planning of their care, only to be informed. This should not be deleted form the regs, as it is an important patients' right.

Plan of Care

"Plan of Care"- Listing the various specific areas to be addressed in the plan of care is very good. This gives facilities a clear framework for care plan development. It is also good that transplantation status and patient education are addressed.
These regulations do not specify that the patient (or designee) is to be involved in the development of the plan of care, only that they sign the document when completed. As stated in the "patient assessment" comments, without such a requirement, the intent of a plan of care which truly addresses each patient?s individual needs and utilizes the strengths of each member of the IDT will not be met. Only paper compliance will be achieved.

Realizing that a requirement for patient involvement is discussed in the preamble, it is important to note that, during most of the ESRD surveys, the Administrative staff frequently argues that they can not be required to comply with something that is not written in the regulations. The regulations, as written, do not include the requirements for patient involvement in care planning and for an actual IDT patient care conference, making enforcement of such requirements difficult.

Care at Home

"Care at Home"- Will a home visit be required at the onset of home-training, and periodically thereafter? The way the reg is written (494.100 (c)(1) (i)), any home visits are dependent on the patient care plan. What if a facility decides a patient's care plan does not require a home visit? Surely the regs should specifically state a requirement for home visits on ALL home patients. The home environment and support can not truly be evaluated through the interview process only.

Although these regs do address the care of patients on home hemodialysis and peritoneal dialysis, they do not address the care of the institutionalized patient. With the increase in dialysis patients in the long term care

Patients' Rights

"Patient Assessment"- It is a good concept to perform an initial comprehensive patient assessment and a follow up assessment within 90 days of the first, however, only an annual reassessment thereafter for stable patients is too long. The dialysis patient has many co-morbid conditions, which even in the stable dialysis these factors needs to be addressed by the health care team more frequently than every 12 months.

Facilities have developed their own definitions of "unstable" patients, but have loosened the definitions to incorporate very few patients. If this were to continue and only an annual reassessment required, many patients' issues would be overlooked and not addressed by the IDT, likely leading to negative outcome.

These regulations do not mention any requirement for the IDT to conduct meetings for discussion of the patients. Facilities should be required to conduct periodic "Patient Care Conferences", and include the patients and/or their families. Clearly, face-to-face discussions by the IDT and patients, of patients? individual issues utilize the knowledge of each discipline, and enhance everyone's understanding of that patient's status and the plan for their care. The elimination of this requirement (V174) would be detrimental to the quality and individuality of patient care. Facilities would then simply "pass around paper" amongst the IDT members, each filling in their portions, then show it to the patient, simply to meet the requirement. There would be no collaborative exchange to maximize the patient?s quality of care and life.

Issues 11-20

Governance

"Governance"- Regarding the discussion in the preamble about staffing ratios, California does not have any for dialysis facilities. We have seen as much as I RN for 21 patients in facilities by one corporate provider. It is very difficult to assess negative patient outcomes related to poor staffing in dialysis, as tracking mortality is difficult and nebulous. When no actual demonstrated outcome could be cited, the above-mentioned corporate facility's response to the citation for poor staffing was that the staffing was at the level identified by the corporation and was, in fact, sufficient, as the only stated requirement was one RN in the building.
To assure the safety of the patients, minimum staffing ratios are necessary, and should be included in the CMS regs.

Personnel Qualifications

"Personnel Qualifications"- Hemodialysis is an extremely invasive procedure, requiring extensive technical knowledge by all levels of patient care staff. The team?s personal experience and practice, that it takes at least 6 months to one year, working with the dialysis machines and the different circumstances which come up with patient emergencies, to acquire an adequate knowledge base. The Charge Nurse at a facility may likely be working in the absence of any other administrative or licensed personnel, in the early morning or after hours. During those times, the Charge Nurse would be expected to have enough knowledge to make critical decisions affecting the health and safety of the patients. Requiring only 3 months of dialysis experience is wholly inadequate, and would risk the patients' safety. In California there are no training guidelines or certification for RNs in dialysis (as with PCTs). This would allow for facilities to hire RNs, inexperienced in dialysis, train them quickly and place them in charge within a 3 month period! A VERY unsafe situation!

The requirement for the Charge Nurses should include at least 6 months in a dialysis setting AFTER training is completed and basic competency verified.

The stated requirements for the PCTS and Water Technicians are great. Currently many facilities leave the Reuse Technicians in charge of the water systems, without adequate education.

"Medical Records"- This condition was reduced too much, as the documentation in the medical records of ESRD patients is often incomplete, inaccurate and not in accordance with identified medical records standards. Dialysis treatment records must include information about the dialysis machine settings and safety checks, information regarding assessment of the patient before, during and after dialysis, any medications and treatments delivered, and any unusual events occurring during the treatment. Often, the treatment records do not include this information, making it impossible to determine what happened during the patient's treatment. This is only one example of how incomplete many of the ESRD patients' medical records are.

The new regs should at least include a statement regarding the adherence to medical records standards; the old V246 was a good tag!

QAPI

"Reuse"- It is appropriate to condense the reuse regulations and to adopt the most current AAMI standard, "RD 47". Refrigeration of used (bloody) dialyzers (in lieu of reprocessing within a 2 hour period) has been associated with bacterial and fungal growth in some infection outbreaks in ESRD facilities. The provision of refrigerating dialyzers should be scrutinized more closely by AAMI and CMS with detailed recommendations regarding this alterative.

Submitter : **Dr. Allan J. Collins** **Date: 04/21/2005**

Organization : **Chronic Disease Research Group**

Category : **Physician**

Issue Areas/Comments

Issues 11-20

Personnel Qualifications

See Attachment

Submitter : **Ms. Valerie Takai** **Date: 04/24/2005**

Organization : **Ms. Valerie Takai**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I have worked for over 20 years as an occupational therapist in acute care, rehabilition, and chronic disease settings as well as in home care. For the past five years I have been a caregiver for my husband, an insulin dependent diabetic for over 40 years who has undergone a subtotal colonectomy for colon cancer, suffers dementia and a gait disorder from a constellation of diagnoses and has ESRD. I have been accompanying him for almost five years to the Yorkville Dialysis Unit in New York and served as his advocate whether in the hospital or the dialysis unit. My unique perspective as an occupational therapist with extensive rehabilition experience in a variety of settings including a five year concentration treating over 1000 different patients with amyothrophic lateral sclerosis along with caring for my husband and extensive time observing and engaging with staff as well as patients at a dialysis facility has helped to formulate my reponses to the Proposed Rule

Submitter : Mrs. Nancy Siekmann

Organization : Holy Name Hospital

Category : Pharmacist

Date: 04/26/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-44-Attach-1.DOC

Attachment #44
Date: April 26, 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. Specifically I wish to comment on Proposed § 494.140 ("Personnel Qualifications") as this section addresses the possible role of a pharmacist within the dialysis facility. I 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.

I am a pharmacist and I understand the complexity of medication and its unwanted consequence side effects that may cause harm to patient.

I believe that pharmacists should be included as part of the dialysis facility multidisciplinary staff for many reasons; some reasons are listed below:

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

I believe above all healthcare providers; pharmacists have the most clinical knowledge in pharmacotherapy. Pharmacist is best qualify to review medication, recognize therapy duplication, prevent potential adverse drug reactions, and will have the most positive impact in this most needed patient population. I appreciate your time and consideration.

Sincerely,

Name: Nancy Siekmann

Signature:

Submitter : **Dr. Timothy Nguyen** **Date: 04/26/2005**

Organization : **Holy Name Hospital**

Category : **Pharmacist**

Issue Areas/Comments

Issues 11-20

Personnel Qualifications

718 Teaneck Road
Teaneck, NJ 07666

April 26, 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. Specifically I wish to comment on Proposed ? 494.140 (?Personnel Qualifications?) as this section addresses the possible role of a pharmacist within the dialysis facility. I 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.

I am a nephrology pharmacist at Holy Name Hospital?s Hospital Regional Dialysis Center. We have about two hundred patients in our unit and my function devotes one hundred percent of caring for these patients. I joined this facility about three years ago and have made significant progress and impact on these patients. I answer all questions related to medications and monitor patient clinical responses. For example, I monitor patient hemoglobin levels, iron indices, parathyroid hormone, calcium, phosphorous levels and drug usage. I am actively involved in the multidisciplinary care team within the dialysis center. I am a member of the continuous quality improvement (CQI) team, the Renal Rehab Taskforce, the division of Nephrology and I serve as a liaison for the nephrology department and the hospital?s pharmacy and therapeutic committee.

The cost of drug treating dialysis patients takes a big junk out of the entire United Healthcare System. We spend over two million dollars (close to three million) each year just on dialysis patients. Last year we initiated a drug switch on anemia management resulted in a saving of over a quarter million dollars.

Due to the complexity of chronic kidney disease condition and the numbers of medications these patients take; dialysis patients need extra caring and to have a pharmacist involve in the multidisciplinary renal care team will not only help patients but also result in controlling the overall cost to the United States Healthcare System.

I believe that pharmacists must be included as part of the dialysis facility multidisciplinary staff for many of the above reasons and other reasons are partially listed below:

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

I believe above all healthcare providers; pharmacists have the most clinical knowledge in pharmacotherapy. Pharmacist is best qualify to review medication, recognize therapy duplication, prevent potential adverse drug reactions, and will have the most positive impact in this most needed patient population. I feel that being a pharmacist and caring for dialysis patients is very challenging and that I have made significant improvement in the care of these patients and help them cope with their daily debilitating chronic kidney disease conditions. I appreciate your time and consideration.

Sincerely,

Timothy V. Nguyen, PharmD
Clinical Nephrology Pharmacist

CMS-3818-P-45-Attach-1.DOC

718 Teaneck Road
Teaneck, NJ 07666
April 26, 2005

Attachment #45
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

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I am writing to offer comments regarding the proposed revisions to the Conditions for Coverage for End Stage Renal Disease Facilities. Specifically I wish to comment on Proposed § 494.140 ("Personnel Qualifications") as this section addresses the possible role of a pharmacist within the dialysis facility. I 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.

I am a nephrology pharmacist at Holy Name Hospital's Hospital Regional Dialysis Center. We have about two hundred patients in our unit and my function devotes one hundred percent of caring for these patients. I joined this facility about three years ago and have made significant progress and impact on these patients. I answer all questions related to medications and monitor patient clinical responses. For example, I monitor patient hemoglobin levels, iron indices, parathyroid hormone, calcium, phosphorous levels and drug usage. I am actively involved in the multidisciplinary care team within the dialysis center. I am a member of the continuous quality improvement (CQI) team, the Renal Rehab Taskforce, the division of Nephrology and I serve as a liaison for the nephrology department and the hospital's pharmacy and therapeutic committee.

The cost of drug treating dialysis patients takes a big junk out of the entire United Healthcare System. We spend over two million dollars (close to three million) each year just on dialysis patients. Last year we initiated a drug switch on anemia management resulted in a saving of over a quarter million dollars.

Due to the complexity of chronic kidney disease condition and the numbers of medications these patients take; dialysis patients need extra caring and to have a pharmacist involve in the multidisciplinary renal care team will not only help patients but also result in controlling the overall cost to the United States Healthcare System.

I believe that pharmacists must be included as part of the dialysis facility multidisciplinary staff for many of the above reasons and other reasons are partially listed below:

- the complex nature of drug therapy in dialysis patients (multiple),

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

I believe above all healthcare providers; pharmacists have the most clinical knowledge in pharmacotherapy. Pharmacist is best qualify to review medication, recognize therapy duplication, prevent potential adverse drug reactions, and will have the most positive impact in this most needed patient population. I feel that being a pharmacist and caring for dialysis patients is very challenging and that I have made significant improvement in the care of these patients and help them cope with their daily debilitating chronic kidney disease conditions. I appreciate your time and consideration.

Sincerely,

Timothy V. Nguyen, PharmD
Clinical Nephrology Pharmacist

Submitter : **Ms. Marilyn Olsen, PA-C** **Date: 04/26/2005**

Organization : **American Academy of Nephrology Physician Assistant**

Category : **Physician Assistant**

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment

CMS-3818-P-46-Attach-1.DOC

Attachment#46

Nephrology & HTN Associates, P.C.
850 Straits Turnpike
Middlebury, CT 06762
203-758-1800
203-758-1804 (fax)

David A. Roer, M.D., FACP
Associate Clinical Professor of Medicine
Yale University School of Medicine

Gregory K. Buller, M.D., F.A.C.P.
Associate Clinical Professor of Medicine
Yale University School of Medicine

Marilyn E. Olsen, PA-C
Adjunct Professor
Quinnipiac University PA Program

Sina Raissi, M.D.

April 26, 2005

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

Dear CMS Team,

I am writing on behalf of The American Academy of Nephrology Physician Assistants (ANNPA). Our organization is the national nephrology specialty chapter of the American Academy of Physician Assistants (AAPA) which represents over 50,000 clinically practicing Physician Assistants (Pas). I am also writing personally on behalf of the many thousands of patients with chronic kidney disease who are seen by Physician Assistants every day.

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

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

As a PA who has been seeing dialysis patients for several years, I feel qualified to speak to this issue. PAs are currently providing daily assessment and ongoing care of patients in dialysis facilities across the nation. They are well trained and provide much needed care to complex patients with chronic illnesses. The physician services provided by PAs are currently reimbursed through CMS, however Physician Assistants are not specifically mentioned anywhere in this document. This oversight could lead to problems with reimbursement for physician services provided by PAs as well

as regulatory and liability issues. In turn, this may lead to a shortage of medical professionals to adequately care for the growing population of dialysis patients.

Physician Assistants function as dependant practitioners in a mutually beneficial collaborative relationship with their supervising physician. Statistics from the US Bureau of Labor and Statistics, coupled with data on the number of patients with chronic kidney disease, indicates that the volume of patients starting dialysis is quickly outpacing the number of nephrologists available to adequately care for them. The Nephrology Physician Assistant is the natural complement to the nephrologist in order to extend quality nephrology physician services to this increasingly needy population. The RPA (Renal Physician Association), ASN (American Society of Nephrology) and CMS have all accepted a Nephrology Physician Assistant as an effective, cost-efficient member of the multidisciplinary team.

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

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

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

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

Please strongly consider addition of the above language so that the spirit of this document to improve quality patient care does not end up limiting that same access to quality care by excluding Nephrology PAs from the health care team.

Feel free to contact me with any questions.

Sincerely,

Marilyn E. Olsen, PA-C, MHS
Member, American Academy of
Nephrology Physician Assistants (AANPA)
Former President, Student Academy of the
American Academy of Physician Assistants (SAAAPA)

Submitter :

Date: 04/26/2005

Organization :

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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. Specifically I wish to comment on Proposed ? 494.140 (?Personnel Qualifications?) as this section addresses the possible role of a pharmacist within the dialysis facility. I 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.

I am a pharmacist and I understand the complexity of medication and its unwanted consequence side effects that may cause harm to patient.

I believe that pharmacists should be included as part of the dialysis facility multidisciplinary staff for many reasons; some reasons are listed below:

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

I believe above all healthcare providers; pharmacists have the most clinical knowledge in pharmacotherapy. Pharmacist is best qualify to review medication, recognize therapy duplication, prevent potential adverse drug reactions, and will have the most positive impact in this most needed patient population. I appreciate your time and consideration.

Sincerely,

Loree A. Levine MS, RPh

Submitter : **Mrs. Camille Miller** **Date: 04/26/2005**

Organization : **AANPA**

Category : **Physician Assistant**

Issue Areas/Comments

GENERAL

GENERAL

April 26, 2005

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

Dear CMS Team,

I am writing on behalf of The American Academy of Nephrology Physician Assistants (ANNPA). Our organization is the national nephrology specialty chapter of the American Academy of Physician Assistants (AAPA) which represents over 50,000 clinically practicing PAs.

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

I am impressed at the amount of hard work that went into these revisions and honor those that put in the time to prepare this extensive document.

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

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

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

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

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

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

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

Feel free to contact me with any questions.

Sincerely,

Camille A Miller PA-C, MPAS
UPMC Lee Regional Market St. Care Center
353 Market St. Suite 106
Johnstown, PA 15901

Phone: 814-536-8949
Fax: 814-539-6065

Submitter : Mr. Rick Russo

Date: 04/26/2005

Organization : ESRD Network of New York

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-3818-P-49-Attach-1.DOC

Attachment #49
Comments on Conditions of Coverage for ESRD Facilities
File Code: CMS-3818
Submitted by Rick Russo, LMSW
US citizen
212-662-0056 (H)
212-289-4524 or 212-571-8500 (W)

Physical Environment (Proposed 494.60)

In regards to power failures: After severe weather occurrences, units did not have emergency power generators available causing much distress among patients. Many patients felt this should be a requirement for dialysis units. Many patients would strongly disagree that dialysis equipment is not life-support equipment and that power failures without back-up generators is not life threatening.

Patients' Rights (Proposed 494.70 (b) (1) and (2))

Excellent additions. However, it would be advantageous to be more specific in requiring facilities to contact their ESRD Network before the point of discharge (i.e. before the 30-day letter of notice is sent and before the final decision to discharge is made). This would allow Networks to provide oversight in the processes of the unit in addressing patient reassessment needs, staff intervention efforts, and add a finer degree of accountability.

Patient Assessment (Proposed 494.80) (a)

It is nonsensical to not include depression as a co-morbid condition. The Interdisciplinary Team should be aware of persons already diagnosed or treated for depression at the time of their initiation on dialysis in order to fine tune their care plan.

Regular screening (after the first 6 months and yearly thereafter) for depression and consequent treatment or referral after an initial adjustment to dialysis period has occurred, should be added to the social worker's agenda. Depression has been shown to be strongly linked to negative outcomes in regards to albumin levels, hospitalization, morbidity, skipped treatment, and other non-adherent and challenging behaviors. The Zung (http://healthnet.umassmed.edu/mhealth/ZungSelfRatedDepressionScale.pdf) and

Hamilton (http://healthnet.umassmed.edu/mhealth/HAMD.pdf) depression scales are both widely used. The Zung is easier and the Hamilton is cited more often in research. Neither is a diagnostic tool, rather an indicator that follow-up work from the social work is required depending on the level of score. This would allow all MSWs to utilize these tools without concern for clinical-level licensure. This would follow the line of thought in proposed 494.90, "the patient's plan of care must include measurable and expected outcomes and estimated timetables to meet the patient's medical and psychosocial needs as identified in the initial and subsequent comprehensive assessments. This section would also specify that the patient's plan of care must address all the services that are to be furnished to achieve and maintain the expected outcomes of care."

494.80 (b) (1) and (2) I strongly support the suggested frequency for the comprehensive assessment for initial and 3-month re-assessment. I would also strongly suggest that at the 6-month point, a simple depression-screening tool be utilized.

494.90 Since the proposed patient's plan of care must include measurable and expected outcomes and estimated timetables to meet the patient's medical and psychosocial needs, an annual long-term care plan should be sufficient as a 6-month short-term requirement would be redundant to those measures, expected outcomes and timetables.

494.90 (a) (5) Transplant referral tracking is necessary. It could be part of the social worker's outcomes-driven practice model for QI. The "necessary actions" listed are extremely necessary. My experience in dialysis units proved too many suitable patients are not even aware of transplant possibilities let alone transplant lists and their right to know about them.

494.70 (a) (5) I support that the patient must sign their care plan.

494.90 (a) (4) I strongly support the proposed vascular access monitoring as written.

494.90 (a) (6) It is quite sensical to marry interdisciplinary team goals with rehabilitation activity.

405.2163 (c) Wording for the role of the social worker needs to be made stronger. It is a social worker requirement to develop an effective therapeutic rapport with patients. This rapport and the effectiveness of the social worker is damaged when the social worker is required by employers to conduct monthly insurance verification information, address patients with billing/payment problems, or serve as a security officer.

Social worker efforts should be centralized in a proactive manner to address patient, family, and staff education and counseling. Over the last few years, the social worker's role has become so bastardized with non-social work activity that their own self-identity as a mental health professional has been destroyed. Patient and staff perception of the role of the social worker has minimized the effectiveness of the mental health orientation with which a qualified MSW comes equipped. Patient adjustment and quality of care suffers in extreme measure when staffing levels and non-social work activity prohibit addressing patient psychosocial issues which in turn adds tremendous cost and burden to the facility due to these poor social work outcomes.

I strongly urge clear, concise, effective language for the role of the social worker as a mental health clinician/technician. Outcomes–driven social work practice models that deal with the existing 405.2163 (c) would assist social workers in regaining their professional identity and accountability.

494.90 (b) The proposed timeframe supports good patient care.

494.90 (b) (4) Monthly in-center physician visits should be required.

494.90 (d) This proposal on Patient Education and Training is key to patient success on dialysis.

Proposal 494.110 is strongly supported. In part (a), I suggest including patient depression scores as part of the list for a dialysis facility's QAPI program.

405.2134 requiring facilities to participate in ESRD Network activities and pursue Network goals should be retained.

494.140 (d) I suggest keeping a clinical educational background requirement for social workers even if they are not licensed for clinical practice in their state. This is suggested because some MSW social workers follow an administrative or a research tract in their education whereas a clinical orientation from a social work education clinical tract is needed in the dialysis facility. Facility social worker services include counseling services, long-term behavioral and adaptation therapy, and grieving therapy, which support a clinical educational background requirement.

The wording concerning social work tasks in regards to other essential services including transportation and information on Medicare and Medicaid eligibility, housing, and medications, should include billing/payment problems, monthly insurance verification and other clerical tasks such as faxing patient transfer information and the wording should be strengthened. All of these tasks consume time that should be spent with patient adjustment and other social work-related tasks in assessment and measurement and follow-up.

494.140 (e) as written is strongly needed in the dialysis community. Suggested is a national standard and testing requirement for certification of technicians.

Responsibilities of the Medical Director Proposal 494.150 are urgently needed in it's entirety. Medical Director responsibility and accountability for the dialysis facility is paramount for the setting of staff attitude and cultural climate of the facility, which so greatly affects staff-patient/(consumer) relations.

Relationship with ESRD Network 494.160. Supported as written.

Governance Condition (Proposed 494.180) and (a) is strongly supported.

Adequate staffing plan in 494.180 (b) (1) is extremely necessary. However, I think a standard acuity formula should be applied universally instead of allowing facilities to come up with their own formula. I believe that leaves too much room for fudging it at the expense of quality patient care and staff burnout. The NKF-CNSW has an

appropriate staffing formula based on 1997 USRDS data. It can be found in their "Professional Advocacy for the Nephrology Social Worker, First Edition 2002" on pages 9 to 11.

Internal Grievance Process 494.180 (e) Grievance policy should not only be made clear to patients, it should also be posted where patients can see it with the name, address, telephone number of the state surveyor office and the ESRD Network office.

Discharge and Transfer Policies and Procedures 494.180 (f) Strongly supported as written including the Medical Director responsibility and dialysis facility accountability with a suggested change that the ESRD Network be notified before the involuntary discharge of any patient.

494.180 (g) (3) Requirement for agreement with a hospital for back-up services is supported. Perhaps wording to include psychiatric and/or extreme behavioral emergencies should be included to not limit use of such an agreement for just medical emergencies.

Electronic reporting 494.180 (h) is supported with a suggestion to include depression scale scores as a CPM. Support public reporting of performance measures to be expanded.

494.30 Condition: Infection Control supported as written.

Personnel qualifications 494.140 (b) Nursing Services strongly support 4 levels of nursing.

Thank you for considering these comments.

Rick Russo, LMSW
April 26, 2005

Submitter : **Ms. Kim Zuber** **Date: 04/27/2005**

Organization : **AAPA/AANPA**

Category : **Physician Assistant**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-50-Attach-1.DOC

CMS-3818-P-50-Attach-2.DOC

Attachment #50
April 26, 2005

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

Dear Sir/Madam:

I am a practicing Nephrology Physician Assistant, one of 50,000 PAs practicing in the US at this time. I have done nephrology for the last 8 years and have taken care of thousands of Medicare and Medicaid patients. I love the work and the feeling that I have made a difference in a patient's life.

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

I have one big concern. Physician Assistants (PAs), like myself, are currently providing daily assessment and ongoing care of patients in dialysis facilities across the nation. These physician services provided by PAs are currently reimbursed through CMS. Unfortunately, Physician Assistants are not mentioned anywhere in this document. This could lead to problems with reimbursement for physician services provided by PAs as well as regulatory and liability issues.

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

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

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

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

Please consider amending the language to read: "Sec. 494.90(b)(4) The facility must ensure every patient is seen at least monthly by a physician and/or physician assistant providing the ESRD care as evidenced by a monthly progress note that is either written in the beneficiary's medical record by the physician and/or physician assistant or communicated from the physician's office and placed in the beneficiary's medical record.

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

Feel free to contact me with any questions.

Sincerely,
Kim Zuber, PAC
Metropolitan Nephrology
2616 Sherwood Hall Lane, Suite 209
Alexandria, VA 22306
(703) 360-3100

ATTCH 5

The AAMI Renal Disease and Detoxification Committee submits the following comment on the Proposed Conditions for Coverage for End Stage Renal Disease Facilities (CMS-3818-P).

Comments on Proposed § 494.40, Water Quality

1. Section § 494.40 (a)

As proposed, Section § 494.40 incorporates by reference the purity standards for water set forth in clauses 4.2.1 and 4.2.2 of ANSI/AAMI RD62:2001 "Water Treatment Equipment for Hemodialysis Applications." Subsection (a) (2) (i) of Section § 494.40 specifies that monitoring of "... bacteria and bacterial endotoxin levels of water/dialysate ..." be performed and that this monitoring should be in accordance with the recommendations provided in Clause 7.2.1 of ANSI/AAMI RD52:2004 "Dialysate for Hemodialysis," which is incorporated by reference. Clause 7.2.1 of ANSI/AAMI RD52:2004 provides general recommendations on microbial monitoring methods for water and dialysate. These requirements suggest that CMS intends dialysate to be monitored. Yet, maximum contaminant levels for dialysate are not specified in Section § 494.40.

With the exception of dialyzer reuse, hemodialysis patients are exposed to fluid in the form of dialysate and hazardous conditions actually occur when contaminants are present in the dialysate, regardless of the quality of the water used to prepare the dialysate. While modern dialysis machines and commercially available concentrates are unlikely to contribute chemical contaminants to the water, dialysis machines and bicarbonate concentrate may contribute microbial contaminants. Therefore, to safeguard patients, and to remove ambiguity from Section § 494.40, we believe it would be appropriate for § 494.40 (a) to incorporate the dialysate quality standards recommended in Clauses 4.3.1 and 4.3.2.1 of ANSI/AAMI RD52:2004.

2. Section § 494.40 (c)

Section § 494.40 (c) (1) should be revised to clarify that the back up carbon tank is in series with the primary carbon tank. A back-up tank could mean a tank that is ready to be put into operation should the first fail.

Section § 494.40 (c) (2) (i) should be revised to include a requirement to replace the first carbon tank if test results are above the levels listed. By only recommending testing of the second tank there is a possibility that the second tank could break through shortly after testing exposing the patient to chlorine in the water. The second tank should become the primary tank and a new secondary tank installed.

Submitter : Mrs. Lori-Ann Iacovino **Date:** 04/27/2005

Organization : Holy Name Hospital

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-51-Attach-1.DOC

CMS-3818-P-51-Attach-2.DOC

Attachment #51
Date: April 26, 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. Specifically I wish to comment on Proposed § 494.140 ("Personnel Qualifications") as this section addresses the possible role of a pharmacist within the dialysis facility. I 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.

I am a pharmacist and I understand the complexity of medication and its unwanted consequence side effects that may cause harm to patient.

I believe that pharmacists should be included as part of the dialysis facility multidisciplinary staff for many reasons; some reasons are listed below:

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

I believe above all healthcare providers; pharmacists have the most clinical knowledge in pharmacotherapy. Pharmacist is best qualify to review medication, recognize therapy duplication, prevent potential adverse drug reactions, and will have the most positive impact in this most needed patient population. I appreciate your time and consideration.

Sincerely,

Lori-Ann Iacovino M.S., R.Ph.
Pharmacy Clinical Coordinator / Infectious Disease Pharmacist

Submitter : Ms. Allison Cubitt

Organization : ViaHealth-Rochester General Dialysis

Category : Social Worker

Date: 04/27/2005

Issue Areas/Comments

GENERAL

GENERAL

Section 494.80(b)(2) Patient Assessment.
We would like clarification on the issue of 'evaluating patient's potential' for rehab status and physical functioning.
Also, Social workers are not trained to do physical function evaluations in the same maner as a Physical or Occupational therapist would be. When you state that we need to assess this routinely, what is the explanation of what this evaluation will be?
494.80(d)(1)
We agree with the time frame for the monthly reassessemtn for unstable patients. However, we think that the facility should have some control over extending this in certain circumstances. For example if a patient has had a hospitalization which resulted in an amputation of a leg, and there is need for rehab, healing and eventually a new prosthetic leg. The time frame may not meet with the monthly schedule. Therefore, there should be a one month assessment and then a reassessment when this process is finished. Otherwise, the team may be doing several assessments with no immediate results. We agree with the paragrah regarding the frail patients who are at baseline frail. Thank you!!!!

405.2163(c)
We strongly agree with the MSW qualifications for Social workers and the suggestion that social workers concentrate on preforming in a more clinical fashion. Bravo!!!
I feel VERY STRONGLY about the title of Social Services verses Social Work Services. Social Serivces is related to an agency that delivers Welfare, Medicaid Food Stamps etc. We are Social Workers and we deliver Social Work Services. There is a big difference!!!

Submitter : Mr. Clifford Bernier

Organization : AAMI

Category : Other Association

Date: 04/27/2005

Issue Areas/Comments

Issues 1-10

Water Quality

The Association for the Advancement of Medical Instrumentation (AAMI) Renal Disease and Detoxification Committee submits the following comment on the Proposed Conditions for Coverage for End Stage Renal Disease Facilities (CMS-3818-P).

Comments on Proposed ? 494.40, Water Quality

1. Section ? 494.40 (a)

As proposed, Section ? 494.40 incorporates by reference the purity standards for water set forth in clauses 4.2.1 and 4.2.2 of ANSI/AAMI RD62:2001 ?Water Treatment Equipment for Hemodialysis Applications.? Subsection (a) (2) (i) of Section ? 494.40 specifies that monitoring of ?? bacteria and bacterial endotoxin levels of water/dialysate ?? be performed and that this monitoring should be in accordance with the recommendations provided in Clause 7.2.1 of ANSI/AAMI RD52:2004 ?Dialysate for Hemodialysis,? which is incorporated by reference. Clause 7.2.1 of ANSI/AAMI RD52:2004 provides general recommendations on microbial monitoring methods for water and dialysate. These requirements suggest that CMS intends dialysate to be monitored. Yet, maximum contaminant levels for dialysate are not specified in Section ? 494.40.

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2. Section ? 494.40 (c)

Section ? 494.40 (c) (1) should be revised to clarify that the back up carbon tank is in series with the primary carbon tank. A back-up tank could mean a tank that is ready to be put into operation should the first fail.

Section ? 494.40 (c) (2) (i) should be revised to include a requirement to replace the first carbon tank if test results are above the levels listed. By only recommending testing of the second tank there is a possibility that the second tank could break through shortly after testing exposing the patient to chlorine in the water. The second tank should become the primary tank and a new secondary tank installed.

CMS-3818-P-53-Attach-1.PDF

Submitter : Kimberly Holdener

Organization : University of Wisconsin Hospital and Clinics

Category : Pharmacist

Date: 04/27/2005

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment for my comments.

CMS-3818-P-54-Attach-1.DOC

Attachment #54

Response to
Proposed Revisions to Conditions for Coverage for
End Stage Renal Disease Facilities

April 27, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
File Code: CMS-3818-P

Dear Dr. McClellan:

I am writing to offer comments regarding the proposed revisions to the Conditions for Coverage for End Stage Renal Disease Facilities. Specifically I wish to comment on Proposed § 494.140 ("Personnel Qualifications") as this section addresses the possible role of a pharmacist within the dialysis facility. I 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.

I am a clinical pharmacist at a university hospital who deals with CKD patients on a daily basis. I work with inpatient transplant patients who often need dialysis services, and I also work with the outpatient kidney clinic. The hospital has an inpatient dialysis unit that would greatly benefit from more direct involvement by a pharmacist. The hospital is also associated with a separately owned outpatient dialysis unit that currently has a part-time pharmacist on staff. I believe the involvement of this pharmacist has improved patient care with regards to drug therapy management.

I believe that consultant pharmacists should be included as part of the dialysis facility staff for the following reasons:

- Most dialysis patients take a high number of medications that can interact with each other and with patient conditions. It is important that patients are educated about their medications and that drug therapy is optimized to reduce the number of medications. Patient education can also help to reduce non-compliance because patients have a better understanding of their medication regimens
- Dialysis can affect the pharmacokinetics and, therefore, the dosing of many medications. As medication experts, pharmacists have the specialized training needed to recognize and adjust for these changes in pharmacokinetics.
- Pharmacists are in a position to understand the pharmacoeconomics of medication use and comparative drug costs. They are able to recommend the most cost

effective medications and also take each patient's economic status into consideration.

- Many high-alert medications are stored in dialysis units. Pharmacists are well equipped to monitor and maintain safe medication storage and usage documentation that will reduce medication errors.
- Dialysis centers frequently employ medication protocols for treatment of anemia, bone and mineral abnormalities, and other medication-related disorders. Studies have confirmed a lack of consistency and quality of these protocols among dialysis units. Pharmacists are able to evaluate and/or develop protocols to ensure that they are effective and safe.
- Pharmacists are very qualified to work in the role of a consultant to dialysis units. All pharmacists receive training regarding medication usage specific to patients receiving dialysis in pharmacy school. However, many pharmacists receive advanced training such as residencies or fellowships in nephrology that even further equip them to work with dialysis patients.

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. Medication reviews should be conducted at least monthly. This frequency is consistent with what is required in skilled nursing and intermediate care facilities.
4. Pharmacists should participate in the development and implementation of medication-related protocols within dialysis to assure cost-effective drug use.
5. 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.

I believe that a requirement for a pharmacist to be included on the multidisciplinary team that serves a dialysis unit is long overdue. I strongly support the development of this requirement.

Sincerely,

Kimberly E. Holdener
Clinical Pharmacist
University of Wisconsin Hospital and Clinics

Submitter : Mr. Scott Vivona

Organization : California Dept. Of Health Services L

Category : State Government

Date: 04/27/2005

Issue Areas/Comments

Issues 1-10

Infection Control

A. Infection Control

. It is not clear which AAMI standards will be enforced.

. There is no mention of cover gowns. If cover gowns are not required, what are the staff members supposed to do when they go into the lunch room, or the stock room? These are areas where the staff normally remove their cover gowns.

. We applaud the proposal to require that an RN be designated as the infection control or safety officer.

Physical Environment

Physical Environment

. A patient in a separate room who is not visible from other locations on the unit needs to have some sort of monitor. If they experience a severe reaction or condition, they may not be able to call out or ring a bell.

. Who will survey and enforce the Life Safety Code requirements contained in the regulations?

Definitions

General (III)

B. Defintions

Does the definition of ?home? include an institution such as a jail, when the treatment is given there?

Plan of Care

Patient Care (V)

C. We strongly support the list of ?necessary actions? listed in this proposal as actions that dialysis facilities would be required to carry out with respect to transplant candidates (care planning, referral, communication, and monthly blood draws).

Issues 11-20

Governance

E. Governance

. We recommend that the regulations include a requirement that the facility report unusual incidents to CMS and the State Agency. This would include such items as unexpected death while present in the facility, any pyrogen reaction, any unexplained water contamination, fire, and any other natural disasters (earthquake, flood, etc.) that affect the operation of the facility.

Personnel Qualifications

A.2. Nursing Service

. Although four categories of nursing personnel are given, the issue of numbers is not addressed. In other words, can one nurse fulfill all four roles if she has the qualifications, or is there some expectation that more than one nurse is required?

. We would recommend that the ?nurse responsible for nursing services in the facility? be further identified as the ?clinic manager?? and that her duties be expanded as well.

Medical Records

D. Medical Records

. We deplore the proposal to eliminate designation of a medical records supervisor at the facility. This is a responsibility that cannot be left to chance, due to the importance of oversight of the function and compliance with regulations.

Submitter : Mr. John Richard

Organization : Renal Care Group

Category : Physician Assistant

Date: 04/28/2005

Issue Areas/Comments

GENERAL

GENERAL

We must keep PA's and NP's in the dialysis units and allow them to bill as it currently stands 4 patient visits, two per nephrologist, two per PA/NP's. The midlevel provider is becoming the backbone of preventive medicine in dialysis...mainly due to higher patient contact hours when compared to the physician. Please keep the midlevel in the dialysis unit and do not change the current billing plan.
Thanks for listening, John Paul Richard PA-C

Submitter : **Dr. Robert Kopelman** **Date: 04/28/2005**

Organization : **Bakersfield Dialysis Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Issues 1-10
See Attachment

CMS-3818-P-57-Attach-1.DOC

Attachment #57
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3818-P
P.O. Box 8012
Baltimore, MD 21244-8012

ATTN: CMS-3818-P

Dear Sirs,

I have been a practicing nephrologist and also a dialysis facility medical director for over 20 years. My comments are based on years of personal experience.

One of the most common problems patients with ESRD face is equitable admission to the dialysis facility of their choice. The existing and proposed Conditions of Coverage include patient protections when their care may be terminated for behavioral, financial or other reasons. They are silent on reasons a patient may be denied acceptance at a facility to begin with.

It is clear that denial of admission to a facility often has the same effect as if care had the terminated by the facility.

Examples of reasons for denial of admission I have personally encountered include:

1- Financial- patients with "better" insurance come first; patients with Medicare primary coverage are disadvantaged

2- Contract- members of a HMO or other entity contracting with the facility are given preference over patients with Medicare primary coverage

3- Network- patients transferring from other facilities with the same owner are given preference

4- Physician- patients of the Medical Director's practice are given preference over patients of other nephrologists on staff at the facility

5- Rumor- patients "rumored" to have psychosocial or other issues are refused admission without any impartial evaluation

6- Compliance- patients whose records reflect even minor compliance issues (such as a few missing scheduled dialysis treatments) are refused

7- Control- patients with "bad" lab results are refused because they will skew the facility results

8- Special Needs- patients with any special needs, such as preferred times for treatment, language barriers, transportation assistance, etc. are refused

9- Medical Needs- patients with dialyzer allergies or other medical conditions that may require additional work or cost are refused

10- Legislative- it is often easier to refuse admission than risk having to terminate care if potential issues are not resolved

Because there are no requirements to establish criteria for admission and no requirements to explain denials to the patient, Network or facility Inspectors, facilities are free to limit access for any reason, however prejudicial it may be.

In most parts of the country there is a lack of staffed but unused dialysis chairs. Thus facilities are not under financial pressure to fill empty spots. If anything, some conclude that it is most profitable to select ("cherry pick") the most attractive patients from the applicant pool.

The following steps would substantially correct this national problem:

1- Require facilities establish written criteria for admission and follow them

2- Require facilities maintain a calendar with the date of application, date of completed application, and date of acceptance or refusal (to prevent a patient from being repeatedly pushed down on the list without being rejected outright).

3- Require facilities provide an explanation, upon request, when admission is denied

4- Require facilities keep their admission records on file for review by Network or other appropriate Inspectors

. There are legitimate reasons to refuse admission and facilities must have the discretion to evaluate every patient who is referred by a member of the medical staff. However, all patients should be guaranteed equal access and at the present time this is simply not the case

Yours truly,

Robert Kopelman, M.D.
Medical Director
Bakersfield Dialysis Center

Submitter : Mrs. Alice Chan **Date:** 04/28/2005

Organization : Mrs. Alice Chan

Category : Dietitian/Nutritionist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-58-Attach-1.DOC

Attachment #58
DATE: April 27, 2005

RE: File Code CMS-3818-P
Comments on Medicare Program; Proposed Conditions for Coverage for End Stage Renal Disease Facilities

I am a registered dietitian and a Board Certified Specialist in Renal Nutrition. I am also a member of the Council on Renal Nutrition and the Renal Practice Group of the American Dietetic Association. I have been working with End-Stage Renal Disease (ESRD) patients for 29 years. I am writing to comment on the proposed Conditions for Coverage for ESRD Facilities.

Patient Assessment (Proposed Sec 494.80)

I think the list of minimum assessment criteria should include **bone disease management**. Bone disease, resulting from the abnormal vitamins and minerals metabolism in chronic kidney disease (CKD), is a major complication in ESRD and carries significant mortality and morbidity in ESRD patients. The interdisciplinary team, especially the dietitians, spends significant amount of time in the assessment, prevention/intervention of bone disease. The parameters and strategies for the management of bone disease are detailed in the NKF-K/DOQI Clinical Guidelines for Bone Metabolism and Disease in CKD.

I support the proposed initial assessment within 20 days of initiating dialysis, and completion of the care plan within the next 10 calendar days. I think exception should be made for the patient who has to be away from the facility either due to hospitalization or other reasons. The time allowed for the assessment and care planning can be combined and be completed within 30 days of admission to the dialysis facility.

I support the re-assessment in three months following the initiation of dialysis treatment. I think this re-assessment can be less extensive. A complete history and physical may not be needed. We should evaluate how the patient is doing, whether the treatment goals are met and how the patient is adjusting to dialysis and the treatment plan.

Patient Care Plan, Proposed Sec 494.90(a) (2)

b. Nutritional status

I agree with the proposed requirements, especially, " ... **the interdisciplinary team** to provide the necessary care and services to achieve and sustain an effective nutritional status." I also applaud the statements: "Effective nutritional status encompasses acceptable levels of protein, calories, and fluid intake as well as acceptable levels of nutrients in the blood" and "Potential clinical outcome

measures of nutritional status include anthropometric measures, clinical signs of nutrient deficiency, urea kinetic modeling, prognostic nutrition indexing, and measurement of biochemical parameters." Therefore, we should follow the nutrition assessment guidelines in the NKF-K/DOQI Clinical Practice Guidelines for Nutrition in Chronic Renal Failure which recommends using a combination of measures. I strongly object to using serum albumin as the **sole** indicator of nutritional status, the same way hemoglobin is used as the indicator for anemia. The focus on the importance of serum albumin as the indicator of nutritional status may result in neglecting malnourished patients who have normal serum albumin.

I do agree that serum albumin should be monitor on a monthly basis as it is a strong indicator of outcome in ESRD patients. The interdisciplinary team should investigate the causes of low serum albumin, as inadequate protein intake is rarely the only culprit.

I suggest that the care plan should include the management of bone disease for the reasons mentioned above.

Care at Home (Proposed Sec. 494.100)

I agree in general that home dialysis patient should receive the same services and care as in-center dialysis patients. However, due to the distance some of the patients have to travel to the clinic, the **stable** home dialysis patients may not need to be seen at the clinic monthly. We required our home patients to send in the required monthly lab and home dialysis records. They are reviewed and discussed at the monthly patient care conference. The nurse calls each patient monthly to monitor and provide feedback. The team members call the patients to provide information or assistance as needed. The interdisciplinary team sees the stable patients at least every three months, or more frequently if they become unstable.

QAPI (proposed Sec. 494.110)

I support the inclusion of nutritional status in the program scope. I would also suggest adding bone disease to the program scope for the reasons mention above.

Personnel Qualifications (proposed Sec. 494.140)

I strongly agree to the inclusion of the dietitian as a member of the Interdisciplinary team and the qualifications as stated especially that the dietitian should have a minimum of 1 year of professional work experience as a registered dietitian. However, I suggest changing the word "professional" to "clinical" to ensure the dietitian has one year of clinical experience rather than research, food service or management experience.

Governance (Propose Section 494.180 (b)

I believe the need to specify the staff to patient ratio rather than leaving it to each dialysis facility and state surveyors to determine whether there is adequate staff. CMS should take the lead in forging a national consensus on the appropriate staff to patient ratio for each discipline within the dialysis facility. For the renal dietitians, I would strongly urge the inclusion of a staffing ratio of one qualified registered dietitian per 100 to 125 dialysis patients. This level of staff is essential for the dietitians to provide optimal care to the dialysis patients. Due to the expanding responsibilities which often include medical protocol management of anemia, bone disease and dialysis adequacy; and participation in QAPI activities, the dietitians often have to compromise the time spent in direct patient contact and individualized care. Also the growing population of older and sicker patients demands more intensive intervention to preserve and optimize the patient's nutritional status. For these reasons, Texas included a ratio of one qualified registered dietitian per 125 dialysis patients in their current ESRD Facility Licensing Rules.

Thank you for the opportunity to comment on the proposed conditions for coverage of ESRD facilities

Submitter : Mrs. Sue Miller **Date:** 04/28/2005

Organization : DaVita--Baltimore County Dialysis Facility

Category : Dietitian/Nutritionist

Issue Areas/Comments

GENERAL

GENERAL

see attachment (one)

CMS-3818-P-59-Attach-1.DOC

#11 CR # 37

4/28/2005 Sue Miller, RD, CSR, LDN—Renal Dietitian—DaVita—Baltimore County Dialysis Facility—Phone 410-521-7851

RD = Registered Dietitian, CSR = Certified Specialist in Renal, LDN = Licensed Dietitian/Nutrition (Maryland)

Comments on CMS Proposed Rules—Conditions of Coverage—ESRD CMS 3818 P

Page # & Section	Proposed Rule	Comments—based on my home facility experience
Pg 6203 494.80 pt assessment	Interdisciplinary team responsible for providing each pt with individualized and comprehensive assessment of his/needs	Agree
Pg 6204 494.80 pt assessment	20 calendar days to complete assessments	**Typical new admission at our facility:** • We draw certain bloodwork weekly (Wed and Thurs with automatic courier set up to transport blood to the lab at end of those 2 days). For example, if a new patient starts treatment on a Friday, his bloodwork would be drawn the following Wednesday. This allows time for the blood flow rate to gradually increase as the patient gets accustomed to dialyzing, thus resulting in a more accurate Kt/V (to assess dialysis adequacy). Lab results would come back on Friday, one week after admission. • Meanwhile, the patient is given a written generic renal diet to start with, usually on the day of admission. Educating the patient and/or family or caregiver begins at this time. Due to anemia (low hemoglobin) and uremia (buildup of waste products), a typical new patient's ability to comprehend and retain information is initially low (if the patient is new to dialysis). Much repetition is needed. • It often takes a patient a few treatments to remember to bring in his home medication list for review. This information is essential before the physician can order medication changes to meet individual patient needs. • Epogen (synthetic erythropoietin) is started on day of admission. • On the day lab results come back, if the PTH is abnormal high (or if pre-admission PTH is available), IV Zemplar (vitamin D for renal bone disease) is generally started. • Phosphate binders, to address elevated phosphorus, would be started when the results come back from lab. It's important to have a home medication list from the patient or caregiver in order to address this and other issues. Many patients don't have their medications memorized. We might ask the patient if he/she is taking a phosphate binder such as Renagel or PhosLo or Fosrenol. The patient may say "No," but when the medication list is brought in, the patient is on a phosphate binder already. • IV iron, if needed, is started the same day labwork comes back or soon thereafter (by paging physician if needed). • Lab test results, and how they relate to the diet and nutrition-related medications, are then discussed with the patient. • Once all this has been handled, I begin doing the initial nutrition assessment, which consists of meeting with the patient or caregiver to individualize the meal plan, working with the nephrologist to determine diet order, and working with the interdisciplinary team to individualize patient care/intervention. • Each initial nutrition assessment requires 3 to 4 hours to complete (see steps above). **Ongoing nutrition intervention for all patients:** On a monthly basis, I meet with each individual patient in the facility to review lab results, discuss causes of abnormal labs and potential solutions, work with interdisciplinary team to address problems, and document this intervention. This Dietitian responsibility occurs monthly, regardless of the number of new admissions. **Summary:** • Assuming the new admission patient isn't hospitalized during the first 20 days of admission and that I don't take any time off from work (vacation), 20 days to do the initial assessment is fairly reasonable. As indicated above, the initial nutrition assessment is a gradual process. I generally try to complete the initial nutrition assessments in the same order the patients are admitted. (It paid off when we had 12 new admissions in one month.) • Thirty days to complete initial assessments would be more reasonable.

Pg 6204 494.80 pt assessment	Follow-up comprehensive reassessment for new patients within 3 months after completion of initial comprehensive assessment	I disagree with this proposed requirement. I feel it's unnecessary. Our interdisciplinary team reviews each patient's bloodwork/response to treatment on a monthly basis, working with the patient and adjusting intervention as needed. Requiring a reassessment at 3 months would achieve no further purpose and would require setting up a tracking system to get the extra paperwork done. I would not change how I intervene based on this 3-month reassessment because there are very few patients who don't need some type of intervention on a monthly basis.
Pg 6204 494.80 pt assessment	Annual comprehensive reassessment	Agree
Pg 6204 494.80 pt assessment	Merge short-term and long-term care plan with measurable outcomes	Agree
Pg 6206 & 6207 494.90	Goals Kt/V >= 1.2, Hemoglobin >= 33.0 (< 33 start synthetic erythropoietin)	Agree. Virtually all patients, starting with admission, require synthetic erythropoietin. A wide range of dosing is required to sustain Hgbx3 of 33.0 (Hgb 11.0) or above.
Pg 6206 494.90	Albumin—check monthly	• Agree. In addition to being an indicator of nutritional status, albumin is affected by other factors such as infection, inflammatory state, or recent hospitalization. So it's important to look at monthly trends in individual patients. • I do **not** recommend the use of other parameters such as total protein, transferrin or prealbumin (additional expense without much benefit) • While protein catabolic rate can be useful for some patients, it is not always accurate (when patient is catabolic or anabolic, or if residual renal function has not yet been checked)
Pg 6215 494.110	Facility's QAPI program should address at least the following, including dialysis adequacy, nutritional status, anemia, vascular access	Agree. Recommend consider adding Renal Osteodystrophy (PTH, phosphorus)
Pg 6218	• Dialysis facility must maintain minimum clinical standards for all patients. If pt's care does not meet standards, team must make adjustments • If pt is unable to achieve the minimum expected clinical outcome, a member of interdisciplinary team must provide an explanation in the patient's medical record	Agree
Pg 6220 494.140	Personnel Qualifications—dietitian must have BS or related advanced degree and >= 1 year clinical nutrition experience	Agree. Would consider modifying this for dietetic interns who have completed a portion of their internship rotations in renal setting, such as a dialysis facility. Some facilities offer an internship rotation and then hire some of former interns after they graduate from the internship. Recommend counting renal portion of the internship towards the year of required clinical experience.

Submitter : Mrs. Debbie Lucki **Date:** 04/28/2005

Organization : Wheeling Renal Care

Category : Social Worker

Issue Areas/Comments

Issues 11-20

Personnel Qualifications

Social Worker 494.140(d)
Dispute of elimination of "grandfather clause" . No language has been included as to how to eliminate existing BSWs from their positions in the ESRD field. Our company employs a very qualified and experienced BSW. Her lack of a Master's degree has no way impeded her expertise in the "bio-psycho-social assessment" of our patients. Our BSW is a vital component of our interdisciplinary team providing quality care to our patients as well as a great resource in our staff development. Also, as with the nursing shortage, there are limited Master's level social workers in our area. As the Assistant Administrator of three dialysis facilities, one of which is located in a rural area,I am extremely concerned that implementing this Condition will difficult to comply. I hope that these existing social workers be given consideration for their expertise and may be retained in their positions with same job responsibilities. Thank you

Submitter :

Organization :

Date: 04/28/2005

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

I have been a dialysis consumer for nearly eight years. I feel quite healthy other than kidney failure. But sometimes I am appalled at what happens in the clinics. The staff do not seem well trained, are there any standards? There do not seem to be sufficient staff. no one would know if I bled to death because sometimes they don't come near me for 30 minutes and I have no call button. It's generally SO cold in there, I don't see what we have to be miserable in addition to sitting still for four hours or more. Infection control seems to vary, I have seen techs pick up things off the floor and then try to touch me (unsuccessfully!) before changing gloves. I have gone to dialysis in Europe a couple times and it was a much more pleasant experience, only RNs work with the patients and each RN only had two patients! We also were given a snack, my unit doen't even have a water fountain. They say it is to help patients with their fluid limits but if patients don't follow the rules at home, keeping water from them for four hours, three times a week will not help. I think if patients were given more responsibility (weigh themselves, figure out how much to take off, etc.) they would do better. Sometimes I go through an entire treatment and no one even says "hello" to me. I feel like an animal at the zoo. Dialysis does NOT mean "death sentence." Many of us are living well but we could do better if we weren't afraid of the staff's incompetence.

Submitter : H. G. Deere-Powell **Date:** 04/28/2005

Organization : H. G. Deere-Powell

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Comments on proposed ESRD regulations
(file code CMS 3818-P)

Existing 405.2136(f)(l)(vi) requires that facilities have patient care policies that cover pharmaceutical services.

Based on my experience as a state surveyor for 17 years and a federal surveyor for 3 years, I have the following suggestions for additions to ensure patient health and safety:

Assure routine assessment and medication regimen review by a qualified consultant pharmacist at least monthly and more often if necessary, based on significant changes in the clinical condition.

A qualified consultant pharmacist must devote sufficient time to plan, organize, conduct and direct the professional pharmaceutical care services of the facility. (For more complete instructions you may refer to the pharmaceutical services revisions made by a panel of experts convened in Baltimore,Md in April, 2005 for CMS nursing home survey and certification branch).

A qualified consultant pharmacist must participate in selection and monitoring of suitable medication regimens for all patients in the unit, as well as the self-dialysis patients.

A qualified consultant pharmacist must assure adequate training of nurses, physicians and other pertinent staff that need to understand pharmaceutical care and its relationship to the quality care and treatment plan of all patients.

A qualified consultant pharmacist must assure adequate training of patients or relevant family/or representatives regarding pharmaceutical care and acquiring medications to maintain quality of care and quality of life for all patients in the unit as well as self-dialysis patients.

A qualified consultant pharmacist must assure the development of current and adequate patient care policies regarding procurement, dispensing, administering, storing or monitoring risk versus benefit of all medications (including nonprescription medications)and dietary supplements/alternative medicines for all patients.

A qualified consultant pharmacist must assure proper and routine feedback to the medical director regarding all the issues above.

A qualified consultant pharmacist must receive no less that 8 contact continuing education hours yearly in the area of pharmaceutical care for dialysis patients.

Submitter :

Date: 04/28/2005

Organization : **Montana Dept of Public Health and Human Services**

Category : **State Government**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-3818-P-63-Attach-1.DOC

Attachment #63
Compliance with Laws and Regulations:

You say, "We may find a facility to be in violation of these conditions for coverage if the facility is found out of compliance with any Federal, State, and local law and regulation pertaining to health and safety requirements." There is a similar regulation under long term care regulations. We've been told we cannot cite anything under this unless the office with authority under the specific regulation has cited it, i.e., the state licensing office cites something from state law and then can we cite the facility for not following local law. Do you intend for us to have more authority than that under this condition?

Infection Control

You say, "facilities should continue to operate in accordance with applicable local laws and accepted public health procedures." I don't know if our state has any regulations pertaining to the disposal of hazardous medical waste. If it doesn't, or if the local authority chooses not to enforce them, can we then cite using the local law?

Water Quality

You say, is there "sufficient evidence to require Medicare-participating dialysis facilities to maintain at least two carbon tanks (that is, primary and back up) as part of their water treatment system, regardless of the current composition of its source water." Two tanks should be required because:

1) if there is only one tank and it fails, the facility may or may not catch the failure before anyone is hurt by the chlorine. However, then they cannot dialyze until another tank is found. In Montana, that could take quite a while. If there are two tanks, they can use the second one and continue to dialyze until another tank is provided; and
2) you are relying on the water treatment facility to call the dialysis facility and let them know there is increased chlorine in the water and this does not always occur.

Reuse of Hemodialyzers and bloodlines

You say, "a febrile reaction in a single patient is rarely attributed to dialyzer reuse. Facilities do not believe it is necessary to terminate reuse or order blood cultures when a febrile reaction occurs in only a single patient." We think a blood culture should be done whenever a febrile reaction occurs, even in only one patient. Since more and more of ESRD patients are over 65 years old and older people do not develop febrile reactions as readily as younger adults, perhaps the only younger patient is the one who will signal there is a problem in time to address it successfully.

Physical environment

You propose to delete the requirement for "a nursing/monitoring station from which adequate surveillance of patients can be made." However, more is done at a nursing station than monitoring. These include charting, medication set up, organizing supplies, telephone conversations, etc. With a centralized nursing station, patients undergoing dialysis can be observed while these other tasks are done. However, if the centralized station is not required, the tasks will have to be done somewhere else, which means fewer staff to observe patients.

LSC says, "Dialysis patients are not as mobile as a person working or visiting an office building or health clinic but more mobile than patients being treated in an inpatient health care facility, such as a hospital or nursing home." However, many dialysis patients are elderly, more and more are coming to the ESRD facility from a nursing home and are extremely debilitated. I did a survey where a patient was a double amputee almost to the hips and needed a lift for transfer to the dialysis chair. Many patients need dialysis because of the complications of diabetes and therefore are more likely to also have amputations. I think they should be given the same level of safety from fire as nursing home residents. You could make the fire safety regulations more stringent and, if the facility could prove their patient population was not that needy, give them a waiver.

Patients rights

You appear to have dropped references to the need of patients who work for non-usual times for dialysis. Certainly people who are able and willing to work should receive some accommodation to make that possible.

In addition to patient rights, we think the criteria for being a transplant candidate should be posted. Patients might be more willing to consider and question if they knew the criteria. Transplant centers have different criteria. How are patients to find out if there is a center that would consider them when the "usual" center used by the facility will not?

Rehabilitation status/social services

It's a great idea. Are you going to pay them anything to do it? I'll tell you that the social workers I see working in ESRD are not trained to provide what you are describing. If you want them to provide specialized services like anger management and vocational counseling then they must be trained in those skills and have time and space to provide the service. Your standard master of social work course does not include specialized skills like those. Frequently the social worker spends the majority of time arranging transportation, arranging for dialysis while the patient is traveling, and accessing financial aid. Most of them seem overwhelmed by the magnitude of the psychosocial problems confronting them and respond by ignoring them. To really address the psychosocial issues of dialysis patients you would need someone with strong clinical training and experience and, frankly, ESRD doesn't pay enough to attract individuals with that level of knowledge and skills.

Transplantation Referral Tracking

First, there should be some consequences for the Transplant Center that fails to communicate with the Dialysis Center. There is no point in giving deficiencies to the Dialysis Center when it is the Transplant Center that is not communicating. The communication should be in writing and address each patient's eligibility for transplant, probability of receiving a transplant, including immunological status, and, if not eligible, anything the patient could do to improve the chances of becoming eligible or of receiving a transplant. The communication should be updated quarterly.

Dialysis of ESRD Patients in NFs and SNFs

We think patients should not be allowed to receive dialysis in the nursing home unless they can do it themselves or have a family member or friend who will do it for them. Nursing home staff should not be involved, just like it would be it the patient was in their own home. The dialysis center would provide the same training, support and consultation to the patient and the family as they would if the patient were in their own home. Trying to make the nursing home staff responsible when there is no way to reimburse for the time and training is ridiculous.

Other Personnel Issues

A conscientious pharmacist has much to offer to someone with as complex a medication usage as a dialysis patient. However, there are two issues to consider when deciding to make a pharmacy review a requirement. The pharmacist has no power. It is up to the doctor whether or not to make changes and specialists tend to be arrogant and uninterested in feedback. How are you going to pay for the pharmacist's services?

ESRD Network

The networks need to share more information with the state agency, especially when the SA is going to do a survey. It would be helpful to know if there were problems with dialysis adequacy or anemia management going in, rather than having to dig it out of patient records and QI data.

Medical Records

Day to day events should be documented by the end of the shift in which they occurred. Once a record is closed, it should be completed within 30 days.

Adequate number of staff

It sounds like a good idea to make the facility responsible for determining what is adequate staffing. There are going to be more and more dialysis patients and fewer and

fewer staff. It does not seem like a good idea to lock into requirements that are unachievable and not likely to be changed for 20 or more years.

Submitter : **Mr. David Bergman**

Organization : **American Association for Marriage**

Category : **Other Practitioner**

Date: 04/29/2005

Issue Areas/Comments

Issues 11-20

Personnel Qualifications

Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8012
Baltimore, MD 21214-8012

Attn: CMS-3818-P

Dear Sir or Madame:

I am writing on behalf of the American Association for Marriage and Family Therapy (AAMFT). The AAMFT is the national professional association representing the interests of marriage and family therapists, including over 50,000 licensed MFTs and 27,000 MFT trainees. We are writing in response to your February 4, 2005, Notice of Proposed Rulemaking, proposing in relevant part for the Medicare End Stage Renal Disease (ESRD) program?s Conditions of Participation to create a new 42 CFR 494.140(d) regarding ?social worker? services. The proposal would 1) eliminate a "grandparent" clause in 42 CFR 405.2102(f) and 2) remove the requirement for social worker specialization in clinical practice.

We oppose these proposed changes because they could well reduce the quality of care for ESRD beneficiaries, and because CMS?s proposed grandparenting change is based on a mistaken premise.

Regarding elimination of the "grandparent" clause, CMS is incorrect in stating that "Since the [relevant grandparenting] clause only applied to social workers without a Master's degree, already employed in a dialysis or transplantation setting as of 1975, we question whether there is any need to retain it." (70 FR 6222.) In fact, in at least one state, California, this provision currently applies to certain Marriage and Family Therapists currently employed at ESRD clinical sites. Thus, under this change, certain Marriage and Family Therapists experienced in providing services to ESRD beneficiaries would no longer be eligible to provide those services, despite the lack of any evidence that their services were problematic.

In addition, CMS proposes to remove ?the requirement for [social worker] specialization in clinical practice, because this designation is not available in all States and may prove a barrier to social workers entering practice in the dialysis area.? (70 FR 6222, emphasis added.) This statement implies that CMS is concerned about a paucity of mental health professionals to serve ESRD beneficiaries (though CMS provides no data to support such a concern). If this reading is correct, it is ironic that CMS is concurrently proposing to eliminate eligibility of certain Marriage and Family Therapists who are experienced in rendering services to ESRD beneficiaries.

Further, we believe CMS?s proposed removal of the requirement for social worker specialization in clinical practice also could reduce quality of care for ESRD beneficiaries. Although social workers specializing in non-clinical areas may have some skills relevant to clinical practice, by definition they are not clinical specialists. We are unaware of any data documenting either that there is a shortage of mental-health clinicians specific to ESRD service sites or that non-clinical specialists obtain clinical outcomes equivalent to those of clinical specialists. We also would note that CMS has not proposed repealing the clinical specialization requirements for psychologists or other health professionals.

Thus, we urge CMS to eliminate the proposed changes at 42 CFR 494.140(d). Thank you for your consideration of our comments.

Sincerely,

David Bergman, JD
Director of Legal and Government Affairs
American Association for Marriage and Family Therapy
112 S. Alfred St.
Alexandria VA 22314
703-253-0461
Fax 703-253-0506
dbergman@aamft.org

Submitter : Mr. Cliff Bernier **Date:** 04/29/2005

Organization : AAMI

Category : Other Association

Issue Areas/Comments

Issues 1-10

Water Quality

The Association for the Advancement of Medical Instrumentation (AAMI) Renal Disease and Detoxification Committee submits the following comment on the Proposed Conditions for Coverage for End Stage Renal Disease Facilities (CMS-3818-P). AAMI Contact: Cliff Bernier, 703 525 4890, ext. 229; cbernier@aami.org

Comments on Proposed ? 494.40, Water Quality

1. Section ? 494.40 (a)

As proposed, Section ? 494.40 incorporates by reference the purity standards for water set forth in clauses 4.2.1 and 4.2.2 of ANSI/AAMI RD62:2001 ?Water Treatment Equipment for Hemodialysis Applications.? Subsection (a) (2) (i) of Section ? 494.40 specifies that monitoring of ?? bacteria and bacterial endotoxin levels of water/dialysate ?? be performed and that this monitoring should be in accordance with the recommendations provided in Clause 7.2.1 of ANSI/AAMI RD52:2004 ?Dialysate for Hemodialysis,? which is incorporated by reference. Clause 7.2.1 of ANSI/AAMI RD52:2004 provides general recommendations on microbial monitoring methods for water and dialysate. These requirements suggest that CMS intends dialysate to be monitored. Yet, maximum contaminant levels for dialysate are not specified in Section ? 494.40.

With the exception of dialyzer reuse, hemodialysis patients are exposed to fluid in the form of dialysate and hazardous conditions actually occur when contaminants are present in the dialysate, regardless of the quality of the water used to prepare the dialysate. While modern dialysis machines and commercially available concentrates are unlikely to contribute chemical contaminants to the water, dialysis machines and bicarbonate concentrate may contribute microbial contaminants. Therefore, to safeguard patients, and to remove ambiguity from Section ? 494.40, we believe it would be appropriate for ? 494.40 (a) to incorporate the dialysate quality standards recommended in Clauses 4.3.1 and 4.3.2.1 of ANSI/AAMI RD52:2004.

2. Section ? 494.40 (c)

Section ? 494.40 (c) (1) should be revised to clarify that the back up carbon tank is in series with the primary carbon tank. A back-up tank could mean a tank that is ready to be put into operation should the first fail.

Section ? 494.40 (c) (2) (i) should be revised to include a requirement to replace the first carbon tank if test results are above the levels listed. By only recommending testing of the second tank there is a possibility that the second tank could break through shortly after testing exposing the patient to chlorine in the water. The second tank should become the primary tank and a new secondary tank installed.

Submitter : **Ms. Fran Rickenbach, CAE, IOM** **Date: 04/29/2005**

Organization : **National Association of Nephrology Technicians**

Category : **Other Practitioner**

Issue Areas/Comments

Issues 1-10

Compliance with Laws and Regulations

Comments on 494.140 (e) Standard: Patient care Technician, item 3.

NANT firmly believes that technician certification will have a significant impact on the quality of care for the ESRD/CKD patient. Successful completion of a national technician certification process demonstrates that an individual technician has achieved a specific level of knowledge to perform patient care as well as equipment repairs in a safe and proficient manner. Technicians have the most direct patient contact in the course of a routine dialysis, yet are in the only direct patient care position that is not required to be certified.

With the current and continuing shortage of nurses, it is imperative that a national requirement for certification of technicians be mandated. This mandate will result in better outcomes for the ESRD/CKD patient. Technicians who have earned certification show experience, skill, pride and a level of professionalism that needs to be shown and seen in the CKD community. To maintain their national certification after the initial period, they must participate in continuing education programs.

NANT also believes that an experienced, certified technician is the primary practitioner who possesses the skill and knowledge to provide adequate proctoring of new technicians. The level of skill and experience needs to be defined for technicians serving in the role of the proctor for the three months following training.

CMS-3818-P-66-Attach-1.PDF

Submitter : Ms. Teri Spencer **Date:** 04/29/2005

Organization : California Department of Health Services

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-3818-P-67-Attach-1.DOC

Submitter : Mrs. Susan Cain **Date:** 04/29/2005

Organization : Iowa Council of Nephrology Nurses and Technicians

Category : End-Stage Renal Disease Facility

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Submitter : Dr. Cheryl Gilmartin **Date:** 04/29/2005

Organization : University of Illinois Outpatient Clinic

Category : Pharmacist

Issue Areas/Comments

Issues 11-20

Personnel Qualifications

see attachment

Submitter : Ms. Jenny Ng **Date:** 04/29/2005

Organization : Renal Pharmacists Network

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-3818-P-70-Attach-1.DOC

Submitter : **Ms. Tammy Gargis** **Date: 04/29/2005**

Organization : **Hattiesburg Clinic Dialysis**

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

Issue Areas/Comments

GENERAL

GENERAL

IV Provisions of proposed part 494 subpart B (patient safety). It would be overly burdensome to require established/new dialysis units to adhere to AIA design standards or HICPAC guidelines.

D. Physical Environment (proposed 494.60 (d((1) (ii) We believe this should read as adequate patient care staff must maintain current CPR certification.

494.60 (e) to adopt the 2000 edition of the National Fire Protection Association's Life Safety Code would be overly burdensome for exisiting or new facilities to follow. We feel that adhering/ following local fire codes in a out patient dialysis is adequate to ensure patient safety. At the very least established units that meet their local fire codes should not be required to follow the NFPA LSC safety requirements. I manage 11 out- patient dialysis units and only one (our newest) unit has a sprinkler system. We believe that existing units or units under construction should be 'grandfathered in' and not have to go through steps to receive a waiver from the State Agency.

I appreciate the opportunity to comment.

Thank You,
Tammy Gargis

Submitter : Ms. Claudia Kok **Date:** 04/30/2005

Organization : DaVita Pacific Coast Dialysis Center

Category : Dietitian/Nutritionist

Issue Areas/Comments

GENERAL

GENERAL

I strongly oppose to the proposed rule for permitting 20 days for dietitians to complete initial patient assessments. It is not uncommon for a newly admitted hemodialysis patient to be re-admitted into the hospital after they had only 1 or 2 treatments at the dialysis center. Sometimes these new patients would be hospitalized for another 2 to 3 weeks (sometimes even longer) before they return to the dialysis center. Therefore, it is unrealistic to allow only 20 days to complete the assessment for a new admission.

In addition, I am also against a follow-up comprehensive reassessment for new patients within 3 months after completion of the initial assessment. Renal dietitians already do monthly progress notes and care plans for every patient every single month. We clearly document any necessary changes in nutritional status, nutritional assessment, intervention and plan in our monthly progress notes and care plans. We also do a minimum of 1 annual comprehensive reassessment for each patient, and more if patient is considered unstable. It is just redundant and unnecessary to keep documenting the same issues over and over again during the same month. The ongoing trend for more and more paperwork nowadays, requiring the completion of even more forms/ assessments does not even make sense anymore when so much valuable time is being consumed by such a huge amount of paperwork instead of being utilized for providing the needed counseling and quality care that our patients deserve.

Submitter : Mr. Steve Bogatz **Date:** 04/30/2005

Organization : Connecticut Council of Nephrology Social Workers

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-73-Attach-1.DOC

Submitter : Mr. Gus Castaneda **Date:** 04/30/2005

Organization : http://www.dailyhemo.org

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

As a paitent, I'd want to know all I could about my care so I could do self-care in a clinic or, better yet, dialysis at home so I wouldn't have to worry about the staff or their qualifications.....

so, the availability of alternatives and dialysis options should be given to the capable patients.

Submitter : Mr. Jim Curtis **Date:** 04/30/2005

Organization : Mr. Jim Curtis

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-75-Attach-1.DOC

Submitter : **Christy Price Rabetoy** **Date: 05/01/2005**

Organization : **Christy Price Rabetoy**

Category : **Nurse Practitioner**

Issue Areas/Comments

GENERAL

GENERAL

Patient's Rights - The CoCs need to clarify that along with RIGHTS come RESPONSIBILITIES. Presently, patients have no responsbility to comply with the treatment regimen, show up for treatment on time and per schedule, nor do they have to display appropriate adult (peds)behaviors. It is important to point out physical or verbal abusive patient behaviors are inappropriate and may lead to discharge from a unit.

Personnel Qualifications - It is embarassing and appalling that dialysis technicians are not nationally certified at this time. There are two national certifications for patient care technicians. All other health care providers are either certified or licensed. On-the-job training is ORIENTATION, not a means for certifying an individual. It has little or no meaning. It is not portable,and there is no respect for such institutional training. If the CoCs can demand a masters degree for social workers, it is an hypocris to not at least require national certification for techs. There is no where in health care or the society where individials are allowed to potentially harm another individual without at least having some indication of competency.

Submitter : **Mr. Bernard Botiller** **Date: 05/02/2005**

Organization : **Self**

Category : **Physician Assistant**

Issue Areas/Comments

Issues 1-10

Plan of Care

Of particular concern is CFR Proposed Sec. 494.90 (b) (4) ?Plan of Care? where specifically it states:
?494.90 (b) (4) would specify that the facility must ensure every patient is seen at least monthly by a physician providing the ESRD care as evidenced by a monthly progress note that is either written in the beneficiary's medical record by the physician or communicated from the physician's office and placed in the beneficiary's medical record.

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

We recommend that the language in 494.90 (b) (4) should be amended to read:
?Sec. 494.90(b) (4) would specify that the facility must ensure every patient is seen at least monthly by a physician, physician assistant or nurse practitioner providing the ESRD care as evidenced by a monthly progress note that is either written in the beneficiary's medical record by the physician/physician assistant/nurse practitioner or communicated from the physician's office and placed in the beneficiary's medical record.?

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

Submitter : **Ms. Christine Lawrence** **Date: 05/02/2005**

Organization : **Centers for Dialysis Care**

Category : **Social Worker**

Issue Areas/Comments

Issues 1-10

Plan of Care

Condition: Patient Assessment: Recommend change "assessment within 20 calendar days" to assessment "within 30 days" to allow social work and team to properly evaluate patient. agree with f/u reassessment within 3 months in order to work towards adjustment.
"unstable patients"- agree this is necessary to focus on significant issues to manage physical and emotional health towards fulfilling needs. Agree with annual assessment timing for all others.

Issues 11-20

Personnel Qualifications

Agree social workers must hold Master's degree specifically in social work in order to best meet patient-in-environment issues. would add that category be created - patient service representative- as mandate to handle clerical tasks like medical evidence forms, insurance, and other duties to allow MSW time to perform psychosocial assessment and intervention. Would allow time for more counseling of high risk pts.

Submitter : Ms. Nancy Sanford **Date:** 05/02/2005

Organization : MaineGeneral Medical Center

Category : Social Worker

Issue Areas/Comments

'GENERAL

GENERAL

The assessment period for a new patient should be 30 not 20 days. Unless CMS is going to REQUIRE that dialysis units stop using social workers for clerical tasks and set a reasonable social worker to dialysis patient ratio (CNSW suggests 75 to 1, I believe) then it is unreasonable to expect an assessment any sooner than that.

Submitter : **Ms. Nancy Armistead** **Date: 05/02/2005**

Organization : **Mid-Atlantic Renal Coalition**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-80-Attach-1.DOC

Attachment #80

File Code: CMS-3818-P

COMMENTS

Medicare Program: Conditions for Coverage for End Stage Renal Disease Facilities

Submitted by: **Mid-Atlantic Renal Coalition**
Attn: Nancy Armistead, Executive Director
1527 Huguenot Rd
Midlothian, Virginia 23113
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narmistead@nw5.esrd.net

Subpart A – GENERAL PROVISIONS

Subpart B – PATIENT SAFETY

494.30 Condition: Infection Control

(a) Standard: Procedures for infection control
(1) We support the incorporation of "CDC Guidelines Recommended Infection Control Practices for Hemodialysis Units at a Glance" and have found this to be an effective tool in our Network to assist providers.
(b) Standard: Oversight
(2)(ii) We would recommend that the composition of the quality improvement committee be specified to assure discipline representation.

494.50 Condition: Reuse of hemodialyzers and bloodlines

(c) Standard: Monitoring, evaluation, and reporting requirements for the reuse of hemodialyzers and bloodlines
(2)(ii) Reference is made to a "cluster of adverse patient reactions." We believe that the term "cluster" should be further defined in a measurable way (i.e., percentage of patients receiving treatment at the time or more than 3 patient reactions, etc).

494.60 Condition: Physical environment

(d) Standard: Emergency preparedness
(3) We support the need for defibrillators in the dialysis facility.

Subpart C – PATIENT CARE

494.70 Condition: Patients' rights

(a) Standard: Patients' rights

(2) Specifies that the patient should receive all information in a way that he/she can understand. We fully endorse this and would also recommend that information be presented in a culturally sensitive manner.

(5) We endorse the concept that patients have a right to be informed about advance directives and believe that this could be strengthened by further clarification. Dialysis units should be required to provide an advance care planning process in which patients are encouraged to 1) identify their preferred surrogate decision-maker in the event of incapacity, 2) complete an advance directive (called a medical power of attorney or durable power of attorney for health care or health care proxy) in which they name their preferred decision-maker, and 3) state how much leeway they want to give this decision-maker. This process preserves patient autonomy and helps nephrologists and dialysis units know with whom to make decisions if the patient loses capacity, a not infrequent occurrence for dialysis patients. In this advance care planning process, the dialysis unit should also identify if there are health states in which the patient would not want to be kept alive with dialysis or other forms of life support. An informed patient's wish not to be resuscitated should be honored in the dialysis unit. Current research indicates that between 15-30% of dialysis units perform CPR on all patients regardless of whether they want it or not. The Renal Physicians Association and American Society of Nephrology Position on Quality Care at the End of Life reads: "To respect the wishes of patients who prefer not to undergo cardiopulmonary resuscitation, nephrologists shall issue do-not-resuscitate orders for their patients who request them. These orders shall be issued in the dialysis unit in a manner that respects patient confidentiality and yet ensures that those treating the patient are aware of them. Physicians are legally required to honor competent patients' treatment decisions. To do otherwise, ie, to perform unwanted cardiopulmonary resuscitation on a competent patient, constitutes medical battery. It is important to note, however, that a do-not resuscitate order does not preclude other standard measures in dialysis treatment such as fluid resuscitation for intradialytic hypotension. A do-not-resuscitate order only becomes effective when the patient has experienced a cardiac or respiratory arrest

494.80 Condition: Patient assessment

The right of the patient to participate in the planning of their medical treatment is imperative for quality outcomes. This goes a long way to providing patients with more feeling of control, reduce stress/anxiety and gives them ownership of their health outcomes.

(a) Standard: Assessment criteria.

We would recommend that the patient assessment include advance care planning for every patient (see comments above).

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

(1) An initial assessment must be conducted within 20 calendar days after the first dialysis treatment. We believe this is insufficient time and that clarification of the first dialysis treatment is required. Is this the patient's first ever treatment (for example in an acute care hospital) or the first dialysis treatment in the dialysis facility?

494.90 Condition: Patient plan of care.

We believe that the patient plan of care should include a reference to the treatment of bone disease.

494.110 Condition: Quality Assessment and performance improvement

Consideration should be given to increasing the Network's role in the oversight of the dialysis facility's quality assessment and performance improvement program. The Networks are quality improvement organizations and compliance with this condition can be better assessed by the Networks as opposed to the State Survey Agencies who have traditional responsibility for compliance with conditions and standards. It should also be noted that the Networks have an ongoing relationship with all facilities where the State Survey Agencies only assess facility compliance every three years (on average).

(a) Standard: Program scope
(2) Quality indicators are listed that the dialysis facility must include in their quality assessment program. Since the facility is required to track the status of patients awaiting transplant, then transplantation should be added to this list.

Subpart D - ADMINISTRATION

494.140 Condition: Personnel qualifications

(d) Standard: Social Worker
We believe that some social workers who were grandfathered under the current regulations are still practicing and that the requirement to have these individuals function under the supervision of a qualified social worker should be retained. Additionally, we would like to encourage the inclusion of language that addresses the inappropriateness of social workers managing services such as transportation and insurance taking away from their availability for direct patient counsel and education.

494.150 Condition: Responsibilities of the medical director

Recognizing that CMS has authority to approve Network goals and objectives, we would like to see a requirement added that the Medical Director, in conjunction with the CEO and governing body, shares responsibility for assuring that the facility complies with Network goals and objectives. We believe that frequently the goals and objectives are clinical in nature and require Medical Director involvement. We would also like to see the Medical Director assume responsibility to either responding to grievances processed through the Network or assigning responsibility to the appropriate individual within the facility to respond to Network grievances.

494.160 Condition: Relationship with the ESRD Network

The wording in this condition is inconsistent with legislation and other sections of the proposed regulations. We would suggest that the reference to the Network's current *statement of work* be deleted and replaced with the Network's *goals and objectives*.

494.170 Condition: Medical records

(a) Standard: Protection of the patient's record.

(2) A listing of when medical record release is authorized is provided. We would suggest a reference be included to the fact that the medical record can always be released to the patient, guardian or other patient representative with legal authority to act on the patient's behalf.

494.180 Condition: Governance

(b) Standard: Adequate number of qualified and trained staff.

(2) We are supportive of the requirement that a registered nurse is present in the facility at all times that patients are being treated.

(5)The proposed regulations specify that there should be a written training program specific to dialysis technicians that include a number of items. We believe that professionalism and conflict resolution training should be added to the list and should be required of all staff and not just the dialysis technician.

Submitter : Dr. Thomas Golper **Date:** 05/02/2005

Organization : Vanderbilt.Univ Med Ctr (acting as individual)

Category : Physician

Issue Areas/Comments

Issues 11-20

Laboratory Services

Convenience lab draws need to be addressed

Governance

I think this is a great step forward.

Responsibilities of the Medical Director

There are too many "ensures." The Med Dir can oversee, support etc, but the Medical Director cannot ensure much. I can ensure my own actions, not those of others. The culprit is often the owner or chain, which flat out refuses to cooperate. You have helped somewhat, actually a lot, by the pressure placed on the governing body (Governance).

QAPI

Overdepnedance on KDOQI

Submitter : Dr. Ronald Sorkness **Date:** 05/02/2005

Organization : University of Wisconsin School of Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-3818-P-82-Attach-1.DOC

Submitter : Ms. Dori Schatell **Date:** 05/02/2005

Organization : Medical Education Institute (non-profit, 501c3)

Category : Other

Issue Areas/Comments

GENERAL

GENERAL

See attachment for comments on Issues 1-10 AND Issues 11-20.

CMS-3818-P-83-Attach-1.DOC

CMS-3818-P-83-Attach-2.PDF

Submitter : Ms. Dori Schatell **Date:** 05/02/2005

Organization : Life Options Rehabilitation Advisory Counc. (LORAC

Category : Other

Issue Areas/Comments

GENERAL

GENERAL

See attached comments on Issues 1-10 AND Issues 11-20.

CMS-3818-P-84-Attach-1.PDF

Submitter : Ms. Twyla Moore **Date:** 05/02/2005

Organization : Arkansas Department of Health

Category : End-Stage Renal Disease Facility

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"