Submitter : **Ms. Sheri Floramo** **Date: 05/05/2005**

Organization : **Circle Medical Management**

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

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-3818-P-215-Attach-1.DOC

Attachment #215
Circle Medical Management, Inc.

1426 W. Washington Boulevard, Chicago, IL 60607

Thank you for the opportunity to respond to the proposed conditions. I have been the administrator of a small independent dialysis facility in Chicago for eighteen years. We provide incenter hemodialysis, CAPD, CCPD, home hemodialysis in skilled nursing facilities, and daily home hemodialysis. I have been a member of the NRAA for seventeen years and spent several years on the Board of Directors. My unit is affiliated with a large urban academic medical center and all of our physicians are in academic, not private medicine.

Please note that I have abbreviated Proposed Conditions of Coverage as PCOC>

Water Quality –

It is most feasible and logical to test chloramines between shifts rather than every four hours. This is particularly true in smaller units where a staff member involved in patient care may also have the responsibility of testing chloramines. Checking between shifts will be as safe and as effective as every four hours.

Physical Environment –

I believe some of the life safety standards are too burdensome for facilities to implement. Local municipalities have very specific building and fire safety codes in place and as with other regulations CMS should default to the state or local regulations. Fire drills four times a year, subcompartmentation, notification systems are all excessive and unnecessary particularly in light of the fact that our business is low risk and there have never been any problems with this issue for facilities.

Patient Assessment –

The initial comprehensive assessment can be completed for incenter hemodialysis patients if the patient is present for all treatments during the first twenty days which is not always the case. Therefore we believe that the assessment should be completed by the tenth treatment. It may be more difficult to complete the comprehensive assessment in twenty days for home patients and recommend that thirty days be allowed for home patients.

In the ninety day reassessment I believe the goal is to review the plan of care to assess how the patient is responding and to determine if changes are needed in the plan of care, not actually duplicate a comprehensive assessment. The wording in the new conditions of coverage should be amended to reflect this.

Patient Plan of Care

"The dialysis facility must ensure that all dialysis patients are seen by a physician providing the ESRD care at least monthly..." A dialysis unit does not control the physician and although we

can address "negligent" physicians we cannot ensure that they will see all of their patients every month. Units cannot be held accountable for physicians who are not employees.

This is also a patient issue. Our physicians have a weekly clinic to see their home patients. There are a group of patients who are non-compliant with their appointments and thus are not seen by the physician that month. The home patient may come in at another time to get labs drawn, etc... but the physician is not present.

Care at Home: Training

A registered nurse should be responsible for the development, implementation, and oversight of home training however aspects of home training should be allowed to be delegated to other staff members. The outcome is the focus and a facility should be able to determine which of their staff "experts" to use in order to make sure the patient has the best training. Example: facilities notoriously have star cannulators. Technicians cannulate day in and day out but our RN's do not thus a star cannulator technician is a much more effective teacher of this aspect of home training than the RN.

As written the proposed conditions of coverage require that training be completed before the initiation of home dialysis. If a facility attempts to train a patient on all the aspects of training as defined in number three (3) prior to the initiation of home dialysis the patient will never go home and will probably quit due to being overwhelmed. The focus of training is teaching the patient how to safely and effectively dialyze. Many of the other aspects identified as required training such as "how to achieve and maintain emotional and social well being" and "implementation of a nutritional plan" are important part of the patient's plan of care but require continuous effort on the part of the facility and patient. It is best to leave the details of the training program to each facility.

Care at Home: Support Services

We disagree with the proposed requirement that staff must make a home visit to patients. Our facility operates in a large urban area and many of our patients live in very dangerous areas. It is not safe for my staff to travel to these areas either alone or with another staff member. This is particularly true for patients who work and are only available in the evening hours.

Care at Home: Dialysis in Nursing Facilities

We have been providing home hemodialysis services (Method 1) to residents of long-term care facilities for several years. Our Medical Director will be presenting our experience at the 2005 American Society of Nephrology meeting. We believe we have an excellent experience and have many comments. Generally we believe that this is a needed service and that it should be handled in a consistent manner as our other modalities with some minor modifications.

1. Patient Appropriateness – if we identify these patients as home dialysis patients and under the care of a chronic dialysis provider than the patients should not be "acute" patients. We are frequently asked to accept patients who are non-responsive, comatose, and very medically unstable. Many providers will accept this patient which we believe is incorrect. There needs to be some guideline on what patients are appropriate for the program. With other home dialysis patients, the provider needs to be able to provide

back-up incenter treatments. We recommend that a requirement be that the patient is capable of being transported to and safely dialzyed in an outpatient dialysis unit in the case back-up services are required.

In the PCOC it states that patients who are considered "short stays" would not be eligible. This is a very big mistake! A significant percentage of the patients served by this type of program are short stays and this has been very beneficial in reducing the patients' length of stay in the facility. Patients require short stays for rehab. If the patient has to transfer to a dialysis facility for treatment the patient will most likely miss a great deal of rehab and be required to stay in the facility for a longer period.

Consider that home patients transiently need incenter dialysis because of medical or home issues. Incenter dialysis patients transiently need home dialysis for medical issues. We strongly recommend having an evaluation period of 30 days for home dialysis patients in long term care facilities. After thirty days the patient becomes a permanent home dialysis patient. This initial thirty day period allows for short stays and to assess if the patient is appropriate for the program. This will also help address the concern of the costs of one patient one machine in this program. Once a patient is deemed "permanent" then the provider is required to meet all the other criteria including a dedicated machine for the patient. As with other home patients the comprehensive assessment and plan of care will be completed within this thirty day period.

This transient concept also is consistent with the directives we get from our network in regard to processing paperwork. Our network does not want any information on the patients in our home hemodialysis for long term care residents unless the patient has been in the program for at least thirty days.

2. Nursing Coverage

We disagree with the proposed requirement that a registered nurse must be in the facility when dialysis in being provided. As with incenter dialysis we believe that an experienced licensed practical nurse is acceptable. The requirement should be that the facility has a nurse who has been trained in the complications of hemodialysis, access management, and general care of hemodialysis patients be in the facility at all times dialysis is occurring. We provide a training program to the nursing staff of the facilities we are in on the care of the dialysis patient to ensure that pre and post complications can be adequately addressed. As part of the training we provide information so that the nursing staff have a general understanding of the general care of the dialysis patient including access, volume, dry weights, common comorbidities, and use and administration of common renal related medications. This model has been very successful and we provide the in-service when we begin the program, annually, and more when there are changes in nursing staff. We also believe that any long term care facility that has residents on dialysis should be required to have staff knowledgeable of the care of ESRD patients regardless is the patient receives dialysis onsite or at a dialysis facility.

3. Training –

The patient training requirement should be waived for patients who are under the care of a home hemodialysis program utilizing dialysis assistants to administer the treatment.

That being said, we strongly recommend that the dialysis assistants be experienced dialysis technicians under the management of an experienced dialysis registered nurse who is an employee of the dialysis facility. The dialysis technicians utilized as home hemodialysis assistants should have a minimum of two years hemodialysis experience.

4. Monitoring

   The dialysis facility should be responsible for monitoring its staff – nursing, technicians, social worker, and dietician, involved in the renal assessment and development and implementation of the plan of care for the patients. We strongly oppose dialysis facilities having any responsibility for the monitoring of the long term care facility staff. Each dialysis facility has an agreement in place with the long term care facility that identifies the responsibilities of each party.

   This being said, we recognize and support ongoing and effective communication between the dialysis provider and the long term care facility regarding the patient's medical status. We suggest that the provider's meet once a month to review the joint patients.

In general, all patients, regardless of modality, should be appropriately assessed and have a plan of care developed by the dialysis facility team. All patients should be monitored monthly, should be part of the facility QAPI process, and be provided with renal nursing, psychosocial, and dietary support services. The current standards of practice should apply to all patients.

Patient Plan of Care:

We disagree with including very specific measures as the standard of practice changes over time and in fact many of the sources cited are dated and now being reconsidered with the publication of new studies. Facilities and practitioners should be held accountable to the current standards of practice.

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

The Proposed conditions of coverage require a registered nurse is present in the facility at all times that patients are dialyzed. We strongly disagree and believe this is incredibly burdensome in light of the current nursing shortage. One of the major chains is actually recruiting nurses from China because they cannot get nurses in the U.S. The problem is not getting better and implementation of this requirement would severely limit access for patients in many units where this has not been a requirement before and facilities are effectively utilizing experienced LPNs. There would most likely be unit closures. Each State has and should continue to identify such requirements via their Nursing Practice Acts.

One explanation for this requirement is that patients are older and sicker and that a registered nurse is required to handle emergencies. Regardless of the patient population or what type of nursing staff is present medical emergencies are handled the same in units – CPR is initiated and 911 is called and unless a physician is present most drugs cannot be ordered and administered.

The other roles of the registered nurse can be accomplished with patients but these roles are not required to be done sixteen hours a day, seven days a week. An RN is completing the comprehensive assessment and plan of care, assessing staff, assessing patients, and directing the

patient care staff. The PCOC even acknowledges that an LPN can serve as charge nurse. This proposed requirement essentially contradicts that. Of note, our access program has been a huge success and commended by our network and it happens to be under the direction of one of our LPNS.

The PCOC can address the concern about quality nursing by requiring that a licensed nurse with a minimum of one year (or greater) hemodialysis experience and certification in patient assessment be present whenever dialysis is taking place and require that a designated registered nurse is available, on call, at al time dialysis is being provided.

Thank you for consideration of my comments.

Yours truly,

Sheri L. Floramo
Administrator
Circle Medical Management, Provider # 14-2540

Submitter : Mr. Chris Lovell **Date:** 05/05/2005

Organization : Dialysis Clinic, Inc

Category : End-Stage Renal Disease Facility

Issue Areas/Comments

GENERAL

GENERAL

See attachment Please contact Chris Lovell 615 342-0526 if the attachment function did not work

CMS-3818-P-216-Attach-1.PDF

Attch #216

DIALYSIS CLINIC, INC.

A Non-Profit Corporation

1633 Church Street
Suite 500
Nashville, TN 37203
Phone: (615) 327-3061
Fax: (615) 329-2513

May 5, 2005

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

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

Dear Administrator McClellan:

Dialysis Clinic, Inc. (DCI) is a non-profit provider of dialysis care founded in 1971, with rehabilitation of the ESRD patient and constant improvement of the patient's care as the principal thrust of its efforts. DCI presently operates 190 free-standing dialysis facilities in 27 states, and serves more than 12,300 patients. Approximately 80% of our patients are Medicare recipients. DCI is pleased to have the opportunity to submit this comment letter to the Centers for Medicare and Medicaid Services (CMS) in response to the proposed rule for Coverage for End Stage Renal Disease Facilities.

Subpart A – General Provisions

Basis and Scope (494.1)

DCI welcomes the evidence based, patient centered method, and the fundamental shift from a process orientation to an outcomes focus. We appreciate the efforts to move toward a less prescriptive approach providing the dialysis facility greater flexibility in the utilization of its resources.

Subpart B – Patient Safety

Infection Control (494.30)

We agree that facilities should demonstrate standard infection control precautions, including the "Recommended Infection Control Practices for Hemodialysis Units at a Glance" published by the CDC. However, we strongly disagree with the exception for screening for Hepatitis C. The argument that transmission of hepatitis C can be prevented by strict adherence to infection control precautions can be made for all infections listed by the CDC, therefore no testing would be required for any of the diseases. The CDC reported in the CDC's National Surveillance of Dialysis-Associated Diseases in the United States, 2002, that 63% of centers tested patients for anti-HCV and 11.5% reported having at least one patient who became anti-HCV positive in 2002 (i.e., tested positive for anti-HCV in 2002 but had previously tested negative). We too have

found an alarming rate of increase in some of our facilities. During our investigations we have found the same results as reported by the CDC. "HCV transmission has occurred in facilities where there were multiple opportunities for cross-contamination among patients, including failure to clean and disinfect contaminated equipment, supplies, and environmental surfaces that were shared between patients." We believe it is very important to test our patients for Hepatitis C so we can counsel patients on how to avoid transmission to their family members, change risky behavior, and be given the risk and benefits of therapeutic options. We have been able to use Hepatitis C transmission as an outcome indictor of the facilities' actual practice of infection control precaution. By testing we can determine if a facility is following infection control practices and prevent an outbreak in a facility. There should be no exception for Hepatitis C testing and payment policy should be aligned with this policy.

The requirement that newly opened hemodialysis units have an isolation room for Hepatitis B positive patients is overkill. For existing clinics it would be quite expensive and in some cases there is not enough room in the existing building to accommodate this requirement. If there are multiple clinics in a service area, providers should be able to cluster Hepatitis B positive patients into a facility with an isolation room. This condition should be replaced with a requirement for a plan of action to provide isolation dialysis for hepatitis B positive patients.

Designation of a registered nurse as the infection control or safety officer is reasonable. However, the language needs to clearly indicate that it is not expected that this is a new full time equivalent (FTE) requirement. Rather, the designated person would complete the infection control duties in addition to their other duties.

Water Quality (494.40)

DCI has already incorporated the AAMI water quality standards and agrees with the proposed rule. We also agree with not proposing the requirement for ultra pure dialysate at this time because currently there is no consensus regarding necessity of its use.

As the proposed rule is written it appears that both Chlorine and Chloramine testing of water is required. AAMI states that this can be accomplished with a single DPD total Chlorine test taken post of the first carbon tank as long as the facility limits are set at the Chloramine limit of <0.1 mg/L. We would ask that this language be added. We agree with the testing frequency being prior to each patient shift.

The proposed rule states that once mixed, bicarbonate concentrate must be used within the time specified by the manufacturer of the concentrate and may not be mixed with fresh concentrate. We strongly disagree with the statement that it may not be mixed with fresh concentrate. This will be an impossible task for some of the larger facilities due to the size of the bicarbonate holding tank in the distribution loop. Most of the facilities have 100 gallon tanks and must make more than one batch per day to be able to complete the treatments for the day. This requirement would not allow the facility to make additional bicarbonate without discontinuing treatments or putting individual patient's machines on jugs while flushing the bicarbonate out of the loop made in the morning before transferring the second batch of the day. These facilities would have to try to retro fit a larger tank into an area that was designed to hold a 100 gallon tank. Existing arrangements were designed by companies that make distribution systems for dialysis facilities (Marcor, Better water, and H20 solutions) and have proven to be safe. Facilities should be able to mix bicarbonate with fresh concentrate as long as it is mixed and used in the same day. Each night, the loop should be flushed with RO treated water and a fresh batch of bicarbonate made prior to the first shift the next day.

Physical Environment (494.60)

It is reasonable to maintain a temperature that is comfortable for the majority of patients. However, it is not reasonable to require the dialysis facility to provide blankets for the use of patients and, as a result, incur the added cost of a cleaning service for blankets. Patients should be allowed to bring there own blankets as long as the facility has the right to deny the privilege if a patient brings in a foul smelling, heavily soiled, and/or insect infested blanket.

We are in favor of emergency preparedness procedures and that patient care staff maintain current CPR certification. Rather than a traditional defibrillator, we require our facilities to have an AED. We discourage the use of traditional defibrillators for a number of reasons. First, the proper use of the traditional defibrillator requires the staff to become ACLS certified. It takes much time and resources to maintain the certification. Secondly, dialysis staff does not get enough experience with their use, as is the circumstance in a hospital setting, to remain proficient. And third, the defibrillators are expensive. The AED is a safer, cost effective alternative.. We ask that language be revised to clearly state that an AED is the defibrillator of choice and/or that the minimum requirement is the AED.

We strongly believe that it is inappropriate to stop dialysis treatments and evacuate patients during a fire drill. To do so is unnecessary and will jeopardize the patient's health and safety.

DCI has a mission and history of providing dialysis in rural or under-served regions. As a non-profit provider, cash flow and profit are not the overriding concern. However, in the environment of limited reimbursement, a major consideration is the cost of opening and operating a new dialysis facility. We believe the proposed rules do not adequately address small facilities in rural or under-served areas. The proposed rules will make it much more difficult to offer dialysis to patients in these areas of the country. Particularly concerning is the adoption of the NFPA LSC chapter 20 and chapter 21 (LSC 2000 edition) to all dialysis facilities regardless of size. Also troubling is the requirement for isolation rooms and the proposal for the AIA design standards. The waiver process outlined on page 68 of the proposed rule is problematic. Our experience in applying for waivers with CMS and/or a State agencies has shown that the process is burdensome, frustrating and is a strong deterrent to its use. As a consequence, we would be less responsive to inquiries for new facilities in under-served areas that would require a waiver approval to be viable. DCI requests that specific language be added to the proposed rules to the waiver process to better accommodate dialysis in underserved areas.

We would be more responsive to inquiries for new facilities in under-served areas if the language described the general guidelines used to grant approval of a waiver. We would suggest that the facility applying for the waiver should be the only facility in the under-served area. The new facility should decrease the round trip travel time for the majority of patients to less than two hours and the facility seeking a waiver should be applying for less than 13 stations. Many times the building size is proportional to the number of stations. However, the under-served community often grants the use of an existing building to keep cost low, but because of the size of the building it would become too expensive to meet the proposed rules. In addition, with the present reimbursement rate from Medicare, it is almost impossible to break-even in a facility with less than 13 stations.

The proposed rule adopts the NFPA LSC Handbook, specifically chapters 20 and 21 which are concerned with emergencies, such as power failures, that are likely to threaten health safety of patients, the staff and the public. An interpretation of what this means would be important. The code also requires egress lighting, which means battery powered light fixtures along the corridors or paths of egress from the building to the exits. This is something that DCI provides in our facilities. Someone could interpret this to mean emergency power for some or all of the electrical features of the building to the extent of requiring an unnecessary emergency generator. The following phrase is contained in the preamble: "This provision does not apply to dialysis facilities because dialysis equipment is not life-support equipment under the Life Safety

Code." We ask that this specific language be added to the final rules clearly stating that emergency power is not required so that there will be no incorrect interruptions of the NFPA LSC Handbook.

The proposed rule requires smoke compartmentation, which means that a one-hour fire and smoke barrier is needed to divide the facility into two compartments. There are certain exceptions for buildings with sprinklers. However, most dialysis facilities are of the size that makes sprinkling an unnecessary, expensive option. Most of our new construction includes a one-hour fire and smoke barrier. This is not expensive in a new facility, but it would be difficult and expensive in an existing building to retro-fit. We ask that specific language be added to the final rules to apply this requirement only to new licenses. As stated above, we have concerns that the wavier process would not solve this problem on a case by case basis for existing facilities.

Subpart C – Patient Care

Patient Rights (494.70)

The patient rights section of the proposed rule requires that patients be "informed" of the facility's policies. This is an appropriate objective and we agree with its intent. However, once again we are concerned about potential misinterpretation and inconsistent application by surveyors and regulators. The proposed rule should specifically state that providing a summary of policies to the patient is satisfactory.

The proposed § 494.70(a)(5) would also require the facility to inform patients of the right to establish an advance directive. Advance directives include written documents including living wills and durable powers of attorney for health care, as recognized by State law. We concur that it is prudent to consider adding advance directives as a requirement in the patients' rights condition of this proposed rule and have already developed policy and procedures to help our facilities comply.

We certainly agree with strengthening the requirement § 494.70(a)(6) to require the dialysis facility to inform and educate the patients on all available treatment modalities and settings, so patients can make an informed decision regarding the most appropriate course of treatment that meets their needs.

The proposed § 494.70(a)(11) requires that patients be informed of the right to receive the necessary services outlined in the patient plan of care in proposed § 494.90. This should be clarified to state that patients have the right to receive the necessary services as authorized by their insurance plan (Medicare or Commercial) or if not covered by the patient's plan; to the extent the patient is willing to pay for non covered services.

DCI desires to create a safe environment for patients to receive dialysis and for staff to administer treatments in an outpatient setting. DCI already has established a policy to provide information regarding the conduct required by patients to maintain a safe clinic environment. This policy addresses conduct which may subject a patient to be involuntarily transferred or discharged from a DCI clinic, and ensures that all patients will receive notice of the contents of this policy upon admission. Our policy is very similar to 494.70(b)(1) and (2), which would require a facility to inform patients regarding its transfer and discharge policies and provide 30 days notice in advance of reducing or terminating patient care services following the discharge and transfer procedure outlined in § 494.180(f). Furthermore, we appreciate that the proposed rules have recognized that there are some patients that make it difficult to treat themselves and interfere with the care provided to the other patients in the facility. We have additional comments in the governance section of this document.

Patient Assessment (494.80) and Patient Plan of Care (494.90)

We agree with the statement that the patient assessment and patient care planning processes are inextricably linked. Therefore, we will discuss them together. We generally agree with the overall approach on the initial comprehensive assessment and care plan. However; we believe the initial comprehensive assessment

proposal is contrary to the overall goal of being more flexible and less prescriptive. The requirement to have an initial comprehensive assessment within 20 days of admission to the facility is too prescriptive. Many team members (social workers, dietitians and physicians) travel to satellite facilities on a monthly basis due to the distance. Therefore, they complete the assessment and care plan at the same time during this visit. To complete both the assessment and plan within 20 days or sooner is a goal we would hope our team members would strive towards; however, it is not reasonable in all situations and would create additional burden and expense. The proposed rule assumes the patient will be in the facility for all prescribed treatments within the first 30 days. Often patients are readmitted to the hospital. We would urge that the proposal be changed to state that the initial assessment and care plan is to be completed within 30 days, any hospital days should be added to the 30 days, and the 20 day requirement eliminated.

We also recognize that patients who are new to dialysis need time to adjust and adapt to the treatment and a follow-up reassessment for new patients within 3 months after the completion of the initial comprehensive assessment should be performed. However, we do not agree with creating extra paper work by re-doing another "comprehensive assessment." We believe our facilities should review the prior assessment and update the changes where they have occurred and make the appropriate changes to the care plan. We would ask that the language of the proposed rule be changed to reflect this standard of practice.

We agree with the premise in section § 494.80(d)(1), that if the patient's condition is stable the facility must perform comprehensive reassessments at least annually to assure that patients receive a continuing program of care that meets their needs. If the patient is unstable, section § 494.80(d)(2) requires a monthly reassessment, to allow for the update of the plan of care and added criteria to specify at a minimum, which patients may be considered to be unstable patients. These criteria include extended or frequent hospitalizations, marked deterioration in health status, a significant change in psychosocial needs, or poor nutritional status, with unmanaged anemia and inadequate dialysis. We think that the focus should be to reassess the areas that are causing the instability. We believe however, that the terms "poor nutritional status" and "unmanaged anemia" are unclear and need better definition. We would suggest that the language be changed to poor nutritional status as indicated by a serum albumin less than 3.5 and percent of usual body weight, adjusted for height. And for unmanaged anemia we suggest hemoglobin which is less than 11 g/dL.

We applaud the efforts to reduce the Federal regulatory burden, by eliminating the separate requirement for a patient long-term program. We believe that there should be a single comprehensive plan of care to ensure that each dialysis patient receives personalized and appropriate patient care within the selected modality and setting of treatment. Moreover, where applicable, the elimination of the facility medical director, the home dialysis physician, and the transplant surgeon as a member of the interdisciplinary team, will be beneficial to transform the current paper shuffling process into a practical course of action. In other sections of the proposed rule, safe guards to promote transplantation have been added. The dialysis facility will be required to have inclusion/exclusion criteria, defined by the transplant surgeon based at the transplant center that would receive the transplantation referral to use in the evaluation of patients. Frequently a patient has a choice of many transplant centers in or out of his/her community. The dialysis facility should be responsible for only the inclusion/exclusion criteria from its own community transplant centers.

The proposal states that the interdisciplinary team must develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and must include measurable and expected outcomes and estimated timetables to achieve these outcomes. We think the statement "estimated timetables" is impractical, and unrealistic. Physiolcial response to therapy is impossible to time as there are too many unpredictable variables at play. Any "timetable" would be a poor guess based on unreliable data and there would of no benefit.

We believe that the patient plan of care must, at a minimum, address: (1) dose of dialysis; (2) nutritional status; (3) anemia; (4) vascular access; (5) transplantation status; and (6) rehabilitation status. However, language should be added to the proposed rule that will result in significant improvement to many patients nutritional status. The proposed rule "§ 494.90(a)(2) would require the interdisciplinary team to provide the necessary care and services to achieve and sustain an effective nutritional status. The language should be modified to state that the facility could provide nutritional supplements to achieve and sustain an effective nutritional status. This would remove the legal uncertainty of providing supplements to patients.

The proposed rule § 494.90(a)(4) includes vascular access as a component of the patient plan of care, conferring upon the interdisciplinary team responsibility for; "evaluation of the hemodialysis patient for the appropriate vascular access type" and "taking into consideration co-morbid conditions and other risk factors". Evaluation of the hemodialysis patient for the appropriate vascular access type is the responsibility of a vascular surgeon. If the patient does not have a fistula or a fistula has not already been ruled out by a surgeon, the most the interdisciplinary team can do is educate, persuade and refer the patient to a vascular surgeon. It is the vascular surgeon that determines what is surgically possible. Vascular access needs to follow the same approach as transplantation. Facilities have very good control of education, persuasion, and referral, but have no control over what a surgeon/center will do. The rule also requires the dialysis center to "Routinely monitor the hemodialysis patient's vascular access to prevent access failure, including routine monitoring of artiovenous grafts and fistulae for stenosis". The term "monitor" should be clearly defined. We are very concerned that this vague language could become an unfunded mandate, perhaps requiring facilities to purchase very expensive equipment. NKF-K/DOQI Guideline for vascular access in guideline 10 defines monitoring, surveillance, and diagnostic testing as: "Monitoring—This term refers to the examination and evaluation of the vascular access by means of physical examination to detect physical signs that would suggest the presence of pathology". We question if a facility that was following the definition of monitoring offered by NKF-K/DOQI would be in compliance.

Dialysis facilities frequently experience frustration communicating with transplant centers. It would be helpful if CMS created an incentive to encourage transplant centers to give patient specific information back to the referring dialysis facility regarding the status of the work up or list status of referred patients. This flow of information should occur on a monthly basis.

Patient rehabilitation is a declared goal in DCI's mission statement. It is important to assist and encourage patients to return to their pre-ESRD level of functioning. The treatment team should encourage each patient to continue with activities determined to be appropriate. However, the role of the interdisciplinary team is to conduct a preliminary assessment and make proper referrals to agencies capable of a thorough analysis to determine each patient's vocational and physical rehabilitation status and potential. As the proposed rule is written it appears that the facilities/interdisciplinary team have been given an additional scope of services that may be beyond their expertise. We believe this is not appropriate.

In regards to social services, we agree until there is consensus on outcomes there should not be an outcome-based requirement for social services in the patient plan of care.

Care at home (494.100)

The proposed approach and the majority of the rules in this section are appropriate, however; there are a few areas of concern. The proposal states that self-care training must be conducted by a registered nurse who meets the personnel qualifications specified in § 494.140(b)(2) (that is, 12 months clinical experience and an additional 3 months of clinical experience in the specific modality for which the registered nurse will provide training). The national nursing shortage has been one of the barriers to growing the utilization of home dialysis therapy in the US. The requirement that self-care training must be conducted only by a registered nurse would further hinder the efforts to make home dialysis an available option to ESRD patients. DCI's experience has

shown that licensed practical nurses (LPN), experienced in dialysis, have demonstrated competency in assisting registered nurses in providing care to home dialysis patients. Section §494.100(a)(1) should be modified to state that, under direct supervision of a registered nurse, a licensed practical nurse who meets the personnel qualifications specified in § 494.140(b)(2) may assist registered nurses in providing training and nursing care to home dialysis patients.

This section contains the statement "for those home patients not receiving equipment and supplies from a DME company the dialysis facility must also purchase and deliver the necessary home dialysis supplies and equipment". This paragraph should be modified to provide that the dialysis facility must purchase or lease and deliver the necessary home dialysis supplies and equipment.

Please accept the following comments with respect to home patients in Nursing facilities (NF) or Skilled Nursing facilities (SNF). There should be a clear distinction between hemodialysis and peritoneal dialysis when considering new regulations for home dialysis in NF or SNF. The hemodialysis procedure is more complex and home hemodialysis requires additional training and safety requirements. For instances, the proposed rule questions if there would be a comparable risk to patient health and safety if a licensed nurse was not on the premises of the NF or SNF and available during multiple simultaneous home NF or SNF dialysis treatments. We would concur that there would be a comparable risk to patient health and safety if a RN was not on the premises during hemodialysis treatments. The NF or SNF registered nurse should have at least 12 months of nursing care experience, and should demonstrate competency in all aspects of the training provided by the ESRD facility. Post-training assessment/evaluation should be completed to ensure that the registered nurse can safely and effectively administer the dialysis treatment and can address any possible complications. With these requirements, the trained NF or SNF registered nurse should be allowed to oversee other non-RN trained caregivers that may be administering dialysis treatments. This NF or SNF non-RN caregiver, although being trained by a certified dialysis facility, would not have adequate experience in hemodialysis in troubleshooting problems and addressing complications that may arise during hemodialysis treatments. Therefore, we believe that when hemodialysis treatments are provided in NF or SNF there needs to be an RN who has been trained by the certified dialysis facility and if other care giver is administering treatments, the RN would be on the premises as a resource.

In contrast, for peritoneal dialysis patients, we do not believe the RN needs to be on the premises during treatments. In addition, we do not believe that in all cases it should be required that the patient take part in the training. By doing so, it would create another barrier to the utilization of home dialysis therapy. As long as the home facility is performing the functions outlined in the proposed rules, regardless of who is performing the actual therapy (patient, significant other, or RN/LPN in a NF or SNF) the patient's safety and well being is assured.

Quality assessment and performance improvement (494.110)

We agree with the provisions of this section of the proposed rule and believe it is appropriate that the dialysis facility's QAPI program address at least the following areas: (1) adequacy of dialysis; (2) nutritional status; (3) anemia management; (4) vascular access; (5) medical injuries and medical errors identification; (6) hemodialyzer reuse program (if applicable); and (7) patient satisfaction and grievances. We believe that facilities should monitor patient satisfaction and grievances as part of the QAPI program and have the flexibility to use the method of their choice to meet this requirement. We are concerned about any approach that would require that a standardized survey be mandated.

The discussion of clinical standards does not belong in the quality assessment and performance improvement section. The proposed codify language, is more applicable to the plan of care section. QAPI activities are more global measurements of performance. For example, The QAPI committee should be asking questions like what percentage of the facility's patients, in a given period, have a KT/V less than 1.2. If this

percentage is unacceptable, the QAPI's responsibility is to develop and implement a system and interventions that focuses on the processes to improve the facilities percentages. Individual patients not meeting expected outcomes should be reviewed by the interdisciplinary team, not by the QAPI committee.

Special purpose renal dialysis facility (494.120)

DCI founded Camp Okawehna, a week long summer camp experience for critically ill children suffering from kidney disease, in 1974. Children, ranging from ages 6 to 18 that have had a kidney transplant or are receiving hemodialysis or peritoneal dialysis attend this camp. Children on hemodialysis and peritoneal dialysis dialyze on the camp site. It is likely that Camp Okawehna is the one vacation camp mentioned in the preamble of the proposed rule which stated "In March 2001, for example, Medicare records indicated that only one vacation camp in the United States was certified as a special purpose renal dialysis facility." DCI does appreciate efforts to reduce the burden of the requirements for all dialysis facilities including vacation camps. We believe that these camps should be continued to be included under the special purpose renal dialysis facility conditions of coverage as outlined in the proposed rules.. An area that should be addressed in the proposed rule is back-up emergency care. We think it is very important to notify the closest hospital, and if children are involved, an additional notification of the nearest children's hospital. The process must also include working out a means of emergency transportation.

Subpart D – Administration

Personnel Qualifications (494.140)

We acknowledge that the nursing requirements are reasonable for most dialysis facilities, however; once again the under-served area may be adversely affected. Many small facilities have a nurse manger and one RN. The minimum requirement of 12 months clinical experience eliminates new graduates from the pool of potential hires. It is often impossible for a small facility in an under-served area to recruit nurses with 12 months of clinical experience. New grads should not be eliminated from potential employment. It is reasonable to require at least 6 months experience before they could work independently.

We agree with the proposed requirements for dietitian services standards. However; it doesn't seem appropriate in all cases for the dietitian to monitor vitamin and mineral supplementation and to manage glycemic control as stated in the preamble. We have many other licensed personnel (such as nurse practitioners, physician assistants, and pharmacists) in some of our facilities who are performing this function. We think the governing body should ensure these topics are assigned to appropriate staff.

We agree with retaining the existing requirements for social workers and also believe that there is a place for nonprofessional or bachelor degree prepared personnel support for some of the services, including social services. Bachelor degree prepared social workers are often utilized in the dialysis facility and provide a cost effective means of providing services when supervised by a Masters qualified employee.

We agree that it would not be prudent to propose a national certification requirement for dialysis technicians at this time for the same reasons that are outlined in the preamble. Also, we believe, 3 months of effective on-the-job, supervised training is necessary before a technician should be permitted to care for patients without close and direct supervision. However, we are concerned with the statement in the preamble. "We see dialysis technician training as a cycle that proceeds from written instruction that would provide a basic foundation of knowledge, to a necessary period of on-the-job training under the supervision of a knowledgeable professional trained in all aspects of patient care, including medical emergencies". We have found that written instruction tends to be tiresome and the learner needs "on the floor", "hands-on" practice and reinforcement at frequent time periods, otherwise the read material is not fully retained. We believe that this experience during the written instruction is valuable and should be counted toward the total 3 month experience requirement.

We concur with the proposal that the technician who carries out water testing and monitoring of the water treatment system must be appropriately trained following a program that has been approved by the medical director and governing body.

Relationship with ESRD network (494.160)

The role and responsibilities of the network do not need to be included in the proposed conditions of coverage. We concur with proposed requirement that each facility cooperate with the ESRD network serving its designated area in fulfilling the terms of the Network's scope of work contract with CMS. The scope of work should emphasize the coordination of network activities across all networks and a limited number of local and national initiatives with specific measurable goals.

Medical Recordkeeping (494.170)

We believe it is in the best interest of the patient, facility and corporation to maintain complete medical records for all patients, including method II home patients. We appreciate that the proposed rule provides the flexibility to manage this process by proposing to eliminate the requirement that the facility designate a staff member to serve as the medical records supervisor.

The following proposed rules are redundant to the HIPAA Piracy laws that all health care providers must follow: § 494.170(a)(2) that the patient's medical record be released only under the following circumstances: (1) the transfer of the dialysis patient to another facility; (2) certain exceptions provided for in law; (3) provisions allowed under a third party payment contract; (4) approval by the patient; or (5) inspection by authorized agents of the Secretary as required for the administration of the Medicare program. And § 494.170(a)(3) to maintain the existing requirement at § 405.2139(b) that the facility obtain written authorization of the patient or legal representative for release of information not required or authorized to be released by law. These sections do not offer the ESRD patient any more protections and are not needed in the conditions of coverage. However, because the HIPAA security rules only apply to electronically created, stored or transmitted information, we agree with retaining the existing 405.2139(b) that requires a facility to protect it patient's medical records against loss, destruction, or unauthorized use because the records are crucial to the patient's care.

Dialysis facilities will have serious logistical problems in trying to comply with the proposed requirement that the facility exchange **all** medical records within 1 working day. We think that this is an admirable goal, but as a condition of coverage, it is unrealistic. It could be argued that the transferring facility's "working chart" was necessary for the receiving facility to care for a patient, and that it should be transferred within one day. We would think that the "working chart" would include: orders, medication list with allergies, problem list, care plan, recent laboratory results, nutritional information, social work services, and rehabilitation status. Patients who have been on dialysis for many years have accumulated large quantities of medical records. Old records are often kept in offsite commercial storage buildings. It is impossible to retrieve, copy, and transfer these boxes in one day. Furthermore, the information in these boxes would not add or diminish the care of the patient.

Governance (494.180)

In its June 2000 report the OIG proposed to "strengthen the accountability of the dialysis facility governing body" by stating "The governing body should be held clearly accountable for the overall quality outcomes provided by the facility. It is important that the governing bodies ensure that authoritative representatives are readily available to respond to queries and/or visits by State survey agencies or Networks. However, this should work both ways as companies operating on a national scale often experience difficulty

obtaining information from State survey agencies or Networks. When corporations request facility specific or aggregate information concerning the facilities the corporation owns, CMS, State survey agencies or Networks should respond to the queries and/or provide the data to the corporations. It would be helpful if the conditions of coverage contained language that would recognize the corporation as a member of the governing body, and give the corporation the right to receive information directly form CMS, State survey agencies and Networks.

We believe the retention of the existing requirement § 405.2162(b)(2) that dialysis facilities ensure an adequate number of qualified personnel are present whenever patients are undergoing dialysis is the most realistic and flexible. Our experience with an acuity based staffing plans has been unsatisfactory. Acuity based system assume that staff will be flexible and reduce their hours when needed, and that staff will be available in whatever quantities are necessary if the acuity goes up. This is unrealistic as an end to the current nursing shortage is not anticipated any time soon.

We agree that a registered nurse must be present in the facility at all times that patients are being treated. However, we would like to add additional language stating that if patients are not being treated and the registered nurse's assessment is that any patients remaining on the premises for non treatment reasons are stable, a registered nurse does not have to be present.

We agree with the proposed new requirement and criteria of competencies for a written approved training program, designed by the facilities, that is specific to dialysis technicians

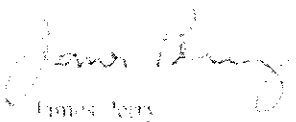
We agree that the governing body should be responsible to oversee appointments to medical staff, including appointments and credentialing for attending physicians, physician assistants, and nurse practitioners and that the governing body ensures that all practitioners who provide care in the facility are informed regarding all patient care policies and procedures as well as the QAPI program.

DCI desires to create a safe environment for patients receiving dialysis and for staff to administer treatments in an outpatient setting. The facility should inform patients regarding its transfer and discharge policies and provide 30 days notice in advance of reducing or terminating patient care services. Furthermore, we appreciate that the proposed rules have recognized that there are some difficult patients who create situations whereby it is necessary to exempt the facility exemption from the 30 day notification requirement in cases when there is an immediate threat to the health and safety of others. We are pleased to see a list of specific patient discharge situations. However, it does not address the cases in which a physician discharges a patient from his/her care, and no other physician is able or willing to take the patient. It is also possible that the physician may lose his/her nephrology privileges at the facility. In both cases, the facility can not obtain physician orders and can not provide care without orders. The patients must be transferred to a facility that can obtain physician orders. It is inappropriate to assume that the medical director can become a patient's primary doctor in such cases. In these situations, we believe the Networks medical review board needs to be involved, but the facility can not be held responsible for these types of discharges/transfers.

The proposed rule, in 494.180(h), requires that dialysis facilities furnish data and information electronically and in intervals that conform to specifications established by the Secretary. We agree with this provided that the data submitted electronically will replace the data collected on paper forms, and that the Networks and CMS include provider representatives to define such data collections efforts. A facility's corporation, home office, or other clearing houses must be able to submit data on behalf of a facility, and such data collection efforts must be implemented in an orderly fashion with at least one year's lead time.

Thank you for the opportunity to comment on this Draft Policy. Please call either one of us if you have any question.

Sincerely,



L. Kent [illegible], M.D.
Chairman of the Board

James Perry
President

Submitter : Dr. Matthew Lewis **Date:** 05/05/2005

Organization : Dr. Matthew Lewis

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-217-Attach-1.DOC

CMS-3818-P-217-Attach-2.DOC

Attachment #217
May 4, 2005

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

Dear Dr. McClellan:

I am writing to offer comments regarding the proposed revisions to the Conditions for Coverage for End Stage Renal Disease Facilities. Specifically I wish to comment on Proposed § 494.140. 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 understand that his section addresses the possible role of a pharmacist within the dialysis facility and having spent 8 years working as a Clinical Pharmacy Specialist with the Division of Nephrology at Hennepin County Medical Center in Minneapolis, I would like to share with you some of my insights. Within this position I was responsible of for the medication dose recommendations and monitoring for patients with varying degrees of kidney function, however, my focus and main responsibility was caring for the dialysis population. For the last two years I have worked as a Medical Liaison with Amgen, Inc. specializing in the clinical support of the dialysis patient with regards to anemia and secondary hyperparathyroidism management.

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

- The complex nature of drug therapy in dialysis patients: this patient population averages 10-12 scheduled medications per day with a huge potential for incorrect doses and potentially serious adverse reaction and/or drug interactions without the proper monitoring.
- The pharmacokinetic complexity of drugs during dialysis: it is critical to understand what medications are removed by dialysis and avoid the potential for sub-therapeutic levels with a lack of monitoring.
- The vulnerability of these patients for adverse medication-related outcomes: approximately 2/3's of medications are entirely or partially metabolized or eliminated by the kidney, therefore, dose adjustment and monitoring are critical.
- The need for storage, preparation, and administration of medications within the dialysis unit.

- The need for cost effective drug therapy: a pharmacist has the ability to determine the most cost effective therapy based on dose alterations in end-stage renal disease patients on dialysis.
- The changing nature of drug therapy that will arise due to the MMA.
- The training of pharmacists that prepares them to serve as consultants to dialysis facilities: in my position at HCMC I served as a preceptor for a nephrology pharmacy residency. I trained eleven pharmacists to provide specialty care to the dialysis population. These pharmacists are currently working throughout the U.S. in hospitals, dialysis units and chronic kidney disease clinics providing drug dosing/monitoring and clinical support to this population.

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.

Having spent several years caring for this special population of patients as a clinical pharmacist I cannot emphasize enough the importance of a pharmacists role on the multidisciplinary dialysis team. I hope that this letter has provided you with enough information to support this conclusion and I thank you for your time and attention to this topic.

Sincerely,

Matthew J. Lewis

Matthew J. Lewis, Pharm.D., BCPS
Regional Medical Liaison
Medical Affairs, Amgen, Inc.

Submitter : Mrs. Maggie Gellens **Date:** 05/05/2005

Organization : End Stage Renal Disease Network #12 (Board)

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See attachments please

CMS-3818-P-218-Attach-1.DOC

CMS-3818-P-218-Attach-2.DOC

NETWORK 12

Attachment #218
April 22, 2005

7505 NW Tiffany
Springs Pkwy
Suite 230
Kansas City, MO 64153
Phone: (816) 880-9990
Fax: (816) 880-1775
Email:
net12@nw12.esrd.net

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

Dear Sir or Madam,
The purpose of this letter is to reply to and comment on the proposed End Stage Renal Disease Conditions for Coverage/ Conditions for Participation that were published on February 4, 2005 by the Center for Medicare & Medicaid Services (CMS) in the Federal Register.

On behalf of the Executive Committee of End Stage Renal Disease Network 12, the attachec comments and opinions regarding various sections of the proposed conditions are being respectfully submitted.

Thank you for reviewing our comments. We look forward to receiving your written reply.
Sincerely,

Mary Gellens, MD
Executive Committee Chair

CC: Lisa F. Taylor, Executive Director
Executive Committee
Medical Review Board

Attachment

Providing data management, quality improvement, and grievance mediation services for kidney dialysis and transplant patients in Iowa, Kansas, Missouri, and Nebraska.

www.network12.org

Submitter : Mr. Kent Thiry **Date:** 05/05/2005

Organization : Kidney Care Partners

Category : Other

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-219-Attach-1.DOC

Attachment # 219
May 5, 2005

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

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

Dear Administrator McClellan:

Kidney Care Partners (KCP) is pleased to have the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments about the Proposed Rule for the Conditions for Coverage for End Stage Renal Disease Facilities (Proposed Rule). 70 Fed. Reg. 6184 (2005). KCP is an alliance of members of the kidney care community that works with renal patient advocates, dialysis care professionals, providers, and suppliers to improve the quality of care of individuals with irreversible kidney failure, known as End Stage Renal Disease (ESRD).[1]

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

[1] A list of Kidney Care Partners coalition members is included in Attachment A.

To summarize, KCP believes:

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

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

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

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

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

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

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

- Is cost-effective and avoids placing significantly higher costs on facilities, especially if the benefit to patients is questionable;

- Recognizes those activities and outcomes over which dialysis facilities are practically able to exercise control and does not hold them responsible for activities and outcomes that they cannot influence; and

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

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

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

Ensuring high-quality care for patients with kidney disease remains the central focus of KCP. Our members have worked diligently to improve quality, as the ESRD Clinical Performance Measures Project recognized when it stated: "Since 1994, [we have] documented continued improvements, specifically in the areas of adequacy of dialysis and anemia management. The providers of dialysis services are to be commended for their ongoing efforts to improve patient care."[2]

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

---

[2]Centers for Medicare and Medicaid Services (CMS), 2003 Annual Report: ESRD Clinical Performance Measures Project 5 (2003).

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

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

Recommendation: KCP strongly encourages CMS to review carefully each proposed Condition to ensure that it allows facilities to provide high-quality care to patients without imposing unnecessary burdens.

II. KCP is concerned that the extensive nature of the Proposed Rule will result in significant increases in costs for facilities at a time when, as MedPAC recognizes, facilities must subsidize the cost of care due to Medicare's longstanding under-funding of the ESRD program.

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

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

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

This proposed Condition would require a significant investment by many dialysis facilities while providing questionable benefits. One KCP member investigated the cost of an automated notification system in the Orlando area. Installation alone would exceed $3000. Monitoring would cost each facility approximately $186 per month. CMS's calculation is much lower because the agency did not include the required back-up phone line that would cost approximately $106 per month. The agency's installation estimate is extremely low, based upon current market prices. Assuming a conservative estimate that only half of U.S. dialysis facilities would need to install new systems, the total cost of this provision alone would be close to $5

million. In addition, dialysis facilities are frequently located in buildings in which they rent space and are limited by the lease as to what remodeling they may do. Also, some facilities are located in buildings that if sprinkler systems must be installed, they will have to be installed in all parts of the building. In these instances, facilities would be forced to relocate and be subject to the additional costs associated with such moves. Because of the financial difficulties facilities already face, it simply does not make sense to require them to shift scarce resources away from patient care to install new systems that will not result in significantly better safety for patients.

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

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

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

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

KCP agrees that one of the primary objectives of the Conditions for Coverage should be to "establish performance expectations for facilities." 70 Fed. Reg. at 6184. Although we are pleased that CMS has proposed revisions that are more patient centered and encourage patients to take a more active role in their treatment, we are deeply concerned that some of the changes would establish performance expectations that dialysis facilities do not have sufficient personnel

resources or authority to influence. We are also concerned that the Proposed Rule would hold dialysis facilities responsible for the activities of other providers, such as nursing facilities, rehabilitation facilities, transplant centers, pharmacists, and attending nephrologists, over which dialysis facilities have no control. Simply put, it is not appropriate for CMS to judge dialysis facilities for activities that they cannot influence and control. Therefore, we strongly urge CMS to modify the Proposed Rule to focus on those aspects of patient care that dialysis facilities have the ability to influence or control.

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

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

The clearest example of how CMS could inappropriately hold dialysis facilities responsible for the activities of other providers over which they have no control is the proposed Condition to make dialysis facilities responsible for ensuring that each patient's physician sees the patient at least once a month. 70 Fed. Reg. at 6250 (§ 494.90(b)(4)). Nephrologists are not employees of dialysis facilities. They are independent providers and receive payments separate and apart from the reimbursement dialysis facilities receive. KCP feels strongly that because the

Conditions for Coverage are meant to ensure that dialysis facilities that participate in the Medicare program meet certain requirements to promote patient care and that failure to meet these requirements may result in exclusion from the Medicare Program, it is inappropriate and counterproductive to hold dialysis facilities responsible for the actions of other providers over which the facilities have no control. Additionally, this Condition appears to be an attempt to regulate nephrologists indirectly. The Social Security Act prohibits CMS from "exercis[ing] supervision or control over the practice of medicine or the manner in which medical services are provided." 42 U.S.C. § 1395. It is inappropriate for CMS to try to regulate how nephrologists practice medicine through the ESRD Conditions for Coverage. For these reasons, we urge CMS to eliminate this requirement.

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

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

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

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

the agency proposes for conducting the patient assessment and establishing each patient's individualized plan of care.

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

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

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

V. Conclusion

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

Sincerely,

Kent J. Thiry
Chairman of the Board
Kidney Care Partners

Attachment A

KIDNEY CARE
PARTNERS

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

Submitter : Ms. Robin Frank **Date:** 05/05/2005

Organization : Healthcare Association of New York State (HANYS)

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-220-Attach-1.DOC

HANYS Healthcare Association of New York State

One Empire Drive, Rensselaer, New York 12144

Attachment #220
May 5, 2005

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

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

To Whom It May Concern:

The Healthcare Association of New York State (HANYS) represents more than 500 health care systems and hospitals across New York State. More than 100 of our members provide end-stage renal disease (ESRD) dialysis services in hospital-based and/or freestanding ESRD facilities, in nursing homes, and in patients' homes. We thank the Centers for Medicare and Medicaid Services (CMS) for receiving electronic comments on these proposed regulations for ESRD facilities. HANYS' comments are focused on the proposed regulations that involve the delivery of dialysis services in skilled nursing facilities (SNFs).

Increasing numbers of individuals with complex medical conditions and requiring dialysis are entering nursing homes for extended care. These patients often have fragile but stable clinical conditions and would be able to have their dialysis needs met by SNFs if public policies were appropriately targeted to address current barriers. HANYS appreciates CMS' recognition of this problem as acknowledged in the proposed rule and the intent for the "care at home" provision to allow SNF residents the same rights and protections as other home dialysis patients. Unfortunately, the proposed regulations for home dialysis do not address the real barriers prohibiting many SNF residents from receiving dialysis in a SNF.

HANYS' Comments on "Care At Home" Dialysis for SNF Residents

Under current Medicare provisions (Section 405.2102), a primary requirement of home dialysis is that it must be "performed by an appropriately trained patient at home." Approximately 20% of the individuals in New York State SNFs are admitted for a short stay such as rehabilitation and neither they nor their families ever consider the facility to be their "home." Typically, these short-stay individuals have received dialysis from an ESRD provider both before and after a SNF

episode. The combined fatigue they experience because of dialysis and their short stay in a SNF makes training and self-performance of dialysis impossible while in a SNF.

The other 80% of SNF residents cannot be appropriately trained or are not strong enough to safely perform self-dialysis due to cognitive and/or functional impairments, and frailties or debilitation created by chronic diseases.

Conclusion
Home dialysis is not appropriate for the vast majority of both short-term and extended stay nursing home residents. We urge CMS to revise its position and make dialysis services accessible and financially feasible for residents in SNFs to receive by addressing the barriers as delineated below.

HANYS' Comments on Dialysis of ESRD Patients in SNFs

Currently, the vast majority of nursing home residents requiring dialysis receive such services at an off-site dialysis provider. This situation has significant drawbacks for residents and for Medicare.

First, it necessitates transport of the resident to and from the ESRD clinic. This often requires the use of an ambulance because the functional impairments of the resident prohibit car transport, clinical status may require immediate medical intervention due to extreme fatigue and debilitation following the dialysis process.

Second, using an off-site dialysis provider requires the resident to be out of the nursing facility for a significant amount of time, which as acknowledged in the proposed rule, increases interruptions in resident care with missed medication administration, treatment regimens, meals, and planned activities.

Third, because of the resident's medical fragility, it is not uncommon for the resident to require the accompaniment of a SNF nurse for the entire event, which reduces staff resources for other SNF residents.

HANYS believes that Medicare conditions of participation should be flexible to allow dialysis to be provided at a SNF bedside by a dialysis facility or a nursing facility. This would substantially improve quality of life and care of a nursing home resident, reduce Medicare costs, and maximize use of clinical resources.

To facilitate quality of resident care and outcomes, with lower costs to Medicare, HANYS urges CMS to investigate the following options:

- the renal dialysis facility providing services at a SNF and paid the composite rate directly;

- a SNF providing the services, and receiving payment outside the Prospective Payment System (PPS) for Part A patients (i.e., services are exempt from consolidated billing); and

- the SNF providing the services, without separate ESRD licensure, for those beneficiaries who have exhausted Medicare Part A (i.e., develop separate conditions of coverage requirements that would apply only to SNFs that already meet SNF conditions of participation).

We believe these options are consistent with existing Medicare law. For residents on Part A, the relevant provisions are Sections 1881(b)(1) and 1888(e)(2)(A)(i)(II) in the Code of Federal Regulations, which refer to providers' requirements and payment requirements.

For residents who are *not* on Part A, the relevant provisions are Section 1861(s)(2)(F) and the "on the premises" requirement in Section 1861(s)(2)(F), where dialysis is excluded from consolidated billing.

Conclusion
For the above-stated reasons, HANYS urges CMS to make dialysis services accessible to SNF residents and financially feasible to deliver whether the patient is under a Part A stay or non-Part A stay and performed by a dialysis provider or by a SNF.

HANYS' Comments on Home Dialysis Proposed Rules
For the few nursing home residents who might benefit from and participate in home dialysis, HANYS has the following comments.

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

However, HANYS does not believe that CMS should address patient-to-caregiver ratios in the regulations. The number of caregivers needed to promote quality care varies with the particular circumstances of any given setting and are determined by a host of complex, interrelated factors. These include patient/resident needs, the experience and skill sets of the particular caregivers involved, and the physical configuration of the facility. Formulas and ratios do not provide needed flexibility. HANYS strongly opposes ratios.

Summary
The numbers of patients who require dialysis and receive SNF services are increasing. The current Medicare conditions of participation create barriers to SNF residents receiving dialysis in ways that promote their quality of care and quality of life. Home dialysis is not appropriate for the vast majority of nursing home residents because of their medical fragility, functional impairments, and inability to self-perform dialysis. HANYS urges CMS to make regulatory changes that promote access to dialysis services and make them feasible for SNF residents to receive from dialysis providers or SNFs at the bedside.

Questions and comments should be directed to Debbie LeBarron, Director Continuing Care, at (518) 431-7702 or dlebarro@hanys.org.

Sincerely,

Robin Frank
Vice President
Governmental Affairs and Continuing Care

Submitter :

Date: 05/05/2005

Organization :

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-221-Attach-1.DOC

Submitter : Dr. Jay Wish **Date:** 05/05/2005

Organization : The Renal Network, Inc.

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

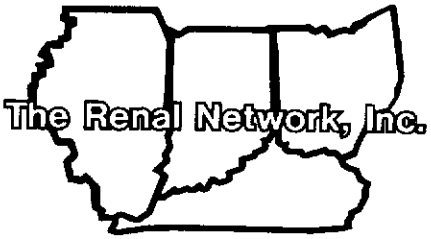
GENERAL

See Attachment

CMS-3818-P-222-Attach-1.PDF

CMS-3818-P-222-Attach-2.PDF

Attch 222



The Renal Network, Inc.

ESRD Networks 9 & 10

911 East 86th Street Ste 202
Indianapolis, IN 46240-1858
(317)257-8265 - 1-800-456-6919
Fax (317)257-8291 - email: info@nw10.esrd.net

May 4, 2005

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

Dear Dr. McClellan,

I am writing on behalf of the Board of Trustees for The Renal Network, Inc. This organization holds the contract for ESRD Network 9/10 comprised of Indiana, Ohio, Kentucky and Illinois. Our collective volunteer force of renal professionals and consumers represents more than 500 dialysis facilities treating 37,000 dialysis patients in the Midwest.

We thank you for the opportunity to comment on the proposed rule updating the Conditions for Coverage (CFC). We are encouraged that CMS has given consideration to prior community comments in developing this document. We believe this draft represents a thoughtful and thorough approach to updating the Conditions and, overall, is representative of community opinion on the delivery of ESRD care. Several issues, however, remain in need of clarification.

Facility Level Standards: The document makes frequent use of the word "standards;" this term must be clearly defined. Standards are "current, evidence-based, community-accepted, minimal requirements" as defined in the OMB Circular A-119. We do not believe that numerical standards should be stated in these federal documents. The goal should be to develop flexible and valid standards, measures and thresholds which are adaptable to a therapeutic environment. Further, a method should be defined for periodic review of such standards to make sure they are in accord with current knowledge and practice. Likewise, references to specific drugs should be deleted to allow introduction and use of new therapies as they develop.

The focus on patient centered care is positive and a step in the right direction. However, as this concept is used throughout the document, no responsibility is

placed on the patient for his or her care. It is critical that patients become partners with their healthcare providers in choosing the best treatment options. It is the responsibility of the patient to follow the chosen course and to take responsibility for his or her actions in this choice.

Similarly, CMS must be careful to hold facilities responsible only for those areas or actions where the facility has control. For example, in the area of patient discharge, the facility has no control when a physician chooses to discharge the patient from his or her service. If the facility has no other physician to assume responsibility for the patient's care, nothing can be done to retain the patient after physician discharge. To do so would be to treat without medical authorization and supervision.

In the area of establishing dialysis adequacy and anemia management as patient level standards, these should be applied only at the facility level, not at the individual patient level. Again, patient decision-making must be taken into consideration when using outcomes indicators. Non-adherence should be documented and allowed to excuse a patient from outcome calculations. This will help alleviate the unintended consequence of "cherry picking" for compliant patients and refusing to admit, or being quick to dismiss, the patient who chooses not cooperate in his or her treatment plan.

Nursing Home Dialysis: In discussion of the definition of "home setting" for "home dialysis," The Renal Network strongly believes that nursing home dialysis should be classified as a separate entity and not be included under home dialysis provisions. The delivery of dialysis within the nursing home setting must be considered as a third alternative, i.e., in-center, home, and nursing home. To classify it within home dialysis imposes rules that make it nearly impossible to maintain compliance, with no guarantee of quality of care. Dialysis patients are entitled to the same level of care from ESRD providers regardless of the location. Although we advocate the provision of dialysis within the nursing home setting, we recognize that the accountability for delivering quality care must be clearly delineated between the nursing home and the dialysis provider and that the survey process must insure that each entity is in compliance with its role, Current economic barriers such as the requirement for one dialysis machine per patient and billing issues for drugs injected during dialysis must be addressed for this modality to be in step with the realities of changing demographics. The proposed CFC would prohibit the use of nursing home hemodialysis for short-term stays. This is detrimental to patients as it would interfere with the purpose of their short term stay "rehab" and can result in longer stays. Since home dialysis patients are allowed to temporarily go in-center when necessary, the reverse should be true: in-center patients should be allowed to receive their dialysis in a nursing home transiently.

Although the role of DME providers in nursing home dialysis is not directly addressed in the CFC, it does impact on patient outcomes and should be

considered at the surveyor level. Nursing home staff should be familiar with pre- and post-dialysis patient care regardless of whether the patient remains at the nursing home or goes to a dialysis facility for dialysis. But the nursing home should also be adequately staffed such that the pre- and post-dialysis patient care does not distract from needed care by other patients. The responsibility of the dialysis facility in training staff at the nursing home who provide pre- and post-dialysis care to patients who receive dialysis at the nursing home should be limited to direct patient care staff, and not to all nursing home staff working with the patient such as physical therapists. Ultimately all parties to nursing home dialysis will need to be accountable for their contractual roles in providing high-quality, safe and cost-effective patient care. It is hoped that CMS will eventually develop a reimbursement model (Method 3) to address the unique issues of nursing home dialysis.

Physical Environment: It is rational and prudent to expect all dialysis providers to maintain defibrillators on the premises. No exception should be made for rural facilities, especially since these facilities are likely to be farther from emergency services than urban centers. Local building codes and other laws should set standards for safety including fire plan.

The proposed CFC requires an RN be present at the dialysis facility any time dialysis takes place, but an LPN can be a charge nurse. Given the severe national shortage of RNs, LPNs with defined minimum training and experience in dialysis should be allowed as the professional present if an RN is not available. Otherwise, dialysis facilities may have to shut down on certain shifts and this will limit patient access to the therapy.

Patient Safety: The Renal Network agrees with the Conditions in recommending adherence to recognized authorities such as AAMI. We would like to further suggest that the expansion of adherence to AAMI recommendations be extended to water purity. The use of ultrapure dialysate should be strongly encouraged but left to AAMI review to establish recommendations.

Patient Assessment: The combination of the long and short term plans is a good idea to reduce duplication of effort while developing a concise plan of care which is understandable for the patient and well defined for the treatment team. The first assessment should be completed within 30 days of initiation of treatment, then readdressed at 90 days, then revised annually thereafter for stable patients. It should be left to the discretion of the physician to define the stable condition for his or her patients. Patients who are judged to be non-stable should be assessed monthly

Surgeon Designee for Transplant Referral: Dialysis units will need to know the rules of referral to the transplant centers and what their acceptance criteria are. Transplant centers will need to publish their exception criteria. This could create unintended consequences of inadvertently excluding eligible individuals or "over-

referral" as facilities are reluctant to deny access simply based on a listing. To have a transplant coordinator visit the facilities would create an unfunded mandate. We believe it is reasonable to expect a transplant center to develop a written agreement with its referring dialysis centers so each will know the practices for the center. Finally, the actual referral to transplant is a medical decision and must be made by the physician.

Patient Satisfaction Activities. Evidence supports the use of patient satisfaction and/or experience of care surveys to improve care. Evaluating and tracking grievances is a good practice, which the Networks are already doing; this should continue.

Certification of Dialysis Technicians: It is reasonable to expect a well-defined training program to be in place within each dialysis unit employing technicians. It is appropriate for the medical director to sign-off on the training. The Conditions need to clarify the three-month training period, especially in the area of supervision.

Administration: The governing body should be responsible to develop a position description of "Medical Director" which lists and explains the responsibilities, and authority, of this office. Further, the governing body must have a policy and procedure in place to protect the medical director, the attending physicians, and the staff when enforcing the policies of the dialysis center. This must be unbiased and include due process in the case of review and/or dismissal or revocation of privileges.

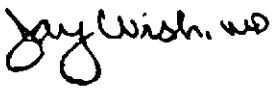
Acuity Based Staffing/Case Mix: There are no data to support the position that mandated staffing ratios improve care. The case mix adjustment formula will need considerable refinement in order to be a true reflection of staff needs and reimbursement based on patient acuity. Revisions must be mindful of causing "cherry picking," where facilities favor patients with favorable case mix indicators and deny others who would be costly to dialyze. There also should be a process built into the system which would establish periodic review of the case mix formula.

Home Dialysis Training: During home training the dialysis facility staff are focused on teaching the patient/caregiver the skills and competency to administer safe and effective dialysis treatments on their own. This should be the primary focus of home training. It should not be required that patients complete training in how to achieve and maintain emotional and social well being or to demonstrate successful meal planning before they "graduate" from their home training and begin to dialyze exclusively at home. Although these issues are also essential for overall patient well-being, they are separate from the focus of the training in dialysis technique and they are also continuous. To require these other skills to be completely developed prior to "graduation" will prolong training to a degree that is frustrating to the patient, family and home training

staff, will delay to ability of the patient/caregiver to "road test" their training at home, and may deter patients from rather than promote home therapies.

Lastly, once the CFC are finalized, CMS must ensure consistency of enforcement through the state survey process. Currently, interpretation of the Conditions is largely viewed as a regional process. This causes inconsistency from state to state and confusion about acceptable levels care within the national dialysis community.

Sincerely,



Jay B. Wish, MD, President
The Renal Network, Inc.
Professor of Medicine
Case Western Reserve University

Submitter : **Ms. Antoinette Kuzmic** **Date: 05/05/2005**

Organization : **HHS/CMS/WCSC**

Category : **Dietitian/Nutritionist**

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-3818-P-223-Attach-1.DOC

Attachment #223
Comments Regarding CMS-3818-P:

Care At Home:

This is a worthy condition, but I also feel that consideration should be given to establishing a condition for the elderly residents receiving ESRD in group or long term care nursing homes. There should be a written agreement that specifically outlines the responsibilities of all parties providing cares to a nursing or group home dialysis residents.

Water Quality:

Recommend the use of AAMI RD52 standards to ensure the most up-to-date standards are followed in order to provide the safest water. These standards are already utilized by most of the ESRD facilities and thus if required would not create undue hardship.

Two carbon tanks should be required for the water treatment system. Having only one tank restricts the dialysis unit's ability to operate, if the tank fails. If another tank cannot be located, the facility would have to shut down until another tank is found. The patients would need to be transferred to another facility for dialysis, which could impose a real hardship.

Physical Environment:

An emergency generator should be required in at least new facilities. Prevention of the interruption of dialysis due to electrical disturbances is important, especially in maintaining adequate dialysis.

Dialysis Technician Certification

Because the technician is the staff person closest to the patient during dialysis, certification of the tech is vital to ensuring the patient is safe, receives adequate dialysis, and is appropriately educated.

Clinical Standards

It is felt that minimum clinical standards should be imposed for dialysis facilities. The K/DOQI minimum clinical standards, when used by facilities, would provide a basis upon which quality improvement can be measured. The standards would also assist in educating the patient on expected outcomes and goals.

Submitter : Mr. WAyne Evancoe **Date:** 05/05/2005

Organization : Hortense and Louis Rubin Dialysis Center, Inc.

Category : End-Stage Renal Disease Facility

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

Submitter : **Mike Halliday** **Date: 05/05/2005**

Organization : **GE Water & Process Technologies**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

Reference CMS-3818-P

See attached

CMS-3818-P-225-Attach-1.DOC

Attachment 225

Reviewers:	Mike Halliday and Sean West		
Subpart	**Condition**	**Page**	**Comment**
Subpart B – Patient Safety	**494.40 – Water Quality**	**260**	As a supplier of centralized bicarbonate distribution system we agree on the proposed standard Subpart B – Patient Safety, 494.40 – Water Quality section (f) *Once mixed, bicarbonate concentrate must be used within the timeframe specified by the manufacturer of the concentrate.* However the discussion of the requirement is open to interpretation. In our centralized system a facility mixes their initial batch of bicarbonate solution and transfers it to a holding tank. The holding tank then supplies the distribution loop. If during the day a facility is required to mix an additional batch of bicarbonate solution the Mix Tank is essentially drained of the original batch and the new batch is mixed. Once complete the new batch is transferred to the holding tank where it will mix with the initial batch. As currently designed the mixing of bicarbonate batches cannot be avoided without changes to current procedures that would require a facility to rinse the entire system and mix new batch of bicarbonate solution or redesigning the current equipment allowing a facility enough capacity to mix a day's worth of treatments. We agree that the standard as written should remain, however there should be clarifying language in the discussion concerning the mixing of bicarbonate batches. If interpreted as a requirement that multiple batches cannot be mixed this would require rewriting current procedures and verifying their effectiveness and the redesigning of a new centralized distribution system and depending upon the complexity of the change required could result in a new 510(k) submission.

Submitter : Mrs. Maria T. Torres **Date:** 05/05/2005

Organization : DaVita Laboratory Services

Category : Laboratory Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-226-Attach-1.DOC

CMS-3818-P-226-Attach-2.DOC

Attachment #226
May 5, 2005

Center for Medicare & Medicaid Services,
Department of Health and Human Services
Attention CMS-3818-P

DaVita Laboratory Services (DLS) is a specialty independent clinical laboratory specially equipped and staffed to serve the special laboratory needs of over 48,000 End Stage Renal Disease (ESRD) patients across the United States. Our laboratory is accredited with Distinction by the College of American Pathologists and we meet all applicable local, state and federal laws with respect to laboratory licensure requirements. DLS guarantees that routine laboratory tests results are available by the next dialysis treatment. Our extensive test menu meets all the laboratory needs of our patients, except when laboratory results are critical to the immediate well being of the patient and results are required in less than 24 hours. DLS respectfully submits the comments below in an effort to promote better access and quality of STAT laboratory services for ESRD patients.

Conditions for Coverage for End Stage Renal Disease Facilities;
Proposed Rule
Reference File Code CMS-38818-P
Laboratory Services

§494.130 Condition: Laboratory services.

Background:

Usually, freestanding End Stage Renal Disease facilities contract with a single specialized clinical laboratory, "primary laboratory", to provide the majority of laboratory testing required by their patients. These specialized laboratories are equipped to serve the special needs of this population and they have sophisticated information and billing systems to comply with Medicare's complex billing rules for ESRD routine and non-routine laboratory tests. Occasionally, a physician may order certain laboratory tests STAT to ensure proper management of the patient when laboratory results are critical to the immediate well being of the patient. These STAT tests must be performed in a laboratory that is in close proximity to the ESRD facility. Therefore, a local lab and not the "primary laboratory" usually perform these tests. Most local labs do not have the required billing software to ensure proper billing of the occasional STAT test performed for ESRD beneficiaries. As a result, many local labs choose not to serve ESRD beneficiaries, which limit access to critical STAT laboratory services for the ESRD patients.

Proposed Additions to §494.130 Condition: Laboratory services.

To ensure proper access to critical STAT laboratory services for ESRD patients, composite rate laboratory tests performed by a local laboratory should be billed to the ordering ESRD facility or the "primary laboratory".

The "primary laboratory" will maintain a centralized database to apply ESRD billing rules to composite rate tests ordered through the ESRD facilities served by the "primary laboratory".

The "primary laboratory" will be the only laboratory permitted to bill Medicare for laboratory tests listed as ESRD composite rate laboratory tests.

The local laboratory that provides STAT testing must be CLIA certified and enter into an agreement with the ESRD facility or the primary laboratory.

The "primary laboratory" will provide the ESRD facility with laboratory data for submission to ESRD Networks.

Attachment #227

II. BACKGROUND

E. Development of Outcome Based Performance Quality Improvement Measures ESRD Facility Performance Standards.

7. Updating Existing ESRD Patient-Specific Performance Measures and Developing Future

Comments: Consideration must be given to 1) small dialysis facilities [i.e., less than 20 patients], and 2) case mix [especially in the case of hospital based facilities] in development, implementation and monitoring of facility-specific performance standards. Small area analysis should be utilized as a reference for updating and/or modifying existing standards.

Subpart A – GENERAL PROVISIONS

494.10 "Definitions"

Comments: This is an area difficult to comment on because of the nature of "home". However, we f eel t hat t he H ome dial ysis def inition s hould be s trengthened. As an ex ample...stating something to the effect... "has satisfactorily passed the prescribed course of training and is deemed capable of performing and/or providing home dialysis services".

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" as a useful tool to assist providers.
(2) (b) Standard: Oversight
(2)(ii) Our recommendation would be that the composition of the quality improvement committee be specified to require 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." The term "cluster" should be additionally defined in a measurable way (i.e., based on percentage of patients receiving treatment at the time or greater than 3 patient reactions, etc).

494.60 Condition: Physical environment

d. Standard: Emergency preparedness
(3) We concur that there should be a requirement for placement of defibrillators in the dialysis facilities, with the applicable policies and procedures for reference.

Subpart C – PATIENT CARE

494.70 Condition: Patients' rights

(a) Standard: Patients' rights

Add "to be reviewed annually."
Add "to be reviewed as needed to address disruptive situations."

(2) Specifies that the patient should receive any and all information in a way that he/she can understand. We concur with this proposal and would also recommend that information be presented in the appropriate language of the patient, as well as in a culturally sensitive manner. Add "require facility to ask the patient to demonstrate understanding of information provided." Without this requirement, it would be easy for staff to believe they had informed a patient without realizing that, in fact, the patient did not understand the information.

(5) We concur with the concept that patients have a right to be informed about advance directives that establish in writing an individual's preference with respect to the degree of medical care and treatment desired or who should make treatment decision if the individual should become incapacitated and lose the ability to make or communicate medical decisions.

This section should be strengthened by also including information on end of life planning.

Add (17) "have access to a qualified social worker and dietitian as needed." Social workers and dietitians often have large caseloads, cover multiple clinics and/or work part-time, and patients often do not know how to contact them when needed.

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

Add (19) "receive referral for physical or occupational therapy, and/or vocational rehabilitation as needed." These interventions have been shown to improve patient rehabilitation outcomes.

Add (20) "be informed that self-cannulation is possible and be offered training to self cannulate." This could help preserve vascular accesses and reduce hospitalizations. Clinics should not be allowed to have a policy denying a willing patient the right to learn to self cannulate.

Add (21) "be informed of topical analgesics for needle pain and how to obtain them." Patients should be able to undergo a painless treatment, and low-cost, over-the-counter 4% lidocaine preparations are available that will not harm the access and will provide pain relief. Patients should be told that these products exist and where to obtain them.

(b) Standard: Right to be informed regarding the facility's discharge and transfer

Add "receive counseling and support from the team to resolve behavioral issues and be informed of behaviors that will lead staff to notify police or refer for evaluation of risk to self or others."

Add (new 2) "not be involuntarily discharged from the facility for non-adherence with the treatment plan, including missing or shortening in-center hemodialysis treatments, excessive fluid weight gain, or lab tests that would suggest dietary indiscretions unless it can be shown that the patient's behavior is putting other patients or the facility operations at risk." Patients often are not educated as to the reasons why these behaviors may be harmful to them; therefore, it is inappropriate to refuse them care due to their lack of knowledge. If consistent difficulties are noted with a patient's ability to follow the treatment plan, a team evaluation should be initiated to investigate and address all potential factors, e.g., a patient who is trying to maintain a full-time job may choose to leave treatment early rather than risk losing employment; or a patient taking medication that causes dry mouth may not be able to follow the fluid limits for in-center hemodialysis.

(c) Standard: Posting of rights.

Add "facilities with patients who cannot read the patients' rights poster must provide an alternate method to inform these patients of their rights which can be verified at survey."

494.80 Condition: Patient assessment

The right of the patient to participate in the planning of their medical treatment is essential for achieving and sustaining quality of care outcomes. In order to become a health care system that empowers patients, the right to participate facilitates the opportunities to 1) increase the feeling of patient independence, 2) may reduce stress and anxiety, 3) encourage the sharing of responsibility for health care outcomes between providers and patients.

Change "social worker" in first sentence to "qualified social worker" to clarify any ambiguity of the social work role.

(a) Standard: Assessment criteria.

We would recommend that the patient assessment include advance care planning for every patient.

Add to (1) "...and functioning and well-being using the SF-36 or other standardized survey that permits reporting of or conversion to a physical component summary (PCS) score and mental component summary (MCS) score and all domains of functioning and well-being measured by that survey.

Change (7) to "evaluation of psychosocial needs (such as but not limited to: coping with chronic illness, anxiety, mood changes, depression, social isolation, bereavement, concern about mortality and morbidity, psycho-organic disorders, cognitive losses, pain, anxiety about pain, body image issues.

Add to (9) "if the patient is not referred for home dialysis, the basis for non-referral must be documented in the medical record. Lack of availability of home dialysis in the facility is not a legitimate basis for non-referral."

(b) Standard: Frequency of assessment for new patients.
(1) An initial assessment must be conducted within 20 calendar days after the first dialysis treatment.

It is thought that this may not be sufficient time and that clarification of "new" and "the first dialysis treatment is necessary" [i.e., is this the patient's first ever treatment (for example in an acute setting) or the first dialysis treatment in this dialysis facility?]

Change "20 calendar days" to "30 calendar days after the first dialysis treatment at this facility." We recommend combining an initial team assessment and care plan as they work in concert: a care plan should address areas for intervention as identified in the assessment. Permitting 30 days for assessment and development of a care plan allows for full team participation and adequate assessment of patient needs.

494.90 Condition: Patient plan of care.

(a) Standard: Development of patient plan of care.
The patient plan of care should address the treatment of mineral metabolism, i.e., bone disease.

Add (new 3) "Psychosocial status. The interdisciplinary team must provide the necessary care and services to achieve and sustain an effective psychosocial status." The chronic nature of ESRD and the intrusiveness of its required treatment provide renal patients with multiple disease-related and treatment-related psychosocial stressors that affect their everyday lives. Psychosocial issues negatively impact health outcomes of patients and diminish patient quality of life. Therefore, "psychosocial status" must be considered as equally important as other aspects of the care plan.

(b) Standard: Implementation of the patient plan of care.
Add to (1)(i) "... inclusive of the patient;"

Add to (3) "... the interdisciplinary team must describe barriers encountered, adjust the patient's plan of care to either achieve the specified goals or establish new goals, and explain why new goals are needed."

494.100 Condition: Care at home.

(a) Standard: Training

Change (iv) to "implementation of a social work care plan". Psychosocial issues negatively impact health outcomes of patients and diminish patient quality of life. Therefore, a social work care plan is as equally important as other aspects of training for home patients. It is important to specify a "social work care plan" to ensure that it is conducted by a qualified social worker.

Submitter : **Patricia Phillibar** **Date: 05/05/2005**

Organization : **ESRD Network 13**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment of comments on CMS-3818-P as approved by members of our Board of Directors and Medical Review Board.

CMS-3818-P-227-Attach-1.DOC

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. Compliance with this condition can be better assessed by the Networks as opposed to the State Survey Agencies that have traditional responsibility for compliance with conditions and standards. It should also be recognized that the Networks have an ongoing relationship with every dialysis and transplant facility in their service areas; whereas, the State Survey Agencies only assess facility compliance on average every three years.

(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

(b) Standard: Nursing services

(1) Nurse manager.
Add (iv) "cannot be a contracted agency nurse."
(2) Self-care training nurse.
Add (iii) "cannot be a contracted agency nurse."
(3) Charge nurse.
Add (iii) "cannot be a contracted agency nurse."

(d) Standard: Social Worker
We recommend the inclusion of language that addresses the need for social workers to function as the mental health care professional within the dialysis and/or transplant communities. Providing services such as transportation coordinator and/or insurance personnel negatively impacts on their ability to provide direct patient counseling and education.

(e) Standard: Patient care dialysis technicians
Training must be equivalent to the recognized National Standards of NANT or other professional technician organization.

494.150 Condition: Responsibilities of the medical director

Recognizing that CMS has the authority to approve Network goals and objectives, we would encourage a requirement be added that the Medical Director, in conjunction with the CEO and governing body, share the responsibility for assuring that the facility complies with Network goals and objectives. The goals and objectives are mainly clinical in nature and subsequently should require Medical Director involvement.

A requirement should also be considered for having the Medical Director assume responsibility of either responding to grievances processed through the Network or assigning responsibility to the appropriate individual within the facility to respond and address Network grievances.

Add "must be present in the facility monthly at a minimum."

494.160 Condition: Relationship with the ESRD Network

The wording in this condition is inconsistent with legislation and other sections of the proposed regulations. Our suggestions would be 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

(a) Standard: Designating a chief executive officer or administrator

Add (5) "address financial/collections issues with patients that impact the functioning of the facility or jeopardize the continuance of provision of dialysis services to the patient."

(b) Standard: Adequate number of qualified and trained staff.
(2) We concur with the proposed 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 strongly recommend that certification be required and that professionalism and conflict resolution training should be added to the technician-training list.

Professionalism and conflict resolution training should be required of all dialysis unit personnel.

Submitter : Ms. Michele Root **Date:** 05/05/2005

Organization : Ms. Michele Root

Category : Nurse

Issue Areas/Comments

Issues 1-10

Basis

Personnel Qualifications I would like to see the proposal for charge nurse include the fact that the experience requirement should NOT include orientation time. I believe that according to Benner a proficient nurse has more experience with the same task than the 3 months that is being proposed.

Definitions

Personnel Requirements While an acuity based staffing system sounds good on paper, the individual states will still want to control their individuals and also there will be too many variables from state to state and even from facility to facility. I don't think that there should be a mandated acuity system because it is too subjective an issue.

Submitter : **Dr. Tracy Anderson-Haag** **Date: 05/05/2005**

Organization : **Hennepin County Medical Center**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-3818-P-229-Attach-1.DOC

Hennepin County Medical Center
HCMC
Level 1 Trauma Center

Department of Medicine
Division of Nephrology

Mailing address:
[illegible]

Physical location:
[illegible]

612-347-5671
FAX: 612-347-2003
www.HCMC.org

Attachment #229

May 1, 2005

Mark. B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
PO Box 8012
Baltimore, MD 21244-8012

Reference File Code: CMS-3818-P

Dear Dr. McClellan:

I am contacting you to voice my comments pertaining to the proposed revision to the Conditions for Coverage for End Stage Renal Disease Facilities. I would specifically like to comment on Proposed § 494.140 ("Personnel Qualifications"). This section includes the possible role of pharmacists within dialysis facilities. I am thrilled to see that the Proposal acknowledges contributions pharmacists can make in improving safety and efficacy of medication use in dialysis patients, a very complex patient population.

After completing my Doctor of Pharmacy degree at the University of Minnesota College of Pharmacy, I completed 2-years of specialty residency programs in Nephrology and Kidney Transplantation at Hennepin County Medical Center (HCMC) in Minneapolis, Minnesota. I have since become a staff clinical pharmacy specialist at HCMC and work within the Division of Nephrology. I currently care for patients with chronic kidney disease, kidney transplants and those treated with different types of dialysis as renal replacement therapy. Our institution has a primary renal service that cares for all patients requiring renal replacement therapy admitted to our hospital; a clinical pharmacist has been an integral part of the inpatient nephrology team for 30 years. In addition, the nephrology pharmacists at HCMC are consulted by nephrologists and nurse practitioners daily about outpatient dialysis patients.

By taking care of this patient population on a daily basis, I have seen first hand the complexity of the medication regimens in dialysis patients, and negative outcomes that can occur when patients do not have a pharmacist reviewing their medication regimens. Nephrology trained pharmacists are experts in ensuring safe and effective medication therapy for chronic kidney disease patients, including those patients on dialysis therapies. These practitioners can provide complete pharmaceutical care to this patient population.

In addition, pharmacists involved in medication management of chronic conditions have been shown to result in positive financial and clinical outcomes. Pharmacists can prevent drug therapy problems and their associated complications from occurring in this population.

The average dialysis patient is on > 10-12 different medications daily, which results in an immense pill burden. They have multiple co-morbidities, which further complicate their medical care. Appropriate drug administration, dosing and avoidance of drug interactions are necessary for these patients to gain safe and effective medical treatment. Pharmacists are the best-trained health care professional to oversee that these issues are addressed on an ***individual patient*** basis.

In addition, dialysis therapies also affect drug clearance. The pharmacokinetic properties of many medications are altered in chronic kidney disease, and further changed with dialysis treatments. With the vast number of different dialysis membranes and dialysis modalities (intermittent, continuous, daily, home-hemodialysis, nocturnal dialylsis) available for end stage kidney disease patients, it is imperative that a pharmacokinetic expert be reviewing medications on a frequent basis to ensure safe and effective utilization of these medicines. Nephrology trained pharmacists are trained extensively in pharmacokinetics and are the best practitioner to provide this expertise and service.

In conclusion, I strongly support this utilization of nephrology trained pharmacists as consultants to dialysis patients within a dialysis facility. Pharmacists are uniquely qualified to provide these clinical consultation services that will improve patient care by reducing drug therapy problems in dialysis patients.

Thank you in advance for your time,

Tracy Anderson-Haag, Pharm.D., BCPS
Clinical Pharmacy Specialist, Hennepin County Medical Center
And
Clinical Assistant Professor, University of Minnesota College of Pharmacy

Submitter : **Mrs. Michele Root** **Date: 05/05/2005**

Organization : **Mrs. Michele Root**

Category : **Nurse**

Issue Areas/Comments

Issues 1-10

Basis

Infection Control I agree with the addition of testing for HCV as a marker for the infection control practices in a dialysis facility. The rate of infection in cohorts of patients sitting near each other can indciate poot infection contorl techniques.

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

Organization : **American Pharmacists Association**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-3818-P-231-Attach-1.DOC

American Pharmacists Association
Improving medication use. Advancing patient care.
APhA

Attachment #231
May 5, 2005

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

Re: CMS-3818-P

Dear Sir/Madam:

The American Pharmacists Association (APhA) welcomes the opportunity to submit comments on the proposed changes to the conditions for Medicare coverage for end stage renal disease (ESRD) facilities. APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 52,000 practicing pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in advancing the profession. APhA, dedicated to helping all pharmacists improve medication use and advance patient care, is the first-established and largest association of pharmacists in the United States.

Facilities that provide dialysis or transplantation services to ESRD patients must meet certain requirements in order to receive reimbursement from the Medicare program. The proposed rule contains a number of changes to the existing conditions for coverage for ESRD facilities. The changes are part of an effort by the Centers for Medicare and Medicaid Services (CMS) to modernize the outdated ESRD regulations and move toward a patient outcomes-based system. The proposed requirements address a range of topics including patient safety, patient care, and facility administration. APhA's comments will focus on the facility administration requirements, specifically proposed Section 494.140 on personnel qualifications.

Personnel Qualifications
Under the proposed rule, ESRD facilities are required to employ the following personnel: a medical director, nursing staff, a dietician, a social worker, patient care dialysis technicians, and water treatment system technicians. Although the rule does not require ESRD facilities to have a pharmacist on the multidisciplinary team, the preamble to the rule contains a brief discussion on what role, if any, a pharmacist should play within the ESRD facility. The Agency also questions what responsibility the ESRD facility should have for pharmaceutical services and the efficient use of medications. APhA appreciates the Agency's acknowledgement of the contributions pharmacists can make to the safe and

effective use of medications – especially for vulnerable patients with ESRD. And we strongly encourage CMS to require ESRD facilities to include a pharmacist(s) on the health care team.

Dialysis patients benefit from a pharmacist's services. Most dialysis patients have complex drug regimens. Dialysis patients typically take between ten to twelve medications – in both oral and injectable dosage forms – and may require multiple doses of these medications each day. Medications for ESRD patients are difficult to dose; because the kidneys play a significant role in drug disposition, and many drugs must be dosed according to patient-specific parameters. And many dialysis patients have multiple chronic conditions which may complicate their kidney disease and require additional medications. Patients with multiple conditions and a complex drug therapy regimen are at higher risk for medication-related problems and adverse events.

Pharmacists can help identify and prevent potential drug-related problems. Pharmacists can provide routine medication reviews – reviewing the patient's medication profile, checking for therapeutic duplication, improper dosing, allergy interactions, drug-drug interactions, and drug-disease interactions, as well as helping patients remain compliant with their medication therapy. Including pharmacists in the care of ESRD patients will help ensure safe and appropriate medication use, improve patient outcomes, and reduce overall health care costs.

One of the greatest uses of health care dollars today is for medications. Pharmacist review of medication records has been found to reduce health care costs related to drug problems. Many patients, especially seniors – who are the fastest growing population of dialysis patients, are hospitalized because of a condition or illness that could have been treated or effectively managed with proper medication use. The average dialysis patient is hospitalized 1.5 times per year.[1] A recent study found that approximately 16.2% of those admissions may be related to avoidable medication-related problems. If a pharmacist-provided medication review was able to identify and resolve even half of those problems, the number of hospital admissions for ESRD patients would decrease. With the average cost of a hospital visit for a dialysis patient costing $11,000, the estimated decrease in hospitalization costs for 100 ESRD patients is $133,650 annually. Pharmacist interventions have also been found to reduce inappropriate or unnecessary medication use. The same study found that if pharmacists reduce inappropriate medication usage in ESRD patients by 0.69 medications per patient – which is the average reduction in medications achieved by pharmacists in non-ESRD patients – pharmacist intervention could reduce medication costs for ESRD patients by an average of $29 per month or $34,884 per year for 100 dialysis patients. Overall, the study concluded that for every dollar spent on pharmaceutical care interventions, the healthcare system saves an estimated $3.98.[2]

It appears that the Agency understands the importance of regular medication reviews for dialysis patients. Under the proposed rule, ESRD facilities would be required to provide patients with an individualized and comprehensive assessment of their needs within twenty days of their first dialysis treatment. A follow-up assessment must occur within three months and must be followed with regular reassessments. CMS has proposed that this patient assessment include a laboratory profile and medication history on each patient. APhA strongly supports this requirement and we believe that

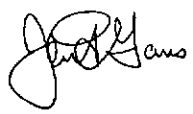
[1] Manley HJ and Carroll CA. The Clinical and Economic Impact of Pharmaceutical Care in End-Stage Renal Disease Patients. Semin Dial 2002: 15: 45-49.
[2] Ibid.

pharmacists are the ideal health care professional to conduct medication history reviews – pharmacists are the medication experts on the health care team.

In closing, we would like to reiterate our strong support for a requirement that ESRD facilities include a pharmacist(s) on the multidisciplinary team. There are many examples of pharmacist-provided services having a positive impact on the health care system including in patients with ESRD. The positive impact pharmacists have on patient outcomes was recently recognized by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 which included coverage for pharmacist-provided medication therapy management services. Through these activities, pharmacists contribute to better patient care and improved patient outcomes – and perhaps most significantly from a financial standpoint – the services pharmacists provide can reduce patient-related costs. Through the use of medication reviews and other medication therapy management services, pharmacists can help ESRD patients appropriately manage their medication use and effectively reduce overall health care costs.

Thank you for your consideration of the views of the nation's pharmacists. Please contact Susan K. Bishop, Associate Director, Regulatory Affairs at 202-429-7538 or SBishop@APhAnet.org with any questions.

Sincerely,



John A. Gans, PharmD
Executive Vice President

cc: Susan C. Winckler, RPh, Esq, Vice President, Policy & Communications and Staff Counsel
Susan K. Bishop, MA, Associate Director, Regulatory Affairs

Submitter : Ms. Jenna Krisher **Date:** 05/05/2005

Organization : Southeastern Kidney Council (ESRD Network 6)

Category : Other Government

Issue Areas/Comments

GENERAL

GENERAL

See attachment

Submitter : Dr. Gary Stein **Date:** 05/05/2005

Organization : American Society of Health-System Pharmacists

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-233-Attach-1.DOC

Attachment #233
May 5, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–3818–P
P.O. Box 8010
Baltimore, MD 21244–1850

American Society of
Health-System Pharmacists®
7272 Wisconsin Avenue
Bethesda, Maryland 20814
301-657-3000
Fax: 301-652-8278
www.ashp.org

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

To Whom It May Concern:

The American Society of Health-System Pharmacists (ASHP) is pleased to respond to the Centers for Medicare & Medicaid Services' (CMS's) February 4, 2005, proposed rule that would revise the requirements that end stage renal disease (ESRD) dialysis facilities must meet to be certified under the Medicare program. ASHP is the 30,000-member national professional and scientific association that represents pharmacists who practice in hospitals, health maintenance organizations, long-term-care facilities, and other components of health systems.

In its preamble discussion of the "Personnel Qualifications" standard of the ESRD conditions of coverage (page 6224), CMS invites "comments regarding what role, if any, the pharmacist should play within the dialysis facility as well as the facility's appropriate responsibility for pharmaceutical services and the efficient use of medications in the new conditions for coverage." CMS makes this request because, although there is no current requirement for a pharmacist to participate on a multidisciplinary team in ESRD facilities, the agency recognizes that "a hospital-based dialysis unit might be able to use the hospital pharmacist as a resource" for improving patient care and reducing medication-related costs.

ASHP and its members wholeheartedly endorse this proposal. CMS rightly acknowledges the complex nature of drug therapy required by dialysis patients and the potential for adverse outcomes if medications are not used appropriately. We are particularly pleased that CMS has acknowledged the significant role that clinical pharmacists can – and do – play in improving health outcomes of ESRD patients as part of an interdisciplinary dialysis team. This is true not only in terms of developing laboratory profiles and patient medication histories, as the preamble to the proposed rule seems to suggest, but throughout a patient's medication-related therapy.

It is fundamental to today's patient care that CMS formally establish pharmacists, professionals specifically trained to detect and address medication-related problems as members of an ESRD's dialysis team. Healthcare literature supports the utilization of

pharmacists in ESRD facilities to improve standards of care outcomes and reduce costs by providing clinical recommendations to the rest of the dialysis team, monitoring laboratory test values and drug dosages, assessing drug effectiveness, evaluating drug usage, enhancing medication adherence, and counseling patients. Reports of the clinical and financial effectiveness of pharmacist-provided management of patients' medication therapies have shown that such services can result in as much as $4 of health care cost savings for every $1 spent on pharmacist's care.

A significant factor among dialysis patients is their frequent hospitalizations due to multiple co-morbid conditions and their multi-drug regimens that increase the risk of adverse drug events. Clinical pharmacists have the education and experience to provide critical services that can promote safer and more effective medication use.

ASHP suggests that CMS include the following principles in a "pharmaceutical services" standard in its final rule on conditions for coverage for ESRD facilities:

1. Each multidisciplinary dialysis team should include a clinical pharmacist with experience or training in nephrology pharmacy.
2. Routine patient care assessment of dialysis patients should include a comprehensive medication review (prescription, over-the-counter, herbal) conducted and documented by a pharmacist prior to or an the initiation of therapy in an ESRD facility, and at clinically appropriate intervals thereafter.
3. Pharmacists should participate in the development and implementation of medication-related protocols within dialysis to assure appropriate, safe, and cost-effective drug use.
4. ESRD 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 collaboration with a pharmacist.

For more than 60 years, ASHP has helped pharmacists and pharmacy technicians who practice in hospitals and health systems improve medication use and enhance patient outcomes. The preamble to the proposed rule states that one of the goals of the revised requirements is to "focus on the patient and the results of the care provided to the patient." This goal would certainly be better met if ESRD facilities were to utilize the expertise of pharmacists in the care of this vulnerable patient population.

ASHP appreciates the opportunity to present comments on this important patient care issue. Feel free to contact me if you have any questions regarding our comments. I can be reached by telephone at 301-664-8702, or by e-mail at gstein@ashp.org

Sincerely,

Gary C. Stein, Ph.D.
Director, Federal Regulatory Affairs

Submitter : **Mr. Steven Bucher** **Date: 05/05/2005**

Organization : **Renal Therapies, LLC**

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

Issue Areas/Comments

GENERAL

GENERAL

please see attached comments

CMS-3818-P-234-Attach-1.DOC

Attachment #234
Centers for Medicare & Medicaid Services
Dept of Health and Human Services
Attn: CMS-3818-P
7500Secrity Blvd, Baltimore, MD 21244-1850

Comments to CMS' proposed rules for ESRD, February 4, 2005 publication

D. Condition: Care at Home (Proposed Sec494.100)

We fully agree with your preamble that home dialysis has been shown to have a positive effect on a patient's quality of life. In to aspect of home dialysis is this more apparent than the provision of home hemodialysis to ESRD patients residing in a SNF or other nursing facility.

We also agree that the quality of care of these home patients should not be diminished because of the venue in which they receive dialysis care.

The following comments relate to Item 2 "Dialysis of ESRD Patients in Nursing Facilities and Skilled Nursing Facilities".

We appreciate the fact that CMS is reviewing this topic of Care at Home in its proposed changes. There are many opportunities to address quality dialysis care for home patients. There are several ideas put forth in the proposed coverage document, however, that would require an unbearable financial burden and make the service financially not viable for the dialysis provider and the NF/SNF.

We currently serve a large number of home hemodialysis patients who reside in SNFs. Based on our experience, we offer the following comments.

As stated in your proposal, the provision of home dialysis to residents of NF or SNF should be an opportunity to improve the quality of life the dialysis residents. As also stated, the current interpretation of a qualified home dialysis patient disqualifies a short-term stay or rehab patient from meeting this definition. We believe that this is an interpretation which is detrimental to the short term/rehab patient and one which inherently violates your stated goal that all ESRD patients should be able to receive the best care possible. You have outlined in your comments several of the detrimental issues of an ESRD patient being transported to an outpatient dialysis facility. By your current interpretation, this would be the only option for a short term rehab ESRD patient. You have, however, left out the most significant issue to both the patient and the Medicare program. That issue is the fact that a rehab patient in a SNF/NF who is transported t o a n o utpatient dial ysis f acility do es not r eceive r ehab on t heir

dialysis days. This significantly extends the rehab stay causing the patient to stay in the nursing facility longer than necessary and costing Medicare a significantly higher amount for the extended stay. Additionally, the onsite provision of dialysis in the SNF/SF can result in patients being discharged earlier from the hospital setting if the transporting problem is eliminated. Again this results in very significant cost savings on hospital stays. An example would be a hip fracture patient. In our experience, the short term stay/rehab patients benefit the most from in nursing facility home dialysis. We strongly request that this interpretation be modified and that the nursing facility be defined as the home of short term stay and rehab patients and they be able to receive their dialysis at the nursing facility. To do otherwise, denies them access to a better venue of care than other patients. We can see no real basis for continuing the artificial restriction. This is indeed their temporary home.

Training

We are supportive of your March 19, 2004 guidelines as they relate to the training issue of nursing home based patients. Most of these patients are not able to be trained and/or have no interest in training. Instead, trained caregivers are assisting in the provision of dialysis and there is no practical reason that these trained caregivers cannot meet the training requirements as outlined in your home dialysis proposed rules. The same issues of competency need to be demonstrated by these caregivers as would be required in an at home assistant and we support the criteria you have proposed. We believe that it is essential that the in nursing facility caregivers have significant prior dialysis experience in an outpatient setting for the safety reasons you have outlined. We believe it is inappropriate that care in this setting be provided by caregivers who have only received a short training course. The National Renal Administrators Association has previously stated in their position paper on nursing home dialysis that these caregivers should have at least two (2) years of previous dialysis experience. We agree with that position. We believe that your current requirement that the training of these on site caregivers must be done by a registered nurse is overly restrictive. If these are experienced dialysis technicians, the additional responsibilities, unique to the nursing home, could well be trained by a LPN who has home dialysis experience. We would encourage the expansion of this trainer to include RNs and LPNs who meet the experience guidelines.

a. Delineation of Responsibility

We agree that there should be coordination of care between the dialysis provider and the NF or SNF. We believe that your published guidelines on nursing home dialysis address the relationship between the dialysis provider and the SNF/NF adequately and appropriately.

b. Nursing Coverage

You have addressed the issue of nurse coverage in both the guidelines to surveyors and the subsequent question and answer document. We agree that a nurse should be on the premises of the NF or SNF when simultaneous dialysis is

being administered to ESRD patients. We support your position that this nurse may either be an employee of the NF or SNF or from the dialysis facility. If they are an employee of the NF or SNF, they should be trained or in-serviced by the dialysis provider to be able to respond to an emergency situation resulting from the administration of dialysis. We feel further delineating or limiting the NF or SNF nurse's duties is not necessary and would only serve to increase costs to the point of making this service not an economically viable option for both the SNF, SNF or dialysis facility.

Caregiver ratios
There should not be patient-to-caregiver ratios mandated when a home patient resides in a NF or SNF. Each NF and SNF experiences different levels of patient acuity. In many instances, experienced and trained caregivers could adequate care for four stable patients simultaneously. A more routine patient to caregiver ratio would be 3.5:1 (7 patients with 2 caregivers) or 3:1. We believe that it should be adequate that surveyors review the appropriateness of staffing given the acuity level of the patients being served.

e. Monitoring
You state "we believe that the ESRD facility should be responsible for monitoring the care of the ESRD patient in the NF or SNF". It is absolutely unrealistic to hold a dialysis facility responsible for the quality of care that a NF or SNF provides to its residents. We are not opposed to periodic competence evaluation of SNF/NF staff who are involved in the dialysis care of their residents to determine that they are prepared to appropriately respond to emergency circumstances but do not believe that there is any basis for a dialysis provider to assess the ability of a SNF/NF to provide care to their residents. Is this not what the role of the surveyor is intended to be??

There should be no requirement for the ESRD facility to "(4) work with the NF or SNF to monitor whether dialysis treatments negatively impact the care of other residents... and CORRECT such impact as appropriate". This too is unreasonable and a financial impossibility without additional reimbursement. The ESRD facility should NOT be responsible for monitoring and correcting the care of other non-dialysis residents in the NF or SNF where home dialysis occurs.

What does "(1) Provide periodic monitoring of the institutional residence to assure that appropriate care is being provided:" m ean? T his is a current challenge and significant responsibility for trained state health surveyors to do, let alone a dialysis facility which has no expertise in this area.

We think there should be minimum competency tests for caregivers who are not the patient's family. We think these tests should be established and administered by the dialysis provider. We think the current qualifications for the nurse are adequate.

Summary Comment
We are in full agreement that the provision of dialysis to ESRD patients residing in SNF/NF should not be less that the care they would have otherwise received in an outpatient dialysis facility. However, often the nursing home based patient is a very inappropriate patient for an outpatient dialysis facility and due to behavior problems o r disorientation t hey do not receive optimal care in the outpatient facility. With proper definition of the qualified nursing home patient as we have outlined and with proper oversight, ESRD patients residing in nursing facilities can receive a much superior care offering in the nursing home setting and can enjoy a much improved quality of life. In addition, there is great opportunity for savings to the health care system by structuring a proper offering of this badly needed service.

What kind of savings are there across the health care system if average length of stays is shortened in NF and SNF as a result of ESRD patients getting better care, consistent medications, therapy, and meals by receiving their dialysis in-house with home dialysis?

Steven Bucher, CEO
Curt Anliker, Executive Director
Renal Therapies
244 Knoll St.
Wheaton, IL 60187
Svbucher @aol.com

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

Organization :

Category : **Social Worker**

Issue Areas/Comments

GENERAL

GENERAL

494.80 Patient Assessment (b) Frequency of assessment for new patients
(I could not find a specific Issue number relating to this.)

Twenty (20) days is often not adequate for a complete assessment of a new patient, particularly a Tuesday, Thursday, Sat. patient who is covered by a part-time social worker and/or dietitian. A comprehensive assessment is rightly being called for and the additional 10 days or 30 days total, gives all disciplines more adequate time to gather the appropriate information. It is possible to do both the assessment and care plan in 30 days, and I would suggest that this be the standard.

Rationale: Patients are often very ill, frightened, and exhausted during their first couple of weeks of dialysis. Especially if there is more than one patient who might begin dialysis the same day or week, it becomes nearly impossible to spend the needed time with the patient to complete the assessment in under 30 days, particularly if the social worker or dietitian is present only one day (or less) each of the patient's initial weeks on dialysis

Issues 1-10

Care at Home

494.10
I believe a new category should be added for dialysis provided in a nursing home setting.
Rationale: Nursing home dialysis differs greatly from dialysis done in one's home. Generally, the patient him/herself is unable to actively particpate in the dialysis treatments due to multiple illnesses and conditions. Nursing homes generally do have have the level of qualified personnel, such as RN's or MSW Social Workers, who are available--and need to be available--for dialysis treatments.

Issues 11-20

Personnel Qualifications

494.140 Personnel Qualifications (d) Standard: Social Worker

I wholeheartedly agree with the proposal that the social worker be a person with an MSW degree from an accredited graduate program but would suggest that an additional requirement be made that the graduate education must have had an emphasis on "clinical Practice" rather than planning and administration. I would also suggest that the language of the condition be changed to

Rationale: Clinical social work training is essential to enable the social worker to offer counseling to patients who have complex psychosocial issues related to ESRD.

Governance

494.180 Governance (b1) Standard: Adequate number of qualified and trained staff

Strongly suggest adding to (1i) "No dialysis clinic should have more than 75 patients per one full time social worker"

Rationale: A specific social worker-patient ratio must be included in the conditions of coverage. Currently, there are no such national ratios. As a result, social workers frequently have unmanageable caseloads, often in multiple, geographically separated clinics. The Council of Nephrology Social Workers has had a suggested acuity-based social work-patient ratio (contact NKF for the formula)for several years which could be used as an alternative to a flat patient-social work ratio. The setting of this acuity-based staffing plan could be made in each clinic, in consultation with the facility social worker.
From my own experience and observation in my 6 years working in the renal setting, I see my own and others large caseloads prohibiting or at least seriously hindering the ability to provide appropriate and needed clinical interventions. Part of the problem is that tasks, such as clerical needs relating to patient travel and insurance coverage become relegated to the social worker who, in most cases, is the staff member with the highest level of education (next to the physicians). This speaks to the need to designate a specific social work case aide or secretarial designee to do these clerical tasks so that social workers can be about the business of talking to/assesing patients, providing counseling and referral, and consultation to other staff so there can be an outcome based plan to improve patient psychosocial outcomes.

Submitter : **Ms. Patricia Tate-Harris** **Date: 05/05/2005**

Organization : **Association of Dialysis Advocates**

Category : **Consumer Group**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-236-Attach-1.PDF

Attch # 236

May 5, 2005

Mark McClellan, MD, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-3818-P
Washington, DC 20201

RE: Conditions for Coverage for End State Renal Disease Facilities - (CMS-3818-P): Proposed Rule

Dear Dr. McClellan:

The *Association of Dialysis Advocates* appreciates the opportunity to respond with our public comments for the ESRD Conditions for Coverage proposed language.

We are a developing patient advocacy group (patients, families and supporters) whose mission statement is the following:

"Association of Dialysis Advocates (ADA) is a grassroots organization of volunteers dedicated to patient advocacy. We believe advocacy that ensures delivery of safe, quality dialysis treatments are imperative for patients and their families, for good patient outcomes, and for cost-effective care. *ADA* is dedicated to empowering patients, through education, to make informed decisions that enable patient responsibility and ultimately improve the medical care that impacts lives.

ADA is assertive in carrying out its goals, objectives, and activities to accomplish its mission for improvements in dialysis care and public policy."

ADA believes that there have been great improvements and organization of the ESRD Conditions proposed language, especially with direction on patient-centered care, of which *ADA* totally supports.

ADA was able to review survey results (Summary of Deficiencies and Plan of Correction – Form 2567) for the time frame August 2003 through September 2004. Our examination of these survey documents consisted of 28 states. After review of these documents, we determined that there are still concerns about actual or potential harm to patients based on questionable care provided in dialysis facilities. We realize that the dialysis industry has entered into an agreement with CMS to deliver care that is within regulatory language and in return CMS will provide reimbursement for said compliance. *ADA* believes that the lack of adherence on the part of the dialysis industry is evident. Therefore, our recommendations are solidly based on the aforementioned.

Again, *ADA* appreciates the opportunity to respond and is looking forward to a working relationship with CMS.

Respectfully,

Patricia Tate-Harris, President
Roberta Mikles, RN BA, Vice President
Carla Faith, Secretary/Treasurer

Association of Dialysis Advocates (ADA)
6344 Silverleaf Avenue
Baton Rouge, LA 70812
(225) 355-5379
dialysisadvocate@bellsouth.net

STAFF QUALIFICATIONS
Condition 494.140

Association of Dialysis Advocates (ADA) proposes that the requirement of one (1) year of clinical experience and six (6) months of dialysis maintenance for a registered nurse responsible for nursing services is insufficient for the complex delivery of patient-centered care required in a dialysis unit. At a minimum, ADA recommends that such registered nurses possess two (2) years of clinical experience and one (1) year of dialysis maintenance experience. We realize that this might place some strain on dialysis units, however, in ADA's review of 2567s, Summary of Deficiencies and Plan of Correction, statement, we noted there to be a substantial number of deficient practices that led to negative outcomes as the direct result of lack of training, experience and/or education on part of registered nurses responsible for nursing care.

Rationale:

The important aspect of separating regulations from being prescriptive demands experienced staff. ADA agrees with CMS as stated in the proposed language that "ESRD is an extremely complex disease requiring highly technical and complex treatment, and patients with this disease have special needs that require highly specialized care that can only be provided by qualified personnel." ADA further agrees, as CMS continues to state " . . . it becomes even more important to have qualified, experienced, and well-trained staff to achieve the targeted clinical outcomes for each patient."

With the aforementioned stated, ADA believes that CMS has stated the rationale for a more intensive qualification requirement. We believe, it is evident that the proposed requirement of one year of clinical experience and six months of dialysis maintenance experience does not support the goal of CMS, at a minimum, to have experienced and qualified staff. We must keep in mind that those in a supervisory and/or charge position will be giving direction, educating and overseeing delivery of care to dialysis patients who present often with complicated problems including, but not limited to, comorbid conditions. All direct care staffs, particularly patient care technicians, do not have medical backgrounds and are not well versed in areas that a licensed nurse will demonstrate; therefore, experience working in dialysis as well as credentials are of utmost importance. Again, ADA supports this as evidenced in the numerous 2567s that were reviewed. Noted negative outcomes often were due to lack of education, experience, training and direction from one who is responsible for nursing services.

ADA realizes the limitations that may be placed on dialysis units due to nursing shortage; however, it is also realized that we are dealing with human life and it is apparent that the existing regulation has supported, as evidenced by 2567s, negative outcomes as a direct result of lack of experience and training. Hospitals, ADA believes, would not assign a nurse with one year of clinical experience to be in charge of a unit which requires specialized skills, education and training, as does dialysis. It is timely that requirements for dialysis staff, particularly those in supervising or charge positions, are elevated to support CMS' stated recognition of the complexities involved in treating dialysis patients.

INFECTION CONTROL
Condition: 494.30

Association of Dialysis Advocates (ADA) proposes the following to strengthen infection control practices in dialysis units:

1. That provisions in the following referenced materials are **mandated** for infection control policies and procedures.

    A. CDC Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients;
    B. CDC Morbidity and Mortality Weekly Report - October 25, 2002
    C. CDC Morbidity and Mortality Weekly Report - June 6, 2003
    D. HICPAC Guidelines, "Hand Hygiene in Healthcare Settings
    E. HICPAC Guidelines, "Guideline for Preventing Intravascular Device-Related Infections

2. That declarative rather than permissive words are used to affirm CMS' expectations regarding infection control practices in dialysis units;

3. That "new" dialysis facilities adhere to AIA design standards and HICPAC guidelines;

4. That patients are given detailed information on infection control practices; and,

5. That NKF/DOQI Guidelines for Vascular Access be used by facilities.

Rationale:

With the rise in healthcare acquired infections, as well as community-based infections, ADA believes there should be consistency as well as continuity within the healthcare industry. This is supported by the numbers of patients who go in between hospitals, nursing homes and dialysis units. The exposure rate increases as more and more patients enter the dialysis unit with comorbid conditions as well as an increasing geriatric population. Dialysis units must not only protect those in units, but have a responsibility to the community as well. ADA reminds CMS that dialysis patients are in a vulnerable situation which, in and of itself, justifies a more prescriptive regulation. Again, ADA directs CMS to survey results showing a gross noncompliance with basic infection control practices due mainly to non-prescriptive language. Additionally, we remind CMS that dialysis patients, being a reservoir for staph require more stringent infection control practices. International and national healthcare organizations have been addressing infection rates in hospitals, and many states have passed laws which require public disclosure of same. This shows that there is a continuing problem with acquired infections.

ADA believes also that in order to fully hold facilities accountable to those they deliver care, patients must be informed of infection control practices to which staff will be adhering. ADA can realistically state that patients, at present, are not educated as to staff practices, therefore, when there is noncompliance patients are placed in a more vulnerable position. ADA believes that it is only fair to patients, whose lives are at risk, to be well informed of infection control practices. JCAHO, as well as other healthcare bodies, found that hand-washing was the number one problem amongst healthcare facilities to which adherence was lacking. We cannot take infection control lightly, especially when the #2 cause for death among dialysis patients is "infections". Those providing care in dialysis facilities must be held accountable to patients and public alike for infection control procedures and practices.

ADA believes that the use of words such as "may" encourages the noncompliance with infection control practices as observed in review of F2567s. We believe and support dialysis facilities having flexibility, however, with the rising number of infections acquired in healthcare facilities and admittance of more medically compromised and elderly patients, we believe, prescriptive language/mandated infection control practices are in order.

ADA proposes that "new" dialysis facilities adhere to AIA design standards, CDC and HICPAC guidelines. As stated within the proposed language, "These CDC infection control recommendations specific to the hemodialysis setting were developed in consultation with other federal agencies and specialists and are based on available knowledge regarding transmission of infectious diseases." The aforementioned supports our position on that all facilities, including "new ones"should be required to adhere to such for benefit of high-risk dialysis patients as well as to provide consistency with infection control practices in dialysis facilities.

ADA proposes that patients are given detailed information on infection control practices. As referenced in HICPAC, it is ok for patients to remind staff to wash their hands. However, in order for patients to be able to support good infection control practices, they must be educated as to practices required by patients and staff alike.

PHYSICAL ENVIRONMENT
Condition 494.60

Association of Dialysis Advocates (ADA) proposes that CMS include (ADD) requirement that dialysis facilities have a mechanism in place for patients' use to summon staff assistance.

Rationale:

Patients need to know that they can call for staff if needed. Often patients, during dialysis procedure, will experience hypotensive, bleeding, and other episodes at which time they might not be able to verbally get the attention of staff. Although there are alarms in place on dialysis machines, patients

need to be able to contact staff if and when problems arise and, at times, prior to sounding of a machine alarm. Demographics of the dialysis population, including elderly, fragile, stable and unstable patients, as well as those with visual, hearing and other impairments, are such that a call mechanism is essential for patients' psychological and physical well-being.

A reality is that staff is not always available and cannot attend to two patients at the same time. In review of 2567s it was noted that there were instances whereby staff admitted to surveyors that they were unable to watch patients all the time or simultaneously, nor be aware of patients' needs at all times. Absence of a call mechanism predisposes patients to an unsafe environment. An added requirement to the Conditions will fill the void for patient/staff contact

PATIENT RIGHTS
Condition: 494.70

Association of Dialysis Advocates (ADA) proposes that the following be included in the ESRD language for dialysis patients in order to have their rights fully considered and respected:

> 474.40(A)(6) That family members, if desired by patients, are to be included in educational conferences regarding dialysis treatment modalities, training activities, and patient care conferences.
>
> 474.70(a)(14) That patients are to be educated on grievance-related authorities of ESRD Networks and State Survey Agencies, i.e., mediation and enforcement respectively, in order to make informed choice for direction of a grievance, as well as to expedite action on grievance issues.

ADA recommends that CMS encourages facilities to utilize an ombudsman for routine and objective relationship with patients and/or their families to ensure that care is delivered in a patient-centered atmosphere.

Rationale:

ADA believes that often, for a variety of reasons, patients do not fully comprehend or are not able to process information given by healthcare providers. Family members are often the only support system that the patient has and therefore need to be actively involved in their treatment in order to be able to comply with treatment goals. This is especially true for the mentally disabled, elderly and severe medically-compromised patients with comorbid conditions. We believe that family members should always be included in the team of patient and staff, should patient desire.

Patients, upon entering dialysis, are provided with many avenues to use should they become dissatisfied with any aspect of their treatment. Patients are verbally and/or via written materials informed that they may file grievances by way of facility, ESRD Network, or State Survey Agency

grievance processes. However, there is no information given relative to authorities granted to ESRD Network and State Survey Agencies. It is imperative, ADA believes, that patients clearly understand that it is the State Survey Agencies, not ESRD Networks, that have authority to enforce ESRD Conditions for Coverage.

ADA is aware of perceived or actual retaliatory incidents that have developed due to situations whereby a patient or family member voiced a complaint or expressed a concern. ADA is also aware of failure, on part of patients and/or family members, to pose questions or express concerns for fear of retaliation or discharge from facilities. ADA believes that an ombudsman, an outsider who has no involvement with the dialysis corporation/facility, will offer opportunity for impartial assessment of patient and family concerns and collaborate with treatment team members on behalf of patient and family to remedy problems that may surface. Use of facility employees to communicate directly with patient and/or family when problems occur presents as a conflict-of-interest and cannot, in reality, effect unbiased deliberations. Human behavior dictates in these situations that employees do what is best for the corporation and their livelihoods (jobs), and not the patient. ADA believes that an ombudsman can serve as a beneficial and advantageous member of the facility/patient partnership envisioned in patient-centered treatment.

PATIENT ASSESSMENT
Condition 494.80

Association of Dialysis Advocates (ADA) proposes retention of language in 405.216(b)(3) as we feel that pre and post assessments are of vital importance in assessing the patient and determining adequacy of treatment. We further propose inclusion of the following to ensure thorough and ongoing assessment of patient status and dialysis prescription modifications, if needed, based on same:

A. Chest Auscultation (fluid status, breath sounds, heart rate/rhythm)
B. Visual Observance (shortness of breath, jugular vein, periorbital edema, extremity edema, pitting edema)
C. Gastrointestinal Evaluation (diarrhea, nausea, vomiting, constipation, pain)
D. Access Site Evaluation (redness, welling, pain, drainage)
E. Patient Symptoms Between Treatment, if any; and

Rationale:

ADA observed from review of 2567s a sufficient number of deficient practices related to pre/post dialysis assessment. Dialysis patients present with comorbid conditions necessitating thorough assessment to ensure accuracy of dialysis treatment procedures. Problems encountered during treatment need to be assessed in order to timely refer patients for attention to medical conditions outside scope of services provided at dialysis facilities. Additionally, the current and projected increase in elderly dialysis patients demand that appropriate assessment be accomplished to identify

and intervene/refer so as to prevent worsening of medical conditions and/or incurring unnecessary medical costs (hospitalizations) due to incomplete assessments.

PATIENT EDUCATION
Condition 494.90

Association of Dialysis Advocates (ADA) proposes that the dialysis facility include an education component to its service delivery and employ a Nurse Educator with specific responsibility for planning, overseeing, implementing and evaluating such component. ADA further proposes that patients, and/or their family members or representatives, be expected to complete a core educational curriculum based on their abilities to do so, and that there are advanced curricula for those patients desiring to increase their knowledge of ESRD and dialysis treatment procedures.

ADA agrees that patient education is of utmost importance and has been lacking in delivery of care. We believe that a large component of existing problems within dialysis facilities, including labeling of patients, is born from patients not being educated and related behaviors misinterpreted by staff. We agree with CMS that, "The education of patients and their families goes beyond providing the necessary information for patients to make an informed choice regarding treatment modality." Over the years to present, we have seen a gross lack of education provided to patients and members of their support systems.

An educated patient is one who can actively participate in her or his care, and who assumes some, if not all, self-management responsibilities to ensure ongoing progress towards achieving goals set out in treatment care plans. While patients bear some responsibility for exercising initiative to learn about ESRD and dialysis treatment procedures, it is crucial that facilities incorporate patient education, in a formal, organized, structured and ongoing manner, to achieve stated goals of the ESRD program, including those to improve the quality of life for dialysis patients and their families and to render patients capable of participating in their own care as equal partner of the dialysis treatment team.

ADA believes that an education component will enhance the concept of patient-centered care and will, in the end, result in improved compliance and relationship between patient and dialysis treatment staff because there is a better understanding of rationale for directions given to maximize the dialysis experience. In conclusion, ADA believes that without a comprehensive patient education program there cannot be patient-centered care.

RESPONSIBILITIES OF THE MEDICAL DIRECTOR
Condition 494.150

ADA believes that the interaction between the Medical Director and the patient's other physicians

is of utmost importance in delivery of patient-centered care. ADA, therefore proposes inclusion of the following into the ESRD language.

"The Medical Director will have direct communication with the patient's other physicians when new or existing comorbid conditions arise during the course of dialysis treatment. The clinic manager may act as representative upon the Medical Director's request."

Rationale:

ADA fully appreciates that the Medical Directors have some great responsibilities. However, we also believe that many patients are not able to communicate with other physicians in a timely manner nor do they possess a full understanding of potential or actual medical problems. The Medical Directors have such capacity for communication and, due to the frequency of observations, are in a position to identify comorbid medical conditions. ADA further believes that comorbid conditions affect dialysis treatment as well as having a direct impact on the patient's overall emotional and physical well-being.

The dialysis patient is more likely to have better outcomes related to compliance and treatment when there is more direct communication between facility Medical Directors and the patient's other physicians when intervening medical problems occur. Avoidable negative outcomes decrease when there is physician-to-physician communication. In conclusion, ADA strongly urges CMS to incorporate this language in order to support "patient-centered" care.

ENFORCEMENT OF ESRD REGULATIONS
New/Add

Association of Dialysis Advocates (ADA) believes that the present enforcement and oversight of CMS Conditions for Coverage have not been sufficient to prevent noncompliance with regulations. Present consequences, including plans of correction, have demonstrated continued ineffectiveness in preventing multiple and recurring noncompliance as evidenced by the number of written plans of correction facilities submit for varied and/or same deficiencies. We, therefore, suggest that CMS address enforcement and oversight to ensure patient safety and effective treatment.

ADA suggests that a grid, similar to that used for nursing home facilities (evaluation of deficient practices/noncompliance) be used to determine scope/severity of regulatory noncompliance at dialysis facilities. The grid would provide direction in determining consequences/sanctions, and would also set forth progressive penalties for noncompliance to include a plan of correction, civil monetary penalty, termination of Medicare payment, and termination of facility. ADA believes that there needs to be a progressive method in place in order to ensure compliance with regulations and to provide accountability to patients, their families and the general public.

Rationale:

ADA believes that dialysis corporations (private, profit, nonprofit) enter into an agreement/contract with CMS. The contract is such that industry will provide a service and comply with regulations in exchange for payment of services.

ADA appreciates that dialysis facilities are able to provide written plans of that which will be corrected to ensure that noncompliance in specific area (of deficient practice) will not occur again. However, we believe that facilities have taken advantage of this and consequently there are repeated plans of correction for same and/or multiple noncompliant actions. There are human lives at stake and errors during dialysis can result in not only negative outcomes of a minimal consequence for a patient, but death. Considering that nurses either in charge or supervising a dialysis unit only have minimal requirements for their positions and fact that patient care technicians do not have medical background, the matters of enforcement and oversight present even more concern for patient safety, as well as compliance with regulations.

ADA has had the opportunity to review "Summary of Deficient Practices" (2567s, results of survey findings) for 28 states that have entered into the Medicare/Medicaid ESRD program agreement. In this review, we found noncompliant situations whereby there were repeated infractions in the same practice with only a written plan of correction required, therefore cultivating more noncompliance behavior with regulations. This, in and of itself, places patients at a great risk when staffs continue to violate the agreed upon conditions under which dialysis treatments are to be carried out. Additionally, ADA, in review of these survey/complaint investigation results, found severe negative outcomes that only warranted a written plan of correction. Such, a plan of correction, does not demonstrate to staff the severity of their errors, especially when there is potential or actual harm or death.

ADA agrees with the following testimony statement made by Dr. Jeffrey King, M.D., Director, Office of Clinical Standards and Quality, Health Care Financing Administration on the Medicare End Stage Renal Disease Program (2000): "Revising our conditions of coverage for dialysis centers is a key part of our plans to further strengthen our ability to improve the quality of ESRD care. Dialysis centers must meet these conditions in order to bill Medicare and Medicaid". ADA therefore believes, with supporting documentation as stated, that enforcement must be a priority.

In conclusion, ADA offers support to CMS in the enforcement aspect of delivery of care and is willing to work jointly with CMS and dialysis providers of service to devise a grid and/or explore further options and solutions to resolve the problems of lack of enforcement and oversight. ADA strongly believes that conditions without appropriate enforcement will perpetuate regulatory noncompliance. We, therefore, firmly urge CMS to immediately act upon strengthening the process of enforcement and oversight by addressing in the Conditions for Coverage.

****

Submitter : **Ms. Marcia Sawyer Sawyer** **Date: 05/05/2005**

Organization : **Michigan Council of Nephrology Social Workers**

Category : **Social Worker**

Issue Areas/Comments

GENERAL

GENERAL

I wish to add support for detailed comments submitted by the National Kidney Foundation, the Council of Nephrology Social Workers, and the Medical Education Institute. See Attachments.

CMS-3818-P-237-Attach-1.DOC

CMS-3818-P-237-Attach-2.DOC

Attachment #237
Hon Mark B. McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-3818-P
Box 8012 Baltimore, MD 21244-8012

Dear Dr. McClellan:

I am writing to support comments submitted by the National Kidney Foundation, the Council of Nephrology Social Workers, and the Medical Education Institute, comments which reflect many years of professional experience and research on providing quality, cost effective care to kidney dialysis consumers.

The Proposed Rule, Medicare Program, Conditions for Coverage for End Stage Renal Disease Facilities, CMS-3818-P, published in the Federal Register on February 4, 2005, contains many progressive recommendations in the Preamble that do not appear on the actual Conditions for Coverage.

Recommendations for Social Services Subpart D-Administration 494.140 (g) Social Services and Personnel Qualifications for the Social Worker, refer to the Federal Government's intent to ensure qualified psychosocial assessment counseling, education, and rehabilitation services be provided to all consumers covered by these ESRD regulations. (Page 6222 of Preamble)

Standards of Practice for Nephrology Social Work, referenced in the attached CNSW document, recommends staffing levels of 1 full time MSW to 75 dialysis patients, in order to achieve the level of care and positive patient outcomes sought by CMS.

However, without any parameters for staffing ratios, the dialysis industry sets I staffing levels at a much higher rate. The result is that in practice, many dialysis centers and chains employ one MSW to 100, 120, or even 150 patients, sometimes spread over a large geographic area in several dialysis clinics.

Therefore, I urge practical consideration of minimal staffing ratio caps to provide for adequate coverage of psychosocial concerns beyond the concrete issues driven by corporate need (insurance, transportation, reimbursement).

Dialysis professionals, including social workers, can help people stay alive on dialysis. But under the present staffing standards controlled by the industry, we cannot help them thrive, or live full lives.

Thank you for your considerations of these comments.

Sincerely,

Marcia Sawyer, ACSW

Attachment #237
Hon Mark B. McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-3818-P
Box 8012 Baltimore, MD 21244-8012

Dear Dr. McClellan:

I am writing to support comments submitted by the National Kidney Foundation, the Council of Nephrology Social Workers, and the Medical Education Institute, comments which reflect many years of professional experience and research on providing quality, cost effective care to kidney dialysis consumers.

The Proposed Rule, Medicare Program, Conditions for Coverage for End Stage Renal Disease Facilities, CMS-3818-P, published in the Federal Register on February 4, 2005, contains many progressive recommendations in the Preamble that do not appear on the actual Conditions for Coverage.

Recommendations for Social Services Subpart D-Administration 494.140 (g) Social Services and Personnel Qualifications for the Social Worker, refer to the Federal Government's intent to ensure qualified psychosocial assessment counseling, education, and rehabilitation services be provided to all consumers covered by these ESRD regulations. (Page 6222 of Preamble)

Standards of Practice for Nephrology Social Work, referenced in the attached CNSW document, recommends staffing levels of 1 full time MSW to 75 dialysis patients, in order to achieve the level of care and positive patient outcomes sought by CMS.

However, without any parameters for staffing ratios, the dialysis industry sets I staffing levels at a much higher rate. The result is that in practice, many dialysis centers and chains employ one MSW to 100, 120, or even 150 patients, sometimes spread over a large geographic area in several dialysis clinics.

Therefore, I urge practical consideration of minimal staffing ratio caps to provide for adequate coverage of psychosocial concerns beyond the concrete issues driven by corporate need (insurance, transportation, reimbursement).

Dialysis professionals, including social workers, can help people stay alive on dialysis. But under the present staffing standards controlled by the industry, we cannot help them thrive, or live full lives.

Thank you for your considerations of these comments.

Sincerely,

Marcia Sawyer, ACSW

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

Organization :

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

Issue Areas/Comments

GENERAL

GENERAL

Issues 1-10

Infection Control

Infection Control

It will be difficult to manage individual patients disposable items. Most likely items such as tape, cloth covered BP cuffs will have to be thrown away after each treatment.

Water Quality

Water Quality

Water analysis testing is to be performed at least annually and when:
The water treatment system is installed.
Reverse osmosis membranes are changed.
Seasonal variations in source water suggest worsening quality.
Reverse osmosis rejection rate fall below 90%.
My comment is that the last two stipulations are redundant in that worsening quality for whatever reason will cause a fall in rejection rates.

Home patient water treatment comments:

? It would be costly for home patient water treatment requirements to mimic in-center facility requirements. Some of the proposed items would not be necessary to have in the patients home:
1. The D.I. tank automatic divert is a costly item for the patient. We currently use a back-up tank system with audio & visual alarms. Patients are trained on the water system and the steps to take if the alarm sounds.
2. Blending valves in the home can be difficult to maintain if not used routinely. Inconsistent operation can cause reoccurring problems and expenses. It seems like a costly supply vs. appropriately training the patient on water temperature requirements and steps to adjust the temperature in the home.
3. LAL testing requires patients to carefully take specimens and use proper technique because the likelihood of contamination. To ensure patient safety from endotoxins, a .05 micron post filter should be used pre-dialysis machine.
4. For home patients to be held to the same standards for chlorine / chloramine levels at least every 4 hours, would require nocturnal patients who dialyze 8 hours, to have to get up in the middle of the night. To ensure patient safety, the home setting should have a secondary carbon tank and confirm acceptable levels of chlorine / chloramine after the first tank and prior to their treatment. Note: Carbon tanks are normally last about 3 months.

Physical Environment

Physical Environment

Manufacturers should set the frequency of preventive maintenance, but the individual sites should be able to determine how often components are replaced to help eliminate the obvious additional revenue from swapping parts before actually necessary.

Plan of Care

Patient Assessment

Does the comprehensive assessment have to be a consolidated assessment among all team members, such as social workers, dieticians, and nursing? Our preference would be to maintain separate documentation for each team member and consolidate goals and objectives on the care plan.

We prefer that the re-assessment for UNSTABLE patients address the area of un-stability vs. completing an entire full assessment.

Definition of new patient: is it a patient new to dialysis or patient new to facility?

Agree with 3 month time period to re-assess new patient

Patient Plan of Care

Can the assessment and care plan be combined in the same document to prevent redundancy?

Care at Home

Care at Home

Home training requirements stipulates a registered nurse, can the registered nurse supervise a pt care technician and perform final review and evaluation prior to patient going home.

Issues 11-20

QAPI

Quality Assessment/Performance Improvement

No specific time frames mentioned for monitoring

We are agreement with the use of patient satisfaction surveys.

Governance

Governance

Discharge/Transfer of Patients

If we discharge a patient, we feel it is the patient?s responsibility to locate a new unit, not the existing facility. The existing facility will assist the patient by providing the patient with a list of potential units.

Submitter : Mrs. Mary R. Perrecone **Date:** 05/05/2005

Organization : Albany Medical Center an d Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Submitted as representative of the Albany Medical Center ESRD Committee

Submitter : **Dr. Jose Arruda** **Date: 05/05/2005**

Organization : **University of Illinois at Chicago**

Category : **Physician**

Issue Areas/Comments

Issues 11-20

Personnel Qualifications

Attachment

Submitter : **Ms. Mary J. Boyle, R.N.** **Date: 05/05/2005**

Organization : **Gateway Dialysis Center**

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

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment

CMS-3818-P-241-Attach-1.DOC

CMS-3818-P-241-Attach-2.DOC

Attachment #241

RESPONSES TO PROPOSED CHANGES TO 42 CRF

CONDITIONS FOR COVERAGE FOR ESRD FACILLITIES

The responses that follow represent the opinions of two Registered Nurses with a combined total of 54 years of experience in the field of Nephrology Nursing. These years include nursing at the Staff Nurse, Charge Nurse, Nurse Manager and Facility Administrator levels.

The Nursing Profession has always striven to set standards of care to ensure that patients are receiving the highest quality of care that will ensure that each individual can achieve and maintain his/her optimal level of health. CMS has also set guidelines to achieve the same outcomes for this specific patient population. In the establishment of standards of care or guidelines, it is imperative to keep in mind that any such standards or guidelines MUST be achievable. Our responses are in keeping with this thought in mind, as well as the fact that the United States is facing a true Nursing staffing crisis (not just a shortage) and in the face of recent reductions to the composite rate reimbursement for an aging population with many more co-morbid medical conditions that require much more care than dialysis patients of twenty to thirty years ago.

We thank you in advance for consideration of our comments and suggestions.

Sincerely,

Mary J. Boyle, R.N., B.S.N.

Lorena Greeley, R.N., C.N.N.

I. INFECTION CONTROL

A. The prevention of the spread of blood borne pathogens is of primary concern in all health care settings and has always been a focus in dialysis facilities. In the years following the emergence of HIV/AIDS, the CDC recommended that "Universal Precautions" be utilized when caring for all patients in any health care setting. In your own document, you state "According to the CDC, transmission of Hepatitis C can be prevented by strict adherence to infection control precautions recommended for all hemodialysis patients." As Hepatitis C, Hepatitis B and HIV are all transmitted in the same manner and Hepatitis C and HIV are increasing in both the general population and the dialysis patient population, why continue to propose that ONLY Hepatitis B positive patients be isolated? Why propose that staff cannot care for both Hepatitis B positive and Hepatitis B negative patients on the same day/shift?

We ask these questions for several reasons:

1. Isolation of patients raises questions in the minds of the other patients as to the reason(s) why a patient is being isolated. This can lead to incorrect assumptions about the isolated patient and any disclosure of the reason for an "Isolation Room" is an automatic violation of recent HIPPA regulations regarding patient information confidentiality.

2. Isolation of patients, in the real world of dialysis facilities, tends to make patient care staff feel that these are the only patients for whom they need to "really" follow ALL the recommendations for care of dialysis patients (i.e., face shields as well as fluid impervious garment and gloves). This is a very dangerous concept if the goal is to prevent spread of disease.

3. Patients who are any blood borne pathogen positive already feel like "outcasts" and physical isolation only furthers this self perception.

4. There are increased costs involved.

B. Testing for HBV and HCV Infections

If the regulation for the isolation of HBV positive patients is removed, the only reason to test for EITHER HBV or HCV is for screening purposes. Screening for these diseases is very important in that early diagnosis of either can lead to early treatment and education, both of which will improve the patient's quality of life. In addition, for HBV negative patients, the Hepatitis B vaccination should continue to be offered. However, again in the face of recent reimbursement cuts, screening tests are very burdensome for the facilities.

C. Common Medication Carts

We do not believe that this is a reasonable guideline, especially in large facilities. To require that a nurse go back and forth from each individual patient to the medication preparation area is neither practical nor realistic.

From a practical point of view, this would take up valuable time that would be better spent in other aspects of patient care (i.e., patient teaching). In many facilities, there may be only ONE nurse present in the ENTIRE facility. Again, in the face of the coming nursing staffing crisis, we ALL need to find mechanisms that are safe for patients AND not burdensome for the nurse(s) caring for them. Realistically, if not for the use of a common medication cart, most nurses will draw up medications in advance and tape them to the top of front of a dialysis machine or put them into a lab coat or scrub suit pocket, both of which are clearly more dangerous than a common cart. Again, adherence to strict infection control practices with the use of a common cart (i.e., maintaining the cart a safe distance from the dialysis machine), makes more sense.

II. WATER QUALITY

The proposed changes may be perceived as too minimal by international standards. However, patient care has not been adversely affected when guidelines are followed. It would be helpful to avoid language that still leaves room for interpretation (i.e., "adequate empty bed contact time"). The proposal to require chlorine/chloramine testing before each shift or every fours hours, whichever is shorter, would necessitate testing treatment in many cases as the machines are often recirculating for a period of time before the patient arrives and/or patient treatment times are historically going beyond four hours. In larger units of 20 or more dialysis stations, the ability to monitor the time element restriction for each

individual station would be very difficult and might require more frequent testing creating a labor intensive situation. For continuity and compliance the regulation should remain that the monitoring procedures must occur before the start of each patient shift.

III. PHYSICAL ENVIRONMENT

Your proposal "that the dialysis nursing staff must be trained on the proper use of emergency equipment and emergency drugs" is exceptionally unreasonable in the setting of an out patient dialysis facility. This would require that the minimal amount of nurses in any facility take on responsibilities of an emergency room nursing staff. Despite the fact that our patients are aging and have many more co-morbid medical conditions, in the out patient setting, the need for this specialized knowledge is not common. And when knowledge and skills are not utilized frequently, they are lost ("if you don't use it, you lose it"). The use of CPR and AED's until EMS arrives is more than adequate in most facilities. How much is CMS going to require of the minimal number of nurses caring for 20+ patients in the chronic dialysis setting? Who is going to provide NURSING care to the other patients dialyzing at the time of an event of this nature? This proposed requirement would be better stipulated to those facilities that do not have an EMS system with ACLS certified personnel readily available to them within 10-15 minutes after a "911" call is placed.

IV. PATIENT'S RIGHTS

1. Patient Assessment.

§ 494.80(b)(2) addresses "a follow-up comprehensive reassessment for *new* patients..." *New Patients* needs to be clearly defined. Is this a patient *new* to ESRD or *new* to a different dialysis facility?

2. Assessment of the Treatment Prescription.

If Kt/V is to be the indicator for the adequacy of the dialysis treatment prescription, monitoring more frequently than monthly is not of value as it may take that long for any change to be noted in the Kt/V.

3. Patient Plan of Care.

a) It is important to maintain the requirement that the Medical Director of a facility be a participant in the interdisciplinary meetings. This proves to be a very valuable opportunity for the Nursing staff to bring him/her up to date on all the patients receiving care at the facility. As the Medical Director is ultimately responsible for all care rendered in the facility, he/she need to have this type of exposure in an environment and circumstance conducive to identifying problems and exploring avenues for resolution. It also gives the patient care staff the opportunity to discuss any problematic "Physician staff response" issue as pertains to patient follow-up with the Medical Director. Lastly,

attending physicians often prove non-adherent to meeting dialysis facility schedules and/or needs that may conflict with private practice commitments.

b) With regard to the transplant surgeon and the inclusion/exclusion criteria, the requirement should state that if a patient is referred to a new dialysis center and transplant as a treatment modality has already been explored and reasonably rejected at the referring facility, the process does not need to be explored again at the new facility until the time that the next Long Term Plan is due. In other words, the decision to exclude transplantation as an option should follow the patient.

c) Vascular Access.

As we are all aware, vascular access proficiency impacts dramatically on the outcomes a dialysis facility may achieve for any given patient. Thus, vascular surgeons need to be held more accountable (perhaps financially) for proper choice of access placement, proper technique, education of the patient and follow-up of the patient. This aspect of a dialysis patient's care lies solely in the vascular surgeon's lap but can impede a facility's ability to achieve set standards/guidelines which in many circumstances may negatively affect reimbursement for the facility.

V. CARE AT HOME

Dialysis of ESRD Patients in Nursing Facilities and Skilled Nursing Facilities

Home dialysis should NOT be performed in NF's or SNF's. Accommodations should be made for entities wishing to establish an ESRD facility on the campus of an NF or SNF in terms of space allocations for secondary services such as dietary and social services to maintain the specialized care recognized numerous times within the body of this document and to accent all the positive benefits that residents of NF's or SNF's receive in this circumstance without placing an onerous financial burden on the ESRD facility. In the same manner, as evidenced by your own statements - "given the relative acuity of nursing home patients...the dialysis care of a patient who requires nursing home services may be more complex than the dialysis care of an independent home dialysis patient, and given their frailty, these patients may be more vulnerable..." - the modifiers for reimbursement should be re-addressed mimicking those modifiers assigned to the pediatric ESRD population. The care of NF and SNF patients requires a higher degree of knowledge and skill (translated: R.N. vs. L.P.N./P.C.T.) and this cannot be achieved with a neutral reimbursement approach.

VI. LABORATORY SERVICES

HMO's that choose to participate in the ESRD program must be willing to refer requests for ESRD required testing mandated by these regulations to laboratories that are equipped to perform such testing. Many HMO laboratories are not equipped to perform such testing and the HMO's usually will not pay for "Out of Network" services (Translation: the HMO's should pay for the services of the laboratory used by the dialysis facility which is being paid for dialyzing that HMO patient).

VII. PERSONNEL QUALIFICATIONS

1. Nursing Services.

"As the demographics of the dialysis population continues to change, producing a more elderly patient population with more co-morbid conditions, direct patient care needs and the skills needed to meet those needs will continue to increase."

By your own words, you have indicated the need for more Registered Professional Nurses to be present in the dialysis facility. Then why is the standard for a charge nurse being LOWERED in the proposed changes. Despite the fact that many L.P.N.'s have the knowledge or experience to make sound clinical judgments an L.P.N. is not expected to do so without the supervision of an R.N. By definition in the Nurse Practice Acts of individual states, it is the R.N., by licensure, who is to be

responsible for the identification of patient problems and to plan and direct the care delivered to the patient.

And again, to meet the care needs of our aging ESRD population, the reimbursement modifiers for the population of 45+ years need to be increased. It is this age group, more so than the 18-44 year olds, who are beginning to exhibit the co-morbid conditions that have been identified by all. And yet there is that neutral reimbursement factor again.

Do NOT lower the standard of care to meet the lowered reimbursement modifier; but rather raise the level of the reimbursement modifier to meet the standard of care we all wish to achieve for those in our care.

2. Other Personnel Issues.

Routine Assessment of Patients' Medications.

Will there be a reimbursement code number for this so that the service can be billed for separately or will the facility have to pay for this service out of our already reduced reimbursement for the patient? This should NOT be a requirement.

Submitter : Diane Carlson **Date:** 05/05/2005

Organization : Renal Network of the Upper Midwest, Inc.

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-3818-P-242-Attach-1.DOC

Attachment #242

ESRD Network 11 Comments
Conditions of Coverage
May 5, 2005

Section #	Title	Comments
§494.10	Definitions	Recommend the development of separate definitions for home hemodialysis and peritoneal dialysis. All proposed rules should specifically address either home hemodialysis patients or home peritoneal dialysis. Peritoneal dialysis patients receiving dialysis in an extended care facility or skilled nursing facility should be considered to be home peritoneal dialysis patients for training and oversight.
§494.10(c)(1)(i)	Definitions	Recommend that home visits only be required for home hemodialysis patients. Home peritoneal dialysis patients need a home visit only when indicated for medical or environmental reasons.
§494.30(c)(2)	Infection Control	Recommend the reinstitution of the *National Surveillance of Dialysis-Associated Diseases in the United States Survey* as a method of reporting important infection control issues.
§494.70(a)(5)	Patient Rights	Support the inclusion of discussion regarding end of life and advance directives as a patient right. Use of the RPA Guidelines as referenced in the preamble would provide the basis that facilities need to implement this portion of the standard.
§494.80(a)(5)	Patient assessment	Support the inclusion of renal bone disease indicators into the patient assessment. Would recommend also including bone disease specifically in §494.90 – Patient plan of care and in §494.110 – Quality assessment and performance improvement
§494.80(d)	Patient assessment	Support the definition of unstable. This will prevent arbitrary use of the

		term. For unstable patients, consider that monthly reassessment might only include those reasons for the unstable designation, e.g. reassessment of nutritional status only, or psychosocial assessment only.
§494.80(b)(1), (2)	Patient assessment	The initial assessment and plan should be completed within a reasonable time frame for the usual processes to proceed. It is reasonable to expect that the assessment be completed within the first 30 days after a patient begins treatment at a given facility. The follow-up assessment should include input from the entire team. A complete reassessment may not be needed at 3 months, rather only an update of previously identified issues.
§494.90(a)(2)	Patient plan of care	As discussed in preamble, there is evidence that nutritional status is linked to outcomes. There are many factors outside of nutritional intake that affect serum albumin concentration, including infection, inflammation, and chronic disease. Recommend that if the target albumin concentration is not met, surrogate markers consisting of adequate dialysis (Kt/V $\geq$ 1.2) and NPCR of $\geq$1.0 should be considered a comparative outcome.
§494.90(a)(3)	Patient plan of care	Recommend that for purposes of treatment of anemia, that treatment should be based on hemoglobin only. Hemoglobin is a direct measurement of the level of anemia and is not affected by volume status.
§494.90(b)(4)(c)	Patient plan of care	Agree that referral criteria developed by the transplant center needs to be followed. Using established criteria, the treating nephrologist and interdisciplinary team should be able to accurately assess suitability for transplant. In situations where a suitable candidate is identified through the evaluation process, documentation

		of a discussion with the treating physician and patient should be required. In situations where transplant is suggested and declined, the issue should be revisited annually and discussion documented.
§494.90	Patient plan of care	Recommend deleting specific numeric ranges for quality indicators (e.g. hemoglobin ≥ 11) and instead refer to K/DOQI guidelines. Specific ranges may change over time that would make the regulations outdated.
§494.90(a)(4)	Patient plan of care	The statement that vascular access must be monitored to prevent access failure is vague. Recommend referencing K/DOQI Vascular Access guideline # 10, 11, and 12 for specific recommendations regarding access monitoring.
§494.100(2)	Care at home	Recommend that regulations be written to apply specifically to hemodialysis patients and not peritoneal dialysis patients, or alternatively separate requirements for peritoneal dialysis patients. The regulations as written impose an undue burden of care for peritoneal dialysis patients. Caregiver ratios should be at the discretion of the ESRD facility providing support, based on physical characteristics of the dialysis environment and patient acuity. Qualifications of skilled nursing dialysis staff should be identical to in-center dialysis staff.
§494.110(a)(2)(iv)	QAPI (Quality assessment and performance improvement)	Support the inclusion of developing a system to monitor and track vascular access. Recommend addition of language to support a system to encourage the increase of AV fistula placement and use. This is consistent with the CMS emphasis on AV fistulas as part of the Fistula First Breakthrough initiative.
§494.140	Personnel qualification	Recommend the addition of advance practice nurse as physician extender.

		Must be Master's level prepared with adequate experience in nephrology and/or renal replacement therapy.
§494.140(b)(3)(i)	Personnel qualification	Disagree with the proposed regulation allowing LPN/LVN to function as charge nurse. Most states define the role of the LPN/LVN as practicing under the supervision of a registered nurse. No state allows an LPN to supervise an RN.
§494.150	Responsibilities of Medical Director	Support that the facility's attending nephrologists should be subject to peer review under the direction of the medical director and subject to discipline if, after due process, there are continued quality problems. The specifics of this process should be developed in conjunction with the RPA and other national societies.
§494.160	ESRD Network	The ESRD Networks provide oversight for both dialysis facilities and transplant centers. Recommend that this condition be expanded to include both dialysis facilities and transplant centers.
§494.180(b)(1)	Governance	Support that staffing ratio decisions should be left to the discretion of the facility. Although in theory acuity based systems are a good idea, the lack of accepted standards or a definition of appropriate staffing leaves the interpretation of appropriate staffing to reviewers and will not be uniform.
494.180(f)	Governance	Support the standard (f)(4) for involuntary discharge of patients only when reassessment of the patient has determined that the "patient's behavior is disruptive and abusive to the extent that the delivery of care to the patient or the ability of the facility to operate effectively is seriously impaired." Also support the use of the interdisciplinary team, including the medical director, to assure that interventions have occurred and are documented, and

		that efforts have been made to attempt to place the patient. Support the notification of the State Survey Agency and the ESRD Network.
494.180 (h)(1)	Governance	Support the continued collection of clinically significant data at a facility and patient level with aggregate reporting on a national level as an important part of the quality improvement process. The data collections include the CPM data collection project and the proposed Core Data Set collection.
§494.180(b)(2)	Governance	Strongly support the requirement that a registered nurse must be present in the facility during the dialysis procedures.
494.180(g)(3)	Governance	Support including the requirement of a back up hospital to provide services and emergency dialysis for a facility's patients.

Submitter : Mrs. Mary R Perrecone **Date:** 05/05/2005

Organization : Albany Medical Center and Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-3818-P-243-Attach-1.DOC

Submitted by: Albany Medical Center ESRD Committee

RE: File Code CMS-3818-P

Attachment #243
III. Provisions of Part 494 Subpart A (General Provisions)
Basis And Scope (proposed 494.1)
The definition of "home" should be limited to "home dialysis" and not include the institutional settings of NFs and SNFs. The definition has been recognized as the assistance of a family member/caregiver, especially in a chronic pediatric dialysis unit. The term home should be limited to this since licensed personnel perform these functions in the NFs and SNFs. Thus, these institutional settings are held to a higher standard including annual competency training and other regulatory bodies to ensure proper training of the staff including infection control standards different than that of a residential "home."

V. Proposed Part 494 Subpart C (Patient Care)

Patient Rights (proposed 494.7)
Some consideration needs to be given to the process for holding an in-center dialysis facility accountable for the disposition of the disruptive or challenging patient when contemplating discharge from that in-center dialysis facility.

Care at Home (proposed 494.100)
We support the 30-day timeframe of receiving report from the supplier, but have some concerns regarding the compliance on the part of the 3rd party (vendor).

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

Organization :

Category : **State Government**

Issue Areas/Comments

GENERAL

GENERAL

494.30 Infection Control

The elevation of infection control to the level of a condition of coverage can only be described as a positive proposal for the health and safety of dialysis patients as well as others. However, the proposal "the facilities must designate a registered nurse as the infection control or safety office" but does not stipulate requirements of the registered nurse to have any training, experience or certification in infection control.

494.90(b)(4) Plan of Care

The proposal specifies that the facility must ensure that 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. What would one expect to see as documentation of "communication" from the physician's office?

Additionally, physicians should be required to see their in-center patients periodically while those patients are being dialyzed in the dialysis facility. It would foster the physician as part of the interdisciplinary team member.

404.100 Care at Home

1. In reviewing the proposals for care at home, the issue of the physician oversight. Would the patient?s physician be required as with the in-center patient's physician to see the home dialysis at least monthly with the same requirement of documentation/communication?

2. Delineation of responsibility (home hemodialysis services provided in a NF or SNF)

a. Nursing Coverage: An RN should be on the premises of the NF or SNF when dialysis services are provided. Additionally, that RN should be provided by the ESRD facility.

b. Caregiver/patient ratios: The in-home ratio of patient/caregiver would be 1:1. A patient residing in a NF or SNF could potentially be more compromised requiring more direct oversight. The issue of multiple patients on different floors/wings of the facility could potentially create a health and safety issue for those patients. Therefore a minimum ratio of onsite patient/staff ratio should be a requirement to ensure the health and safety of the patients receiving home hemodialysis within a SNF or NF.

Submitter : **Mr. Larry Reis** **Date: 05/05/2005**

Organization : **PharMerica**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-3818-P-245-Attach-1.DOC

Attachment #245
April 27, 2005

Larry Reis, Regional Director of Clinical Services
PharMerica
111 East Merced Street
Fowler, California 93625
Email: lxr9995@pharmerica.com
Phone: 559-289-8906

Center for Medicare and Medicaid Services
Baltimore, MD

RE: CMS-3818-P
Comments on Proposed Rule Conditions for Coverage End Stage Renal Disease Facilities

PharMerica is pleased to have the opportunity to respond to the proposed changes to the Conditions for Coverage End Stage Renal Disease Facilities. These comments have been developed by an interdisciplinary team at PharMerica consisting of consultant pharmacists, clinical department pharmacists, and operations executives. For your reference, PharMerica is one of the largest providers of pharmacy services to long term care facilities in the United States, and a wholly owned subsidiary of AmerisourceBergen Corporation. Information on our company may be obtained on the internet at pharmerica.com.

Our comment will focus on page 6224 of the Federal Register, February 4, 2005, section 6, titled "other personnel issues". This refers to 405.2136 (f) (l) (vi) regarding patient care policies for pharmaceutical services. The initial comments in this section relate how there is currently no requirement for a pharmacist to participate in the interdisciplinary team.

The risks of medication related problems in dialysis patients are clearly stated in this document, including the common multiple medication utilization, and the complex pathophysiology of the dialysis patient. Appropriate dosing, including timing of dose in relation to dialysis, as well as the necessity for dose reductions in renally cleared products are examples of areas where a pharmacist's evaluation can be of value. The multiple symptoms exhibited often generate Polypharmacy, and caution must be used to assure that medication related side effects are not being treated with additional therapy. Specific therapy often required for ESRD patients, such as epoiten, while vital for improved quality of life, and reduced morbidity and mortality, if not properly monitored for effect and end point, can in fact cause fatal adverse effects.

The new patient assessment condition 494.80(a) (3) includes the need for a laboratory profile and comprehensive medication history. This is an excellent beginning, but proper use of a pharmacist to evaluate and assist in managing the regimen is critical for positive

outcomes, and this is not included in the current language. Having the data will be meaningless unless appropriate health professionals, including the pharmacist, properly evaluate and act to create positive outcomes and reduce medication related problems.

It is our recommendation that a pharmacist review each patient's medication regimen and laboratory profile at least monthly. With current technology, it is not necessary for this review to be done on-site at the clinic. However, this should be done on a timely basis after admission to service. Changes in the medication regimen are often required after laboratory assessment, so a mechanism should be designated to make this information available for the pharmacist to review. Specific documentation of medication regimen review should be provided not less than monthly, with comments having a requirement to be acted upon. This doesn't mean there will always be agreement with the pharmacist recommendation, but that the comments will be clinically assessed and appropriately acted upon.

In addition, legend medications are often stored and administered in the clinics, so provisions should be included for on-site inspection, not less than quarterly. This would mandate at least an on-site inspection of such storage areas, and procedural processes at least quarterly.

In addition, the pharmacist should be a member of an interdisciplinary quality team that would meet at least quarterly to review policies, procedures, and protocols. Language could easily be pulled from current Federal Regulations addressing the pharmacist involvement in long term care facilities, and adapting to meet the above criteria.

We strongly feel that mandated involvement of the pharmacist will result in fewer medication related problems, and increased positive outcomes, and urge you to consider inclusion of the pharmacist in your regulations. Thank you.

Sincerely,

Larry R. Reis, Regional Director of Clinical Services
PharMerica

Submitter : Mrs. Koby Catellier **Date:** 05/05/2005

Organization : DaVita Denison Dialysis Center

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-246-Attach-1.DOC

Attachment 296

To Whom it May Concern,
I am a Social Worker at the DaVita Denison Dialysis Center. Below are the conditions for Coverage comments and recommendations based on the CNSW's response that I fully support and urge you to strongly consider. These are important issues not to be taken lightly. Please carefully and respectfully deliberate these changes and additions.
Sincerely,
Kobv Catellier. LMSW

LOCATION OF COC	PROPOSED DIALYSIS COC that are identified in this document can be found at: http://a257.g.akamaitech.net/7/257/2422/09feb20050800/edocket.access.gpo.gov/2005/pdf/05-1622.pdf
494.70 Condition Patients' Rights (a) Standard: Patients' rights	***Comment:*** CNSW supports the language of a5 ***Rationale:*** Advance directives establish in writing an individual's preference with respect to the degree of medical care and treatment desired or who should make treatment decisions if the individual should become incapacitated and lose the ability to make or communicate medical decisions. ***Add***: (new 17) "Have access to a qualified social worker and dietitian as needed" ***Rationale:*** Social workers and dietitians often have large caseloads, cover multiple clinics and/or work part-time, and patients often do not know how to contact them when needed. ***References:*** Bogatz, Colasanto, Sweeney, 2005; Forum of ESRD Networks, 2003; Merighi & Ehlebracht, 2004a ***Add***: (new 18) "Be informed that full- or part-time employment and/or schooling is possible on dialysis" ***Rationale:*** New patients do not know what to expect from dialysis and may be told that they must go on disability, when paid employment (with insurance) or schooling may be possible for them, particularly if they have access to evening shifts, transplant or home dialysis therapies. The purpose of dialysis is to permit the highest possible level of functioning despite kidney failure, thus this element of rehabilitation is crucial. ***References:*** Curtin et al,1996; Rasgon et al, 1993, 1996 ***Add***: (new 19) "Have a work-friendly modality (PD or home hemodialysis) or schedule that accommodates work or school" ***Rationale:*** Same as above for new 18. ***References:*** Same as above for new 18, plus:Mayo 1999 ***Add***: (new 20) "Receive referral for physical or occupational therapy, and/or vocational rehabilitation as needed" ***Rationale:*** These interventions have been shown to improve patient rehabilitation outcomes. ***References:*** Beder, 1999; Dobrof et al., 2001; Witten, Howell & Latos, 1999.

	Add: (new 21) "Attend care planning meetings with or without representation." ***Rationale***: Promoting patient participation in care requires that patients have the right to attend their own care planning meetings. ***Add***: (new 22) "Request an interdisciplinary conference with the care team, medical director and/or nephrologists." ***Rationale***: Patients don't realize that they can convene a care conference, and this is one way to obtain feedback from the team outside of the normal care planning meeting, which might only be done once/year. ***Add***: (new 24) "Be informed that self-cannulation is possible and be offered training to self cannulate." ***Rationale***: Having a single, consistent cannulator can help preserve vascular accesses and reduce hospitalizations. Since the patient is always present for the hemodialysis treatment, he or she should be encouraged whenever possible to become his/her own cannulator. Clinics should not be allowed to have a policy denying a willing patient the right to learn to self-cannulate. ***Add***: (new 25) "Be informed of topical analgesics for needle pain and how to obtain them" ***Rationale***: Needle fear and needle pain are largely unaddressed issues in hemodialysis, despite the large (14-15 gauge) needles that must be used at each treatment. Patients should be able to undergo a painless treatment, and low-cost, over-the-counter, 4% lidocaine preparations are available that will not harm the access and will provide pain relief. Patients should be told that these products exist and where to obtain them. ***Reference:*** McLaughlin et al., 2003 ***Add***: (new 26) "Receive counseling from a qualified social worker to address concerns related to the patient's adjustment to illness, including changes to life-style and relationships because of his illness, developmental issues affected by his illness, and any behavior that negatively affects his health or standing in the facility." ***Rationale***: Patients are faced with numerous adjustment issues due to ESRD and its treatment regimes. Master's level social workers are trained to intervene within areas of need that are essential for optimal patient functioning and adjustment ***References:*** McKinley & Callahan, 1998; Vourlekis & Rivera-Mizzoni, 1997

494.80 Condition Patient assessment (a) Standard: Assessment criteria.	***Change***: The language of "social worker" in the first sentence to "qualified social worker" ***Rationale***: This will clarify any ambiguity of the social work role. ***Add***: (a1) "...and functioning and well-being using the SF-36 or other standardized survey that permits reporting of or conversion to a physical component summary (PCS) score and mental component summary (MCS) score and all domains of functioning and well-being measured by that survey. If the MCS or mental health domain score is low, assess for major depression using the PHQ-2 or another validated depression survey or referring the patient to further mental health evaluation." ***Rationale***: The preamble to the *Conditions for Coverage* discussed the importance of measuring functioning and well-being—but stated that there was "no consensus" about which measure to use. In fact, the literature clearly supports the value of the PCS and MCS scores to independently predict morbidity and mortality among tens of thousands of ESRD patients—and these scores can be obtained from any of the tools currently in use to measure functioning and well-being. The composite scores (PCS and MCS) have been proven to be as predictive of hospitalization and death as serum albumin or Kt/V. Scores can be improved through qualified social work interventions. ***References;*** DeOreo, 1997; Kalantar-Zadeh, Kopple, Block, Humphreys, 2001; Knight et al. 2003; Kroenke, Spitzer & Williams, 2003; Lowrie, Curtin, LePain & Schatell, 2003; Mapes et al., 2004 ***Comment:*** CNSW supports the language of a2, a3, a4, a5, a6 ***Change***: (a7) to "Evaluation of psychosocial needs (such as but not limited to: coping with chronic illness, anxiety, mood changes, depression, social isolation, bereavement, concern about mortality & morbidity, psycho-organic disorders, cognitive losses, somatic symptoms, pain, anxiety about pain, decreased physical strength, body image issues, drastic lifestyle changes and numerous losses of [income, financial security, health, libido, independence, mobility, schedule flexibility, sleep, appetite, freedom with diet and fluid], social role disturbance [familial, social, vocational], dependency issues, diminished quality of life, relationship changes; psychosocial barriers to optimal nutritional status, mineral metabolism status, dialysis access, transplantation referral, participation in self care, activity level, rehabilitation status, economic pressures, insurance and prescription issues, employment and rehabilitation barriers)." ***Rationale***: Much like the elaboration of a1, a4, a8, a9, elaborating what "psychosocial issues" entails will ensure national coherence of the exact psychosocial issues that must be assessed for each patient. There is clear literature that identifies these psychosocial issues throughout this response.

	Comment: CNSW supports the language of a8 ***Add***: (a9)(new i) "The facility must include in its evaluation a report of self-care activities the patient performs. If the patient does not participate in care, the basis for nonparticipation must be documented in the medical record (i.e., cognitive impairment, refusal, etc.)." ***Rationale***: Life Options research has found that patients on dialysis 15 years or longer who participated actively in their own care did better; follow-up research with a random sample of 372 in-center hemodialysis patients found participation in self-care is correlated with higher functioning and well-being, which, in turn, predicts reduced hospitalization and mortality. ***References:*** Curtin, Bultman, Schatell & Chewning, 2004; Curtin & Mapes, 2001 ***Add***: (9)(new ii) "If the patient is not referred for home dialysis, the basis for non-referral must be documented in the medical record. Lack of availability of home dialysis in the facility is not a legitimate basis for non-referral." ***Rationale:*** Requiring that the basis for non-referral for home dialysis be documented will help to ensure that patients have access to these therapies and will provide needed data for QAPI purposes. ***Comment:*** CNSW supports the language of a10, a11, a12, a13
494.80 Condition Patient assessment (b) Standard. Frequency of assessment for new patients	***Change***: (b1) to "An initial comprehensive assessment and patient care plan must be conducted within 30 calendar days after the first dialysis treatment." ***Rationale***: We recommend combining an initial team assessment and care plan as they work in concert: a care plan should address areas for intervention as identified in the assessment. Permitting 30 days for assessment and development of a care plan allows for full team participation and adequate assessment of patient needs. ***Comment:*** CNSW supports the language of b2
494.80 Condition Patient assessment (d) Standard: Patient reassessment	***Change***: (d2iii) to "significant change in psychosocial needs as identified in 494.80 a7." ***Rationale***: Referring back to the specific psychosocial issues recommended to be added to 494.80 a7 will eliminate any ambiguity of needs to reassess

	Add: (v) "Physical debilitation per patient report, staff observation, or reduced physical component summary (PCS) score on a validated measure of functioning and well-being." ***Rationale:*** Low PCS scores predict higher morbidity and mortality in research among ESRD patients. ***References:*** DeOreo, 1997; Kalantar-Zadeh, Kopple, Block, Humphreys, 2001; Knight et al. 2003; Kroenke, Spitzer & Williams, 2003; Lowrie, Curtin, LePain & Schatell, 2003; Mapes et al., 2004 ***Add***: (new vi) "Diminished emotional well-being per patient report, staff observation, or reduced mental component summary (MCS) score on a validated measure of functioning and well-being." ***Rationale:*** Low MCS scores predict higher morbidity and mortality in research among ESRD patients. Low MCS scores are also linked to depression and skipping dialysis treatments. ***References:*** DeOreo, 1997; Kalantar-Zadeh, Kopple, Block, Humphreys, 2001; Knight et al. 2003; Kroenke, Spitzer & Williams, 2003; Lowrie, Curtin, LePain & Schatell, 2003; Mapes et al., 2004 ***Add***: (new vii) "Depression per patient report, staff observation or validated depression screening survey" ***Rationale:*** Multiple studies report a high prevalence of untreated depression in dialysis patients; depression is an independent predictor of death. ***References;*** Andreucci et al., 2004.; Kimmel, 1993; Kimmel, 1998; Kutner et al., 2000.; Wuerth, Finklestein & Finklestein, 2005 ***Add***: (new viii) "Loss of or threatened loss of employment per patient report" ***Rationale***: Poor physical and mental health functioning have been linked to increased hospitalizations and death. Loss of employment is linked to depression, social isolation, financial difficulties, and loss of employer group health plan coverage. Identifying low functioning patients early and targeting interventions to improve their functioning should improve their physical and mental functioning and employment outcomes. ***References;*** Blake, Codd, Cassidy & O'Meara, 2000; Lowrie, Curtin, LePain & Schatell, 2003; Mapes et al., 2004; Witten, Schatell & Becker, 2004
494.90 Condition Patient plan of care. (a) Standard: Development of patient plan of care.	***Add***: (a) the *patient* to those developing the plan and include: "If the patient or his or her representative does not participate in care planning, the basis for nonparticipation must be noted in the patient's medical record, the patient or his or her representative must initial the reason provided, and sign the care plan." ***Rationale***: The patient must be explicitly listed as part of the care planning process

	Add: (new 3) "*Psychosocial status.* The interdisciplinary team must provide the necessary care and services to achieve and sustain an effective psychosocial status." ***Rationale & References***: Eighty-nine percent of ESRD patients report experiencing significant lifestyle changes from the disease (Kaitelidou, et al., 2005). The chronicity of end stage renal disease and the intrusiveness of its required treatment provide renal patients with multiple disease-related and treatment-related psychosocial stressors that affect their everyday lives (Devins et al., 1990). Researchers including Auslander, Dobrof & Epstein (2001), Burrows-Hudson (1995), and Kimmel et al. (1998) have found that psychosocial issues negatively impact health outcomes of patients and diminish patient quality of life. Therefore, "psychosocial status" must be considered as equally important as other aspects of the care plan. ***Add***: (new 6) Home dialysis status. All patients must be informed of *all* home dialysis options, including CAPD, CCPD, conventional home hemodialysis, daily home hemodialysis, and nocturnal home hemodialysis, and be evaluated as a home dialysis candidate. When the patient is a home dialysis candidate, the interdisciplinary team must develop plans for pursuing home dialysis. The patient's plan of care must include documentation of the (i) Plan for home dialysis, if the patient accepts referral for home dialysis; (ii) Patient's decision, if the patient is a home dialysis candidate but declines home dialysis; or (iii) Reason(s) for the patient's non-referral as a home dialysis candidate as documented in accordance with § 494.80(a)(9)(ii) of this part. ***Rationale***: Home therapies allow greater flexibility, patient control, fewer dietary and fluid restrictions, need for fewer medications, potential for improved dialysis adequacy, and improved likelihood of employment. CMS has stated encouragement of home dialysis as a goal. Every patient must be informed of home dialysis options, evaluated for candidacy for home dialysis, and, if not a candidate, the reason(s) why not should be reported. This allows quality assessment and improvement activities to be undertaken in the area of home dialysis.
494.90 Condition Patient plan of care. (b) Standard: Implementation of the	***Add to 3b***: "If the expected outcome is not achieved, the interdisciplinary team must describe barriers encountered, adjust the patient's plan of care to either achieve the specified goals or establish new goals, and explain why new goals are needed."

patient care plan.	***Rationale***: When goals are not met, barriers must be identified and goals re-examined for feasibility of success. Sometimes barriers can be eliminated so original goals can be met; other times, new goals must be set that are more reasonable.
494.90 Condition Patient plan of care. (c) Standard: Transplantation referral tracking	***Comment:*** CNSW supports the language of (c) and recommends its inclusion in the final conditions. In addition, we would also like to see language which would outline the responsibilities of transplant centers and their responsibilities for following up and informing dialysis units of the transplant status of patients referred for transplant.
494.90 Condition Patient plan of care. (d) Standard: Patient education and training.	***Add to d***: "The patient care plan must include, as applicable, education and training for patients and family members or caregivers or both, and must document training the following areas in the patient's medical record: (i) The nature and management of ESRD (ii) The full range of techniques associated with treatment modality selected, including effective use of dialysis supplies and equipment in achieving and delivering the physician's prescription of Kt/V or URR, and effective erythropoietin administration (if prescribed) to achieve and maintain a hemoglobin level of at least 11 gm/dL (iii) How to follow the renal diet, fluid restrictions, and medication regimen (iv) How to read, understand, and use lab tests to track clinical status (v) How to be an active partner in care (vi) How to achieve and maintain physical, vocational, emotional and social well-being (vii) How to detect, report, and manage symptoms and potential dialysis complications (viii) What resources are available in the facility and community and how to find and use them (ix) How to self-monitor health status and record and report health status information (x) How to handle medical and non-medical emergencies (xi) How to reduce the likelihood of infections (x) How to properly dispose of medical waste in the dialysis facility and at home **Rationale**: Life Options Research has demonstrated among 372 randomly-selected in-center hemodialysis patients that higher levels of dialysis knowledge are correlated with higher mental component summary (MCS) scores on the SF-12, which are, in turn, predictive of longer survival and lower hospitalization. The specific aspects of education delineated above are what Life Options believes to be core skills that ESRD patients must gain in order to become active partners in care, producing their own best health outcomes and monitoring the safety and quality of the care that is delivered to them. ***References:*** Curtin, et al. 2002; Curtin, Klag, Bultman & Schatell, 2002; Curtin, Sitter, Schatell &

	Chewning, 2004; Johnstone, et al., 2004
494.100 Condition Care at home.	***Comment:*** CNSW agrees that services to home patients should be at least equivalent to those provided to in-center patients. **Rationale**: Home dialysis patients are patients of the ESRD facility and are entitled to the same rights, services, and efforts to achieve expected outcomes as any other patient of the facility. ***Add***: (new 3iv) "Implementation of a social work care plan" ***Rationale & References***: Eighty-nine percent of ESRD patients report experiencing significant lifestyle changes from the disease (Kaitelidou, et al., 2005). The chronicity of end stage renal disease and the intrusiveness of treatment provide renal patients with multiple disease-related and treatment-related psychosocial stressors that affect their everyday lives (Devins et al., 1990). Researchers including Auslander, Dobrof & Epstein (2001), Burrows-Hudson (1995), and Kimmel et al. (1998) have found that psychosocial issues negatively impact health outcomes of patients and diminish patient quality of life. Therefore, a social work care plan is as equally important as other aspects of training for home patients. It is important to specify a "social work care plan" to ensure that it is conducted by a qualified social worker as identified below.
494.100 Condition Care at home. (c) Standard: Support services.	***Add to 1i***: "Periodic monitoring of the patient's home adaptation, including at minimum an annual visit to the patient's home by all facility personnel if geographically feasible (RN, social worker, dietitian, and machine technician) in accordance with the patient's plan of care." ***Rationale***: Members of the interdisciplinary team can offer better care to patients after seeing the patient in his/her home environment where they can observe barriers and supports first-hand. The members should be specified to ensure equal visitation of the team members across all dialysis units. The language of this part of the proposed conditions is vague and subject to varying interpretation (i.e. exactly who are the "facility personnel" who will visit the patient's home?) ***Add to 1iv***: "Patient consultation with all members of the interdisciplinary team, as needed." ***Rationale***: The language of this part of the proposed conditions is vague and subject to varying interpretation
NEWCONDITION Staff assisted skilled nursing home dialysis	***Add:*** A new condition for dialysis provided in a nursing home setting (that is not incorporated into the "home" condition 494.100) ***Rationale***: Nursing home dialysis is typically provided by staff. Home dialysis (PD or home hemodialysis) is typically performed by a trained patient and/or a helper. Making these treatments equivalent obscures

	important differences between them, including the staff training/supervisory needs of nursing home dialysis patients. To include care in a nursing facility/skilled nursing facility (NF/SNF) under "care at home" is inappropriate. There is a tremendous difference in what CMS must do to protect the health and safety of highly functioning, trained patients who do self-care at home (or have assistance from a trained helper at home) and patients who require personnel in an NF/SNF to perform dialysis because they are too debilitated to travel to a dialysis facility. ***Reference:***Tong & Nissenson, 2002 ***Add:*** Language to this proposed condition that would mandate " A Nursing facility/Skilled Nursing Facility providing full-care dialysis to residents with ESRD, must be certified as a dialysis facility and comply with all sections of this rule, including personnel qualifications." ***Rationale***: Patients receiving dialysis in NF or SNF should not be deprived of essential services that they would normally receive in an outpatient dialysis facility, including consultation with a qualified nephrology social worker. While NFs and SNFs may employ social workers, these social workers may not hold a master's degree and will not have the specialized knowledge of the complex social and emotional factors affecting the dialysis patient. To ensure that the health and safety of NF or SNF hemodialysis patients is protected, any proposed requirements should specifically incorporate Secs 494.70, 494.80 and 494.90 of the proposed conditions of coverage.
§**494.110 Condition** Quality assessment and performance improvement. (a) Standard: Program scope.	***Add***: (1) "The program must include, but not be limited to, an ongoing program that achieves measurable improvement in physical, mental, and clinical health outcomes and reduction of medical errors by using indicators or performance measures associated with improved physical and mental health outcomes and with the identification and reduction of medical errors." ***Rationale:*** To ensure patient-centered care, patient functioning and well-being must be one of the quality indicators that is monitored and improved. ***Add***: (2)(new iii) "Psychosocial status." ***Rationale & References***: Eighty-nine percent of ESRD patients report experiencing significant lifestyle changes from the disease (Kaitelidou, et al., 2005). The chronicity of end stage renal disease and the intrusiveness of its required treatment provide renal patients with multiple disease-related and treatment-related psychosocial stressors that affect their everyday lives (Devins et al., 1990). Researchers including Auslander, Dobrof & Epstein (2001), Burrows-Hudson (1995), and Kimmel et al. (1998) have found that psychosocial issues negatively impact health outcomes of patients and diminish patient quality of life. Therefore, "psychosocial status" must be considered as equally important as other aspects of quality

	improvement. CNSW has many resources and tools, available through the National Kidney Foundation, that can be used to track social work quality. ***Add***: (2)(new ix) "Functioning and well-being as measured by physical component summary (PCS) and mental component summary (MCS) scores (or other equally valid measure of mental and physical functioning) and vocational status using the same categories as reported on the CMS 2728 form" ***Rationale:*** These scores provide a baseline and ongoing basis for QAPI activities to improve patient rehabilitation outcomes. ***Comment:*** CNSW agrees that dialysis providers must measure patient satisfaction and grievances. CNSW supports the use of a standardized survey (such as the one being currently developed by CMS) for measuring patients' experience and ratings of their care. Such a survey would provide information for consumer choice, reports that facilities can use for internal quality improvement and external benchmarking against other facilities, and finally, information that can be used for public reporting and monitoring purposes. The survey should be in the public domain and consist of a core set of questions that could be used in conjunction with existing surveys.
494.140 Condition Personnel qualifications	***Comment:*** CNSW recommends that this section be renamed "Personnel qualifications and responsibilities", with the addition of specified personnel responsibilities to each team member's qualifications. If it is decided that adding "personnel responsibilities" to this section is inappropriate, we would suggest the alteration of 494.150 to be renamed "Condition: Personnel Responsibilities" and include a discussion of the responsibilities of each team member (instead of just the medical director as is currently proposed). CNSW suggests possible responsibilities for social workers in the next section, where we comment on "494.140 Condition Personnel qualifications (d) Standard: Social worker." These suggestions can be used in a new "responsibilities" section. ***Rationale & References***: It is critically important to clearly delineate personnel responsibilities in some fashion in these new conditions of coverage to ensure that there is parity in the provision of services to beneficiaries in every dialysis unit in the country. It is just as important to outline each team member's responsibilities as it is the medical director's, as is currently proposed. This is especially important regarding qualified social work responsibilities. Currently, many master's level social workers are given responsibilities and tasks that are clerical in nature and which prevent the MSW from participating fully

	with the patient's interdisciplinary team so that optimal outcomes of care may be achieved. It is imperative that the conditions of coverage specify the responsibilities of a qualified social worker so that dialysis clinics do not assign social workers inappropriate tasks and responsibilities. Tasks that are clerical in nature or involve admissions, transportation, travel, billing, and determining insurance coverage prohibit nephrology social workers from performing the clinical tasks central to their mission (Callahan, Witten & Johnstone, 1997). Russo (2002) found among the nephrology social workers that he surveyed 53% were responsible for making transportation arrangements for patients, and 46% of the nephrology social workers in his survey were responsible for making dialysis transient arrangements (which involved copying and sending patient records to out-of-town units). Only 20% of his respondents were able to do patient education. In the Promoting Excellence in End-of-Life Care 2002 report, End-Stage Renal Disease Workgroup Recommendations to the Field, it was recommend that dialysis units discontinue using master's level social workers for clerical tasks to ensure that they will have sufficient time to provide clinical services to their patients and their families. Merighi and Ehlebracht (2004b; 2004c; 2005), in a survey of 809 randomly sampled dialysis social workers in the United States, found that: • 94% of social workers did clerical tasks, and that 87% of those respondents considered these tasks to be outside the scope of their social work training. • 61% of social workers were solely responsible for arranging patient transportation. • 57% of social workers were responsible for making travel arrangements for patients who were transient, which required 9% of their work time. • 26% of social workers were responsible for initial insurance verification. • 43% of social workers tracked Medicare coordination of benefit periods. • 44% of social workers were primarily responsible for completing patient admission paperwork. • 18% of social workers were involved in collecting fees from patients. (Respondents noted that this could significantly diminish trust and cause damage to the therapeutic relationship). • Respondents spent 38% of their time on insurance, billing and clerical tasks vs. 25% of their time spent assessing and counseling patients. • Only 34% of the social workers thought that they had enough time to sufficiently address patients' psychosocial needs. This evidence clearly demonstrates that without clear definition and monitoring of responsibilities assigned to the qualified social work (as is the current case), social workers are routinely assigned tasks that are inappropriate, preventing them from doing appropriate tasks. For all of these reasons, CNSW is strongly

	urging the addition of "personnel responsibilities" to the new conditions of coverage (either in this section, or the next section).
494.140 Condition Personnel qualifications (d) Standard: Social worker.	***Change the language of d to***: *Social worker.* The facility must have a qualified social worker who—(1) Has completed a course of study with specialization in clinical practice, and holds a masters degree from a graduate school of social work accredited by the Council on Social Work Education; (2) Meets the licensing requirements for social work practice in the State in which he or she is practicing; and (3) Is responsible for the following tasks: initial and continuous patient assessment and care planning including the social, psychological, cultural and environmental barriers to coping to ESRD and prescribed treatment; provide emotional support, encouragement and supportive counseling to patients and their families or support system; provide individual and group counseling to facilitate adjustment to and coping with ESRD, comorbidities and treatment regimes, including diagnosing and treating mood disorders such as anxiety, depression, and hostility; providing patient and family education; helping to overcome psychosocial barriers to transplantation and home dialysis; crisis intervention; providing education and help completing advance directives; promoting self-determination; assisting patients with achieving their rehabilitation goals (including: overcoming barriers ; providing patients with education and encouragement regarding rehabilitation; providing case management with local or state vocational rehabilitation agencies); providing staff in-service education regarding ESRD psychosocial issues; recommending topics and otherwise participating in the facility's quality assurance program; mediating conflicts between patients, families and staff; participating in interdisciplinary care planning and collaboration, and advocating on behalf of patients in the clinic and community-at-large. The qualified social worker will not be responsible for clerical tasks related to transportation, transient arrangements, insurance or billing, but will supervise the case aide who is responsible for these tasks. ***Rationale & References***: Clinical social work training is essential to offer counseling to patients for complex psychosocial issues related to ESRD and its treatment regimes. Changing the language of this definition will make the definition congruent to that of a qualified social worker that is recommended by CNSW for the transplant conditions of coverage. CNSW supports the elimination of the "grandfather" clause of the previous conditions of coverage, which exempted individuals hired prior to the effective date of the existing regulations (September 1, 1976) from the social work master's degree requirement. As discussed in the preamble for these conditions, we recognize the importance of the professional social worker, and we believe there is a need for the requirement that the social worker have a master's degree. We agree that since the extension of Medicare coverage to individuals with ESRD, the ESRD patient

	population has become increasingly more complex from both medical and psychosocial perspectives. In order to meet the many and varied psychosocial needs of this patient population, we agree that qualified master's degree social workers (MSW) trained to function autonomously are essential. We agree that these social workers must have knowledge of individual behavior, family dynamics, and the psychosocial impact of chronic illness and treatment on the patient and family. This is why we argue that a specialization in clinical practice must be maintained in the definition. Master's level social workers are trained to think critically, analyze problems, and intervene within areas of need that are essential for optimal patient functioning, and to help facilitate congruity between individuals and resources in the environment, demands and opportunities (Coulton, 1979; McKinley & Callahan, 1998; Morrow-Howell, 1992; Wallace, Goldberg, & Slaby, 1984). Social workers have an expertise of combining social context and utilizing community resource information along with knowledge of personality dynamics. The master of social work degree (MSW) requires two years of coursework and an additional 900 hours of supervised agency experience beyond what a baccalaureate of social work degree requires. An MSW curriculum is the only curriculum, which offers additional specialization in the biopsychosocialcultural, person-in-environment model of understanding human behavior. An undergraduate degree in social work or other mental health credentials (masters in counseling, sociology, psychology or doctorate in psychology, etc.) do not offer this specialized and comprehensive training in bio-psycho-social assessment and interaction between individual and the social system that is essential in dialysis programs. The National Association of Social Workers Standards of Classification considers the baccalaureate degree as a basic level of practice (Bonner & Greenspan, 1989; National Association of Social Workers, 1981). Under these same standards, the Masters of Social Work degree is considered a specialized level of professional practice and requires a demonstration of skill or competency in performance (Anderson, 1986). masters-prepared social workers are trained in conducting empirical evaluations of their own practice interventions (Council on Social Work Education). Empirically, the training of a masters-prepared social worker appears to be the best predictor of overall performance, particularly in the areas of psychological counseling, casework and case management (Booz & Hamilton, Inc., 1987; Dhooper, Royse & Wolfe, 1990). The additional 900 hours of supervised and specialized clinical training in an agency prepares the MSW to work autonomously in the dialysis setting, where supervision and peer support is not readily available. This additional training in the biopsychosocial model of understanding human behavior also enables the masters-prepared social worker to provide cost-effective interventions such as assessment, education, individual, family and group therapy and to independently monitor the outcomes of these interventions to ensure their effectiveness.

	The chronicity of end stage renal disease and the intrusiveness of required treatment provide renal patients with multiple psychosocial stressors including: cognitive losses, social isolation, bereavement, coping with chronic illness, concern about worsening health and death, depression, anxiety, hostility, psycho-organic disorders, somatic symptoms, lifestyle, economic pressures, insurance and prescription issues, employment and rehabilitation barriers, mood changes, body image issues, concerns about pain, numerous losses (income, financial security, health, libido, strength, independence, mobility, schedule flexibility, sleep, appetite, freedom with diet and fluid), social role disturbance (familial, social, vocational), dependency issues, and diminished quality of life (DeOreo, 1997; Gudes, 1995; Katon & Schulberg, 1997; Kimmel et al., 2000; Levenson, 1991; Rabin, 1983; Rosen, 1999; Vourlekis & Rivera-Mizzoni, 1997). The gravity of these psychosocial factors necessitates an assessment and interventions conducted by a qualified social worker as outlined above. It is clear that social work intervention can maximize patient outcomes: • Through patient education and other interventions, nephrology social workers are successful in improving patient's adherence to the ESRD treatment regime. Auslander and Buchs (2002), and Root (2005) have shown that social work counseling and education led to reduced fluid weight gains in patients. Johnstone and Halshaw (2003) found in their experimental study that social work education and encouragement were associated with a 47% improvement in fluid restriction adherence. • Beder and colleagues (2003) conducted an experimental research study to determine the effect of cognitive behavioral social work services. They found that patient education and counseling by nephrology social workers was significantly associated with increased medication compliance. This study also determined that such interventions improved patients' blood pressure. Sikon (2000) discovered that social work counseling can reduce patients' anxiety level. Several researchers have determined that nephrology social work counseling significantly improves ESRD patient quality of life (Chang, Winsett, Gaber & Hathaway, 2004; Frank, Auslander & Weissgarten, 2003; Johnstone, 2003). Nephrology social work interventions also tend to be valued by patients. Siegal, Witten, and Lundin's 1994 survey of ESRD patients found that 90% of respondents "believed that access to a nephrology social worker was important" (p.33) and that patients relied on nephrology social workers to assist them with coping, adjustment, and rehabilitation. Dialysis patients have ranked a "helpful social worker" as being more important to them than nephrologists or nurses (Rubin, et al., 1997). In a study by Holley, Barrington, Kohn and Hayes (1991), 70% of patients said that social workers gave the most useful information about

	treatment modalities compared to nurses and physicians. These researchers also found that patients thought that social workers were twice as helpful as nephrologists in helping them to choose between hemodialysis and peritoneal dialysis for treatment.
494.140 Condition Personnel qualifications	***Add***: (e) Standard: Case aide. Dialysis units that have more than 75 patients per full time social worker must employ a case aide who- As supervised by the unit social worker, performs clerical tasks involving admissions, transfers, billing, transportation arrangements, transient treatment paperwork and verifies insurance coverage. ***Rationale & References***: We agree with the preamble that dialysis patients need essential social services including transportation, transient arrangements and billing/insurance issues. We also firmly agree with the preamble that these tasks should not be handled by the qualified social worker (unless the social worker has fewer than 75 patients per full time equivalent social worker), as caseloads higher than this prevent the MSW from participating fully with the interdisciplinary team so that optimal outcomes of care may be achieved. It is imperative that the conditions of coverage identify a new team member who can provide social service assistance-the preamble recommends that these clerical tasks should be done by someone other than the MSW, but does not specify who that person is-adding this section (e) will eliminate any ambiguity surrounding this issue, and ensure adherence to this recommendation across all settings. Tasks that are clerical in nature or involve admissions, billing, and determining insurance coverage prevent nephrology social workers from performing the clinical tasks central to their mission (Callahan, Witten & Johnstone, 1997). Russo (2002) found that all of the nephrology social workers that he surveyed felt that transportation was not an appropriate task for them, yet 53% of respondents were responsible for making transportation arrangements for patients. Russo found that 46% of the nephrology social workers in his survey were responsible for making dialysis transient arrangements (which involved copying and sending patient records to out-of-town units), yet only 20% were able to do patient education. In the Promoting Excellence in End-of-Life Care's 2002 report, End-Stage Renal Disease Workgroup Recommendations to the Field, workgroup members recommended that dialysis units discontinue using master's level social workers for clerical tasks to ensure that they will have sufficient time to provide clinical services to their patients and their families. Merighi and Ehlebracht (2004b; 2004c; 2005), in a survey of 809 randomly sampled dialysis social workers in the United States, found that: • 94% of social workers did clerical tasks, and that 87% of those respondents considered these tasks to be outside the scope of their social work training. • 61% of social workers were solely responsible for arranging patient transportation.

	• 57% of social workers were responsible for making travel arrangements for patients who were transient, taking 9% of their time. • 26% of social workers were responsible for initial insurance verification. • 43% of social workers tracked Medicare coordination periods. • 44% of social workers were primarily responsible for completing admission packets. • 18% of social workers were involved in collecting fees from patients. Respondents noted that this could significantly diminish therapeutic relationships and decrease trust. • Respondents spent 38% of their time on insurance, billing and clerical tasks vs. 25% of their time spent counseling and assessing patients. • Only 34% of the social workers thought that they had enough time to sufficiently address patient psychosocial needs. This evidence clearly demonstrates that there needs to be another team member who can handle these clerical social service needs. This position would be cost-effective, as the person in this role can help patients obtain insurance coverage for dialysis that they normally would not have and increase facility's reimbursement. As discussed and referenced below in detail, CNSW recommends a ratio of 75 patients per full-time equivalent social worker. If a dialysis clinic has fewer patients per full-time equivalent social worker than less than 75:1, the social worker can address concrete social service needs of patients. However, patient ratios over 75 patients per full-time equivalent social worker require a case aide.
§**494.180 Condition** Governance. (b1) Standard. Adequate number of qualified and trained staff.	***Add***: (1i) No dialysis clinic should have more than 75 patients per one full time social worker. ***Rationale & References***: A specific social worker-patient ratio must be included in the conditions of coverage. Currently, there are no such national ratios and as a result social workers have caseloads as high as more than 300 patients per social worker in multiple, geographically separated, clinics. This is highly variable among different dialysis units-letting dialysis clinics establish their own ratios will leave ESRD care in the same situation as we have now with very high social work caseloads. For many years, CNSW has had an acuity-based social work-patient ratio (contact the National Kidney Foundation for the formula) which has been widely distributed to all dialysis units. This has largely been ignored by dialysis providers, who routinely have patient-to-social work ratios of 125-300. The new conditions of coverage must either identify an acuity-based social work staffing ratio model to be used in all units (we would recommend CNSW's staffing ratio), or set a national patient-social worker ratio. Leaving units to their own devices regarding ratios will not affect any change, as is evidenced by today's large caseloads and variability in such. CNSW has determined that 75:1 is the ideal ratio. If CMS refuses to include language

	about social work ratios, we strongly urge that the final conditions include language for "an acuity-based social work staffing plan developed by the dialysis clinic social worker" (rather than having nursing personnel who have limited understanding of social work training or role to determine social work staffing). Large nephrology social work caseloads have been linked to decreased patient satisfaction and poor patient rehabilitation outcomes (Callahan, Moncrief, Wittman & Maceda, 1998). It is also the case that social workers report that high caseloads prevent them from providing adequate clinical services in dialysis, most notably counseling (Merighi, & Ehlebracht, 2002, 2005). In Merighi and Ehlebracht's (2004a) survey of 809 randomly sampled dialysis social workers in the United States, they found that only 13% of full time dialysis social workers had caseloads of 75 or fewer, 40% had caseloads of 76-100 patients, and 47% had caseloads of more than 100 patients. In a recent study by Bogatz, Colasanto, and Sweeney (2005), nephrology social workers reported that large caseloads hindered their ability to provide clinical interventions. Social work respondents in this study reported caseloads as high as 170 patients and 72% of had a median caseload of 125 patients. The researchers found that 68% of social workers did not have enough time to do casework or counseling, tasks mandated by the current conditions of coverage, 62% did not have enough time to do patient education, and 36% said that they spent excessive time doing clerical, insurance, and billing tasks. One participant in their study stated: 'the combination of a more complex caseload and greater number of patients to cover make it impossible to adhere to the federal guidelines as written. I believe our patients are being denied access to quality social work services' (p.59). Patient-social work ratios are critical so that social workers can effectively intervene with patients and enhance their outcomes. It is clear that social work intervention can maximize patient outcomes (doing these requires reasonable ratios): • Through patient education and other interventions, nephrology social workers are successful in improving patient's adherence to the ESRD treatment regime. Auslander and Buchs (2002), and Root (2005) have shown that social work counseling and education led to reduced fluid weight gains in patients. Johnstone and Halshaw (2003) found in their experimental study that social work education and encouragement were associated with a 47% improvement in fluid restriction adherence. • Beder and colleagues (2003) conducted an experimental research study to determine the effect of cognitive behavioral social work services. They found that patient education and counseling by nephrology social workers was significantly associated with increased medication compliance. This study also determined that such interventions improved patients' blood pressure. Sikon (2000)

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

REFERENCES

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Submitter : **Ms. Marcia Sawyer Sawyer** **Date: 05/05/2005**

Organization : **Michigan Council of Nephrology Social Workers**

Category : **Social Worker**

Issue Areas/Comments

GENERAL

GENERAL

I am verifying previous comments have been properly submitted.

CMS-3818-P-247-Attach-1.DOC

CMS-3818-P-247-Attach-2.DOC

Attachment #247
Hon Mark B. McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-3818-P
Box 8012 Baltimore, MD 21244-8012

Dear Dr. McClellan:

I am writing to support comments submitted by the National Kidney Foundation, the Council of Nephrology Social Workers, and the Medical Education Institute, comments which reflect many years of professional experience and research on providing quality, cost effective care to kidney dialysis consumers.

The Proposed Rule, Medicare Program, Conditions for Coverage for End Stage Renal Disease Facilities, CMS-3818-P, published in the Federal Register on February 4, 2005, contains many progressive recommendations in the Preamble that do not appear on the actual Conditions for Coverage.

Recommendations for Social Services Subpart D-Administration 494.140 (g) Social Services and Personnel Qualifications for the Social Worker, refer to the Federal Government's intent to ensure qualified psychosocial assessment counseling, education, and rehabilitation services be provided to all consumers covered by these ESRD regulations. (Page 6222 of Preamble)

Standards of Practice for Nephrology Social Work, referenced in the attached CNSW document, recommends staffing levels of 1 full time MSW to 75 dialysis patients, in order to achieve the level of care and positive patient outcomes sought by CMS.

However, without any parameters for staffing ratios, the dialysis industry sets I staffing levels at a much higher rate. The result is that in practice, many dialysis centers and chains employ one MSW to 100, 120, or even 150 patients, sometimes spread over a large geographic area in several dialysis clinics.

Therefore, I urge practical consideration of minimal staffing ratio caps to provide for adequate coverage of psychosocial concerns beyond the concrete issues driven by corporate need (insurance, transportation, reimbursement).

Dialysis professionals, including social workers, can help people stay alive on dialysis. But under the present staffing standards controlled by the industry, we cannot help them thrive, or live full lives.

Thank you for your considerations of these comments.

Sincerely,

Marcia Sawyer, ACSW

Attachment #247
Hon Mark B. McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-3818-P
Box 8012 Baltimore, MD 21244-8012

Dear Dr. McClellan:

I am writing to support comments submitted by the National Kidney Foundation, the Council of Nephrology Social Workers, and the Medical Education Institute, comments which reflect many years of professional experience and research on providing quality, cost effective care to kidney dialysis consumers.

The Proposed Rule, Medicare Program, Conditions for Coverage for End Stage Renal Disease Facilities, CMS-3818-P, published in the Federal Register on February 4, 2005, contains many progressive recommendations in the Preamble that do not appear on the actual Conditions for Coverage.

Recommendations for Social Services Subpart D-Administration 494.140 (g) Social Services and Personnel Qualifications for the Social Worker, refer to the Federal Government's intent to ensure qualified psychosocial assessment counseling, education, and rehabilitation services be provided to all consumers covered by these ESRD regulations. (Page 6222 of Preamble)

Standards of Practice for Nephrology Social Work, referenced in the attached CNSW document, recommends staffing levels of 1 full time MSW to 75 dialysis patients, in order to achieve the level of care and positive patient outcomes sought by CMS.

However, without any parameters for staffing ratios, the dialysis industry sets I staffing levels at a much higher rate. The result is that in practice, many dialysis centers and chains employ one MSW to 100, 120, or even 150 patients, sometimes spread over a large geographic area in several dialysis clinics.

Therefore, I urge practical consideration of minimal staffing ratio caps to provide for adequate coverage of psychosocial concerns beyond the concrete issues driven by corporate need (insurance, transportation, reimbursement).

Dialysis professionals, including social workers, can help people stay alive on dialysis. But under the present staffing standards controlled by the industry, we cannot help them thrive, or live full lives.

Thank you for your considerations of these comments.

Sincerely,

Marcia Sawyer, ACSW

Submitter : Ms. Margaret Navitski **Date:** 05/05/2005

Organization : NJ Dept of Health

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-3818-P-248-Attach-1.DOC

Attachment #248
"Infection Control" 494.30

Should include requirements for compliance with the relevant sections of the HICPAC guidelines entitled "Hand Hygiene in Healthcare Settings" and the "Guideline for Preventing Intravascular Device-Related Infections.

Strongly agree with the requirement for a designated staff member who maintains current infection control information..... **Don't agree that it must be an R.N.**, although there should be some minimal education/degree requirements (i.e., microbiologists , M.T.'s, function and are certified as infection control practitioners in other facilities).

"Water Quality" 494.40

Should be a requirement to comply with **all of AAMI RD52**

Agree with the requirement for 2 carbon tanks in series, **but a maximum limit on usage –time, flow, volume or testing for Iodine number should be required.**

Reuse of Hemodialyzers 494.50

©1 – Should specify what reactions should be monitored, particularly pre and post temps.

Physical Environment 494.60

(b) – should specify space provisions for and documentation of equipment maintenance

Patient Care 494.70

Patient rights should include the right to decline dialyzer reuse and to receive single use treatment in the facility

Personnel Requirements 494.140

(e) Should pursue national certification system for patient care technicians

While in training, PCT's should be identified as trainees

Margaret Navitski
NJ Dept of Health & Senior Services

Submitter : Ms. Elizabeth Witten **Date:** 05/05/2005

Organization : Subgroup of Council of Nephrology Social Workers

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

Attached comments cover several issues.

CMS-3818-P-249-Attach-1.DOC

Attachment #249

	CMS-3818-P Social Workers' Comments from CNSW Business Meeting
494.140 Condition Personnel qualifications	***Comment:*** We, the undersigned, recommend that this section be renamed "Personnel qualifications and responsibilities", with the addition of specified personnel responsibilities to each team member's qualifications. If it is decided that adding "personnel responsibilities" to this section is inappropriate, we would suggest the alteration of 494.150 to be renamed "Condition: Personnel Responsibilities" and include a discussion of the responsibilities of each team member (instead of just the medical director as is currently proposed). We suggest possible responsibilities for social workers in the next section, where we comment on "494.140 Condition Personnel qualifications (d) Standard: Social worker." These suggestions can be used in a new "responsibilities" section. ***Rationale & References***: It is critically important to clearly delineate personnel responsibilities in some fashion in these new conditions of coverage to ensure that there is parity in the provision of services to beneficiaries in every dialysis unit in the country. It is just as important to outline each team member's responsibilities as it is the medical director's, as is currently proposed. This is especially important regarding qualified social work responsibilities. Currently, many master's level social workers are given responsibilities and tasks that are clerical in nature and which prevent the MSW from participating fully with the patient's interdisciplinary team so that optimal outcomes of care may be achieved. It is imperative that the conditions of coverage specify the responsibilities of a qualified social worker so that dialysis clinics do not assign social workers inappropriate tasks and responsibilities. Tasks that are clerical in nature or involve admissions, transportation, travel, billing, and determining insurance coverage prohibit nephrology social workers from performing the clinical tasks central to their mission (Callahan, Witten & Johnstone, 1997). Russo (2002) found among the nephrology social workers that he surveyed 53% Ire responsible for making transportation arrangements for patients, and 46% of the nephrology social workers in his survey Ire responsible for making dialysis transient arrangements (which involved copying and sending patient records to out-of-town units). Only 20% of his respondents Ire able to do patient education. In the Promoting Excellence in End-of-Life Care 2002 report, End-Stage Renal Disease Workgroup Recommendations to the Field, it was recommend that dialysis units discontinue using master's level social workers for clerical tasks to ensure that they will have sufficient time to provide clinical services to their patients and their families. Merighi and Ehlebracht (2004b; 2004c; 2005), in a survey of 809 randomly sampled dialysis social workers in the United States, found that: • 94% of social workers did clerical tasks, and that 87% of those respondents considered these tasks to be outside the scope of their social work training. • 61% of social workers Ire solely responsible for arranging patient transportation. • 57% of social workers Ire responsible for making travel arrangements for patients who Ire transient,

	which required 9% of their work time. • 26% of social workers Ire responsible for initial insurance verification. • 43% of social workers tracked Medicare coordination of benefit periods. • 44% of social workers Ire primarily responsible for completing patient admission paperwork. • 18% of social workers Ire involved in collecting fees from patients. (Respondents noted that this could significantly diminish trust and cause damage to the therapeutic relationship). • Respondents spent 38% of their time on insurance, billing and clerical tasks vs. 25% of their time spent assessing and counseling patients. • Only 34% of the social workers thought that they had enough time to sufficiently address patients' psychosocial needs. This evidence clearly demonstrates that without clear definition and monitoring of responsibilities assigned to the qualified social work (as is the current case), social workers are routinely assigned tasks that are inappropriate, preventing them from doing appropriate tasks. For all of these reasons, CNSW is strongly urging the addition of "personnel responsibilities" to the new conditions of coverage (either in this section, or the next section).

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

Rationale & References: Clinical social work training is essential to offer counseling to patients for complex psychosocial issues related to ESRD and its treatment regimes. Changing the language of this definition will make the definition congruent to that of a qualified social worker that is recommended by CNSW for the transplant conditions of coverage. We support the elimination of the "grandfather" clause of the previous conditions of coverage, which exempted individuals hired prior to the effective date of the existing regulations (September 1, 1976) from the social work master's degree requirement. As discussed in the preamble for these conditions, we, the undersigned, recognize the importance of the professional social worker, and we believe there is a need for the requirement that the social worker have a master's degree. I agree that since the extension of Medicare coverage to individuals with ESRD, the ESRD patient population has become increasingly more complex from both medical and psychosocial perspectives. In order to meet the many and varied psychosocial needs of this patient population, I agree that qualified master's degree social workers (MSW) trained to function autonomously are essential. We agree that these social workers must have knowledge of individual behavior, family dynamics, and the psychosocial impact of chronic illness and treatment on the patient and family. This is why I argue that a specialization in clinical practice must be maintained in the definition.

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

Hamilton, Inc., 1987; Dhooper, Royse & Wolfe, 1990). The additional 900 hours of supervised and specialized clinical training in an agency prepares the MSW to work autonomously in the dialysis setting, where supervision and peer support is not readily available. This additional training in the biopsychosocial model of understanding human behavior also enables the masters-prepared social worker to provide cost-effective interventions such as assessment, education, individual, family and group therapy and to independently monitor the outcomes of these interventions to ensure their effectiveness.

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

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

- Through patient education and other interventions, nephrology social workers are successful in improving patient's adherence to the ESRD treatment regime. Auslander and Buchs (2002), and Root (2005) have shown that social work counseling and education led to reduced fluid light gains in patients. Johnstone and Halshaw (2003) found in their experimental study that social work education and encouragement Ire associated with a 47% improvement in fluid restriction adherence.
- Beder and colleagues (2003) conducted an experimental research study to determine the effect of cognitive behavioral social work services. They found that patient education and counseling by nephrology social workers was significantly associated with increased medication compliance. This study also determined that such interventions improved patients' blood pressure. Sikon (2000) discovered that social work counseling can reduce patients' anxiety level. Several researchers have determined that nephrology social work counseling significantly improves ESRD patient quality of life (Chang, Winsett, Gaber & Hathaway, 2004; Frank, Auslander & Iissgarten, 2003; Johnstone, 2003).
- Nephrology social work interventions also tend to be valued by patients. Siegal, Witten, and Lundin's 1994 survey of ESRD patients found that 90% of respondents "believed that access to a nephrology social worker was important" (p.33) and that patients relied on nephrology social workers to assist them with coping, adjustment, and rehabilitation. Dialysis patients have ranked a "helpful social worker" as being more

	important to them than nephrologists or nurses (Rubin, et al., 1997). In a study by Holley, Barrington, Kohn and Hayes (1991), 70% of patients said that social workers gave the most useful information about treatment modalities compared to nurses and physicians. These researchers also found that patients thought that social workers Ire twice as helpful as nephrologists in helping them to choose betlen hemodialysis and peritoneal dialysis for treatment.
494.140 Condition Personnel qualifications	*Add: (e) Standard: Case aide. Dialysis units that have more than 75 patients per full time social worker must employ a case aide who- As supervised by the unit social worker, performs clerical tasks involving admissions, transfers, billing, transportation arrangements, transient treatment paperwork and verifies insurance coverage.* Rationale & References: We, the undersigned, agree with the preamble that dialysis patients need essential social services including transportation, transient arrangements and billing/insurance issues. I also firmly agree with the preamble that these tasks should not be handled by the qualified social worker (unless the social worker has feIr than 75 patients per full time equivalent social worker), as caseloads higher than this prevent the MSW from participating fully with the interdisciplinary team so that optimal outcomes of care may be achieved. It is imperative that the conditions of coverage identify a new team member who can provide social service assistance-the preamble recommends that these clerical tasks should be done by someone other than the MSW, but does not specify who that person is-adding this section (e) will eliminate any ambiguity surrounding this issue, and ensure adherence to this recommendation across all settings. Tasks that are clerical in nature or involve admissions, billing, and determining insurance coverage prevent nephrology social workers from performing the clinical tasks central to their mission (Callahan, Witten & Johnstone, 1997). Russo (2002) found that all of the nephrology social workers that he surveyed felt that transportation was not an appropriate task for them, yet 53% of respondents Ire responsible for making transportation arrangements for patients. Russo found that 46% of the nephrology social workers in his survey Ire responsible for making dialysis transient arrangements (which involved copying and sending patient records to out-of-town units), yet only 20% are able to do patient education. In the Promoting Excellence in End-of-Life Care's 2002 report, End-Stage Renal Disease Workgroup Recommendations to the Field, workgroup members recommended that dialysis units discontinue using master's level social workers for clerical tasks to ensure that they will have sufficient time to provide clinical services to their patients and their families. Merighi and Ehlebracht (2004b; 2004c; 2005), in a survey of 809 randomly sampled dialysis social workers in the United States, found that: • 94% of social workers did clerical tasks, and that 87% of those respondents considered these tasks to be outside the scope of their social work training. • 61% of social workers Ire solely responsible for arranging patient transportation. • 57% of social workers Ire responsible for making travel arrangements for patients who Ire transient,

	taking 9% of their time. • 26% of social workers Ire responsible for initial insurance verification. • 43% of social workers tracked Medicare coordination periods. • 44% of social workers Ire primarily responsible for completing admission packets. • 18% of social workers Ire involved in collecting fees from patients. Respondents noted that this could significantly diminish therapeutic relationships and decrease trust. • Respondents spent 38% of their time on insurance, billing and clerical tasks vs. 25% of their time spent counseling and assessing patients. • Only 34% of the social workers thought that they had enough time to sufficiently address patient psychosocial needs. This evidence clearly demonstrates that there needs to be another team member who can handle these clerical social service needs. This position would be cost-effective, as the person in this role can help patients obtain insurance coverage for dialysis that they normally would not have and increase facility's reimbursement. As discussed and referenced below in detail, CNSW recommends a ratio of 75 patients per full-time equivalent social worker. If a dialysis clinic has fewer patients per full-time equivalent social worker than less than 75:1, the social worker can address concrete social service needs of patients. However, patient ratios over 75 patients per full-time equivalent social worker require a case aide.
§494.180 Condition Governance. (b1) Standard. Adequate number of qualified and trained staff.	*Add: (1i) No dialysis clinic should have more than 75 patients per one full time social worker.* Rationale & References: A specific social worker-patient ratio must be included in the conditions of coverage. Currently, there are no such national ratios and as a result social workers have caseloads as high as more than 300 patients per social worker in multiple, geographically separated, clinics. This is highly variable among different dialysis units-letting dialysis clinics establish their own ratios will leave ESRD care in the same situation as I have now with very high social work caseloads. For many years, CNSW has had an acuity-based social work-patient ratio (contact the National Kidney Foundation for the formula) which has been widely distributed to all dialysis units. This has largely been ignored by dialysis providers, who routinely have patient-to-social work ratios of 125-300. The new conditions of coverage must either identify an acuity-based social work staffing ratio model to be used in all units (I would recommend the Council of Nephrology Social Work's [CNSW] staffing ratio), or set a national patient-social worker ratio. Leaving units to their own devices regarding ratios will not affect any change, as is evidenced by today's large caseloads and variability in such. CNSW has determined that 75:1 is the ideal ratio. If CMS refuses to include language about social work ratios, I strongly urge that the final conditions include language for "an acuity-based social work staffing plan developed by the dialysis clinic social worker" (rather than having nursing personnel

who have limited understanding of social work training or role to determine social work staffing).

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

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

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

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

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

REFERENCES

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Jane Kretzner, MSW, LCSW, CADC-II
Lynnetta Leach, ACSW, LCSW-C, BCD
Eleanor Colten LCSW-C
Helene Zeltser, LCSW-C/LISW
Loma Grasmick, MSW, CAC III
Holly Jenkins Riley, MSW, ACSW
Gena Wilson, LCSW
Randi Solomon, LCSW – New York
Marthajane Weaver, ACSW, LCSW – New Jersey
Belinda Lindsay, LGSW
Eileen Guiney, ACSW, LCSW
Debra R. Galperin, ACSW, LCSW
Stepahnie Sciotto, LCSW
Nicole Camerano MSW – New York
Cindy A. Cornell, MSW
Deborah Carruthers, MSW, LGSW
Meryle Bromberg, MSW, LCSW
Colleen Kerby, MSW
Christine Simes, MSW
Gwen Reisner, MSW, LCSW – New Jersey
Annunciata Watson, MSW, LSW
Jackie L. Jellison, LCSW
Janice Malofsky-Berlow, LCSW
Judy Amir, MSW, LCSW
Sharon Rasmussen, LCSW
Emily Williams, MA, LCSW
Ivis Bird, LMSW
Vicki Danner, LISW
Camille Coiro, LCSW
Nicole S. Kisslak, LMSW

Jan Chapin, LCSW-C
Janine Ansais, LCSW-C
Sandra Darlene Stein, MSW – Las Vegas, NV
Robin Siegal, LCSW – Los Angeles, CA
Cynthia Cornejo, MSW, LGSW – Fairfax, VA
Jessica Ussi, MSW – Springfield, VA
Trenean Hart, MSW, LGSW
Anne Street Smith, MSW, LICSW
Abbey Kendzior, MSW, LGSW
Martha Donoho, LCSW
Jeannine Jones-Matthews, LMSW-AP
Karen K. Fielder, LCSW
Betsy Heilman, LCSW

Submitter : Mary J. Boyle, R.N. **Date:** 05/05/2005

Organization : Mary J. Boyle, R.N.

Category : Nurse

Issue Areas/Comments

Issues 1-10

Compliance with Laws and Regulations

See Attachment

Physical Environment

See Attachment

Water Quality

See Attachment

Infection Control

See Attachment

Patients' Rights

See Attachment

Basis

See Attachment

Definitions

See Attachment

Plan of Care

See Attachment

Care at Home

See Attachment

CMS-3818-P-250-Attach-1.DOC

Attachment #250

RESPONSES TO PROPOSED CHANGES TO 42 CRF

CONDITIONS FOR COVERAGE FOR ESRD FACILLITIES

The responses that follow represent the opinions of two Registered Nurses with a combined total of 54 years of experience in the field of Nephrology Nursing. These years include nursing at the Staff Nurse, Charge Nurse, Nurse Manager and Facility Administrator levels.

The Nursing Profession has always striven to set standards of care to ensure that patients are receiving the highest quality of care that will ensure that each individual can achieve and maintain his/her optimal level of health. CMS has also set guidelines to achieve the same outcomes for this specific patient population. In the establishment of standards of care or guidelines, it is imperative to keep in mind that any such standards or guidelines MUST be achievable. Our responses are in keeping with this thought in mind, as well as the fact that the United States is facing a true Nursing staffing crisis (not just a shortage) and in the face of recent reductions to the composite rate reimbursement for an aging population with many more co-morbid medical conditions that require much more care than dialysis patients of twenty to thirty years ago.

We thank you in advance for consideration of our comments and suggestions.

Sincerely,

Mary J. Boyle, R.N., B.S.N.

Lorena Greeley, R.N., C.N.N.

I. INFECTION CONTROL

A. The prevention of the spread of blood borne pathogens is of primary concern in all health care settings and has always been a focus in dialysis facilities. In the years following the emergence of HIV/AIDS, the CDC recommended that "Universal Precautions" be utilized when caring for all patients in any health care setting. In your own document, you state "According to the CDC, transmission of Hepatitis C can be prevented by strict adherence to infection control precautions recommended for all hemodialysis patients." As Hepatitis C, Hepatitis B and HIV are all transmitted in the same manner and Hepatitis C and HIV are increasing in both the general population and the dialysis patient population, why continue to propose that ONLY Hepatitis B positive patients be isolated? Why propose that staff cannot care for both Hepatitis B positive and Hepatitis B negative patients on the same day/shift?

We ask these questions for several reasons:

1. Isolation of patients raises questions in the minds of the other patients as to the reason(s) why a patient is being isolated. This can lead to incorrect assumptions about the isolated patient and any disclosure of the reason for an "Isolation Room" is an automatic violation of recent HIPPA regulations regarding patient information confidentiality.

2. Isolation of patients, in the real world of dialysis facilities, tends to make patient care staff feel that these are the only patients for whom they need to "really" follow ALL the recommendations for care of dialysis patients (i.e., face shields as well as fluid impervious garment and gloves). This is a very dangerous concept if the goal is to prevent spread of disease.

3. Patients who are any blood borne pathogen positive already feel like "outcasts" and physical isolation only furthers this self perception.

4. There are increased costs involved.

B. Testing for HBV and HCV Infections

If the regulation for the isolation of HBV positive patients is removed, the only reason to test for EITHER HBV or HCV is for screening purposes. Screening for these diseases is very important in that early diagnosis of either can lead to early treatment and education, both of which will improve the patient's quality of life. In addition, for HBV negative patients, the Hepatitis B vaccination should continue to be offered. However, again in the face of recent reimbursement cuts, screening tests are very burdensome for the facilities.

C. Common Medication Carts

We do not believe that this is a reasonable guideline, especially in large facilities. To require that a nurse go back and forth from each individual patient to the medication preparation area is neither practical nor realistic.

From a practical point of view, this would take up valuable time that would be better spent in other aspects of patient care (i.e., patient teaching). In many facilities, there may be only ONE nurse present in the ENTIRE facility. Again, in the face of the coming nursing staffing crisis, we ALL need to find mechanisms that are safe for patients AND not burdensome for the nurse(s) caring for them. Realistically, if not for the use of a common medication cart, most nurses will draw up medications in advance and tape them to the top of front of a dialysis machine or put them into a lab coat or scrub suit pocket, both of which are clearly more dangerous than a common cart. Again, adherence to strict infection control practices with the use of a common cart (i.e., maintaining the cart a safe distance from the dialysis machine), makes more sense.

II. WATER QUALITY

The proposed changes may be perceived as too minimal by international standards. However, patient care has not been adversely affected when guidelines are followed. It would be helpful to avoid language that still leaves room for interpretation (i.e., "adequate empty bed contact time"). The proposal to require chlorine/chloramine testing before each shift or every fours hours, whichever is shorter, would necessitate testing treatment in many cases as the machines are often recirculating for a period of time before the patient arrives and/or patient treatment times are historically going beyond four hours. In larger units of 20 or more dialysis stations, the ability to monitor the time element restriction for each

individual station would be very difficult and might require more frequent testing creating a labor intensive situation. For continuity and compliance the regulation should remain that the monitoring procedures must occur before the start of each patient shift.

III. PHYSICAL ENVIRONMENT

Your proposal "that the dialysis nursing staff must be trained on the proper use of emergency equipment and emergency drugs" is exceptionally unreasonable in the setting of an out patient dialysis facility. This would require that the minimal amount of nurses in any facility take on responsibilities of an emergency room nursing staff. Despite the fact that our patients are aging and have many more co-morbid medical conditions, in the out patient setting, the need for this specialized knowledge is not common. And when knowledge and skills are not utilized frequently, they are lost ("if you don't use it, you lose it"). The use of CPR and AED's until EMS arrives is more than adequate in most facilities. How much is CMS going to require of the minimal number of nurses caring for 20+ patients in the chronic dialysis setting? Who is going to provide NURSING care to the other patients dialyzing at the time of an event of this nature? This proposed requirement would be better stipulated to those facilities that do not have an EMS system with ACLS certified personnel readily available to them within 10-15 minutes after a "911" call is placed.

IV. PATIENT'S RIGHTS

1. Patient Assessment.

§ 494.80(b)(2) addresses "a follow-up comprehensive reassessment for *new* patients..." *New Patients* needs to be clearly defined. Is this a patient *new* to ESRD or *new* to a different dialysis facility?

2. Assessment of the Treatment Prescription.

If Kt/V is to be the indicator for the adequacy of the dialysis treatment prescription, monitoring more frequently than monthly is not of value as it may take that long for any change to be noted in the Kt/V.

3. Patient Plan of Care.

a) It is important to maintain the requirement that the Medical Director of a facility be a participant in the interdisciplinary meetings. This proves to be a very valuable opportunity for the Nursing staff to bring him/her up to date on all the patients receiving care at the facility. As the Medical Director is ultimately responsible for all care rendered in the facility, he/she need to have this type of exposure in an environment and circumstance conducive to identifying problems and exploring avenues for resolution. It also gives the patient care staff the opportunity to discuss any problematic "Physician staff response" issue as pertains to patient follow-up with the Medical Director. Lastly,

attending physicians often prove non-adherent to meeting dialysis facility schedules and/or needs that may conflict with private practice commitments.

b) With regard to the transplant surgeon and the inclusion/exclusion criteria, the requirement should state that if a patient is referred to a new dialysis center and transplant as a treatment modality has already been explored and reasonably rejected at the referring facility, the process does not need to be explored again at the new facility until the time that the next Long Term Plan is due. In other words, the decision to exclude transplantation as an option should follow the patient.

c) Vascular Access.

As we are all aware, vascular access proficiency impacts dramatically on the outcomes a dialysis facility may achieve for any given patient. Thus, vascular surgeons need to be held more accountable (perhaps financially) for proper choice of access placement, proper technique, education of the patient and follow-up of the patient. This aspect of a dialysis patient's care lies solely in the vascular surgeon's lap but can impede a facility's ability to achieve set standards/guidelines which in many circumstances may negatively affect reimbursement for the facility.

V. CARE AT HOME

Dialysis of ESRD Patients in Nursing Facilities and Skilled Nursing Facilities

Home dialysis should NOT be performed in NF's or SNF's. Accommodations should be made for entities wishing to establish an ESRD facility on the campus of an NF or SNF in terms of space allocations for secondary services such as dietary and social services to maintain the specialized care recognized numerous times within the body of this document and to accent all the positive benefits that residents of NF's or SNF's receive in this circumstance without placing an onerous financial burden on the ESRD facility. In the same manner, as evidenced by your own statements - "given the relative acuity of nursing home patients...the dialysis care of a patient who requires nursing home services may be more complex than the dialysis care of an independent home dialysis patient, and given their frailty, these patients may be more vulnerable..." - the modifiers for reimbursement should be re-addressed mimicking those modifiers assigned to the pediatric ESRD population. The care of NF and SNF patients requires a higher degree of knowledge and skill (translated: R.N. vs. L.P.N./P.C.T.) and this cannot be achieved with a neutral reimbursement approach.

VI. LABORATORY SERVICES

HMO's that choose to participate in the ESRD program must be willing to refer requests for ESRD required testing mandated by these regulations to laboratories that are equipped to perform such testing. Many HMO laboratories are not equipped to perform such testing and the HMO's usually will not pay for "Out of Network" services (Translation: the HMO's should pay for the services of the laboratory used by the dialysis facility which is being paid for dialyzing that HMO patient).

VII. PERSONNEL QUALIFICATIONS

1. Nursing Services.

"As the demographics of the dialysis population continues to change, producing a more elderly patient population with more co-morbid conditions, direct patient care needs and the skills needed to meet those needs will continue to increase."

By your own words, you have indicated the need for more Registered Professional Nurses to be present in the dialysis facility. Then why is the standard for a charge nurse being LOWERED in the proposed changes. Despite the fact that many L.P.N.'s have the knowledge or experience to make sound clinical judgments an L.P.N. is not expected to do so without the supervision of an R.N. By definition in the Nurse Practice Acts of individual states, it is the R.N., by licensure, who is to be

responsible for the identification of patient problems and to plan and direct the care delivered to the patient.

And again, to meet the care needs of our aging ESRD population, the reimbursement modifiers for the population of 45+ years need to be increased. It is this age group, more so than the 18-44 year olds, who are beginning to exhibit the co-morbid conditions that have been identified by all. And yet there is that neutral reimbursement factor again.

Do NOT lower the standard of care to meet the lowered reimbursement modifier; but rather raise the level of the reimbursement modifier to meet the standard of care we all wish to achieve for those in our care.

2. Other Personnel Issues.

Routine Assessment of Patients' Medications.

Will there be a reimbursement code number for this so that the service can be billed for separately or will the facility have to pay for this service out of our already reduced reimbursement for the patient? This should NOT be a requirement.

Submitter : **Mr. Michael Eging** **Date: 05/05/2005**

Organization : **Hoffmann-La Roche Inc.**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-251-Attach-1.DOC

Roche

Attachment #251
May 5, 2005

SUBMITTED ELECTRONICALLY &
BY HAND DELIVERY

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

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

Dear Administrator McClellan:

Hoffmann-La Roche Inc. ("Roche") submits the following brief comments in response to the proposed rule revising the requirements that end stage renal disease (ESRD) dialysis facilities must meet to be certified under the Medicare program.[1] Roche, based in Nutley, New Jersey, is the U.S. prescription drug unit of Roche Group, a research-based health care company that ranks among the world's leading manufacturers of pharmaceutical and diagnostic products. Roche provides innovative products that enhance public health and quality of life by preventing and treating diseases and disorders. Roche currently manufactures, or is actively developing, medical products to treat persons with kidney disease and kidney transplant patients. We appreciate the opportunity to provide comments on this rule.

Pursuant to the instructions included in the Notice of Proposed Rulemaking, each comment is set forth under a caption referencing the section of the proposed rule to which that comment relates.

Patient Assessment

The proposed ESRD facility conditions of coverage are focused on patient outcomes, and Roche strongly supports this approach. We also support the proposed requirement that dialysis facilities prepare a comprehensive needs assessment for each new dialysis patient and evaluate the factors associated with anemia as part of that assessment (proposed §494.80). Further, we agree with establishing timeframes for conducting those assessments, as well as the requirement that patients with unmanaged anemia be comprehensively re-assessed on a monthly basis.

We note that CMS did not define what constitutes "unmanaged anemia" for an ESRD patient, and we suggest that CMS clarify this in the final rule. Patient hemoglobin and hematocrit levels can fluctuate around the target over a given time period, which presents a medical

---

1 70 Fed. Reg. 6184 (February 4, 2005).

Hoffmann-La Roche Inc.
340 Kingsland Street
Nutley, New Jersey 07100-1109

management challenge for caregivers. In setting the standard for "unmanaged anemia," we recommend that CMS avoid setting a specific numerical target in the coverage conditions and instead have the conditions defer to the most recently updated NKF-K/DOQI Anemia Guidelines, which is consistent with the proposed requirements with respect to the patient care plan (discussed below), as well as any other relevant practice guidelines that may be developed and issued in the future. Practice guidelines are intended to be an aid to practitioners, allowing them to remain at the forefront of quality care. If the standard for "unmanaged anemia" is based on the most recently updated clinical guidelines, CMS will ensure that the standard set forth in the coverage conditions reflects the most up-to-date clinical recommendations available, without the Agency having to go through a burdensome rulemaking process each time the clinical standard is updated.

Plan of Care

Roche supports CMS' proposed requirement that facilities develop patient care plans that include measurable and expected outcomes based on accepted clinical practice guidelines, such as the NKF-K/DOQI guidelines, and estimated timetables for achieving these outcomes (proposed §494.90). We also agree that with respect to anemia management, patient hemoglobin/hematocrit levels should be measured at least monthly, and that the facility must conduct an evaluation to determine whether the patient is a candidate for erythropoietin based on the most current recommended clinical guidelines, which currently provide that a patient is a candidate if he or she has a hemoglobin less than 11 gm/dL or hematocrit of less than 33 percent. Roche also supports requiring facilities to include the standard in the most recent NKF-K/DOQI Guidelines as the minimum threshold value for anemia management in a patient's care plan, as well as requiring facilities to update their plans of care within an acceptable timeframe when relevant clinical guidelines are updated.

We note that although we agree with using the standards set forth in the most recent NKF-K/DOQI guidelines, it is possible that the clinical guidelines may not be revised in time to promptly incorporate the latest medical research in appropriate treatments for patients with ESRD. We recommend that CMS provide leadership in this area and as promptly as possible incorporate into the ESRD conditions of coverage the latest clinical developments for ESRD that are supported by strong, direct evidence. Particularly with respect to evidence-based, ground-breaking innovations which will likely incur a delay before they are incorporated into the NKF-K/DOQI guidelines, CMS has an opportunity and a responsibility to show strong leadership and vision, which will aid in improving patient outcomes.

Governance

We endorse CMS' proposal to require all dialysis facilities to furnish data on all patients as part of the ESRD Clinical Performance Measures (CPM) project. Roche agrees that requiring facilities to report data on the adequacy of dialysis, anemia management, serum albumin, and vascular access management will help the Agency better evaluate and monitor facilities to ensure the necessary services are being provided, as well as help patients evaluate dialysis providers and make better choices about where to access their care. Although we endorse CMS' decision to post on the Dialysis Facility Compare website the percent of patients treated in an ESRD facility with a $Kt/V \geq 1.2$, and the percent of patients with hemoglobin levels within the targets recommended in the latest NKF-K/DOQI guidelines, we encourage CMS to post other relevant laboratory values in addition

to those measuring the facility's performance in the area of dialysis adequacy and anemia management.

Conclusion

Roche appreciates the opportunity to submit comments to CMS regarding the proposed conditions of coverage for dialysis facilities. We look forward to working with CMS in the future on issues related to quality of care for ESRD patients.

Respectfully submitted,

Michael J. Eging
Executive Director
Public Policy and Federal Government Affairs

Submitter : **Miss. Katherine Finch** **Date: 05/05/2005**

Organization : **Miss. Katherine Finch**

Category : **Dietitian/Nutritionist**

Issue Areas/Comments

Issues 1-10

Plan of Care

20 days for completion of the nutrition assessment is too soon. Nutrition assessment is an interactive process. Even at 30 days from admission, the patient can still be uremic, in denial, or the family can be unavailable. Most patients are overwhelmed by the change in their life when first starting dialysis treatments. Diet is going to be a change that they will have to slowly get used to. Many times it takes several 'visits' with the patient to get through the information gathering and instruction that completes the nutrition assessment. To get this all done in a meaningful way within 20 days could be very difficult.
Reassessment can be completed using the care plan, and not a separate required review like the one proposed now.

Submitter : Mrs. Charlotte Hodder **Date:** 05/05/2005

Organization : CMS, DS&C, RO V

Category : Federal Government

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT

Submitter : **Ms. Anne Ishmael** **Date: 05/05/2005**

Organization : **Council Renal Nutrition Southeast Texas**

Category : **Dietitian/Nutritionist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment that represents the collective input of Robin J.Holland, RD LD, Christie Wacker, RD LD, Rosario D Abcede, RD CSR LD, Marilyn B Tambo, RD LD, Janet Price RD LD, Midori H. Palmer, Lorrie Mays RD LD, Brian Armentrout, RD, Corby Webb, RD LD CDE, Carolyn Duffy, RD LD, Jane Louis, RD CSR, LD, Anne Ishmael, MS RD LD and Johnetta Turner, CSR, RD LD

CMS-3818-P-254-Attach-1.DOC

Submitter : Joan Solanchick **Date:** 05/05/2005

Organization : TransAtlantic Renal Council NW3

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-3818-P-255-Attach-1.DOC

Attachment #255
DATE: May 3, 2005

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

We are registered dietitians and members of the Council of Renal Nutrition Southeast Texas. We are currently working with End-Stage Renal Disease (ESRD) patients.

Patient Assessment (Proposed Sec 494.80)

We 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.

We support the proposed initial assessment within 20 days of initiating dialysis, and completion of the care plan within the next 10 calendar days. We 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.

We 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

We agree with the proposed requirements, especially, " ... **the interdisciplinary team** to provide the necessary care and services to achieve and sustain an effective nutritional status." We 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. We 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.

We 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.

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

Care at Home (Proposed Sec. 494.100)

We 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)

We 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)

We 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, we 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)

We 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, We 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

Signature/Title	Print Name/ Title

Submitter : **Ms. Cathy Bridges** **Date: 05/05/2005**

Organization : **DaVita Patient Citizens**

Category : **Consumer Group**

Issue Areas/Comments

GENERAL

*GENERAL

See attachment.

CMS-3818-P-256-Attach-1.DOC

Citizens
Our Dialysis Community

Attachment #256
May 5, 2005

Via Email and Overnight Courier
Secretary Mark Leavitt and Administrator Mark McClellan
Centers for Medicaid and Medicare Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave., S.W.
Washington, D.C. 20201

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

Dear Secretary Leavitt and Administrator McClellan:

We are writing on behalf of DaVita Patient Citizens (DPC) in response to your invitation to comment on the proposed *Medicare Program: Proposed Conditions for Coverage for End Stage Renal Disease Facilities*, 70 Fed. Reg. 6184 (Feb. 4, 2005).

DPC is a nationwide, non-profit organization of dialysis patients, led by dialysis patients, with over **6,000 members, almost all of whom are dialysis patients**.

At this time, we would like to make these general comments:

1. We believe that we dialysis patients are entitled to the best quality of care possible, and to information necessary for us to participate to the fullest in our care.
2. One of our charter elements is adequate funding for dialysis. We believe that CMS must ensure there is adequate funding for any conditions imposed.
3. We believe that medical decisions about our care should be made by our physicians in consultation with ourselves – not by the government.

It is our intention to continue to provide substantive comments on this very important proposal. We trust you will consider these comments and continue to solicit public input as you work to finalize the Conditions of Coverage.

Thank you in advance for your consideration.

Sincerely,

Cathy Bridges, Patient/President
DPC Board of Directors

Micah H. Naftalin, Patient
DPC Board of Directors

Robert C. Mize, Patient/Communications Committee
DPC Board of Directors

601 Hawaii Street, El Segundo, CA 90245
Toll Free Number: 866-877-4242
Website: www.dialysispatients.org
Email: dpc@dialysispatients.org

Submitter : **Mr. Hal Daub** **Date: 05/05/2005**

Organization : **American Health Care Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Submitter : Carla Faith **Date:** 05/05/2005

Organization : Carla Faith

Category : Individual

Issue Areas/Comments

Issues 1-10

Basis

Please note I tried to enter comment which I cut and pasted and it would not go through. Will send by postal mail or try again by email tomorrow.

C. Faith

Submitter : Mr. Ronald Lawler **Date:** 05/05/2005

Organization : NJ Dept. of health and Senior Services

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

With respect to 494.40: RD 52 of the Association for the Advancement of Medical Instrumentation (AAMI), must be made part of the regulation. RD 52 is the most current standard relative to dialysate in an ESRD clinical setting.

Submitter : **Dr. Jose Arruda** **Date: 05/05/2005**

Organization : **University of Illinois at Chicago**

Category : **Physician**

Issue Areas/Comments

Issues 11-20

Personnel Qualifications

See attached

CMS-3818-P-260-Attach-1.DOC

Attachment #260

May 5, 2005

Mark B. McClellan MD, PhD

Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

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

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

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

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

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

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

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

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

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

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

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

Thank you for your consideration.

Jose A. L. Arruda, MD

Professor of Medicine and Physiology
Chief, Section of Nephrology

Submitter : Mr. Hal Daub **Date:** 05/05/2005

Organization : American Health Care Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Submitter : **Mrs. Bonnie Orlins** **Date: 05/05/2005**

Organization : **Shelby County Kidney Center**

Category : **Social Worker**

Issue Areas/Comments

GENERAL

GENERAL

I am a Social Worker representative for Network 9 and 10. Based on my experience of 30 years as a renal social worker, I agree with the position of CNSW that there should be a patient/social worker ratio of no more than 75 patients per fulltime social worker. Favorable outcome is difficult at best with a ratio greater than this number. Larger ratios interfere with social work goals of emotional support, community research linkage, education, and vocational rehabilitation.

Submitter : Ms. Patty Salvey-Sunde **Date:** 05/05/2005

Organization : Ms. Patty Salvey-Sunde

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

See attachments

CMS-3818-P-263-Attach-1.DOC

CMS-3818-P-263-Attach-2.DOC

Attachment #263

May 5, 2005

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

Please see the attached document for my comment regarding the Proposed Dialysis Conditions of Coverage. As a Nephrology Social Worker who has worked with patients a families living with kidney disease for the past 16 years, I strongly support the comments and recommendations proposed by the National Kidney Foundation's Council of Nephrology Social Workers and revisions to the existing Dialysis Conditions of Coverage.

I would like to suggest that the following recommendations be strongly considered.

- 449.60 Condition Physical Environment
  (c) Patient Care Environment:
  Please add the requirement that dialysis facilities are to be accessible to people with disabilities in accordance with the Americans with Disabilities Act.
  Please add a requirement that Facilities have a place for confidential to hold interviews with patients and families or for privacy of when a patient's care requires body exposure.

- 494.70 Condition Patients' Rights
  (a) Standard: Patients' rights:
  I strongly support the language in item 6 (a) with the recommendation that facilities be required to inform patients of all available treatment modalities and provide patients and families with a list of facilities where the treatments are offered within 120 miles of the facility.

- 494.140 Condition Personnel qualifications
  (d) Standard: Social Worker: The clinical training of a master prepared social worker is essential to the provisions of counseling support patient's

adaptation to renal disease, treatment and the psychosocial impact. I support the elimination of the "grandfather " clause in the previous conditions of coverage, which exempted individuals hired prior to September 1976 from master's degree requirement.

- 494.180 Condition Governance
  (b1) Standard Adequate number of qualified and trained staff. A specific social worker – patient ratio must be included in the conditions of coverage to ensure the social work services are consistently available to patients and families. I recommend the ratio to be 1 social worker to 75 – 100 patients.

Thank you for the opportunity to comment of the Dialysis Conditions of Coverage.

Sincerely,

Patty Salvey-Sunde, MSW, LCSW
Social Worker
Pacific Northwest Renal Services
Renal Care Group