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

Organization :

Category : **State Government**

Issue Areas/Comments

GENERAL

GENERAL

See attachment. Thanks.

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

Organization :

Category : **Dietitian/Nutritionist**

Issue Areas/Comments

GENERAL

GENERAL

Consider adding a recommended staffing ratio of number of patients to Dietitian. Some clinics have as many as 180 patients assigned to one Dietitian. Review of previous American Dietetic Association publications recommend 100-120 patients per Dietitian.

Issues 1-10

Plan of Care

Recommend initial assessment period be 30 days. Consider eliminating the need for follow up assessment within 3 months. Patients are required to be seen monthly and problems are addressed each month. A required complete reassessment will increase paperwork for the Dietitian and decreae the amount of actual time spent with the patient.

Submitter : Dr. Keith Fender **Date:** 05/04/2005

Organization : Blue Ridge Counseling, LLC

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

04-05-2005

Thank you for allowing feedback and comment regarding conditions for coverage of end stage renal disease. I have worked in this field for approximately seven years.

During this time, I have encountered numerous changes in my job description that resulted in confusion for patients regarding the role of the nephrology social worker in the dialysis clinic. In addition to my work in dialysis, I have tought at the college level for 7 years and have maintained a private practice for 9 years.

I can tell you that both the clinical preparation and course work a master level social worker has is often underutilized in the dialysis setting. Primarily because the language is too vague and ambiguous in terms of outlining responsibilities.

This results is the dialysis companies shifting other responsibilities on to social workers. I must say that I don't believe this to be intential wrong doing. I believe it is because many of the top executives are not aware of the differences between a social worker (as in department of social services) and a clincial nephrology social worker or a licensed clinical social worker.

The result is that "all" billing and insurance related issues are automatically perceived to be a responsibility of the social worker. This is a correct assumption in cases that the patient does not have adequate insurance or needs assistance in the form of advocacy. This is a valid psychosocial issue. However, this has led to social workers being put into positions of having patients sign contracts which say they have not brought in necessary paperwork and could be terminated from treatment due to non-payment.

Now, from a business point of view I understand the need to get paid for services. However, it is never a consideration of how the patient is going to feel about the social worker and that the patient is likely going to talk to other patients about the situation. Soon, there are certain patients who view the social worker as the "money collector" or "billing person".

I have never been comfortable with this. It recently slapped me in the face. After working with a patient for over a year on a bi-weekly sometimes weekly basis on the need to bring in insurance related documents, I learned from another source that the patient's child had cancer. I began to wonder why the patient had not shared the information with me. But, the answer was very clear. In her eyes, I was no longer there as a social worker concerned about her well-being and psychosocial needs, I was the "bill collector."

Now, when I walk onto the treatment floor, she avoids eye contact and seems to hope "he don't come bother me".

I do not believe that this is the intended dynamic of a therapeutic relationship between an ESRD patient and social worker.

There have been staffing ratios in publication for years that are constantly ingnored. Often, a companies own policies are ignored. For example, a social worker covering 1 clinic with 100 patients is much different that a social worker covering 100 patients in 4 different clinics (which is the norm. in rural areas not the exception).

These issues must be addressed so that clinical social workers can get back to patient centered care. I have attached specific recommendations along with rationale. I appreciate your careful consideration of each.

Please see attachment.

Respectfully Submitted,

Keith E. Fender, Ph.D.,LCSW

CMS-3818-P-143-Attach-1.DOC

Attachment 143

Issue Identifier	CNSW Comment on Conditions for Coverage for End Stage Renal Disease Facilities File code CMS–3818–P
LOCATION OF COC	PROPOSED DIALYSIS COC that are identified in this document can be found at: http://a257.g.akamaitech.net/7/257/2422/09feb20050800/edocket.access.gpo.gov/2005/pdf/01622.pdf
494.10 Definitions Dialysis facility *NEW* Staff assisted skilled nursing home dialysis	***Add:*** A new category for dialysis provided in a nursing home setting ***Rationale***: Nursing home dialysis is typically provided by staff. Home dialysis (PD or home hemodialysis) is typically performed by a trained *patient* and/or a helper. Making these treatments equivalent ignores the important differences between them, including the staff training/supervisory needs of nursing home dialysis patients. ***Reference:***? Tong & Nissenson, 2002
494.20. Condition Compliance with Federal, State, and local laws and regulations	***Add:*** "Facilities must accommodate mobility, hearing, vision, or other disabilities or languag and communication barriers" ***Rationale***: Healthcare settings are covered entities under the Americans with Disabilities Ac ***References:*** ADA
494.60 Condition Physical Environment. (c) Patient care environment	***Add to c1***: Require facilities to be accessible to people with disabilities. ***Rationale***: Americans with Disabilities Act ***Reference:*** ADA ***Add to c1***: Require facilities to have a place for confidential interviews with patients and families and to provide for privacy during body exposure. ***Rationale***: HIPAA privacy ***Reference:*** *Protecting the Privacy of Patients' Health Information* ***Comment***: CNSW Supports the inclusion of the proposed (c) (2) regarding facility temperature. ***Rationale***: A common complaint from dialysis patients is in regards to the facility climate. A patient-centered care approach dictates that facilities need to have a plan in place to accommodate patients' preferences for climate, and address the concerns of patients who are not comfortable.
494.70 Condition Patients' Rights (a) Standard: Patients' rights	***Add***: (2) Require facility to ask the patient to *demonstrate understanding* of information provided. ***Rationale***: Without this requirement, it would be very easy for staff to believe that they had informed a patient without realizing that, in fact, the patient did not understand the information. ***References:*** Johnstone, 2004; Juhnke & Curtin, 2000; ?Kaveh & Kimmel, 2001 ***Comment & Addition to a6:*** CNSW supports the language of a6 with the recommended addition of requiring facilities to inform patients of all available treatments (in-center hemodialysis, CAPD, CCPD, conventional home hemodialysis, daily home hemodialysis, nocturnal home hemodialysis, transplant), and to provide a list of facilities where treatments are offered within 120 miles if the facility does not offer that treatment. ***Rationale:*** We propose to require that a facility inform patients about all available treatment modalities

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

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

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

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

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

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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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

will have sufficient time to provide clinical services to their patients and their families. Merighi and Ehlebracht (2004b; 2004c; 2005), in a survey of 809 randomly sampled dialysis social workers in the United States, found that:

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

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

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

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

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

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

7 • 18% of social workers were involved in collecting fees from patients. (Respondents noted that this could significantly diminish trust and cause damage to the therapeutic relationship).

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

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

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

494.140 Condition Personnel qualifications (d) Standard: Social worker.	Change the language of d to: Social worker. The facility must have a qualified social worker who—(1) Has completed a course of study with specialization in clinical practice, and holds a masters degree from a graduate school of social work accredited by the Council on Social Work Education; (2) Meets the licensing requirements for social work practice in the State in which he or she is practicing; and (3) Is responsible for the following tasks: initial and continuous patient assessment and care planning including the social, psychological, cultural and environmental barriers to coping to ESRD and prescribed treatment; provide emotional support, encouragement and supportive counseling to patients and their families or support system; provide individual and group counseling to facilitate adjustment to and coping with ESRD, comorbidities and treatment regimes, including diagnosing and treating mood disorders such as anxiety, depression, and hostility; providing patient and family education; helping to overcome psychosocial barriers to transplantation and home dialysis; crisis intervention; providing education and help completing advance directives; promoting self-determination; assisting

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

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

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

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

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

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

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

1 adherence.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 discovered that social work counseling can reduce patients' anxiety level. Several researchers have determined that nephrology social work counseling significantly improves ESRD patient quality of life (Chang, Winsett, Gaber & Hathaway, 2004; Frank, Auslander & Weissgarten, 2003; Johnstone, 2003). A study currently being conducted by Cabness shows that social work intervention is related to lower depression.

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

§494.180 Condition Governance. (b4) Standard. Adequate number of qualified and trained staff.	Comment: CNSW agrees that all employees must have an opportunity for continuing education and related development activities.
§494.180 Condition Governance. (b5) Standard. Adequate number of qualified and trained staff.	Add (5ix): Add "Psychosocial issues related to ESRD and its treatment regimes, as provided by the facility social worker." Comment: Technicians have the most contact with patients and need to be attuned to patients' psychosocial issues so as to most effectively collaborate with the social worker and achieve patient outcomes.
§494.180 Condition Governance. (h) Standard: Furnishing data and information for ESRD program administration.	(h) Standard: Furnishing data and information for ESRD program administration. Add: (3)(new iv) "Annual reporting of facility aggregate functioning and well-being (physical component summary scores and mental component summary scores) and vocational rehabilitation status according to categories on the CMS 2728 form." Rationale: These data would be easy to collect, would permit comparisons between clinics, and would serve as a

	basis for QAPI.

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Submitter : Mr. Danilo Concepcion **Date:** 05/04/2005

Organization : St. Joseph Hospital, Orange, CA

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-144-Attach-1.DOC

Attachment #144

The opportunity seems perfect to have our position heard on certification. CMS have made their argument as to why, at this time, certification is not being proposed by the agency. I propose that our comment on certification be submitted to CMS. For review, edit, and comment I offer the following:

Hemodialysis Technicians make up the largest number of caregivers in dialysis. Also, as stated, "It is not unusual for a single technician to provide dialysis care to three or four patients at a time." As stated in the CMS proposal, "States are currently using a variety of approaches and methodologies to regulate dialysis technicians." Page 162, last paragraph: "There is no consensus within the renal community regarding the efficacy of technician certification to produce improved patient outcomes." Page 160 states, "Increased numbers of patient hospitalizations, which in turn result in higher costs to both public and private payers, could also be a direct outcome of poor patient care from dialysis technicians." Page 163, "Without clear evidence that certification would produce better patient outcomes, we are reluctant to propose any new requirements that would drive ups costs for technicians in current practice, dialysis facilities, or both."

CMS should not take the pessimistic attitude "that there is no clear evidence that certification would produce better patient outcomes..." Any qualification that challenges individuals to meet a higher standard and goal would only result in a positive outcome. If you don't have a gauge to determine excellence and achievement, you can't get there. Certification is the gauge. Achieving certification validates individual skill, competency and knowledge. Certification is also a demonstration to patients, physicians, and the dialysis health care community that an individual possesses a formal and recognized evidences that he/she has mastered a level of proficiency validated by an exam produced from a credible and recognized testing entity.

The argument that there is no clear evidence that certification would produce better patient outcomes could be interpreted in the opposing argument that certification could reduce patient hospitalizations, which in turn would decrease higher costs to both public and private payers due to enhanced patient care from individuals whose skill and competency has been validated by certification. Certification would result in standardization, professionalism and validation of the technician, which would result in increased patient safety and better patient outcomes.

A number of states currently require certification. Reimbursements to states that require certification have not increased and there have been no major economical outcries from both public and private payers as a result of the certification requirement.

Due to the major roles technicians play in the care of CKD patients, technicians can impact patient safety and patient outcomes along with physicians and nurses. Physicians and nurses require licensure. Their salary is significantly higher than technicians and no concern of economical impact to private and public payers is considered in requiring them to be licensed.

The proposed conditions for coverage that include expanded water equipment requirements as set forth by RD52 and RD62 are not too minimal for dialysis application. AAMI/ANSI has discussed the two standards at length and have received national comments from practitioners. Requiring more rigorous standards above the AAMI recommendations may not be practical in some settings and may be too expensive in other settings. The design specifications and requirements are supplemented by increased surveillance recommendations and tighter parameters. Water distributors may vary in the concentration of chlorine/chloramine in the feed water supply, but the concentration typically is maintained between .5 mg/L to 3 mg/L at the point of use. The requirement of the total 10 minute EBCT with 2 GAC in series

should be more than adequate to handle seasonal variations in feed water condition; therefore, Medicare-participating dialysis facilities should maintain at least two carbon tanks in series. The requirement is technically feasible and not cost prohibitive.

The reuse of bloodline is an exception in our industry, rather than as an accepted widely practiced procedure. AAMI is withdrawing TIR6:1989 Reuse of hemodialyzer blood tubing. As such, this practice should be reviewed by CMS. Degradation of the pump segment as a result of the constant peristaltic force has been documented. There are other practices and areas that can be investigated to reduce cost. Also, I know of only one blood tubing brand that the labeling specifically allows multiple reuse on the packaging.

Danilo B. Concepcion, CCHT, CHT
Manager, Renal Technology Services
St. Joseph Hospital, Orange, CA

Medical Review Board Member, Network 18
AAMI Renal Disease and Detoxification Committee Member
President-elect, National Association of Neprhology Technicians/Technologist.

Submitter : Ms. Virginia Mason **Date:** 05/04/2005

Organization : Ms. Virginia Mason

Category : Dietitian/Nutritionist

Issue Areas/Comments

GENERAL

GENERAL

Changes in the timeliness of intial assessments and a 3 month foolow-up are excellent ideas for nutrtion helath for ESRD pts on dialysis, but needed requirements to reduce Dietiain work loads is essential to prevent current pts from suffering fom the increase in time required for new pts.

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

Organization : **American Society of Consultant Pharmacists**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Attachment

CMS-3818-P-146-Attach-1.PDF

Attch 146

American Society of Consultant Pharmacists
1321 Duke Street
Alexandria, VA 22314-3563
Phone: 703-739-1300
FAX: 703-739-1321
E-mail: info@ascp.com
www.ascp.com

May 4, 2005

Mark McClellan
Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8012
Baltimore, MD 21244-8012

RE: File code CMS-3818-P

ASCP Comments on Conditions for Coverage of ESRD Facilities

Dear Dr. McClellan:

The American Society of Consultant Pharmacists is pleased to offer comments to the Centers for Medicare & Medicaid Services (CMS) on the proposed rule for conditions for coverage of end stage renal disease (ESRD) facilities. This proposed rule represents an important step forward in improving and promoting quality of care provided to ESRD patients.

The American Society of Consultant Pharmacists (ASCP) is the international professional association that provides leadership, education, advocacy, and resources to advance the practice of consultant and senior care pharmacy. Consultant pharmacists are essential participants in the health care system, recognized and valued for the practice of pharmaceutical care for the senior population and people with chronic illness. In their role as medication therapy experts, consultant pharmacists take responsibility for their patients' medication-related needs; ensure that their patients' medications are the most appropriate, the most effective, the safest possible, and are used correctly; and identify, resolve, and prevent medication-related problems that may interfere with the goals of therapy. ASCP's 7,000 members manage and improve drug therapy and improve the quality of life of geriatric patients and other individuals residing in a variety of environments, including nursing facilities, subacute care and assisted living facilities, psychiatric hospitals, hospice programs, and in home and community-based care. Visit ASCP's Web site at www.ascp.com.

Subpart C—494.80

CMS regulations for nursing facilities require that a pharmacist conduct a monthly drug regimen review on each resident [42 CFR 483.60(c)]. Intermediate care facilities for the mentally retarded (ICF/MR) are required by CMS to have a drug regimen review conducted by a pharmacist on each resident on a quarterly basis [42 CFR 483.460(j)]. Medicare certified home health agencies are also required to conduct a drug regimen review as part of the initial patient assessment [42 CFR 484.55(c)], although this review is not required to be performed by a pharmacist in home health.

In stark contrast, CMS proposes only that a "medication history" [(494.80(a)(3)] be obtained for renal dialysis patients. Elsewhere in this section, evaluation of numerous elements is proposed to be required (e.g. nutritional status, psychosocial needs, current patient physical activity level) but there is no requirement for evaluation of the medication regimen.

For the highly medically complex renal patients, who typically take an average of 12 medications, a drug regimen review should be a critical part of the patient assessment. This assessment should be performed by a pharmacist because of the complexity of this population and the number and nature of medications used.

Although some renal dialysis facilities are associated with hospitals or nursing facilities, it is estimated that about 84% are freestanding. Thus, the pharmacist who would serve these facilities would most likely be a consultant pharmacist.

ASCP Recommendations:

1. In the list of members of the interdisciplinary team at the beginning of this section, ASCP recommends that CMS insert the phrase "a pharmacist."

2. ASCP recommends that 494.80(a)(3) be changed to read "laboratory profile" and that a new element be added to the list of items at 494.80(a): "drug regimen review."

Page 6224—(VI)(A)(6)—Other Personnel Issues

CMS is seeking input on whether to require that dialysis facilities have a pharmacist involved in the care of patients. **ASCP strongly supports a requirement in CMS regulations that dialysis facilities have consultant pharmacist involvement.** ASCP members have extensive experience providing services in a variety of settings, including dialysis facilities, and we list below some of the functions and services that pharmacists provide to improve care for patients served by these facilities.

Broadly speaking, consultant pharmacist services can be divided into two parts: patient-focused services and facility-focused services. Examples of patient-focused services include:

- Drug regimen review: comprehensive evaluation of the medications, dosages, laboratory test results, progress toward achieving therapeutic goals, identification of adverse effects, etc.
- Communicating drug regimen review findings and recommendations to the prescriber and other members of the interdisciplinary team
- Review of the medication regimen with the patient, evaluating patient comprehension and ability to follow the drug regimen, assisting the patient with adherence to prescribed therapy

These patient-focused activities are especially valuable in this population because of the need to:

- avoid certain medications that pose a high risk to this population
- adjust medication dosages based on renal function and dialysis interventions
- adjust medication dosing schedules in coordination with dialysis interventions
- assist in managing drug costs or coordination of drug benefits between Medicare Part B and other payers

The pharmacist can assist in minimizing drug costs by ensuring accurate dosing of medications and adherence to appropriate medication protocols, especially involving expensive biotechnology medications. Since eligibility for payment of certain medications under Medicare Part B depends upon the location of the patient when the medication is administered, the pharmacist can also assist the interdisciplinary team in ensuring that medications are administered appropriately to receive Medicare Part B reimbursement.

Beginning in January 2006, Medicare beneficiaries who also receive Medicaid benefits will have their primary drug benefit from the new Medicare Part D program instead of Medicaid. The coordination of benefits between Medicare Part B and Medicare Part D will be especially important for this population, since Medicare Part B is supposed to be the primary payer of medications. The consultant pharmacist can advise the interdisciplinary team on how best to ensure proper administration of medications to coordinate proper payment.

Medication adherence (or compliance) is also a particular challenge for these patients because of the number of medications and the complexity of scheduling some medications in coordination with dialysis interventions. The pharmacist is the health professional with the particular expertise to perform these functions. Counseling of the patient by the pharmacist can be particularly valuable in identifying and resolving obstacles to medication adherence.

The drug regimen review by the pharmacist should be conducted as part of the initial patient assessment, and periodically thereafter. Even if the pharmacist is not on-site at the time the patient is present, a review of the patient's medical

record (e.g. medication list, laboratory test results, diagnoses, and other pertinent information) by the pharmacist can be valuable.

Facility-focused services are also important in helping to ensure quality patient care. Examples of these services include:

- Assist the facility in developing or revising policies and procedures related to medication acquisition, storage, administration, and disposition
- Oversee development and implementation of strategies to ensure accountability of controlled substances in the facility
- Provide in-service education to facility staff on issues related to medication administration, such as prevention of medication errors, infection control, safety, etc.
- Quality assurance role in observing facility compliance with established procedures and providing input to the medical director and/or nurse manager, as appropriate

A 2003 GAO Report found medication errors to be a particular concern in dialysis facilities [Dialysis Facilities: Problems Remain in Ensuring Compliance with Medicare Quality Standards (GAO–04–63)]. With expanded access to their services, consultant pharmacist could play an important part in helping to address these issues in renal dialysis facilities. The state of Florida, for example, requires monthly visits by a consultant pharmacist to renal dialysis facilities.

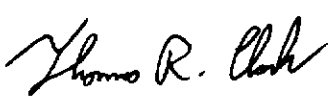
ASCP Recommendation:

ASCP recommends that CMS add the following item at Subpart D 494.140: "Standard: Pharmacist. The facility must have a pharmacist who must be licensed to practice pharmacy in the State in which he or she is employed."

ASCP would welcome the opportunity to work with CMS in further development of regulations, survey guidance, or interpretive guidelines related to CMS oversight of dialysis facilities. ASCP has extensive experience working with CMS on similar issues for oversight of nursing facilities and ICFs/MR. We would also be pleased to answer any questions or provide clarification or additional information about any of the issues addressed in this letter.

Thank you for the opportunity to comment on these issues.

Sincerely,



Thomas R. Clark, RPh, MHS
Director of Policy & Advocacy
E-mail: tclark@ascp.com

Submitter : Dr. Derrick Latos **Date:** 05/04/2005

Organization : Wheeling Renal Care

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attached Word document

CMS-3818-P-147-Attach-1.DOC

Attachment #147

Wheeling Renal Care
500 Medical Park, Suite 200
Wheeling, WV 26003

May 4, 2005

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

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

Dear Dr. McClellan:

I am writing to commend CMS for its hard work in trying to improve the quality of care for Medicare beneficiaries with end-stage renal disease (ESRD). As you well know, clinicians and providers of dialysis services have long awaited the proposed Conditions of Coverage, which, when finally approved, will create a framework for care for all patients undergoing dialysis care, not just those covered by Medicare.

I especially support CMS' intent to incorporate the use of evidence-based quality assessment and performance improvement into its ESRD regulations. Other organizations, especially the Forum of ESRD Networks, the Renal Physicians Association, the American Association of Kidney Patients, and others, have submitted for your consideration detailed comments regarding many of the technical issues in the proposed Conditions document. I wish to extend my personal support for those comments, but need to also highlight my concerns regarding some specific points.

It is critical that CMS differentiate between "standards" and "guidelines." In recent years the nephrology community has developed several practice guideline statements, whose purpose is to provide clinicians with decision-making tools. None of these guideline statements have been "*intended to define a standard of care, and should not be construed as one. Neither should they be interpreted as prescribing an exclusive course of management.*" Throughout the proposed Conditions document, it appears that CMS expects providers to achieve and adhere to prescriptive target numbers (for anemia, dialysis adequacy, etc.). The fact that current guideline statements recommend such numbers as targets must not be translated into using these as

standards of care. The rules should not incorporate nor require prescriptive number targets, since these are subject to change over time as additional clinical evidence becomes available. Moreover, use of overly codified language ignores the impact of newer technologies and an extremely diversified clinical environment. Most importantly, patient preference may also affect many of the outcome measures.

I wish to provide you with detailed comments regarding a single section of the proposed Conditions of Coverage: Social Worker Qualifications

Social Worker (Proposed §494.140(d)

The proposed Conditions would eliminate the "grandfather clause" which exempted individuals hired prior to the effective date of the existing regulations (September 1, 1976) from the social work master's degree requirement. Current regulations permit an individual with one year's experience in a dialysis setting who has a consultative relationship with a social worker with a master's degree to work in ESRD facilities.

While I recognize and support the important role of the professional social worker in providing care for ESRD patients, I strongly believe that circumstances still exist that warrant consideration for continuation of this exemption, or some variation thereof. I am fully aware that the NKF Council of Nephrology Social Workers is opposed to the exemption, citing the need for expertise and experience in dealing with the myriad of problems facing ESRD patients and their families. I beg to disagree with their position on the grounds that implementing such a rigid requirement will pose serious barriers for many excellent clinical social workers who currently work along with MSW staff in dialysis settings. This is particularly problematic for dialysis facilities located in rural areas, or in locations in which master's degree prepared social workers are not readily available.

My own experience over the last 28 years provides an example. My group of four nephrologists, along with staff of a small independent dialysis provider, currently provides care for approximately 170 ESRD beneficiaries in three free-standing facilities in the upper Ohio Valley. Two of these facilities are located several miles away, one in a small rural community. Because of the logistics of providing consistent care to our patients, many of whom reside in remote counties, we employ three social workers working together as a team. Two are MSW, but the other, a BSW with 22 years of clinical social work experience, 10 in ESRD, works closely and essentially interchangeably with her colleagues. All social work assessments and care plans are reviewed as a team, and an MSW has final sign-off.

Interestingly, the BSW-trained individual has extensive experience in dealing with our complex patient population, since her career has focused on geriatric care. She also coordinates our use of a variety of patient functional measures (SF-36), the Unit Self-Assessment Tool (for rehabilitation purposes), an annual patient satisfaction survey, a quarterly patient newsletter, and regularly provides in-service programs to local hospitals and colleges. She regularly attends (and has participated in developing) local and national nephrology social work educational programs. Personal circumstances and the difficulty of traveling long-distances to obtain her master's degree have impeded her obtaining the MSW certificate. Particularly important is that none of the MSW programs within reasonable driving distance will grant this individual advanced standing toward a master's degree, since her undergraduate training was longer than 20 years ago. Despite her uninterrupted work in the field of clinical social work for 22 years, she would be required to begin her studies de novo.

I cite her activity and experience as an illustration of the type of highly qualified and competent individual that could be eliminated unless the Conditions allow for some type of

exemption. I suspect that many similar situations exist throughout the country. I believe that the Conditions must allow for such individuals to continue their work in ESRD facilities.

Moreover, the scope of authorized responsibilities for licensed social workers, including those with BSW qualifications, varies considerably from state to state. In West Virginia, for example, the Board of Social Work Examiners, in its Qualifications for Licensure as a Social Worker, permits licensed social workers, including BSW graduates, to perform duties that are determined by the employer, so long as the licensee meets all criteria for licensure and which are consistent with the social worker's training and experience. The State of Ohio has more explicit regulations concerning licensed social workers. The scope of practice for a Licensed Social Worker in Ohio includes in the range of duties several tasks deemed necessary in working with ESRD patients:

- psychosocial assessment and diagnosis
- intervention planning
- psychosocial intervention
- counseling
- social psychotherapy under supervision
- evaluation

Although the ESRD population is arguably among our nation's most complex and most ill, patients with many other chronic medical conditions receive excellent care from non-MSW trained social workers. In view of the nature of social work licensure and current practice patterns throughout the United States, I respectfully request that the ESRD Conditions of Coverage not be overly restrictive by establishing policy that has been proposed. I think you would agree that much of the expertise gained by any professional is iterative, and not based solely on meeting requirements for an academic certificate.

If the "grandfather clause" is eliminated, I suggest that language be created that allows for waiver of the MSW requirement under specified circumstances. These could include the requirement that an explicit working (not just consultative) relationship be in place with an MSW. CMS must not ignore the value of a BSW working as an active member of a "renal treatment team", in contrast to simply requiring that social workers have a master's degree. Certainly, when an MSW is personally directing the social work care in the same dialysis program, appropriately trained and experienced BSW staff should be allowed to function as an integral part of the team. Certainly, a BSW-trained social worker is a professional and she/he must be permitted to function at a higher role with greater responsibilities than non-professional personnel.

At a time when individuals potentially pursuing careers in the health professions are facing many attractive alternative career opportunities, the ESRD Conditions of Coverage should not pose additional barriers to qualified and experienced individuals in any discipline. There is no evidence to support the notion that a BSW social worker with years of experience, who has worked closely as a member of an ESRD team for many years, provides care of a lesser quality. In our own experience, the many years our BSW spent in geriatrics social work has proven invaluable to the success of our program, the benefit of our patients, and even to our entire team, including her MSW colleagues. Perhaps CMS should urge the social work profession (i.e., the Council of Nephrology Social Workers) to investigate various models of social work care in the ESRD setting prior to adopting such restrictive language in the final Conditions of Coverage.

In addition, I urge that CMS adopt language that emphasizes that meeting patients' needs, particularly with respect to social workers' services, should be based on local circumstances and

the availability of staff. The proposed Conditions have set precedence for using "non-qualified" individuals, by retaining the alternate option: Medical Director (proposed §494.140(a)) provides for "...the alternate option for situations when a physician who meets this criterion (*a physician who has completed a board-approved training program in nephrology and has at least 12 months experience providing care to patients receiving dialysis*) is not available that allows another physician to direct the facility."

The alternate option for medical directors was created to address those unique and infrequent circumstances when an otherwise qualified nephrologist is not available. I can envision similar situations for social workers, especially in remote or rural areas, but also in certain urban locations. Regardless, when a BSW social worker works closely with an MSW in the same dialysis program, she/he should be permitted to function to the degree that her/his expertise and experience allows.

I appreciate the opportunity to provide you with my comments, and look forward to working with CMS in its implementation of the final Conditions of Coverage regulations. These comments have the full endorsement by all four nephrologists comprising Nephrology Associates, Inc, (Wheeling, WV) and the entire staff and administration of Wheeling Renal Care.

Sincerely,

Derrick L. Latos, MD, MACP

Medical Director, Wheeling Renal Care
President, Forum of ESRD Networks
Officer, Board of Directors,
Mid-Atlantic Renal Coalition

Submitter : Mrs. Phylis Ermann **Date:** 05/04/2005

Organization : American Kidney Fund

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-148-Attach-1.DOC

American Kidney Fund
6110 Executive Boulevard
Suite 1010
Rockville, Maryland 20852

301.881.3052 voice
301.881.0898 fax
800.638.8299 toll-free
866.300.2900 Español
www.kidneyfund.org
Member: CFC 0508

American Kidney Fund

Attachment #148
Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-3818-P

Dear Dr. McClellan:

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

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

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

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

We believe CMS must also consider the financial implications of these potential regulations on dialysis providers so that unintended negative consequences do not occur. There must be adequate financial resources available for dialysis facilities to implement many of the proposed conditions. Certain requirements, such as staff ratios and infection control nurses, have the potential to improve patient care, but also to increase costs, which must be fairly reimbursed. Over the last seven years ESRD facilities have received only a 3.6% increase in reimbursement for dialysis treatments provided. During the same

time, because of market basket adjustments, hospitals have received a 12% increase and the Consumer Product Index has gone up 16.9%. The Fund supports CMS' efforts to further improve patient outcomes and believes payment policy must be adjusted concomitantly.

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

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

Patient Safety

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

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

Patients Rights and Responsibilities--Section 494.70

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

- We suggest adding a requirement that facilities document that patients have demonstrated their understanding of the information provided or document that staff have made a concerted effort, as defined by written policy, to help the beneficiary understand established patients rights and responsibilities. **(a)(2)**
- We strongly support the language of **(a)(5)** which describes the right of patients to participate in the planning of their care and proposes patients be informed of their right to establish written advance directives describing an individual's preference with regard to the degree of medical care and treatment desired and who should make treatment decisions if the individual becomes incapacitated. We strongly support the proposal that the patient or designee must sign the care plan, regardless of participating in the planning process.
- In addition to informing patients of all available treatment modalities, including all home options, we advocate adding the requirement that patients must be notified of where treatments modalities are offered within a 120 mile radius if the facility does not provide a particular modality. **(a)(6)**
- We propose adding a requirement that patients have access to a qualified dietitian and social worker, as appropriate. Currently, social workers and dietitians often have unrealistic caseloads, cover multiple facilities and/or work part-time and patients often don't know how to contact them when needed.
- We also propose adding a requirement that patients should be informed at the initiation of treatment, that employment and/or schooling are possible for those requiring dialysis.
- We support the proposal that facilities should inform patients of its written transfer and discharge policies and procedures and make them available to all patients when they start dialysis. **(b).**
- We support the 30-day notice requirement for patient discharge **(b)(1)** and **(2)** except in the instance of actual or potential physical harm to patients or staff, in which case the facility should have the right

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

Patient Assessment—Section 494.8

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

Patient Plan of Care--Section 494.90

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

- Regarding measures of dialysis outcomes (a)(1-3), the Fund believes the Conditions of Coverage should require facilities to adhere to the National Kidney Foundation KDOQI® guidelines and performance measures developed by CMS achieving minimum threshold values for dialysis adequacy, anemia management, nutrition, and vascular access. These are mostly evidence-based standards accepted by the nephrology community. Conditions of Coverage should be updated as the science matures and/or new guidelines are established. CMS should enlist the panel of experts suggested earlier for developing the interpretive guidelines to assist with changes in the guidelines.
- Transplant status **(a) (5)**, we do not agree to deleting the requirement for someone from the transplant center sign the care plan as proposed. We suggest a transplant surgeon, physician, or transplant coordinator sign the plan, which documents the patients' degree of suitability and interest in transplantation. Successful transplantation has long been recognized as the preferred standard of care, and documentation of discussion and planning may lead to increased numbers being transplanted and decrease patient allegations of not having discussed transplantation during the patient care plan sessions at the dialysis center.
- The care plan should also stress rehabilitation goals with appropriate referrals to physical therapy, occupational therapy, psychological therapy and vocational counseling services as needed. The Fund also supports a requirement that facilities offer modalities and schedules which are work/study-friendly or provide a list of facilities which do.
- We suggest the addition of a requirement that patient care plan include a report on the self-care activities the patient performs or the basis for non-participation.

Care at Home—Section 494.100

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

Quality Assurance and Performance Improvement--Section 494.110

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

Personnel Qualifications—Section 494.140

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

- The Conditions of Coverage should continue to require that the Medical Director of a dialysis facility be either board certified or board eligible in nephrology.

- Clinical social work training is essential to provide appropriate counseling to patients for the complex psychosocial issues related to ESRD and its treatment. Therefore, we urge CMS to change the language regarding Social Workers **(d)** to include: 1) Completion of a course of study with specialization in clinical practice and receiving a masters degree from a graduate school of social work accredited by the Council on Social Work Education and 2) Licensure in the state in which s/he is practicing.

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

Governance –Section 494.180

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

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

Sincerely,

Andrew Givens
Chair, Board of Trustees

Submitter : Ms. Valerie Takai OTR **Date:** 05/04/2005

Organization : Ms. Valerie Takai OTR

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-3818-P-149-Attach-1.DOC

Attachment #149

Docket: CMS-3818P – End Stage Renal Disease (ESRD) Conditions for Coverage

Valerie Takai OTR
May 4, 2005

Introduction and General Comments

I am grateful to have this opportunity to comment on the Proposed Rule for the first major revision since 1976 of the Medicare Program: Conditions for Coverage for End Stage Renal Disease. My comments are honest and frank. My goal is simply to promote a better life for this population with improved care.

My unique perspective as an occupational therapist with over 20 years of experience in acute care, rehabilitation, and chronic disease facilities as well as in home care along with my present role as an ESRD caregiver for 5 years spending extensive time observing and interacting with patients and staff at the Yorkville Dialysis Unit in New York City have helped me formulate my responses to the Proposed Rule.

I have been a very involved caregiver for my husband, an insulin dependent diabetic for over 40 years, who, in addition to having ESRD, has undergone a colonectomy for colon cancer and has a dementia and gait disorder from a constellation of neurologic conditions. I accompany him three times a week to dialysis and serve as his advocate.

From rehabilitation I learned that the patient centered team approach is essential for quality care and good treatment outcome. Over several years I treated over 1,000 patients as a member of an interdisciplinary team in a special clinic for patients with amyotrophic lateral sclerosis seen throughout the course of their terminal illness. Quality of life as well as improved physical and psychological function for the disabled has been an important focus of my career.

Issues 1 – 10

Physical Environment
(Proposed 494.60)

An early concern of mine when my husband started dialysis was the problem of safety for an individual patient leaving the dialysis unit alone taking the elevator downstairs to the lobby to await transportation home. I have witnessed that approximately half of the patients in the dialysis unit have limited ambulation and problems with balance and endurance due to a wide range of factors which often worsen immediately following dialysis treatment. Many use canes or rolling walkers, and some wear orthotics or prostheses. There is no phone or intercom between the lobby and the dialysis unit on the second floor and at that time once a patient walked out of the Unit he or she was essentially on his own.

While I had to escort my husband in his wheelchair to the lobby I also found myself assisting other patients and on at least two occasions prevented patients from falling. Staff appeared oblivious to the problem. After letters to Administration at Beth Israel Medical Center and the Yorkville Dialysis Unit, one of which described an incident where I found a stranger urinating in the downstairs lobby and going through the trash, a security guard was finally hired. He can watch out for the safety of the dialysis unit as well as the safety of individual patients and when necessary procure a wheelchair or physically escort a patient.

494.60(e) Dialysis centers in New York City are often located on the 2nd floor of small office buildings some with only one small elevator and one staircase. A large and growing population of patients has impaired ambulation and some patients are wheelchair bound. I propose that as part of standard equipment for such facilities an emergency EVAC chair (commonly used by firefighters and others) be standard equipment available to assist staff in evacuating patients in the case of fire or in the case of an elevator being out of order (a not unusual occurrence).

Patients' Rights

494.70 (a) Proposals emphasizing the right to be treated as an individual with dignity, and respect are essential. It has been my

experience that many staff in daily contact with dialysis patients are not trained to consider the psychosocial needs of ESRD patients. It is important for all staff including receptionists and dialysis technicians as well as physicians, nurses, social workers, and dieticians be expected to treat ESRD patients with respect.

Regarding the proposal to inform patients of their right to establish an advance directive this is critical. Just leaving healthcare proxy forms and living wills on a display table is not enough. It has been my experience that staff at the dialysis center treating my husband is uncomfortable dealing with end of life discussions and there is no policy for handling the topic. Patients need to have a knowledgeable person on staff comfortable communicating with patients on advanced directives and initiating discussion. Patients learn of other patients' deaths and express their own anxiety when they wonder how they died, was there any pain and suffering, and do not learn the answer. It should not fall into the lap of the social worker because the nephrologists or nurse practitioners do not wish to handle the issue. Sensitivity to medical ethical issues is critical. Patients need to be made aware of hospice and palliative care should it be needed.

I quote from the AAHPM Bulletin, Quarterly Newsletter of the American Academy of Hospice and Palliative Medicine Vol 3. No 1 Fall 2002 article "Discontinuation of Dialysis: The Role of Hospice and Palliative Care," "If ever a subgroup of dying patients deserved palliative care, it is the growing group of patients whose dialysis has been discontinued and who face a mean of only eight days to live." The article mentioned that in the United States more than 20,000 end-stage ESRD patient deaths followed dialysis discontinuation between 1990 and 1995. In New England patient deaths preceded by decisions to terminate death rose from 10% to 28% in the past decade covered in the article. The article mentions a Bayside Medical Center prospective study which examined all ERSD deaths not just those preceded by dialysis termination and found that 57% of respondents were unsure or believed that the patient died with pain and 24% thought the death was not peaceful while 43% regretted that the patient had not fulfilled his or her final wishes at the end of life.

Patient Assessment

(Proposed 494.80) The initial period of dialysis was a terrifying experience as my husband had been hospitalized for six weeks for a subtotal colonectomy and started on hemodialysis just prior to coming to the dialysis center. He had to travel by ambulance from home for the first four and a half months. He was very frail and disoriented. On his second visit on the evening shift he stood up and his permacatheter got disconnected. I was informed in the waiting room of the dialysis center that there was an emergency and that he had been taken to the ER and that he would be alright. I met him in the ER just as the nurse was in the midst of taking his blood pressure with the tightened cuff placed over his new fistula. He had to be hospitalized then to repair the permacatheter and have another surgery for a fistula. I only learned what actually happened several months later from an ambulance driver who caught him as he came to standing and from a patient receiving dialysis situated in a chair next to him at the time. This incident was to be one of several emergencies occurring in the dialysis unit over the course of almost five years resulting in hospitalization.

Our first impression of the dialysis unit was to have a lasting effect. In the waiting room I remember handouts delineating regulations about bringing weapons and signs posted for how to file grievances and some pamphlets relating to diet. The receptionist was cold and curt and sat behind a closed window with a lock which she opened reluctantly. There were doors everywhere which had to be opened. Healthcare proxy and living will forms I discovered much later on a counter in the dialysis unit.

As a new patient neither my husband nor myself received psychological support and the assessment by the nurse practitioner merely sought verification of his complicated medical history. The only person who involved us in the assessment was the nutritionist who called me at home prior to the initial visit to the dialysis unit and who spent much time introducing me in detail to the new diet taking into consideration my husband's individual cultural as well as physical needs. I relied on my own skills as an occupational therapist to anticipate his rehabilitation needs as he gained strength and fortunately through my initiative he was able to receive physical therapy through Visiting Nurse home care.

His nephrologist never saw him in the dialysis unit but instead he had to be brought by ambulance from home to his office (only 4 blocks

from the dialysis unit) at great inconvenience to the patient (and at a large expense to Medicare) who had to travel another three other days in the same week by ambulance to dialysis.

Approximately a year later when his condition was stable and he was traveling by car service, I was asked to sign a copy of the treatment plan. There had been no prior discussion or input from the patient or myself. It was the first time that we actually saw a plan which had almost no comments.

The initial assessment sets the groundwork for the patient's introduction to dialysis and the many changes taking place. Patients have questions but when there is no orientation and minimal discussion with staff and no input from the patient dialysis is overwhelming. It would have been very helpful to know what to anticipate in the gradual adjustment of the body to dialysis and relieved much of the discomfort of some of the side effects and medical complications. A three month time frame for reassessment of new patients and if necessary in special cases a six month time frame would help to alleviate many of the physical discomforts and reduce much of the anxiety and stress that new patients feel. It could also help to focus on such issues as depression and clarify further treatment goals, confront noncompliance and give patients the opportunity to ask and receive answers to their concerns about treatment.

It should be emphasized that the assessment be done by an interdisciplinary team so that staff can have a clear unified vision of treatment goals and thus can work together to promote optimal patient care, and, that the patient be involved from the very beginning. An important benefit to the team approach is the learning that staff from different disciplines gain from each other as well as from the patient.

Patient Plan of Care

(Proposed) 494.90 A single patient plan developed by input from the interdisciplinary team in the assessment should include the patient's nephrologist, nurse or nurse practitioner, nutritionist, and social worker. Additional members to consider adding are a physical therapist and a consulting psychiatrist if indicated. When staff work together to promote treatment goals it gives patients a strong sense of support and a more

hopeful yet realistic outlook for the future. When the patient has input there is a better chance that he or she will be more motivated to take better responsibility for his or her own care.

Rehabilitation Status (Proposed) 494.90 (a) (6) (7)

Renal rehabilitation has not forcefully addressed on a widespread basis the potential for physical restoration, employment, and the pursuit of an active life. Rehabilitation promotes maximum physical function and emotional wellbeing. It is concerned with overall quality of life.

I heartily agree with the contents of this section and emphasis on rehabilitation as a distinct plan of care category and its essential role in treatment and recovery and its emphasis on an ongoing process. Rehabilitation should be addressed when possible before the patient even begins dialysis. Nephrologists tend to underestimate the potential of rehabilitation and the benefits that can be realized by their patients with focus on exercise, basic skills for living, education, and vocational evaluation and training. Rehabilitation looks at the total patient and seeks to enhance physical and psychological function.

We all know that exercise is beneficial for us, but it is especially beneficial for dialysis patients, who suffer from various co-morbidities, including hypertension, diabetes, and cardiovascular diseases. In addition, patient may suffer from bone disease, cancer, progressive neurological disorders, etc. Their deconditioned status is further exacerbated by the fact that they are required to remain stationary for over 12 hours a week. Rehabilitation when it involves medical needs is required to be through referral of a physician and not under social service.

My husband was fortunate to receive physical therapy at the Yorkville Dialysis Unit for progressive lower extremity exercise while undergoing dialysis and at home following acute hospitalizations under Visiting Nurse homecare. Without physical therapy he would be in a nursing home. It was essential for me to be able to walk him up steps at the entrance and lobby of our apartment building and get him in and out of a car by myself, otherwise, I could not bring him to dialysis. Ambulette is out of the question due to the high cost of private pay. A slight

decrease in his ability to ambulate means I am not able to care for him at home.

Physical activity and rehabilitation programs can benefit patients by improving strength, coordination, flexibility, endurance, and reducing depression. Individually tailored physical therapy programs are easily accomplished through resistance training and/or hand weights, a stationary cycle, or recumbent stair climber. An on-site physical therapist can assist with home programs of exercise as well as in-center exercise. Groups of patients can be doing exercise at the same time while on dialysis machines.

Formal guidelines need to be established to integrate physical activity and exercise training into the routine care of dialysis patients. Exercise programs are an easy way to help patients maintain their functional independence while living at home and taking care of themselves. The preventative attitude can stop the downward spiral of physical deterioration which occurs in renal patients, reducing not only their suffering but also costs, and resulting in positive benefits for patients, the healthcare system, and society.

494.90g. **Social Services**

It is my feeling that the social worker has a tremendous burden handling a difficult caseload alone without support, and, in addition counseling staff. The social worker counsels and educates patients and provides much needed specific information and referrals to outside agencies assisting with obtaining Medicare and Medicaid benefits and so forth.. Many patients are extremely angry and often belligerent and depressed. Staff also can be frustrated, angry, and depressed by their caseload. The first year at the dialysis unit my husband and I were confronted with a burned out staff who resented coming to work and treating dialysis patients. The patients were also angry. When we greeted staff there was often no response. Often there was no conversation between a nurse or technician and the patient during the entire course of treatment. There were many staff arguments and complaints in front of patients and many patients were highly anxious and depressed. There were battles between ambulance and ambulette drivers and individual staff in front of everyone. If only there had been a psychiatrist available to help the social worker and staff deal with staff

burnout and to treat patients who were suffering moderate to severe depression.

I strongly recommend the availability of a consulting psychiatrist to work with staff individually or in a group to help them deal with their own individual feelings about patients and to also help prescribe medication for patients when needed consulting with the patient's nephrologist. Staff burnout is detrimental to patient care and should be dealt with directly and without delay. Good staff leave if burnout is not handled properly. Dialysis patients are a challenging group to treat and their treatment outcome can be rewarding to all if staff and patients can work together.

Implementation of the Patient Plan of Care

(Proposed 494.90 (b) (4)) It has been many months since my husband has been seen by his nephrologist providing the ESRD care but his record has been reviewed by the nurse practitioner and conveyed to him. His nephrologist is an extremely competent dedicated knowledgeable overworked physician who while not seen often in person by patients is available 24/7 for their care. It is rare that his physician or other nephrologists see their patients in the Yorkville dialysis unit. His physician cares for over half of the patients in the dialysis unit who must schedule a separate appointment in order to see him. This kind of scheduling makes it difficult for patients who work or going to school or who are frail and essentially homebound who have to sacrifice enough of their free time just to receive dialysis and then have to make an additional trip to the doctors office which generally involves a long wait. To me this refutes the idea of patient centered care. Patients benefit from individual contact with their physicians and not just through an intermediary. Dialysis staff also benefit from seeing the physicians in the unit from time to time.

Patient Education and Training

(Proposed 494.90 (d)) Because of so many unanticipated physical changes in the patient and major life changes and decisions to be made the patient and family especially need support during the early transition onto dialysis and education and training in the regime they need to follow and a chance to ask many questions and have them answered. Much

time and concentration on the patient during the first few months will contribute significantly to the outcome. My experience with my husband was minimal education and no goal setting with the patient and family. The major way of learning about dialysis was from other patients, technicians and nurses who would merely answer questions posed by patients rather than initiate any training.

Docket Number: CMS-3818P – End Stage Renal Disease (ESRD) Conditions for Coverage

Issues 11-20

Condition: Quality Assessment and Performance Improvement (Proposed 494.110)

QAPI

I would like to stress the importance of establishing internal systems for identifying and analyzing causes of medical injuries and medical errors. The overall goal should be to improve quality care. It has been my experience at the Dialysis Unit medical injuries are often not documented and that injuries are frequent. I have found that certain technicians do not report possible injuries to their supervisors or nurses on duty and that little information is shared by staff when a problem arises. Just one small example occurred with my husband when a technician used plastic tape to secure the needles in the new graft site in his leg. When he removed the tape he removed large pieces of skin with it. When we arrived at the dialysis center the next scheduled appointment we became aware that the technician never even conveyed the incident to the nurse supervising him. Fortunately my husband still had a functioning permacatheter as he had to wait over six weeks before the skin over the graft site had healed sufficiently for the graft to be used again. To this day technicians have to be told to use paper tape and what direction to insert the needles in the graft in his leg. Better training of technicians is needed.

There needs to be a positive supportive atmosphere where staff is willing to come forward with information about possible injuries and are free to question.

Just two months ago my husband had an emergency hospitalization for blood transfusions when a needle became dislodged and appropriate help was delayed due to technicians not responding to three signals for assistance. The technician who finally responded gave extra saline without checking the graft site while the dialysis machine was pulling blood out of his body but not returning it. The ambulance to the hospital a few blocks away cost 1,400 dollars and the hospitalization several thousand dollars.

Personnel Qualifications

Medical Director

(Proposed 494.140 (a) and Proposed 494.150) This is an extremely important position and demands direct involvement with staff and responsibility for the direction of medical care and quality of staff. The Medical Director's name and title should be posted so that staff and patients know who the Director is. Recently posing the question of the name of the Medical Director to the receptionist, several patients, and staff no one was able to name the Director. It indicates that the Medical Director is not very involved with the Dialysis Unit and its focus on patient care. For five years there has been no posting of the Medical Director's name and no dissemination of information regarding his or her name. I strongly support that the proposal that the medical director should be on-site and directly responsible for the quality of care delivered and have the authority to develop and monitor quality improvements, serve as a much needed educational resource for all medical and nursing staff, and when necessary terminate or report to the appropriate authority those who are not performing according to acceptable standards of care.

Social Worker

(Proposed 494.140 (d) I strongly support the proposal of the requirement for an MSW and the strengthening of the social service role by freeing up the social worker using nonprofessional staff to perform the clerical duties involved with information on Medicaid, Medicare, medication, and transportation. Psychosocial evaluations and counseling are critical for patient care. I would like to stress again the importance of access to a psychiatrist to assist the social worker when referrals are indicated for medication for treatment of depression in

consultation with the nephrologists and provide support for working with staff to deal with their own feelings in handling a complex and difficult caseload.

Dialysis Technician

(Proposed 494.140 (e)) In reviewing the 72 page Proposed Rules document I was shocked but I must admit not surprised by the limited training of the dialysis technicians, the frontline deliverers of patient care. It is amazing to me that there is no uniform national credentialing, licensing, or minimal qualification requirements and yet these individuals with sometimes less than a high school degree and three months education and three months on the job training by a nurse have such tremendous responsibility. It is no wonder to me that there are many problems with preservation of working fistulas and grafts many of which are preventable. My experience is that the skill of individual technicians is highly variable and that incompetent technicians are kept on staff. A chain is as strong as its weakest link and one incompetent technician rotated amongst many patients can cause tremendous harm and directly affect the overall quality of care of patients in the dialysis unit. Patients are most troubled by the lack of skill of individual technicians and the harm done to their fistulas and grafts by those initiating cannulation and venipuncture with large gauge needles without the necessary fine hand skills and training. The emotional cost to patients and their families as well as the physical suffering and the expense of additional surgeries and hospitalizations is high. I learned that in Japan physicians insert the needles. A Japanese nephrologist told me that Asian patients have smaller blood vessels and are started out on finer gauge needles than are available here and that there are fewer complications with fistulas.

Concentration on upgrading dialysis technician qualification and working toward a national certification system is critical to improving patient care and in the long term should reduce hospitalizations caused by medical injuries.

Medical Records

(494.170) Medical records should be up to date and accurate. When incidents occur they need to be reported without fear of retribution. Medical emergencies need to be reported immediately and

need to be tracked to prevent future incidents. Patients need to keep the nurse in charge of their care updated on changes in medications so that they can be entered in the record. Phone numbers and emergency contact information of patients need to be up to date. Consideration should be given to the entering of healthcare proxies into the medical record as is done when patients are hospitalized.

Ownership of Dialysis Facility

Existing 405.2136 (a) covers the full disclosure of ownership for facilities that are independently owned, controlled by a partnership, or wholly owned by corporate entities. It is not transparent to patients or staff who owns the Yorkville Dialysis Unit and the exact relationship of Fresenius and Beth Israel Hospital. With the sudden closing of the Singer Division of Beth Israel Hospital last July due to severe financial problems and rumored accounting irregularities it is an especially important issue. There is no sign at the entrance and only in the last month was a sign put up with Beth Israel North Division posted in the hallway and names without titles with arrows pointing in the direction of their offices.

(Proposed 494.180) This proposal is critical to resolve the lack of transparency regarding legal ownership with an identifiable governing body. The proposal 494.180g stipulating that the governing body be responsible for emergency coverage and for written instructions to staff and patients for obtaining emergency medical care is essential. Medical emergencies arise suddenly without warning and patients need to know before an emergency arises what hospital emergency room will accept them and how their records will be transferred to and from the dialysis unit to the accepting hospital.

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

Organization :

Category : **Social Worker**

Issue Areas/Comments

Issues 1-10

Plan of Care

494.80 (b) (1) and (2) The proposal for assessments to be completed within 20 days is not very feasible. When you are covering 3 clinics, with an average patient census of 188, travel time of 30 to 40 minutes between clincs and dealing with dialysis schedules and hospitalizations it becomes a juggling act. The current 30 days is reasonable. I can agree with the need for a re-assessment of new patients. However 3 months is to soon to do an reassessment. Most patients take at least 6 months to really began to feel better and are able to reassess their situation. 494.80(d)(2) From a social work standpoint a complete monthly psycho social assessment is not necessary. Any changes can and should be reported in a problem list available to the entire team as those changes take place. Three months should be considered for unstable patients.

Submitter : Ms. Mary Lopez **Date:** 05/04/2005

Organization : Community Medical Centers

Category : End-Stage Renal Disease Facility

Issue Areas/Comments

GENERAL

GENERAL

See attachment:
I am a director of both a critical care service and inpatient dialysis for 5 hospitals as well as 2 outpatient hemodialysis clinics and 1 Continuous Ambulatory Peritoneal Dialysis clinic
So i represent both hospital and ESRD facility

CMS-3818-P-151-Attach-1.DOC

CMS-3818-P-151-Attach-2.DOC

Attachment #151
May 4, 2005

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

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

To Whom It May Concern:

Community Medical Centers in Fresno, California appreciates the opportunity to comment on the proposed rule regarding conditions for coverage of end stage renal disease (ESRD) facilities.

Dialysis of ESRD Patients in Skilled Nursing Facilities

Background

We are concerned about the provisions regarding dialysis in skilled nursing facilities (SNFs) and subacute distinct part facilities. We are seeing an increasing number of patients who have complex medical needs and require dialysis, but are otherwise stable. These patients could be cared for by nursing facilities. We currently are required to hold patients in ICU's because they have a home ventilator and require dialysis. Even though the subacute facility can manage the home ventilator, they cannot manage the dialysis component, nor are we allowed to go into the facility and perform dialysis. Additionally, home dialysis is meant for patients who can assume a high level of responsibility and accountability for their care. To avoid peritonitis and sub-optimal treatment which affects their KT/V ranges and anemia management strategies, both outcomes measured for quality of care indicators. Additionally, patients would be required to have a private room or have access to a private room to perform peritoneal dialysis. Any residents in a semi-private or ward room would put them at high risk for peritonitis for the peritoneal dialysis (CAPD). In this situation, the SNF or subacute facility would have to employ a trained dialysis nurse or dedicate SNF staff for specialized staff training.

We appreciate the Centers for Medicare and Medicaid Services' (CMS) recognition of this problem as set forth in the proposed rule. Allowing SNF residents to access home dialysis, however, does not solve the problem. We urge CMS to revise its position and make it financially feasible for nursing facility patients to receive dialysis at the bedside from a dialysis facility or the SNF.

Provision of Home Dialysis to SNF Patients Is Inappropriate

Nursing home patients who typically require dialysis are extremely fragile. The stability of their health status is precarious and can change at a second's notice. The home dialysis benefit, on the other hand, is designed for dialysis patients who are healthier and

heartier than the average dialysis patient. Thus, home dialysis is not medically appropriate for the vast majority of SNF patients who require dialysis.

In addition, for these patients their stay in the SNF is a short break in the midst of on-going dialysis treatment. Rarely, if ever, are these patients on home dialysis prior to or after the SNF stay. Requiring these patients to switch from chronic dialysis to home dialysis and back again within a one-month timeframe is unrealistic. This includes a surgical procedure for catheter placement that puts these fragile patients at risk for infection, healing time and extends their time in an acute facility. Not efficient, nor effective. The current system cannot support demands for such quick benefit coverage decisions. Thus, patients' continuity of care is jeopardized by the proposed rule.

For these reasons, use of home dialysis in nursing homes is inappropriate for the vast majority of nursing home residents.

Bedside Dialysis Services Provided by Dialysis Facility or Nursing Facility Covered by Medicare Statute

Currently, the vast majority of nursing home patients requiring dialysis receive such services at an off-site dialysis clinic. This situation has significant drawbacks. First, it necessitates use of an ambulance – and Medicare resources – to transport the patient to and from the clinic. Second, being transported to/from the clinic and sitting up in a dialysis chair is extremely taxing on residents whose health is already seriously compromised. Third, it requires the patient to be out of the nursing facility for a significant amount of time, missing medication administration, treatment regimens, meals and planned activities. Fourth, it is not uncommon for the resident to require accompaniment of a SNF nurse, which pulls resources away from other SNF residents.

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

Not only do we believe these options are the right thing to do, we believe that they are consistent with existing Medicare law. As set forth in more detail in the comment letter from the California Hospital Association (CHA), the applicable statutory provisions provide leeway for interpretation. **Thus, we urge Medicare to interpret existing law so as to make it financially feasible for SNF residents to receive dialysis services at the SNF, whether under a Part A stay or Non-Part A stay and whether performed by a dialysis provider or by the SNF.**

Conclusion

The numbers of patients who require dialysis, but could otherwise be cared for in a nursing facility are increasing. Home dialysis is inappropriate for the vast majority of nursing home residents because of their medical fragility. We urge CMS to interpret

existing law in such a manner as to make it financially feasible for SNF residents to receive dialysis services from dialysis providers and SNFs at the bedside.

If you have any questions or comments, please contact Mary Lopez at (559) 459-2443 or mrlopez@communitymedical.org. or Elizabeth Samoylenko, Manager Dialysis at (559) 459-2560 or esamoylenko@communitymedical.org.

Sincerely,

Mary Lopez MSN, RN
Director Critical Care/Telemetry/Dialysis Services
Community Medical Centers
PO Box 1232
Fresno, California 93715-1232
(559) 459-2443

Submitter : Dr. Nathan Levin **Date:** 05/04/2005

Organization : Renal Research Institute

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment."

Submitter : **Ms. Barbara Dennler** **Date: 05/04/2005**

Organization : **Covenant Medical Center**

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

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-153-Attach-1.DOC

Covenant
Health System

3421 West Ninth Street
Waterloo, IA 50702-5499
Tel 319/272-8000

A member of the Wheaton Franciscan System in partnership with Schoitz Health Resources

Attachment #153
May 3, 2005

Centers for Medicare and Medicaid Services (CMS)

To Whom It May Concern:

In reviewing the proposed conditions of coverage for End Stage Renal Disease Facilities, the following comments and suggestions are being made and outlined below:

Provisions of Proposed Part 494 Subpart B (Patient Safety)

A. 494.30 (a)(1)–Infection Control
To require new units to incorporate an isolation room, I feel would be a financial burden, especially to smaller units. Also would this proposal regulation be for newly built facilities, or would a facility remodeling be held to this standard? Clarification is needed in what would be considered an isolation station and what would be the required make-up of such a room (i.e., a room with a door, moveable panels, or screens and if acceptable would the dividers need to go from floor to ceiling? What would be the requirements for the room's make-up and size?).

In addition, if a hospital-based unit has off site dialysis units affiliated with their program would these smaller off site units require an isolation room if Hepatitis B patient(s) can be accommodated at the "home" hospital based unit? The issue of staffing a smaller unit for a Hepatitis B patient would create increased financial inefficiencies and would be of concern for smaller units and dialysis programs overall.

B. 494.40 (2)–Water Quality
Water is a critical element in the hemodialysis procedure. If chlorine/chloramines are checked every patient shift this would be three to four times a day depending on the size of the unit. I recommend that the section, chlorine/chloramines be sampled every four hours, which ever is shorter, be eliminated due to being too restrictive. Dialysis units that operate very long hours with patient treatments of three to three and one-half hours would need to sample water as much as six to eight times daily, which I feel is redundant. Sampling water prior to each patient shift would be sufficient.

494.40 (d) I am requesting clarification of mixing a fresh batch of bicarbonate with another. Our unit usually mixes more than one batch of bicarbonate daily. During the last shift of patients you may have two jugs half full from earlier in the day. Is it permissible to combine bicarbonate that was mixed the same day? Would this pertain to the large bicarbonate mixing systems currently utilized by units, which include a mixing tank and a holding tank? With central delivery systems mixing of batches occurs and is unavoidable in order to not introduce air into the system lines.

C. 494.50 (b) (3)–Reuse of Hemodialyzers and Bloodlines
Clarification of germicidal use for reprocessing "other than bleach" is needed. It is unclear what that indicates as it is not our facility's practice to use bleach as a germicide for reuse.

Provisions of Proposed Part 494 Subpart C (Patient Care)

A. 494.70 (a) (5)–Patients' Rights
The proposed change required that the patient or designee sign the care plan. What qualifies as the care plan and how frequent would this need to occur?

B. 494/80 (b) (1) and (2)
Completion of assessments in a timely manner is very important. Our facility is recommending 30 calendar days due to fact that we (i.e., dietitian, social worker, renal care coordinator) share staff among our units and it would be difficult to require all interdisciplinary groups to complete all assessments in 20 days.

We are also requesting clarification of what a comprehensive reassessment entails. We agree that if there are no changes in a patient it seems very redundant to do an initial comprehensive assessment, then in three months do another.

494.80(d) (1)
Clarification of what the interpretation of "unstable" patient criteria would include and what does the reassessment need to include?

C. 494.90 (b) (1)–Patient Plan of Care
Our facility is recommending expanding the 20 days to 30 days from initiation of treatment to complete the comprehensive assessment and after this is completed to allow 15 days to develop the plan of care. This would give our facility a maximum of 45 days to complete the comprehensive assessment and plan of care. The rationale behind this is again due to the sharing of staff between units and allowing time for complete assessments in the patient's best interest.

Clarification is needed on what are the time frames for updating a patient's plan of care? Does a plan of care need to be updated each time a comprehensive assessment is done/updated? Is this patient plan of care replacing the current short term care plan in the current regulations?

D. 494.10–Quality Assessment and Performance Improvement
It would be very beneficial if a standard patient satisfaction survey for all dialysis units cold be created. This would enable the dialysis units to compare with each other in order to strive for higher quality performance.

Provisions of Proposed Part 494 Subpart D (Administration)

A. 494.140–Personnel Qualifications
I feel that a Medical Director should be board certified or board eligible. Medical Directors have the ultimate responsibilities that dialysis programs are run safely and effectively. To lower standards for Medical Directors could jeopardize patient care across the nation. Those physicians who have completed their certification or have gained board eligibility need to be recognized and rewarded for their knowledge.

494/140 (e) (3) Other personnel issues – the requirement to ensure routine assessment of patient medications by a pharmacist is a good idea, but may be difficult for dialysis units. If this is required the concern would be the reimbursement to those pharmacists. A suggestion would be possibly a direct reimbursement, not out of the ESRD composite rate.

B. 494/180–Governance
494.180 (b) (2) Proposing a registered nurse be present in facility at all times that patients are being treated, but under A. 494.140–Personnel Qualifications a licensed practical nurse can be

in charge of a shift of patients. Clarification of those proposals is needed. It seems like they are conflicting.

In closing I would like you to consider these comments and recommendations. I have carefully reviewed the proposed changes and believe the input would improve the changes for quality care in the dialysis community and also assist in making clearer the future proposed regulations.

Sincerely,

Barb Dennler, R.N.
Dialysis Nurse Manager
Covenant Medical Center

Submitter : Mrs. Geraldine Cannon **Date:** 05/04/2005

Organization : Mrs. Geraldine Cannon

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-154-Attach-1.DOC

Attachment #154
Department of Health and Human Services
Centers for Medicare and Medicaid Services

Response from:
Geraldine P. Cannon RN, CNN
31 years experience in Nephrology Nursing
Acute and Chronic settings
Staff nurse, Charge Nurse, Staff Development Nurse
Currently Administrator of 15 Station Outpatient Dialysis Facility
Responses are personal and in no way to be attributed to current employer

COMMENTS REGARDING FILE CODE CMS-3818-PD

General comments and observations;

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

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

2) RN coverage in a dialysis facility:

It is to the patient's best interest to have sufficient RN coverage to meet the needs of the patient. One RN in the building may not be enough to provide safe coverage under many circumstances. It would be preferable to establish safe guidelines and patient to RN ratio's. The patient and the caregivers would benefit from such guidelines. In any dialysis facility, multiple emergencies can occur at any given time, requiring the full attention of an RN. When patient numbers increase, of course opportunities for emergent situations increase as well. If the administrator is not also an RN, there may be less than safe RN coverage in the building with just one RN required.

3) Dialysis Staff education:

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

COMMENTS SPECIFIC TO SPECIFIED CONDITIONS OF PARTICIPATION

ISSUE IDENTIFIER:

494.60 : PHYSICAL ENVIRONMENT

(c): patient care environment

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

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

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

comfortable temperatures.

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

While the comfort of the dialysis patient is of prime importance, there are other issues in the dialysis clinic. Dialysis staff are forced by OSHA regulations to wear heavy, impermeable, long sleeved and full length personal protective gowns over full clothing. They are also shielded from fresh air flow for most of the day due to the wearing of face shields and masks. The Dialysis staff must be able to work continuously , moving from one task to the next. They often suffer from over-heating , sometimes to the point of profuse perspiration and faintness. Under these conditions, ability to move quickly and to think clearly can be impaired. Facility temperatures must be conducive to the health and welfare of the dialysis staff as well as the patient. Patients can use blankets to keep them warm, dialysis staff have no recourse. A temperature that is fair to all should be the standard.

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

494.80 : PATIENT ASSESSMENT

(a) Standard: Assessment Criteria

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

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

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

This proposal enables primary care physicians and HMO'S to shirk their professional and ethical responsibilities toward patients. It lays excessive burden on the Nephrologist and the dialysis team to be broad based care givers and facilitators and is not appropriate or reasonable.

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

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

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

494.90: PATIENT PLAN OF CARE

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

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

(6) Rehabilitation status

The language in this section is ambiguous and leaves much opportunity for misinterpretation by

individual inspectors. "**Must provide the necessary care and services** for the patient to achieve and sustain an appropriate level of productive activity.....etc"
While providing **referrals for services** is reasonable and standard, it is not reasonable to expect the Dialysis clinic staff to do more than provide the referral. Dialysis clinics have neither the resources or the funds to provide for anything beyond referrals.

(c)Standard: Transplantation referral tracking

. It is unrealistic to expect the dialysis team to be responsible to maintain communication with the Transplant facility. Once a transplant referral is made and the patient is seen, it is more appropriate that the Transplant Coordinator and the Transplant Center be held accountable for communication with the patient and the dialysis facility. This language makes the dialysis team responsible for others' area of service and scope of practice. This requirement also takes individual responsibility away from the patient, who should be encouraged to be independent and personally accountable for as much as possible in their lives. A patient who takes an active role in their care is much more likely to achieve a desired outcome. This approach infantizes and disempowers patients who should be given every opportunity to advocate for themselves.
Once the referral is made, the burden of responsibility should not rest with the dialysis team.

494.140 : CONDITION: PERSONEL QUALIFICATIONS

(b) Standard: Nursing services

(2) Charge nurse

The standards for the dialysis clinic must be held as high as possible. While many practical nurses may have adequate experience and aptitude to be a charge nurse, it is the Registered Nurse who is trained to do so and is legally responsible. The algorhythm for delegation is from Registered Nurse to practical nurse. To open the door for practical nurses to assume charge nursing responsibilities is to open the door for less than ethical practices by some whose intention is merely to save money.

(c) Standard: Dietitian

(3) Work experience

The requirement of one year's professional work experience is unnecessary as long as the Dietitian Candidate has met the conditions for registration with the Commission on Dietetic Registration and is mentored and followed by a seasoned and experienced Renal Dietitian. It is highly improbable and unlikely that one year experience will better prepare them to work with Renal patients, as this area is such a highly specialized area that one has to work in the field to gain expertise as a Renal Dietitian. To require this length of time in professional work experience will lead to the potential loss of excellent candidates who could be trained and mentored by experienced and qualified people.

Thank you for taking the preceding comments and observations under advisement.

Submitter : **Dr. Nathan Levin** **Date: 05/04/2005**

Organization : **Renal Research Institute**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Issues 1-10

Plan of Care

494.180
Plan of care does not adequately describe the essential participation of the transplant facility. Every patient should have the opportunity of being interviewed at an early stage of their care by representatives of the transplant facility(ies) which supports the dialysis facility to ensure appropriate evaluation.

Care at Home

The current situation of dialysis of group residential individuals treats them as if they were able bodied and capable of playing a role in their dialysis treatments. For patients who are physically or mentally impaired travel to an out patient facility is cruel but also unnecessary since what is needed is to permit patients to be dialyzed in groups and give up the 'home' dialysis category. This should be inspected to ensure that the situation is not being taken advantage of! The facility should be given a different status with ESRD professionals providing care on site. All factors relating to governance, safety and monitoring should be required as an integral part of the certification of this type of facility.

Infection Control

494.30 Infection Control
Because hepatitis C is an important pathogen for dialysis patients and spread with facilities it should be screened and paid for.

Water Quality

R52 Regulations regarding water must be combined with those regarding dialysate. AAMI RD52 (NOT RD 62) combined discussion and standards for dialysate and water, both bacteriologic and chemical. Further it provides details of concentrate distribution systems that are important for patient safety. It should be recognized that bicarbonate in solution is the most vulnerable part of the dialysis system and is prone to contamination. This need to be emphasized and the system inspected.

Home dialysis patients should not be treated with water of lower quality than those in centers. To achieve this, specific requirements for equipment and maintenance are suggested.

494.50 Reuse
In addition to blood and dialysate cultures, endotoxins should be measured in the dialysate. Often cultures may be negative with high endotoxin levels.

Issues 11-20

QAPI

494.110
Serious objection must be raised to the statement that the dialysis facility must measure quality indicators or other aspects of performance that the facility adopts or develops that reflect the process of care.

Leaving this to the facility when we have highly universally (nationally and internationally) evidence based practice guidelines is unacceptable. There can be no coherent reason to have this thought in the proposed conditions.

1. The DOQI and K/DOQI guidelines on HD; PD, anemia & vascular access are evidence based and meet high standards of comprehensiveness, generalizability and applicability. Use guidelines that have been associated with increase in adequacy of dialysis and improvement in anemia or shown by your CPMs. It would be a most retrogressive step to permit individual units to propose their own targets. Nothing can be gained for patient care. If facilities have difficulties meeting the targets for adequacy or anemia they must provide a plan to improve. Networks should provide assistance.

Personnel Qualifications

494.140
Increasingly PCTs are performing many of the duties of the RN and especially with current nursing shortages. They should be certified using a standard curriculum and examination. The new continuing education must be the responsibility of the Medical Director.

(4) This is vague: there should be a minimum requirement for continuing education and development which should also apply to PCTs.

Responsibilities of the Medical Director

The functioning of the patient care part of the dialysis unit is directly dependent on the work of the Medical Director. Your changes are certainly an improvement on the previous conditions of coverage but needs to go further. It must be the responsibility of the Medical Director to ensure that every patient is receiving adequate care (as defined by established standards such as DOQI/ or K/DOQI) or has in place a plan to achieve that level of care. In addition current regulations permit nurse practitioners to see patients to see patients in place of physicians for 3 of 4 visits in a month without a reduction in G code reimbursement. It must be the responsibility of the Medical Director to organize a system in the facility with the other health professional to alert them of any systematic reduction in the quality

of care. This then has to be brought to the attention of the physician.

Submitter : **Ms. Janet Smith** **Date:** **05/04/2005**

Organization : **Purity Dialysis Centers**

Category : **Social Worker**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-156-Attach-1.DOC

Attachment #156
May 3, 2005

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

Re: CMS Proposed Conditions
For Coverage for ESRD Facilities

To Whom It May Concern:

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

Thank you for your consideration of the following opinions.

Sincerely,
Janet Smith, LCSW
Purity Dialysis Centers - Fort Atkinson
525 Handeyside Lane
Fort Atkinson, WI 53538

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

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

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

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

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

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

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

Submitter : **Miss. Penelope Solis** **Date: 05/04/2005**

Organization : **American Heart Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-3818-P-157-Attach-1.PDF

Attch #157

American Heart Association.
Learn and Live.

Advocacy Department
Office of Legislative and Regulatory Affairs
1150 Connecticut Ave., NW Ste 300
Washington, DC 20036
Tel 202.785.7900
americanheart.org

May 4, 2005

VIA EMAIL

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

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

To Whom It May Concern,

On behalf of the American Heart Association (AHA), including the American Stroke Association (ASA) and over 22.5 million AHA and ASA volunteers and supporters, we submit the following comments in response to the Centers for Medicare and Medicaid Services' (CMS) notice of proposed rule making (NPRM) concerning the Conditions of Coverage (COC) for End Stage Renal Disease (ESRD) facilities referenced as file code CMS-3818-P.[1]

Since 1924, the American Heart Association has dedicated itself to reducing disability and death from cardiovascular disease and stroke — the #1 and #3 leading causes of death in the United States — through research, education, community based programs and advocacy. AHA's efforts include, but are not limited to the following:

- The development of evidence-based clinical practice guidelines designed to help advise physicians and other providers on the prevention, treatment and chronic management of cardiovascular disease and stroke;[2]

[1] 70 Fed. Reg. at 6184 (February 4, 2005).

[2] To see a complete listing of AHA guidelines, including joint ACC/AHA guidelines go to: http://www.americanheart.org/presenter.jhtml?identifier=3004546

- The development of international guidelines for emergency cardiovascular care (ECC), in collaboration with the international liaison committee on resuscitation (ILCOR); and

- The development of a series of high-quality courses and training materials that serve to educate the public on how to recognize the signs of heart attack and stroke, how to administer cardiopulmonary resuscitation (CPR) and instruction on proper operation of an automated external defibrillator.[3]

For the foregoing reasons, the American Heart Association is qualified to provide comments on those sections of the conditions of coverage for end-stage renal disease facilities as they relate to providing emergency cardiovascular care. We limit our comments to the following recommendations, each of which are explained in detail below, but can be summarized as follows:

(1) The American Heart Association strongly supports the inclusion of defibrillators in the definition of "fully equipped" end stage renal disease facility;

(2) The American Heart Association recommends training on the use of automated external defibrillators (AEDs) be provided in conjunction with cardiopulmonary resuscitation training to further staff instruction on the chain of survival; and

(3) The American Heart Association would urge CMS to provide smaller and rural facilities with a grace period of one year, and would further urge the agency not exempt facilities from complying with the defibrillator/AED requirement as a condition of coverage.

I. The American Heart Association supports the inclusion of defibrillators in the definition of a "fully equipped" facility as a condition of coverage for the Medicare program.

Most adults that can be saved from cardiac arrest are in ventricular fibrillation (VF) or pulseless ventricular tachycardia.[4] The most important type of therapy for this class of patients is electrical defibrillation and the greatest chance of survival occurs by minimizing the interval between the start of VF and the delivery of defibrillation. Access to and proper use of defibrillators has been shown to save lives in a variety of settings, including office buildings, stadiums, airplanes and airports, where survival rates for

[3] See http://www.americanheart.org/downloadable/heart/1053032137284healthsafety_courses.pdf

[4] Kloeck W, Cummins RO, Chamberlain D, Bossaert L, Callanan V, Carli P, Christenson J, Connolly B, Ornato JP, Sanders A, Steen P. , Early defibrillation: an advisory statement from the Advanced Life Support Working Group of the International Liaison Committee on Resuscitation. *Circulation*: 1997 95(8):2183-4.

cardiac arrest are otherwise less than one (1) percent.[5] A logical extension would be the inclusion of AEDs in outpatient settings, such as end stage renal disease facilities where patients may have a cardiac arrest.

For this reason, the American Heart Association applauds CMS' decision to revise and update the requirements for ESRD facilities for purposes of coverage under the Medicare program; and we strongly support the agency's decision to revise §405.2140 (d)(3) to require the inclusion of defibrillators or automated external defibrillators in the definition of a "fully equipped" ESRD facility. We believe that the inclusion of defibrillators within the "fully equipped" definition will reduce the rate of deaths that occur for patients with ESRD during their course of treatment at these facilities. This will allow the nursing staff to defibrillate a patient without requiring the immediate presence of a physician and will increase the chance of patient survival. Therefore, we strongly support the inclusion of "defibrillators" as a condition of coverage for ESRD facilities.

II. The American Heart Association recommends training on the use of automated external d efibrillators (AED) be provided in c onjunction w ith c ardiopulmonary resuscitation training to further staff instruction on the chain of survival

In the preamble to the NPRM, the agency states that dialysis nursing staff should receive training on the proper use of emergency equipment and drugs. With respect to use of defibrillators, CMS notes the nursing staff could receive training on the use of AEDs in conjunction with CPR training.[6] AHA supports the agency's decision to require training on the proper use of emergency equipment and drugs. We further note that, many facilities do provide combined CPR and AED training by using programs such as the American Heart Association "Heartsavers AED.[7]"

Irrespective of which training course is used, the American Heart Association would urge that CPR and AED courses taken by the nursing staff include quality course content consistent with policies and procedures that are commonly accepted and that training occur every two years. Moreover, we would strongly recommend that training on the use of automated external defibrillators be provided in conjunction with CPR training to further ESRD nurse understanding of the chain of survival, thus ensuring the highest patient survival rate.

It is critical to remember that early defibrillation is only one component implemented as part of the chain of survival concept, which includes: (1) early recognition of cardiopulmonary a rrest, (2) e arly activation o f t rained r esponders, (3) b asic C PR, (4)

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[5] Introduction to the International Gudilines 200 for CPR and ECC: A Consensus of Sicene. *Circulation* 2000; 203:I-1.

[6] See Fed.Reg. at 6198.

[7] See http://www.americanheart.org/presenter.jhtml?identifier=3011940

early defibrillation (when indicated), (5) management of the airway and ventilation and (6) intravenous administration of drugs.[8] By combining AED with CPR training, the importance of the chain of survival is emphasized to nursing staff that may have to perform basic life saving activities.

III. The American Heart Association would urge CMS to provide smaller and rural facilities with a grace period of one year, and would further urge the agency not exempt facilities from complying with the defibrillator/AED requirement as a condition of coverage.

In the proposed rule, CMS asks for comments on whether "small, predominately rural dialysis facilities should receive special consideration and possibly an exemption from the defibrillator requirement.[9]" The rationale for granting this exemption is the cost burden associated with procuring an AED for a facility. AHA recommends that all facilities should be required to have an AED on site and have the appropriate nursing staff trained for the following reasons.

Access to an automated external defibrillator is critical in a small rural facility where the duration of time before a paramedic is able to arrive at an ESRD facility may be less timely, due to the distances involved. Moreover, recent studies show that data comparing the time-to-shock treatment between first responders versus paramedics is significantly shorter among first responders.[10] Survival rates for victims have been reported as high as 90% when defibrillation is achieved within the first minute of collapse. However, survival rates decline 7-10% with every delayed minute until defibrillation. Cardiac arrest victims without defibrillation beyond 12 minutes have less than 2-5% survival rate.

Additionally, the cost of purchasing an automated external defibrillator is not prohibitive for rural facilities. On average, AEDs range from $2000-$3000 and have an expected life of between 5-10 years. Because cardiac disease accounts for 43% of mortality for ESRD patients, providing ESRD patients access to a defibrillators in both inpatient and

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[8] Cummins RO, Ornator JP, Thies WH, Pepe PE. Improving Survival from Sudden Cardiac Arrest: the "Chain of Survival" Concept: A statement for Health Professional from the Advanced Cardiac Life Support Subcommittee and the Emergency Cardiac Care Committee, American Heart Association. *Circulation* 1991; 83: 1832-1847.

[9] See Fed. Reg. at 6198.

[10] Franklin, B.A., Bonzheim, K. Gordon, S. and Timmis. G.C. Safety of medically supervised outpatient cardiac rehabilitation exercise therapy: a 16 year follow-up. *Chest.* 114: 902–906, 1998.

Haskell, W.L. Cardiovascular complications during exercise training of cardiac patients. *Circulation.* 57: 920–924, 1978.

Hossack, K.F., and Hartwig. R. Cardiac arrest associated with supervised cardiac rehabilitation. *J. Cardiac Rehabil.* 2: 402–408, 1982.

outpatient facilities (such as ESRD facilities), and in other public areas is critical.[11] For this reason, the American Heart Association would strongly urge that CMS not grant an exemption to rural facilities, but rather delineate a phase-in period of a year that would allow them adequate time to research and purchase an automated external defibrillator and train their nursing staff on use of the AED.

IV. Conclusion

For the foregoing reasons, AHA strongly supports the agency's decision to include defibrillators as a condition of coverage for end stage renal disease facilities. We would further urge the agency not to grant exemptions to smaller rural facilities, and would urge the agency to designate a phase in period for smaller and rural facilities to comply with the revised conditions of coverage. Access to an automated external defibrillator is critical in all environments, especially where paramedic services response time is longer, as may be the case in rural areas. By doing so, this will increase the patient's chance of survival by allowing the first responder to provide both CPR and defibrillation.

If you need any additional information, please do not hesitate to contact Penelope Solis, J.D., Manager of Regulatory Relations at (202) 785-7905 or via email at penelope.solis@heart.org.

Sincerely,

Katherine Krause

Katherine Krause
Executive Vice President of Advocacy
American Heart Association

[11] US Renal Data System. USRDS 2003 Annual Data Report; National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, MD, USA, 2003.

Submitter : Mrs. Stephanie Chick **Date:** 05/04/2005

Organization : Mrs. Stephanie Chick

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-3818-P-158-Attach-1.DOC

CMS-3818-P-158-Attach-2.DOC

Attachment #158
Department of Health and Human Services
Centers for Medicare and Medicaid Services

Response from:Stephanie Chick, Rn
6 years experience in Nephrology Nursing
Acute and Chronic settings
Staff nurse, Charge Nurse
Currently Administrator of 12 Station Outpatient Dialysis Facility
Responses are personal and in no way to be attributed to current employer

COMMENTS REGARDING FILE CODE CMS-3818-PD

General comments and observations;

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

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

2) RN coverage in a dialysis facility:

It is to the patient's best interest to have sufficient RN coverage to meet the needs of the patient. One RN in the building may not be enough to provide safe coverage under many circumstances. It would be preferable to establish safe guidelines and patient to RN ratio's. The patient and the caregivers would benefit from such guidelines. In any dialysis facility, multiple emergencies can occur at any given time, requiring the full attention of an RN. When patient numbers increase, of course opportunities for emergent situations increase as well. If the administrator is not also an RN, there may be less than safe RN coverage in the building with just one RN required.

3) Dialysis Staff education:

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

COMMENTS SPECIFIC TO SPECIFIED CONDITIONS OF PARTICIPATION

ISSUE IDENTIFIER:

494.60 : PHYSICAL ENVIRONMENT

(c): patient care environment

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

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

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

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

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

Patients can use blankets to keep them warm, dialysis staff have no recourse. A temperature that is fair to all should be the standard.

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

494.80 : PATIENT ASSESSMENT

(a) Standard: Assessment Criteria

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

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

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

This proposal enables primary care physicians and HMO'S to shirk their professional and ethical responsibilities toward patients. It lays excessive burden on the Nephrologist and the dialysis team to be broad based care givers and facilitators and is not appropriate or reasonable.

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

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

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

494.90: PATIENT PLAN OF CARE

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

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

(6) Rehabilitation status

The language in this section is ambiguous and leaves much opportunity for misinterpretation by individual inspectors. "**Must provide the necessary care and services** for the patient to achieve and

sustain an appropriate level of productive activity.....etc"

While providing **referrals for services** is reasonable and standard, it is not reasonable to expect the Dialysis clinic staff to do more than provide the referral. Dialysis clinics have neither the resources or the funds to provide for anything beyond referrals.

(c)Standard: Transplantation referral tracking

. It is unrealistic to expect the dialysis team to be responsible to maintain communication with the Transplant facility. Once a transplant referral is made and the patient is seen, it is more appropriate that the Transplant Coordinator and the Transplant Center be held accountable for communication with the patient and the dialysis facility. This language makes the dialysis team responsible for others' area of service and scope of practice. This requirement also takes individual responsibility away from the patient, who should be encouraged to be independent and personally accountable for as much as possible in their lives. A patient who takes an active role in their care is much more likely to achieve a desired outcome. This approach infantizes and disempowers patients who should be given every opportunity to advocate for themselves.

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

494.140 : CONDITION: PERSONEL QUALIFICATIONS

(b) Standard: Nursing services

(2) Charge nurse

The standards for the dialysis clinic must be held as high as possible. While many practical nurses may have adequate experience and aptitude to be a charge nurse, it is the Registered Nurse who is trained to do so and is legally responsible. The algorhythm for delegation is from Registered Nurse to practical nurse. To open the door for practical nurses to assume charge nursing responsibilities is to open the door for less than ethical practices by some whose intention is merely to save money.

(c) Standard: Dietitian

(3) Work experience

The requirement of one year's professional work experience is unnecessary as long as the Dietitian Candidate has met the conditions for registration with the Commission on Dietetic Registration and is mentored and followed by a seasoned and experienced Renal Dietitian. It is highly improbable and unlikely that one year experience will better prepare them to work with Renal patients, as this area is such a highly specialized area that one has to work in the field to gain expertise as a Renal Dietitian. To require this length of time in professional work experience will lead to the potential loss of excellent candidates who could be trained and mentored by experienced and qualified people.

Thank you for taking the preceding comments and observations under advisement.

Submitter : **Ms. Theresa Kwechin**

Organization : **Ms. Theresa Kwechin**

Date: 05/04/2005

Category : **Nurse**

Issue Areas/Comments

Issues 1-10

Basis

III Provisions of Proposed Part 494 Subpart A-General Provisions:
A. Basis and Scope (Proposed 494.1)
All facilities should be recertified every three years to ensure appropriate oversight for this high-risk patient population. Facilities that have condition level deficiencies should be placed on yearly surveillance cycles till such a time as they have demonstrated safe care for two consecutive years. Money should be allocated to step up surveillance for the ESRD facilities that have not been able to meet the minimal requirements for safe and adequate care of the ESRD patient. Monetary sanctions should be in the regulatory language for facilities that do not meet condition level requirements for two recertification cycles.

Plan of Care

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

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

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

I recommend that if patients are not being referred for home dialysis, then the exclusion criteria used must be documented in the patient's plan of care.
I agree with the requirement that the patients be expected to meet minimum threshold values for the patient plan of care. These clinical goals are measurable; outcome oriented and evidenced based. If a patient does not meet minimum threshold values for adequacy, then the physician must develop an action plan.

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

I agree with the NKF -K/DOQI Guidelines as minimum standards for dialysis adequacy and anemia management. These guidelines have been universally adopted as evidenced-based community accepted standards.
I agree that the proposed time frame of 30 days to complete the patient assessment and plan of care is ample time. A timely and comprehensive needs assessment by the team is critical for the benefit of the patient to begin to adjust to dialysis and move toward emotional and physical health. Rehabilitation goals of the dialysis patient are most likely to be achieved if initiated early in the course of the treatment plan.

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

Care at Home

D. Condition: Care at Home (Proposed 494.100)
I agree that providing dialysis services in nursing homes is, in theory, ideal. The travel to dialysis centers for this fragile group of patients is very disruptive to their lifestyle and most times interferes with their care and treatment plan. I agree that dialysis centers in long term care institutions should not be an undue burden to the SNF. Unfortunately, our experience has been that the physical environment, staffing and overall service in the nursing home units is inferior to the in-center facilities. The dialysis units in the SNF/NF are usually quite small and the facilities find providing all the required services for dialysis patients cost prohibitive. There is therefore a tendency for the dialysis unit to rely on the SNF to provide some of the minimal service requirements or these services are not provided at all. Especially lacking are social services, dietary counseling and adequate oversight of the water treatment system. We all want these units to be successful but we can't turn our backs to the poor care being delivered. This is our most vulnerable group of patients in the ESRD population. CMS should develop a task force to assist these small units to be able to come into compliance with the requirements for minimum standards of care.

I do not agree that dialysis can be performed and supervised by the SNF staff. If dialysis is taking place in the nursing home, then the same requirements for care apply as for the in-center patients. That is that a qualified Registered Nurse be on site and directly supervising the treatments whenever patients are being dialyzed. This patient population is more likely then any other group to have more serious and more frequent complications. These patients are also less likely to be able to participate in their care.

Definitions

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

Compliance with Laws and Regulations

C. Compliance with Federal, State, and Local Laws and Regulations(Proposed 494.20)
I agree with the proposal that dialysis facilities must be in compliance with appropriate Federal, State, and local laws and regulations regarding drug and medical device usage.

Water Quality

B. Water Quality (Proposed 494.40)
I agree with the inclusion of a separate condition regarding water quality.
I agree with the proposed frequency of water purity testing.
I agree with proposed requirement for a minimum of two carbon tanks regardless of the current composition of its source water. This should be in place, as an emergency back up should the water treatment system in the community change. ESRD facilities must commit to being able to be more self sufficient and more able to respond to the emergency needs of their patients. Without the back up of a second carbon tank, should the only tank connected to the system saturate the entire water system must be shut down. Patients must therefore be transferred to other facilities, more often to the hospital back up unit. This emergency plan puts an undue strain on the resources of the community hospitals.
I agree with the proposed regulation that the bicarbonate concentrate be used within the specified time as recommended by the manufacturer.
I agree with the CMS adoption of the current AAMI standards for minimum safety requirements for water treatment. I also agree that water quality is of vital importance to health and well being of the dialysis patient. Surveillance of the safety of the product water used for dialysis includes frequent monitoring of culture and endotoxin levels. Many facilities are now conducting 'onsite testing' of endotoxins with little or no quality controls. Regulation should require that facilities use only certified labs for (specifically certified for environmental cultures) analysis of bacteria growth and LAL testing.

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

Physical Environment

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

I disagree with the deletion of the requirement of a nursing/monitoring station from which adequate surveillance of patients receiving dialysis services can be made. Contrary to CMS comment, design of the ESRD facilities is a physical environment issue. Since regulation requires that only one professional nurse be available for patient care in the unit, it is imperative that that one nurse has easy visual access to as many patients as possible. Even if facilities were required to have a nurse call system, due to the advanced age and multiple co-morbidities of the patients, a vast number of patients are not able to use the call system.

Infection Control

IV. Provisions of Proposed Part 494 Subpart B (Patient Safety)
A. Infection Control (Proposed 494.30)
I agree with Proposed requirement that facilities demonstrate that they follow CDC 'Recommended Infection Control Practices for Hemodialysis Units' with the following exception: HBV infection is still a significant potential problem for hemodialysis patients in an 'in-center' setting. There is documented evidence of conversions each year. CDC does not recommend that HBV positive patients use the designated isolation rooms or areas exclusively. Multiple interpretations have been submitted to the State Agencies from CDC that allows 'immune' patients to use 'positive' machines in isolation rooms and stations. For the protection of this 'more at risk' population, truly dedicated isolation rooms, stations, machines and equipment should be used for HBV infected patients only and without exception. 'HBV immunity' as defined as anti-HBs >10 mIU/ml is not protection for life. ESRD patients have demonstrated immune deficiencies and are labeled as 'poor responders'. The current CDC recommendation for annual surveillance for anti-ABs does not ensure adequate protection for patients that are potentially exposed to virus from known infected patients by allowing 'immune protected' patients to be dialyzed in isolation rooms or areas designated for HBs AG carriers. There should be very strong language in this regulation to prohibit this practice.

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

Patients' Rights

V. Proposed Part 494 Subpart C (Patient Care)
A. Patient's Rights (494.70)
ESRD patients are often forced by facilities to sign 'waivers' for early termination of treatments as described as against medical advice. I strongly recommend that there be language in the regulation to protect patients whose request for toileting, pain management etc. is resolved not only by termination of treatment. At the very least, licensed personnel should first assess patients who are forced by a universal facility policy to terminate treatment. Protection of patient?s dignity should fall on qualified personnel.

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

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

I agree that there are rare circumstances when a facility must act immediately to discharge a patient due to criminal and dangerous behavior in the unit. I also recognize that facilities have discharged patients for lack of payment from the uninsured. Without an accepting facility, these patients are left to use the hospital emergency rooms for care. This alternative puts an exhaustive stress on the resources of the hospitals and it is substandard care for these patients. I recommend that before a facility can resort to this action as a permanent solution, a mandated referral should be made to the ESRD network for alternative solutions and arbitration on behalf of the patient if needed.
B. Patient Assessment (Proposed 494.80)
I agree with the proposed addition of the condition of patient assessment.

I agree with the 3-month time frame for reassessment of new patients. The newly diagnosed ESRD patients are usually too sick or depressed to participate in life altering decisions regarding their care and treatment plan. Frequently, it is the referring physician who chooses the treatment modality on behalf of the patient. I strongly recommend that CMS mandate that a Registered Nurse or physician conducts all patient assessments. There should also be language in the regulation that states all medications are administered by licensed personnel.

Issues 11-20

Personnel Qualifications

VI. Provisions of Proposed Subpart D: Administration
A. Personnel Qualifications (Proposed 494.140)
I disagree with the proposed change in the qualifications of the facility Medical Director. CMS should retain the requirement that the Medical Director be Board Certified or Board eligible. Board Certification is the accepted industry standard for evidence of proficiency in a particular specialty.

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

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

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

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

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

Responsibilities of the Medical Director

B. Condition: Responsibilities of the Medical Director (Proposed 494.150)
I agree with the expansion of the language in this condition that assigns more accountability to the Medical Director regarding the overall care of the patients. There should be a requirement for annual renewal of credentials and evaluation of the attending physicians by the Medical Director. This annual evaluation should include, at a minimum, compliance with:

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

Governance

E. Condition: Governance (Proposed 494.180)
I agree that in a typical unit, the volume, scope, and complexity of administrative, financial, and operational responsibilities requires the day-to-day attention of a separate CEO/administrative position. Because of the volume of responsibilities I recommend that CMS limit the number of facilities an administrator may operate. It is not unusual to have administrators be responsible for 4 or more facilities.

I agree to retain the existing requirement that a dialysis facility ensure that an adequate number of qualified personnel are present whenever patients are undergoing dialysis. I also appreciate the difficulty CMS would have devising a common regulation that would encompass the multitude of differences and complexities of the various State licensing and certification laws, and union contracts. I do however recommend that CMS require that each individual facility have a written policy that describes safe staffing in their unit, given their patient population, the acuity of the patients they care for, the availability of personnel resources and in compliance with State law. Each safe staffing policy should include:
1. RN/patient ratio.
2. LPN/patient ratio
3. Social worker/patient ratio
4. Dietician/patient ratio
5. PCT/patient ratio
This would allow each facility the flexibility to make decisions regarding their personnel needs without CMS being too prescriptive. It will also protect the patients from inadequate staffing. The facility should evaluate their staffing policy at least annually in their QAPI program.

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

I agree to the proposal that facilities be responsible for their staff adherence to the facility's discharge or transfer policies and procedures. I recommend that for patients who are discharged against their will and before a facility can resort to this action as a permanent solution, a mandated referral should be made to the ESRD Network for alternative solutions and arbitration on behalf of the patient if needed.
I agree that data from ESRD facilities be mandatory instead of voluntary. I recommend that random audits be conducted by the ESRD Networks to validate accuracy of data submitted since data submitted is self-reported.

ESRD Network

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

Special Purpose Renal Dialysis Facilities

F. Condition: Special Purpose Renal Dialysis Facilities (Proposed 494.120)
I agree with the proposed changes to make access to care for patients in disaster conditions more available.

Laboratory Services

G. Laboratory Services (Proposed 494.130)
I agree to retain the existing requirements.

Medical Records

D. Condition: Medical Records (494.170)
I disagree with the proposed elimination of the requirement that facilities have written policies and procedures for record keeping. The facility staff need guidance to ensure that patients' rights of confidentiality are adhered to.

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

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

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

QAPI

E. Condition: Quality Assessment and Performance Improvement
(Proposed 494.110)
I agree with the inclusion of a separate condition for QAPI.

I recommend that the Program scope include mortality reviews, surveillance of the water treatment system, review of infection control programs and a

comprehensive central venous catheter reduction program.

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

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

Submitter : Ms. Sara Yerkes
Organization : International Code Council
Category : Association
Date: 05/04/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-160-Attach-1.DOC

INTERNATIONAL CODE COUNCIL®

Setting the Standard for Building Safety™

Headquarters
5203 Leesburg Pike, Suite 600 • Falls Church, VA 22041-3405 U.S.A.
Tel: +1 (703) 931-4533 • Fax: +1 (703) 379-1546
www.iccsafe.org

Attachment #160
May 5, 2005

Centers for Medicare and Medicade Services
U.S. Department of Health and Human Services
Attention: CMS-3818-P
PO Box 8012
Baltimore, MD 21244-8012

Subject: Comments Proposed Rule RIN 0938-AG82
(70 Fed Reg 6184 et. sec., February 4, 2005)

To whom it may concern:

The International Code Council (ICC) submits the following comments regarding the proposed rule issued by the U.S. Department of Health and Human Services, Centers for Medicare and Medicade Services (HHS CMS) (70 Fed Reg 6184) to revise the requirements that end stage renal disease (ESRD) dialysis facilities must meet to be certified under the Medicare Program.

The ICC is a 35,000 + member association dedicated to building safety whose mission is to provide the highest quality codes, standards, products, and services for all concerned with the safety and performance of the built environment. This mission and the activities of the ICC directly relate to Sections 1881 (b)(1) and 1881 (f)(7) of the Social Security Act, as amended by P.L. 95-292, wherein the Secretary of HHS is to prescribe safety requirements for ESRD facilities. The current conditions for coverage of ESRD facilities are to protect patient health and safety. The ICC believes the proposed rule can be modified to further enhance patient health and safety with respect to the building facilities provided to house ESRD services through a reference to the ICC Codes.

The codes developed under the auspices of the ICC serve as a baseline for the design, construction, operation and maintenance of the majority of both public and private sector buildings in the U.S. As such the ICC Codes are readily recognized and understood by building owners, product manufacturers, designers, contractors, code officials and all others involved in building design, construction, approval, and operation. The majority of U.S. state and local government agencies that adopt codes adopt and implement building safety and fire prevention codes developed by the ICC. In addition most federal agencies have building construction policies that require the use of the ICC Codes or those policies refer to the state or local code proximate to the federal facility. This helps fulfill the direction of the National Technology Transfer and Advancement Act (P.L. 104-113), a key point referenced in the supplementary information pertaining to the proposed rule, requiring federal agencies to participate in the

development of and to adopt codes and standards developed in the private sector. In brief, the ICC Codes are the basis for the vast majority of U.S. construction regulations. In using those codes as a basis for its rules HHS CMS would further consistency and uniformity, while reinforcing patient health and safety.

Of particular importance and relevance is the establishment of the ICC by the three U.S. model building code organizations (Building Officials and Code Administrators International, International Conference of Building Officials, and Southern Building Code Congress) in 1994. Prior to that date model codes were developed separately by each of these organizations and state and local government adopted one of the three model codes, and standards referenced therein, on a regional basis. In an effort to unify the U.S. the ICC set out to develop one family of model codes to take the place of these three different sets of model codes. In 2000 the first complete family of the ICC International Codes was published and in 2003 the three model code organizations consolidated their operations as the ICC. This has resulted in one coordinated family of model codes and one supporting organization for those codes - the national uniformity that industry, building owners, regulators and others have demanded. The unification also addressed a concern of federal agencies about the lack of a singular national model code that forced agencies to either choose one of the three model codes over the others or run the risk of applying conflicting codes and standards throughout agency facilities. Federal, state and local governments adopting building regulations have adopted the I-Codes as they undertook to update their regulations that had historically adopted one of the three regional model codes. This has resulted in significant progress toward uniformity in building regulations throughout the U.S.

It is important to point out that this consolidation and focus of the U.S. model code system occurred recently and after current HHS CMS criteria became effective and guiding Federal legislation was signed into law.

General

To fully understand and address ICC's comments it is important to have an understanding of the current situation regarding federal, state and local building regulations. With the publication of the ICC International Codes, federal, state and local government have a singular consolidated solution to addressing building safety and performance issues. With few exceptions federal, state and local government have adopted and are using these codes. Federal agencies are doing so in response to the National Technology Transfer and Advancement Act and the need to update their building-related policies and requirements. State and local agencies are doing so in response to the scheduled updating of their building-related regulations.

As the HHS CMS rules apply to private sector construction that is subject to state and local building and fire safety regulations based on the ICC Codes, the imposition of the proposed rules to ESRD facilities will create an avoidable dilemma. The dilemma created is satisfaction of HHS CMS rules that may conflict with state and local codes and which the property must also satisfy. In the interest of consistency and uniformity between the federal and private sectors the ICC recommends that HHS CMS specifically reference the ICC Codes in the regulations. These codes provide equal or better protection to those cited in the proposed rule. This creates a basis for uniformity in federal, state and local building regulations as opposed to establishing a

situation where HHS CMS rules create a conflict with other rules the private sector must also satisfy. It also ensures that ESRD facilities constructed or operated in areas without codes or with codes not updated to the ICC Codes would meet some minimum provisions as currently established in the proposed rule.

For the reasons stated above, the ICC comments focus on the basic premise that HHS CMS should adopt by reference a coordinated set of codes as a foundation for rules on ESRD facility design, construction, renovation, and operation. The ICC Codes are that coordinated set of provisions. They have been widely adopted throughout the U.S. and apply to other federal facilities such as those of the General Services Administration, Department of State and Department of Defense, as well as state and local facilities and private sector facilities throughout the U.S. The ICC Codes are the baseline codes and include by reference a large number and wide range of standards developed by many organizations, including many from NFPA, ASME, etc. To impose codes and standards for ESRD facilities that are not based on the same foundation as other federal, state and local requirements fosters non-uniformity and will likely increase the costs of construction and facility operation. It can also foster a decrease in worker and patient safety wherein what is "standard" elsewhere is not applied in ESRD facilities. For example, private sector interests subject to state and local codes but wishing to participate in HHS CMS programs will likely pass along the expense in time and construction cost associated with multiple and conflicting rules in the costs of providing health care, if they can even comply with multiple sets of conflicting regulations.

With this overarching concept of building upon an existing foundation of consistent federal, state and local rules the following specific comments are offered for HHS CMS consideration.

Specific Comments

The following specific comments are offered in response to questions raised in the proposed rule.

- The last paragraph under "D, Establishment of Central Requirements" on page 6187 requests public comment on improving the fundamental shift toward performance based regulations while not adversely affecting patient health and safety. With respect to building design, construction, renovation and operation the ICC Codes, and all federal, state and local codes based on the ICC Codes, have a path to compliance that is based on performance. As long as what is proposed is no more hazardous nor less safe than something specifically provided by the code then the alternative can be approved on the basis of performance equivalency. We would encourage HHS CMS to embrace the acceptance of building designs and construction on the basis of equivalent performance to any minimum prescribed criteria.

- The first paragraph under "7, Updating Existing ESRD .... Standards" on page 6190 refers to the NTTAA and OMB Circular A-119 as the basis for federal agencies using private sector technical standards. The ICC Codes satisfy such directives and support performance-based design while design-specific technical specifications. On this basis federal agencies have adopted and/or rely on the ICC Codes and a reference to the ICC Codes by HHS CMS for ESRD facilities would reinforce federal uniformity.

- With respect to "compliance with federal, state and local laws and regulations" on page 6191 the ICC notes that a requirement that ESRD facilities be in compliance with federal, state and local laws and regulations pertaining to fire safety, equipment and other relevant health and safety issues (42 CFR 494.20 proposed) and a requirement to satisfy the Life Safety Code is generally duplicative, highly impractical and creates a significant problem for state and local government and ESRD facility owners and operators. As private sector operations, ESRD facilities must comply with state and/or local building and fire safety regulations as a condition for initial construction and continued occupancy. To impose a duplicative and unnecessarily conflicting set of HHS CMS requirements on such facilities for their initial design and construction as well as their operation essentially leaves two outcomes: operation in violation of state and/or local law; or failure to qualify for HHS CMS programs. To eliminate this conflict the ICC recommends that the rule be revised to provide an option for facility design, construction and operation in accordance with state or local building and fire safety codes that are no less stringent than the latest edition of the ICC Codes.

- With respect to "physical environment" on page 6197 the ICC notes that in adopting the ICC Codes a number of the issues raised would be addressed. The issue of comfort is addressed in the International Building and Mechanical Codes and the International Energy Conservation Code addresses lighting design. Note also the American Society of Heating, Refrigerating and Air Conditioning Engineers (ASHRAE) have a standard to address human comfort (ASHRAE 55) and the Illuminating Engineering Society of North America (IES NA) has standards addressing illumination levels and lighting quality. In relying on state or local codes as suggested above and adopting ASHRAE and IES standards as a minimum alternative in the absence of state or local codes based on the ICC Codes, HHS CMS need not be silent on these aspects related to patient comfort. As stated in proposed 42 CFR 494.60, the ICC Codes provide a basis for satisfaction of the performance statements therein related to the building and patient care environment. To establish such performance oriented objectives and then later in the rule mandate one approach (the Life Safety Code) appears to be at odds with the intent of the proposed rules. ICC also notes that the ICC Codes provide clear detail on addressing natural disasters that would address the issue of emergency preparedness.

- With respect to "physical environment" on page 6199 the ICC recommends also adopt the ICC Codes and allow its use in lieu of the Life Safety Code. As stated above this ensures some consistency and uniformity with state and local codes applicable to such facilities, allows for performance-based alternatives, ensures patient safety and health, is fully consistent with NTTA and OMB directives to federal agencies, and fully meets the intent of the rule to provide for patient health and safety. The ICC realizes that a state can currently request of HHS CMS that the state code be allowed to be applied to ESRD facilities in lieu of the Life Safety Code. Unfortunately HHS CMS does not have any guidelines in place for such a request and the one request they have received from a state has been burdened by the lack of such guidelines. The direct reference to the ICC Codes in the rule would eliminate considerable time, manpower and federal resources in developing and considering what could easily be 20 or more individual state requests all

based on the same ICC Codes. Also of relevance to this issue is the significant role the CEO or administrator will play in the overall success of the facility in providing patient care, safety and health. Given all the operational issues of importance to HHS CMS, it appears to ICC that burdening the CEO or administrator with the task of satisfying state and local codes concurrently with differing HHS CMS building standards will detract from as opposed to reinforce patient health and safety. Recognition of the ICC Codes and permitting of the facility as per state or local regulations would allow the facility CEO or administrator to focus his/her attention on items related to patient care, health and safety that may not already be covered by state or local law. Another statement supporting a reference to the ICC Codes is found on page 6240 of the Federal Register notice. In indicating that the proposed rule requires the facility meet the 2000 Life Safety Code HHS CMS indicates that most dialysis facilities meet this document "because of state and local building codes". Those building codes do not reference nor adopt the Life Safety Code but instead adopt the ICC Codes and in the past the model codes that preceded the ICC Codes. This recognition by HHS CMS that state and local codes sufficiently provide a firm foundation for patient health and safety with respect to facility construction and operation would seem to support ICC's recommendation to reference the ICC Codes in the rule.

- With respect to "special purpose renal dialysis facilities" on page 6219 the ICC notes that such facilities are approved on a short term (currently 8 month basis). The application of state and local codes would have applied to buildings intended to house such facilities when initially constructed and as a condition for a change of use. This is another example where the ICC Codes should be specifically recognized in the rule. Consider the situation where a facility is converted for a short term basis to serve renal dialysis patients and after securing state and local building code approval must then attempt to comply with the Life Safety Code. This would seem counterproductive to serving the short term need and might not likely be accomplished in the 8 month window associated with a short term use.

- In discussing the alternatives considered under item 1 on page 6243 HHS CMS notes that the current regulations inhibit the ability for the agency to ensure better patient care outcomes and that the proposed regulations address that issue by eliminating numerous processes and procedural requirements. As noted above, the lack of clear direction with respect to how a state should prepare a request for and document the acceptability of a state code is in fact a process and procedural requirement that in reality may hinder patient safety and health. A clear indication by HHS CMS in the rule that state and local codes based on the ICC Codes are acceptable in lieu of the referenced Life Safety Code would in actuality eliminate processes and procedural requirements that exist today and would continue to exist under the proposed rule.

Closing Comments

The ICC believes that the best way to address patient safety in ESRD facilities is to adopt the

same requirements for protection of public health and safety already widely adopted, applied and enforced by federal, state and local government agencies. This ensures that all those involved with the design, construction, renovation and use of such facilities are able to technically and administratively work from the same baseline, especially considering the ESRD facility owner must already comply with state and/or local building and fire safety codes. Consistency between the baseline HHS CMS requirements and such state and local codes will benefit everyone involved in ESRD facility design, construction, operation and maintenance.

The ICC appreciates the opportunity to provide comments and hopes HHS CMS will consider the opportunity it has to further solidify the uniformity and consistency of U.S. building regulation. Should additional information be needed please do not hesitate to contact us.

Sincerely,

Sara C. Yerkes

Sara C. Yerkes
Senior Vice President of Government Relations

Submitter : **Dr. Greg Bradford** **Date: 05/04/2005**

Organization : **Dr. Greg Bradford**

Category : **Pharmacist**

Issue Areas/Comments

Issues 11-20

Personnel Qualifications

See attachment

CMS-3818-P-161-Attach-1.DOC

Attachment #161

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 ("Personnel Qualifications") as this section addresses the possible role of a pharmacist within the dialysis facility. I appreciate that the Proposed Rule acknowledges the well-documented contributions a pharmacist can make to the safe and effective use of medications in vulnerable dialysis patient population.

I am a Clinical Pharmacy Specialist at Brookwood Medical Center in Birmingham, AL. I assist our nephrologists in medication therapy management, optimizing drug regimens for their patients during hospitalization. A majority of dialysis patients have co-morbid conditions requiring several medications for treatment.

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

Specifically, I would like to make the following recommendations:

1. The multidisciplinary dialysis team should include a consultant pharmacist with experience or training in nephrology pharmacy.
2. The routine patient care assessment of dialysis patients should include a medication review by a pharmacist.

3. Medication reviews should be conducted at least monthly. This frequency is consistent with what is required in skilled nursing and intermediate care facilities.
4. Pharmacists should participate in the development and implementation of medication-related protocols within dialysis to assure cost-effective drug use.
5. Dialysis facilities should develop and maintain appropriate policies for the safe storage, preparation and administration of medications within the facility. These policies should be developed and maintained in consultation with a pharmacist.

Thank you for taking the time and consideration of this important matter.

Greg Bradford, PharmD
Clinical Pharmacy Specialist
Brookwood Medical Center
Birmingham, AL
Phone: 205.877.1995
Email: Gregory.Bradford@tenethealth.com

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

Organization : American Academy of Physician Assistants (AAPA)

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Comments are in attached letter

CMS-3818-P-162-Attach-1.DOC

American Academy of Physician Assistants
950 North Washington Street ■ Alexandria, VA 22314-1552 ■ 703/836-2272 Fax 703/684-1924

Attachment #162

May 3, 2005

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

RE: Proposed Rule on Conditions for Coverage for ESRD Patients

The American Academy of Physician Assistants (AAPA) is the only national professional organization representing the more that 55,000 clinically practicing physician assistants throughout the nation. Physician assistants (PAs) working in nephrology play an increasingly important role in providing services to end-stage renal disease (ESRD) patients. We appreciate having this opportunity to comment upon the proposed rule on conditions for coverage for end-stage renal disease (ESRD) facilities.

AAPA supports efforts by the Centers for Medicare and Medicaid Services (CMS) that seek to set qualitative standards of care for ESRD patients. We welcome regulations that will improve and expand beneficiary access to timely, high quality care.

PAs are authorized under the Social Security Act (Section 1395x(S)(2)(K)) to deliver "physician services" to Medicare beneficiaries. While PAs work with physician supervision, they exercise a high degree of autonomy in the provision of medical care to patients, in keeping with state law and Medicare regulations. Some aspects of the proposed rule on conditions of coverage for ESRD patients, such as those dealing with the medical director of an ESRD facility, should be reserved to a medical doctor or doctor of osteopathic medicine. Other parts of the proposed rule should reflect and acknowledge the ability of PAs to deliver physician services to ESRD patients.

A specific example of the proposed rule that should authorize PAs to deliver care includes:

- Section 494.90: specifies that "every patient is seen at least monthly by a physician providing the ESRD care...."

AAPA encourages CMS to appropriately include PAs in the proposed rule and in the Conditions for Coverage to assure that beneficiaries continue to have access to needed renal disease services.

Sincerely,

Michael Powe, Director
Health Systems and Reimbursement Policy

Submitter : **Dr. Michelle Chapman** **Date: 05/04/2005**

Organization : **Tufts-New England Medical Center**

Category : **Pharmacist**

Issue Areas/Comments

Issues 11-20

Personnel Qualifications

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 write to comment on the proposed revisions to the Conditions for Coverage for End Stage Renal Disease Facilities and specifically on Proposed ? 494.140 (?Personnel Qualifications?). This section addresses the role of a pharmacist within dialysis facilities.

I am a board certified pharmacotherapist who is a member of the Division of Nephrology at Tufts-New England Medical Center. I currently volunteer my time to the dialysis unit, owned and operated by Dialysis Clinic, Inc., and provide services such as conducting patient medication histories, answering drug information questions, assisting in medication use protocol development and attending patient care rounds.

There are many reasons why pharmacists are valuable in this setting. Patient-specific reasons include the fact that drug therapy is complex in dialysis patients and because of kidney failure patients are more vulnerable to experiencing adverse medication-related outcomes. From a facility point of view, there is the need for proper storage, preparation, and administration of medications within the dialysis unit and also for proper medication use protocol development. Pharmacists are well trained and prepared to meet these needs and serve as consultants to dialysis facilities. Furthermore, positive clinical and financial outcomes have been reported when pharmacists are involved in the management of conditions (including anemia, metabolic bone disease, and diabetes mellitus) that frequently occur in ESRD patients.

The participation of pharmacists in the care of dialysis patients should not be an unfunded mandate, Sufficient financial remuneration must accompany including consultant pharmacists as members of the dialysis facility staff. Studies have shown that effective medication therapy management by pharmacists, both for individual patients and those served by hospital-affiliated dialysis facilities, resulted in as much as $4 of health care cost savings for every $1 spent.

Specifically, I would like to make the following recommendations:
1. Financial remuneration be available for consultant pharmacists working within dialysis facilities.

2. A comprehensive medication review for each dialysis patient should be conducted by a pharmacist prior to or at the initiation of dialysis and at clinically appropriate intervals thereafter. Documentation of the review should include generation of an updated list of medications including drug name, dose, frequency, and special instructions. All medication-related problems should be documented and a plan of action to prevent or correct the problems should be recommended to the medical director of the facility. The pharmacist should provide counseling and education to patients to assure understanding of the proper use of their medications and to promote adherence with the medication regimen.

3. Pharmacists should participate in the development and implementation of medication-related protocols within dialysis to assure cost-effective drug use.

4. Dialysis facilities should develop and maintain appropriate policies for the safe storage, preparation and administration of medications within the facility. These policies should be developed and maintained in consultation with a pharmacist.

Thank you for your consideration of these comments.

Sincerely yours,

Michelle M. Chapman, Pharm.D., FCCP, BCPS

Assistant Professor of Medicine
Tufts University School of Medicine

Special and Scientific Staff
William B. Schwartz Division of Nephrology
Tufts-New England Medical Center

750 Washington Street, Box 391
Boston MA 02111

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

Organization : California Hospital Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Dialysis of ESRD patients in nursing facilities and skilled nursing facilities. See attachment.

CMS-3818-P-164-Attach-1.DOC

Attachment #164
May 3, 2005

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

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

To Whom It May Concern:

The California Hospital Association (CHA) represents nearly 500 California hospitals and health systems. We appreciate the opportunity to comment on the proposed rule regarding conditions for coverage of end-stage renal disease (ESRD) facilities.

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

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

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

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

In addition, 65 percent were 65 years and older; 92 percent were 50 years and older. More than 60 percent were on Medicare Part A stay in the SNF. Approximately 15 percent were dually eligible, and a mere 5 percent were insured by Medicaid only.

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

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

Provision of Home Dialysis to SNF Patients Is Inappropriate

Patients are Too Fragile for Home Dialysis

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

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

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

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

Home Dialysis is Problematic for Short-Stay Patients

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

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

As a result, these patients who are typically on chronic dialysis would have to switch to home dialysis and back again to chronic dialysis within a very short and unrealistic time

frame. The current system cannot support demands for such quick benefit coverage decisions. Thus, patients' continuity of care would be jeopardized.

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

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

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

CHA urges CMS to investigate more thoroughly the possibility of the following options:

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

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

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

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

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

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

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

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

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

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

Conclusion

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

Comments on Home Dialysis Proposed Rules

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

Nursing Coverage

The proposed rule would require that a registered nurse (RN) be on the premises whenever in-center patients are being treated. This requirement would take the place of

the current requirement that a licensed health professional experienced in rendering ESRD be on duty. CHA supports this approach in the proposed rule. We believe that having an RN on the premises is appropriate with promoting good patient care in the nursing home setting.

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

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

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

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

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

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

If you have any questions or comments, please contact Judy Citko at 916/552-7573 or jcitko@calhealth.org.

Sincerely,

C. Duane Dauner
President

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

Organization : Nebraska HHSS Regulation & Licensure

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

See attatchment

CMS-3818-P-165-Attach-1.DOC

Attachment #165
Comment to the Proposed ESRD regulations:

Physical environment
Although a requirement for AED would save lives, in rural Nebraska this would be a burden to require this in a dialysis facility. Many of the small 2-4 station facilities are actually based within a hospital in rural Nebraska and the emergency equipment of the hospital is utilized by the dialysis staff with assistance of other hospital staff responding to the emergency. In other instances, there are some small facilities that have no ties to the local hospital/medical facilities and this would be a good requirement for them. Possibly, a determination of how the dialysis facility is associated with nearby hospital/medical and emergency facilities would be a determining factor in small units.

Patient plan of care
Social Service must be a part of the patient plan of care and outcomes for social service should be developed and required. Although the Social Worker works with the patient any goals or outcome for social service most likely missing from the care plan. In order to be an interdisciplinary process the care plan must include all the disciplines. Nurses are comfortable with the care plan process but to social workers, this may be a foreign process. Requiring the patient plan of care to contain outcomes for social service would help the social worker realize how they fit into the plan of care. At least one company that owns dialysis facilities in Nebraska does not even have a section in their current plan of care for the social worker to insert information.

Personnel Qualifications
Registered Nurses should be required to have clinical experience but also training in the care of patients with chronic renal disease. The facility may determine the training program but the program should teach the nurse to be more than a "machine nurse". This means that the registered nurse should understand the physical, emotional and psychosocial issues that go along with renal disease and dialysis. Every Registered Nurse working in a dialysis unit should be able to explain all lab values, explain how renal disease and dialysis effect each body system, and be able to explain this to the licensed practical nurse and the technician. If the registered nurse is to supervise the technician while in the technician trains and then works in the dialysis unit the registered nurse should know everything that is in the technician training program. Therefore, the registered nurse should be required to go through an extensive training program as well as on the job training of the technical aspects of dialysis patient care including reuse and water treatment.

Governance
Adequate Number of Qualified and Trained Staff should include the amount of time the Dietician and the Social Worker work in a facility. Often times the Dietician and the Social Worker are expected to staff multiple facilities in rural areas. This gives these staff members only the bare minimum amount of time needed to meet patient needs. When determining adequate staffing the Dietician and Social worker should be considered.

I agree that a Registered Nurse should be present in the facility at all times patients are being treated. The Registered Nurse should be in the treatment area.

General Comments

The existing regulations have no regulations addressing basic care. Outcome based surveys are the correct avenue but there should be basic regulations outlining care. For example, care should be under the direction of a physician. Nurses and technicians should follow physician orders. Patient's vital signs and access site should be monitored during treatment and the monitoring should be documented. Neither the existing nor the proposed regulations cover these things or other areas of basic care. Although the proposed regulations are being written to be outcome oriented and not process oriented some amount of regulatory framework should be in place that covers the basics of care. I know many surveyors feel that the existing regulations are weak in many ways because of this and I see nothing in the proposed regulations to change this feeling.

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

Organization : **MaryLou Pederson**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Aee attachments

CMS-3818-P-166-Attach-1.DOC

CMS-3818-P-166-Attach-2.DOC

Attachment #166
Department of Medicare and Medicaid Services
Depart of Health and Human Services
Attention: CMS-3818-P
PO Box 8012
Baltimore, MD 21244-8012

May 4, 2005

Dr. McClellan, Administrator:

Working in the ESRD field with patients and staff in five states for the past five years has given me a unique opportunity to observe the success, or lack of same, of the current Conditions for Coverage for End-Stage Renal Disease Facilities.

The attached document prepared by the Council of Nephrology Social Workers addresses many of the concerns I have about the proposed new Conditions for Coverage. Please accept these comments as part of my input to them.

In addition, although I do not have the bibliography to cite for specific comments, I would like to address a few other points that are not noted in the attachment.

Physical Environment (Proposed 494.60)
Under the existing text in 405.2140(d)(3) regarding emergency equipment the proposed new rule comments about "Additional patient safety protections such as defibrillators in the emergency equipment list...."
COMMENT: I strongly urge that small predominately rural dialysis facilities **not** receive special consideration and possibly an exemption from the defibrillator requirement.
Rationale: These rural units are more likely to be further away from emergency personnel who can assist them, and thus especially need AED's in their units, If funding is required to assist them to afford this, then CMS needs to explore how to provide this funding. It is unfair to limit the safety of rural unit patients because the cost of requiring AED's may be prohibitive under the current payment schedule.

Patient's Rights (494.70)
Current rule 405.2138 is proposed to be changed to "holding the facility accountable for the outcome, which is to ensure that each patient's rights and the ability to exercise them are protected."
COMMENT: What does "holding the facility responsible mean? Where does the buck stop? Who is finally accountable if you remove the accountability from the CEO?
Rationale: Language that is not specific lends itself to many interpretations and confuses the accountability when holding ESRD facilities accountable for following the Rules.

Current rule 405.2138(c) is proposed to change to 494.70(a)(2) requiring a "dialysis facility to provide information to patients in an understandable manner."
COMMENT: This needs to address more specifically— I suggest that oral communication be from medical staff fluent in the language needed, or by a medical translator.

Rationale: This will provide accurate information for the patient. It has been shown often this does not occur when a family member or non-medical staff person is used as the translator.

Patient Plan of Care (Proposed 494.90)
COMMENT: Under all the rules noted here leave an open statement concerning new standards that may become accepted as studies continue and new information becomes available.
Rationale: This allows for new standards to become incorporated that will benefit patients instead of holding them in state of inadequate treatment based on out-dated information.

Under Vascular Access (Proposed 494.90 (a)(4)) it is "proposed to include vascular access as a component of the patient plan of care...."
COMMENT: Why not include a statement strongly urging the education of the patient regarding the most successful and effective access for the majority of patients, the Arterio-Venous Fistula?
Rationale: The current national ESRD project, Fistula First, is based on the tenet that the AVF is the most effective and successful access for the majority of patients. CMS supports this project based on all the current scientist of evidence.

Under Rehabilitation Status (Proposed 494.90(a)(6))"rehabilitation as a specific category" is included and "...the essential role of rehabilitation in the treatment and recovery process must be continuously conveyed to patients and their families."
COMMENT: When do Table 8 need to include all ages and this emphasis on improvement for all patients.
Rationale: It makes no sense to limit the ages included in the current Table 8 to a maximum of 55. That is 'old thinking' that is based on the 1976 timeframe. Also, things like managing the activities of daily living to the best of one's ability ought to be recognized as rehabilitation, as stated in the Life Options list of five "E's," along with activities involved in being a homemaker.

Implementation of the Patient Plan of Care (Proposed 494.90(b)(4))
This "specifies that the facility must ensure every patient is seen at least monthly by a physician providing the ESRD care...."
COMMENT: The November 7, 2003 final rule regarding the revisions to the payment policies under the physician fee schedule for calendar year 2004 has seriously effected the quality of the care a patient receives regardless of the increased quantity of visits by his/her doctor. Some patient now see their doctor more frequently but for less time and never in private office visits where they can safely discuss private concerns.
Rationale: Two, three or five brief five minute chair-side visits by the doctor per month does not equate to one 15-20 minute intense visit in a private office where the patient can discuss more in-depth issues, more personal/private issues, etc. with the doctor. The doctor is not motivated to provide this kind of care under the November 2003 rule. This is very frustrating for those patients who had a much more effective relationship with their physicians previously. Quality of care is being affected and more complaints are

being made by patients about lack of communication and education with and by their physicians. Additionally, this is a negative experience for facilities with multiple locations and doctors with patients in those multiple locations. Either the doctor spends (wastes) valuable time traveling between sites, or patients see an on-site doctor who is helping to cover care but then is limited in his/her previously less limited contact with the primary physician.

Quality Assessment and Performance Improvement
Patient Satisfaction (Proposed 494.110(a)(2)(viii))
1. OIG identified assessment of patient satisfaction as a means of identifying patient concerns often missed by the complaint process. "...AHRQ recommended that a standardized survey for measuring in-center hemodialysis patient's experience and ratings of their care be developed..."to "...use for public reporting and monitoring purposes."
COMMENT: Surveys are subjective. It is difficult to feel they are valid to use for public reporting and monitoring purposes.
Rationale: Surveys are subjective. They are like statistics – you can make them 'say' whatever you want them to say.
2. "We are soliciting comment on how evaluating and tracking grievances can be used to improve patient outcomes of care."
COMMENT: It is important to do this such that all entities use the same instrument.
Rationale: Internal assessment is important to quality improvement in patient satisfaction.

Responsibilities of the Medical Director (Proposed 494.150)
"In a January 2002 report..., the OIG recommended that the ESRD conditions for coverage specify the responsibilities of the Medical Director in situations where there is a quality problem related to an ESRD facility physician...."
COMMENT: It is important for the Medical Director to have a more active role. The Medical Director needs to understand this responsibility when he/she takes the job.
Rationale: Without leadership from the top the rest of the staff is unable to effect the necessary changes needed in a quality problem situation. The Medical Director needs to accept the responsibility for all parts of the role, getting appropriate training in management, quality, or personnel policies as needed.

Governance
Under the proposed Adequate Number of Qualified and Trained Staff (Proposed 494.180(b)) "there is a new requirement (494.180(b)(5)) for a written approved training program, designed by the facilities, that is specific to dialysis technicians." "We are proposing that every dialysis patient care technician-training program contain criteria that would provide at least a minimal set of skills..." and "we invite public comment on the basic criteria proposed...."
COMMENT: It is imperative that more than one hour of the technician training be devoted to ethics and professionalism, and communication skills with an emphasis on how to respond appropriately to conflicts and challenging situations.
Rationale: In my job I deal with patient and staff complaints from a five state area. All calls eventually reflect communication problems of one sort or another with a majority

also related to lack of professionalism/ethical behavior. Staff cannot do what they do not know. They need adequate, appropriate, and continued training over the time of their employment. This needs to be a required element for all staff, including administrative and adjunct staff. The majority of problems would be small and resolved quite quickly on the local level with appropriate skills applied by all staff members. One cannot gain these skills without adequate training.

Thank you very much for this opportunity to respond to the proposed Conditions of Coverage for End Stage Renal Disease Facilities, CMS-3818-P. It is exciting to think there will finally be updated, relevant rules for the care of ESRD patients.

Sincerely,

MaryLou Pederson, RN, MA
2727 Fairview Ave East #8
Seattle, WA 98102

Submitter : **Ms. JOANNE BELTRAN** **Date: 05/04/2005**

Organization : **Ms. JOANNE BELTRAN**

Category : **Social Worker**

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT.

CMS-3818-P-167-Attach-1.DOC

Attachment #167
Department of Health and Human Services
Centers for Medicare and Medicaid Services

Response from:
Joanne C. Beltran, MSW
24 years as a Nephrology Social Worker
Out-Patient Hemodialysis and Peritoneal Dialysis
Currently covering two facilities in Vacaville, California (15 and 12 stations)
Responses are personal and should not be attributed to my current employer

COMMENTS REGARDING FILE CODE CMS-3818-PD

General comments and observations;

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

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

2) RN coverage in a dialysis facility:

It is to the patient's best interest to have sufficient RN coverage to meet the needs of the patient. One RN in the building may not be enough to provide safe coverage under many circumstances. It would be preferable to establish safe guidelines and patient-to-RN ratio. The patient and the caregivers would benefit from such guidelines. In any dialysis facility, multiple emergencies can occur at any given time, requiring the full attention of an RN. When patient numbers increase, of course opportunities for emergent situations increase as well. If the administrator is not also an RN, there may be less than safe RN coverage in the building with just one RN required.

3) Dialysis Staff education:

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

COMMENTS SPECIFIC TO SPECIFIED CONDITIONS OF PARTICIPATION

ISSUE IDENTIFIER:

494.60 : PHYSICAL ENVIRONMENT

(c): patient care environment

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

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

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

comfortable temperatures.
The statement "make reasonable accommodations for patients who are not comfortable at the temperature that is comfortable for the majority" is vague and nebulous. The dialysis clinic would be placed under a condition that cannot realistically be met.
While the comfort of the dialysis patient is of prime importance, there are other issues in the dialysis clinic. Dialysis staff are forced by OSHA regulations to wear heavy, impermeable, long sleeved and full length personal protective gowns over full clothing. They are also shielded from fresh air flow for most of the day due to the wearing of face shields and masks. The Dialysis staff must be able to work continuously , moving from one task to the next. They often suffer from over-heating , sometimes to the point of profuse perspiration and faintness. Under these conditions, ability to move quickly and to think clearly can be impaired. Facility temperatures must be conducive to the health and welfare of the dialysis staff as well as the patient.
Patients can use blankets to keep them warm, dialysis staff have no recourse. A temperature that is fair to all should be the standard.
There are also issues with temperatures of solutions such as the Paracetic Acid used for reprocessing and sterilizing dialyzers. This solution must be kept at a constant temperature of about 72 degrees. In older clinics where the air conditioning system may not be as sophisticated, the temperature of these solutions increase as the ambient temperature increases, creating unacceptable storage environments.

494.80 : PATIENT ASSESSMENT

(a) Standard: Assessment Criteria

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

The language used in this sentence leaves the door open to hold dialysis clinics and staff responsible to address each of a patients co-morbid conditions, regardless of their significance in the dialysis setting. There are no boundaries or parameters set, thus leaving the area of assessment open to individual interpretation. While it may be appropriate for the Nephrologist and dialysis staff to address certain applicable co-morbidities, in general co-morbid conditions should be addressed and followed by the patient's primary physician.
It is unreasonable to expect dialysis clinics to be broad based health clinics; they have neither the staffing nor the financial resources to do so.
This proposal enables primary care physicians and HMO'S to shirk their professional and ethical responsibilities toward patients. It lays excessive burden on the Nephrologist and the dialysis team to be broad based care givers and facilitators and is not appropriate or reasonable.

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

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

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

494.90: PATIENT PLAN OF CARE

The first paragraph in this section includes the following language " plan of care.....must include measurable and expected outcomes and **estimated timetables to achieve these outcomes.**
The main concern here is that there are times when, even with the best and most conscientious intervention, patients do not or can not, for a variety of reasons, meet the expected outcomes. The patient is a major player in the success or failure of many outcome goals. They are given choices and their right and freedom to choose to comply or not to comply with medical recommendations must be respected. Dialysis clinics should not be held responsible or payment reduced, when medical intervention is appropriate, yet outcomes or timetables fail to be met. The major concern is: " what will the Medicare response be, if all efforts fail to aid the patient to achieve the expected outcomes?"

(6) Rehabilitation status

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

While providing **referrals for services** is reasonable and standard, it is not reasonable to expect the Dialysis clinic staff to do more than provide the referral. Dialysis clinics have neither the resources or the funds to provide for anything beyond referrals.

(c)Standard: Transplantation referral tracking

. It is unrealistic to expect the dialysis team to be responsible to maintain communication with the Transplant facility. Once a transplant referral is made and the patient is seen, it is more appropriate that the Transplant Coordinator and the Transplant Center be held accountable for communication with the patient and the dialysis facility. This language makes the dialysis team responsible for others' area of service and scope of practice. This requirement also takes individual responsibility away from the patient, who should be encouraged to be independent and personally accountable for as much as possible in their lives. A patient who takes an active role in their care is much more likely to achieve a desired outcome. This approach infantizes and disempowers patients who should be given every opportunity to advocate for themselves.

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

494.140 : CONDITION: PERSONEL QUALIFICATIONS

(b) Standard: Nursing services

(2) Charge nurse

The standards for the dialysis clinic must be held as high as possible. While many practical nurses may have adequate experience and aptitude to be a charge nurse, it is the Registered Nurse who is trained to do so and is legally responsible. The algorhythm for delegation is from Registered Nurse to practical nurse. To open the door for practical nurses to assume charge nursing responsibilities is to open the door for less than ethical practices by some whose intention is merely to save money.

(c) Standard: Dietitian

(3) Work experience

The requirement of one year's professional work experience is unnecessary as long as the Dietitian Candidate has met the conditions for registration with the Commission on Dietetic Registration and is mentored and followed by a seasoned and experienced Renal Dietitian. It is highly improbable and unlikely that one year experience will better prepare them to work with Renal patients, as this area is such a highly specialized area that one has to work in the field to gain expertise as a Renal Dietitian. To require this length of time in professional work experience will lead to the potential loss of excellent candidates who could be trained and mentored by experienced and qualified people.

Thank you for taking the preceding comments and observations under advisement.

Submitter : **Ms. Janet Prokop** **Date: 05/04/2005**

Organization : **Purity Dialysis Centers**

Category : **Social Worker**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3818-P-168-Attach-1.DOC

Attachment #168
May 3, 2005

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

Re: CMS Proposed Conditions
For Coverage for ESRD Facilities

To Whom It May Concern:

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

Thank you for your consideration of the following opinions.

Sincerely,
Janet Prokop, LCSW
Purity Dialysis Centers - Oconomowoc
1253 Corporate Center Drive
Oconomowoc, WI 53066

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

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

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

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

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

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

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

Submitter : Mrs. Gene Gentry **Date:** 05/04/2005

Organization : Davita

Category : Dietitian/Nutritionist

Issue Areas/Comments

Issues 1-10

Plan of Care

A large no. of RD'S in the field of renal work part-time, therefore; shortening assess. time from 30 to 20 days will mean that there could be assessments that will not be done in a timely manner. Unsure as to the reason for reduced assessment time. Is there any specific data to support that cutting assessment time frame by 10 days improves outcomes?

In my company we review labs monthly, and when doing so, also assess pts. wt., appetite, and other contributing factors that have occurred since last labs. Anything out of the norm is addressed. I not sure how an additional assessment tool would be of benefit for new patients at 3 months.

Submitter : Mrs. Gaynell Irving **Date:** 05/04/2005

Organization : Mrs. Gaynell Irving

Category : Dietitian/Nutritionist

Issue Areas/Comments

GENERAL

GENERAL

K/DOQI guidelines are addressed in most areas but not in RD/patient ratio. Many companies exceed recommended numbers at the expense of patient care. I believe this area needs to be addressed.

For the assessment of patients rather than 20 calendar days I believe 13 treatments is better because RDs who cover multiple units in rural areas and have no coverage during vacations will not be able to meet the 20 calendar days with the high influx of new patients.

Submitter : **Dr. Allan Collins** **Date: 05/04/2005**

Organization : **Minneapolis Medical Research Foundation**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-3818-P-171-Attach-1.DOC

Attachment #171 April 20, 2005
Dear Dr. McClellan:

I have read the new proposed ESRD Conditions of Coverage and I would like to comment specifically on § 494.140--"Personnel Qualifications"—the role of the pharmacist.

I am writing these comments, not in my official capacity as the Director of the United States Renal Data System (USRDS) Coordinating Center or President-Elect of the National Kidney Foundation, but as a practicing nephrologist and a Medical Director of one dialysis unit in Minneapolis-St. Paul, MN.

I strongly believe that pharmacists should be recognized by Medicare as a valuable member of the ESRD health care team.

The Division of Nephrology and the Department of Pharmacy at Hennepin County Medical Center (HCMC, a public county hospital and teaching facility for the University of Minnesota, School of Medicine and College of Pharmacy) has employed pharmacists to evaluate, detect and manage medication-related issues in our dialysis and renal transplant patients for three decades. I have worked directly with several pharmacists who have provided these services over the years, and I feel that they've filled a void in end-stage renal disease (ESRD) patient care that other health care practitioners can not adequately fill.

ESRD patients represent a medically complex population of patients with multiple comorbidities. Data from the USRDS shows that 44% of incident ESRD patients have diabetes as primary cause of ESRD, but 62% carry a diagnosis of diabetes. Most prevalent ESRD patients are hypertensive and are anemic, a majority have various cardiovascular diseases and all ESRD patients are at high risk for metabolic, bone and nutritional disorders, as well as psychiatric conditions such as depression. Dialysis therapies are also becoming more complex. The majority of patients continue to receive intermittent hemodialysis, but 10% of patients are using various peritoneal dialysis techniques. A small but increasing percentage of patients are undergoing daily or nocturnal dialysis. There are over 100 hemodialysis membranes on the market today, all exhibiting different drug clearance characteristics. All of the conditions above affect drug disposition and clearance. Frankly, there are hundreds of drugs on the market today, and it is difficult or impossible to keep up with the nuances of every single drug utilized in my ESRD patients.

ESRD patients need to have access to a practitioner who can take an accurate medication history, obtain information on over-the-counter drugs and alternative therapies, determine that they're on the best, most cost-effective drugs for their medical problems, make sure that their drug dosage regimens are correct for their medical conditions (including kidney failure) as well as their type of dialysis therapy. In addition, these patients are at high risk for drug-drug and drug-food interactions because of the number of medications they take. Thus, they need someone who can proactively determine if there may be issues.

My experience shows that pharmacists who have some experience in nephrology can provide the necessary expertise to develop a rational therapeutic plan taking all of the things above into consideration. It is unclear if any other practitioners have the requisite background to be able to optimally provide excellent medication management services to dialysis patients. In addition, the pharmacists that I've worked with have helped develop medication protocols and algorithms for use in ESRD patients. Pharmacists can provide the necessary expertise to develop medication plans that will be more efficient and cost-effective.

As you probably are aware, dialysis patients cost the Medicare system, on average, over $50,000 per year. About half of these costs are hospital costs. The average dialysis patient is hospitalized 14.4 days per year. The USRDS and other investigators have shown that many dialysis patients do not appear to be receiving medications, proven in clinical trials to be effective, for their medical conditions. In the long-run, optimal medication management in ESRD patients has the potential to reduce hospitalizations and decrease the average per member per month cost to the Medicare system.

Pharmacists are considered a valued member of the ESRD health care team at HCMC. All ESRD patients in the U.S. ought to have a knowledgeable pharmacist available that can provide individualized medication therapy management services. Dialysis programs would benefit from having access to individuals that have specialized knowledge about developing medication protocols, patient medication assistant programs, drug storage, inventory and delivery.

Medicare suggests that nephrologists see their patients up to four times a month. I think that a pharmacist should review ESRD patient medications for medication-related issues at least once a month, consistent with Medicare policy for nursing home patients.

To summarize, pharmacists are the only health care professionals today that have the specialized background to routinely provide optimal medication therapy management services to ESRD patients who are at least, if not more, complicated than the average nursing home patient. Pharmacists need to be recognized by Medicare as an essential ESRD health care team member.

Regards,

Allan J. Collins, MD, FACP
Professor of Medicine, University of Minnesota
Director of Chronic Disease Research Group, Minneapolis Medical Research Foundation at Hennepin County Medical Center
914 South Eighth Street, Suite D-206
Minneapolis, MN 55404 USA

Submitter : Miss. Christine Wacker **Date:** 05/04/2005

Organization : Davita Dialysis, Inc.

Category : Dietitian/Nutritionist

Issue Areas/Comments

GENERAL

GENERAL

see attachement

CMS-3818-P-172-Attach-1.RTF

Submitter : **Dr. Nancy Mason** **Date: 05/04/2005**

Organization : **University of Michigan**

Category : **Pharmacist**

Issue Areas/Comments

Issues 11-20

Personnel Qualifications

See attachment

CMS-3818-P-173-Attach-1.DOC

CMS-3818-P-173-Attach-2.DOC

Attachment #173

University of Michigan
College of Pharmacy
428 Church St.
Ann Arbor, MI 48109-1065

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 you to offer comments regarding the proposed revisions to the Conditions for Coverage for End Stage Renal Disease Facilities. Specifically, I wish to comment on Proposed § 494.140 ("Personnel Qualifications") as this section addresses the possible role of a pharmacist within the dialysis facility. I am pleased to see that the Proposed Rule acknowledges the contributions a pharmacist can make to the safe and effective use of medications in a vulnerable dialysis patient population.

I am a nephrology pharmacist working in an academic medical center. I have seen first-hand the difficulties experienced by patients and health care providers alike in managing the many complications associated with end-stage renal disease. Relatedly, medication-related problems are common in this population with such complex therapeutic regimens. A pharmacist knowledgeable in specific medication issues of dialysis patients will be of great benefit to patients and other members of the health care team.

I believe that pharmacists should be recognized as an integral part of the dialysis health care team due to the:

- large number of concurrent diseases in this patient population,
- huge number of prescription and over-the-counter medications prescribed,
- increased risk for adverse medication-related outcomes,
- pharmacodynamic and pharmacokinetic changes in drug disposition due to kidney disease
- pharmacokinetic variability of drugs during various dialytic procedures,
- need for cost effective drug therapy,
- complex nature of drug dosage regimens in dialysis patients,
- training of pharmacists that prepares them to serve as consultants to dialysis facilities,
- need for storage, preparation, and administration of medications within the dialysis unit,

- changing nature of drug therapy that will arise due to the Medicare Modernization Act and Medicare Part D implementation

Specifically, I would like to make the following recommendations:

1. The multidisciplinary dialysis team should include a pharmacist with experience or training in nephrology pharmacotherapy.
2. The routine patient care of dialysis patients should include a comprehensive pharmacotherapy assessment by a pharmacist at initiation of dialysis, including the identification of drug-related problems.
3. Pharmacotherapy follow-up evaluations including documentation of progress in achieving goals of therapy should be conducted at least monthly. This frequency is consistent with what is required in skilled nursing and intermediate care nursing facilities.
4. Pharmacists should participate in the development and implementation of medication-related protocols within dialysis units or programs 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.

Medication therapy management services have been demonstrated to save substantial health care resources, while ensuring that individual patients receive effective and safe drug therapies. Because medications play such a vital role in the care of patients with end-stage renal disease, inclusion of a pharmacist as part of the dialysis health care team is essential.

Sincerely,

Nancy Mason

Nancy A. Mason, Pharm.D.
Clinical Associate Professor and
Director, Experiental Training Program and Continuing Education
University of Michigan College of Pharmacy
nmason@umich.edu
(734) 763-4981

Submitter : **Mrs. Rosalyn Brunson** **Date: 05/04/2005**

Organization : **Yorkville Dialysis Patient**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

April 30, 2005

Comments to Medicare Program; Conditions for Coverage for End Stage Renal Disease facilities; Proposed Rule

A fairly new member of the ESRD community, I appreciate the opportunity to comment on these proposed policies. Some existing policies should remain. However, changes have taken place in the delivery of services to dialysis patients and advances that do not reflect in existing policies, therefore changes are due to bring the renal community into the 21st Century.

Dialysis Technicians
Dialysis technicians are the ?primary caregivers? with the least amount of training (only three months). I believe a Federal certificate requirement should be mandatory. A minimum requirement for on the job training and experience should be one (1) year under the supervision of a registered nurse.
Renal technicians training is vital, not only to the health but to the life of the patients. The adverse outcome for dialysis patients of improper care from inadequately trained technicians could be blood leaks, access damage, incorrect dialysis, infections and hypotension. Increased numbers patients hospitalized for blood transfusions and access repair. If the access is badly damaged, it may have to be moved to a different site and a host of other problems, which in turn result in higher cost- for positive patient outcomes requires an adequately trained ?primary caregiver.

Emergency Preparedness

I believe a defibrillator would be an asset to the emergency preparedness program. Patients routinely treated in dialysis centers are at risk for medical emergency, many older ESRD patients have multi illnesses. As a result standard facility medical practice dictates the facility have emergency equipment. Automated external defibrillators on the premises would have the potential to save lives.
Staff training would be evaluated at least annually and staff must demonstrate knowledge of emergency preparedness.

Water Quality

I believe water system technicians-independent of the primary caregivers would benefit both patients and facility. Since the quality of water is vital to the health of patients. Water purity is important in protecting patients safety, the water system must be adequately monitored and properly collected and tested. Therefore its imperative the system is free from contaminants. Contaminated water could have fatal consequences to the patients.

Rosalyn Brunson
Yorkville Dialysis Patient
New York City

Submitter : **Mrs. Carolyn Parker** **Date: 05/04/2005**

Organization : **Mrs. Carolyn Parker**

Category : **Dietitian/Nutritionist**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-3818-P-175-Attach-1.DOC

Attachment #175
Department of Health and Human Services
Centers for Medicare and Medicaid Services

Response from:
Carolyn M. Parker MS,RD
18 years Clinical and Renal Nutrition
Currently Renal Dietitian of 15 Station Outpatient Hemo-Dialysis Facility
And Peritoneal Dietitian for 25 patients.
Responses are personal and in no way to be attributed to current employer

COMMENTS REGARDING FILE CODE CMS-3818-PD

General comments and observations;

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

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

2) RN coverage in a dialysis facility:

It is to the patient's best interest to have sufficient RN coverage to meet the needs of the patient. One RN in the building may not be enough to provide safe coverage under many circumstances. It would be preferable to establish safe guidelines and patient to RN ratio's. The patient and the caregivers would benefit from such guidelines. In any dialysis facility, multiple emergencies can occur at any given time, requiring the full attention of an RN. When patient numbers increase, of course opportunities for emergent situations increase as well. If the administrator is not also an RN, there may be less than safe RN coverage in the building with just one RN required.

3) Dialysis Staff education:

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

COMMENTS SPECIFIC TO SPECIFIED CONDITIONS OF PARTICIPATION

ISSUE IDENTIFIER:

494.60 : PHYSICAL ENVIRONMENT

(c): patient care environment

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

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

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

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

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

Patients can use blankets to keep them warm, dialysis staff have no recourse. A temperature that is fair to all should be the standard.

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

494.80 : PATIENT ASSESSMENT

(a) Standard: Assessment Criteria

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

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

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

This proposal enables primary care physicians and HMO'S to shirk their professional and ethical responsibilities toward patients. It lays excessive burden on the Nephrologist and the dialysis team to be broad based care givers and facilitators and is not appropriate or reasonable.

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

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

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

494.90: PATIENT PLAN OF CARE

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

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

(6) Rehabilitation status

The language in this section is ambiguous and leaves much opportunity for misinterpretation by individual inspectors. "**Must provide the necessary care and services** for the patient to achieve and

sustain an appropriate level of productive activity.....etc"

While providing **referrals for services** is reasonable and standard, it is not reasonable to expect the Dialysis clinic staff to do more than provide the referral. Dialysis clinics have neither the resources or the funds to provide for anything beyond referrals.

(c)Standard: Transplantation referral tracking

. It is unrealistic to expect the dialysis team to be responsible to maintain communication with the Transplant facility. Once a transplant referral is made and the patient is seen, it is more appropriate that the Transplant Coordinator and the Transplant Center be held accountable for communication with the patient and the dialysis facility. This language makes the dialysis team responsible for others' area of service and scope of practice. This requirement also takes individual responsibility away from the patient, who should be encouraged to be independent and personally accountable for as much as possible in their lives. A patient who takes an active role in their care is much more likely to achieve a desired outcome. This approach infantizes and disempowers patients who should be given every opportunity to advocate for themselves.

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

494.140 : CONDITION: PERSONEL QUALIFICATIONS

(b) Standard: Nursing services

(2) Charge nurse

The standards for the dialysis clinic must be held as high as possible. While many practical nurses may have adequate experience and aptitude to be a charge nurse, it is the Registered Nurse who is trained to do so and is legally responsible. The algorhythm for delegation is from Registered Nurse to practical nurse. To open the door for practical nurses to assume charge nursing responsibilities is to open the door for less than ethical practices by some whose intention is merely to save money.

(c) Standard: Dietitian

(3) Work experience

The requirement of one year's professional work experience is unnecessary as long as the Dietitian Candidate has met the conditions for registration with the Commission on Dietetic Registration and is mentored and followed by a seasoned and experienced Renal Dietitian. It is highly improbable and unlikely that one year experience will better prepare them to work with Renal patients, as this area is such a highly specialized area that one has to work in the field to gain expertise as a Renal Dietitian. To require this length of time in professional work experience will lead to the potential loss of excellent candidates who could be trained and mentored by experienced and qualified people.

Thank you for taking the preceding comments and observations under advisement.

Submitter : Mrs. diana hlebovy **Date:** 05/04/2005

Organization : non

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

see attachment

Submitter : **Mrs. Deborah Collinsworth** **Date:** **05/04/2005**

Organization : **Mrs. Deborah Collinsworth**

Category : **Social Worker**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-3818-P-177-Attach-1.DOC

CMS-3818-P-177-Attach-2.DOC

Attachment #177

File Code – CMS - 3818-P

Comments:

Patient Assessment – 494.80 Proposed Part 494 Subpart C:

The **proposed 20 calendar time limit** for the team to conduct a comprehensive assessment of new patients is too brief. I support retaining the more realistic 30 day time frame or 13 treatments for completing patient assessments. In the proposed language, a time frame of 20 calendar days assumes the inclusion of Saturdays and Sundays, typical non-work days for some of the team members. Excluding weekends, the team would only have 13 working days to complete the assessment. While I agree that patient assessment is important in designing a plan of care and should be completed as soon as possible when admitting a new patient, there are many instances in which it just can't be accomplished that quickly, usually due to factors beyond staff control. Examples are 1)patients can be too uremic in the early treatment days to fully participate in interviewing and strengths assessment; 2)patients sometimes experience complications resulting in re-hospitalization or symptoms that would force a delay in obtaining a thorough assessment; 3)limited access to family members to consult with in completing assessment if patient's mental status prohibits their providing information for assessment; 4) staff coverage of multiple units or utilization of part-time clinical staff (dieticians and social workers) may result in assessment being delayed due to work schedules, rotations thru the various units, and time off for vacation, holiday, or sick time. My recommendation to CMS is that consideration be given to using the number of dialysis treatments provided (no fewer than 13) as a time frame for assessment completion rather than the number of calendar days cited in the regulations.

The rationale for the **proposed 3 month re-assessment** of new patients is valid. However, CMS recognizes the additional burden it places on the interdisciplinary team. My recommendation is a rewording of the regulations to require a team follow-up "focused" assessment, rather than a repeat of the comprehensive assessment conducted at initial admission. Much of the information gathered at initial assessment is historical, and will not have changed.
A focused assessment would be directed at reviewing and assessing the patient's adjustment and adherence since beginning dialysis, identifying strengths, barriers to achieving positive clinical outcomes, and transplant and rehabilitation status. The team would determine the patient's response to the treatment program, for example: 1)understanding and ability to access/utilize information; 2) level of progress, i.e. significant, limited; 3) denial, hesitancy or unwillingness to follow treatment recommendations. Based on assessment of the patients' response to treatment, education, and counseling, the care plan would be reviewed and revised. Requiring a focused assessment would meet CMS objectives and limit the burden on the team by not requiring redundancy in documentation.

Providing **quality of life testing and evaluation** to determine the patient's self-report of their overall functioning and well-being can be helpful in delivery of care and services to ESRD patients. However, there are costs to providing quality of life surveys and interpretations, so if mandated, an adjustment to the composite rate should be made to cover this additional service. It should be recognized that not every patient can participate in a survey such as the SF-36, so if mandated, facilities should not be cited for those patients who were unable to complete a QOL instrument. There are also some patients who, over time, develop "instrument fatigue" and will voice reluctance to complete the survey, or sabotage it to give higher scores due to over familiarity with the survey. There are occasions when social workers will offer the survey and find some patients who require too much help and explanation to understand the survey thereby making their results questionable, so a determination will be made that they can not participate in QOL administrations.

Patient Plan of Care – 494.90

I support the deletion of the requirement for a **Long Term Medical Program**. Currently all of the information required on the LTMP is found in other portions of the patient's medical chart.

I support the change in requiring the **Patient Care Plan** to be completed on stable patients on an annual basis rather than the current 6 months intervals. Any effort to decrease the tremendous amount of paperwork required is appreciated, so that time can be more productively spent in working with the patients directly on improving quality of life and adjustment to ESRD/dialysis.

Personnel Qualifications – 494.140

The standard that the social worker must possess a Master's Degree is supported. The complex nature of the work involved in the ESRD setting requires the advanced training provided in an MSW education program. However, there is a role in the Social Service Dept. of facilities for BSW's or case aides to work under the supervision of an MSW to carry out clerical tasks associated with referrals to community services, accessing resources, and other tasks related to transportation, DME, travel, housing, and insurance. This should be an option for facilities if it will better accommodate their staffing needs. These services are important to the wellbeing and rehabilitation of the patient and should be documented by the BSW or case aide in the patient's medical chart as part of the interventions delivered by the team to address the plan of care. In addition to directing the activities related to the psychosocial needs of the patients, the MSW should be responsible for providing patient/family counseling, assessment and care planning, and interventions to mediate staff/patient conflict.

Submitter : **Mrs. diana hlebovy** **Date: 05/04/2005**

Organization : **non**

Category : **Nurse**

Issue Areas/Comments

GENERAL

GENERAL

see attachment: Note I have been trying to send the attachement and it is NOT goint thru- please advise

CMS-3818-P-178-Attach-1.DOC

Attachment #178
May 5, 2005

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

Re: Comments on Conditions of Coverage for ESRD Facilities

Dear Administrator McClellen:

As a Nephrology Nurse for close to 30 years, I have literally grown up in dialysis using the current "Conditions of Coverage" as one of the facilities main references-sometimes referred to as the facilities "bible". I have been a staff nurse, CQI coordinator, educator, manager, and administrator. Currently, I travel across the nation educating hemodialysis staff on providing patients with a safe and efficient treatment thru the use of the Crit-line monitor for Fluid Management.
I commend the Agency's decision to update the "Conditions of Coverage". As you do so, please consider the following comments. These are based on my years of experience as well as observations noted in facilities throughout the industry and our nation.

Background

I wholeheartedly agree with the shift toward a patient outcome-based system that focuses on quality. The majority of my comments will be to assist in helping attain that goal.

While noting that Dialysis is "the process of cleaning the blood" please also state it's role in fluid removal. Adequacy of dialysis is both toxin and fluid removal.

Definitions

494.10: Please include a definition for "New Patient". Are you referring to "new" to dialysis, or new to the facility-as in a transfer in from another facility? Clarification is necessary for compliance to the patient assessment requirements.

Clarifications of the definition of "direct supervision" cited in 494.140 (e) (3) needs to be made. I interpret direct supervision to mean that the supervisor is not only on premise, but actually in the room that the treatment is being performed. If this is not clarified- the

supervisor may be in a room –floors and minutes away from the actual patient and treatment.
Please clarify the definition of "patient reactions". Surveillance of this is discussed in later sections. Are you referring only to surveillance of possible water purification reactions, or adverse reactions (intradialytic morbidities) that occur related to other factors occurring during the dialysis process? Currently intradialytic morbidities (Nausea/vomiting, hypotension, cramping etc.) are not routinely tracked. I believe they should be as they are preventable and can cause long-term patient damage. In the majority of facilities these have been considered as an expected part of the treatment- and they should not be. Some facilities actually use hypotension as a sign of getting the patient to their "Dry" weight. The K/DOQI guidelines 15-16 in the Adequacy section, note that hypotension should not be used as an indicator of Dry weight. They actually go on to say that they are especially concerned with the clinical practice of causing hypotension to establish dry weight. Intradialytic morbidities should be tracked as the first step in identifying the problem, determining the cause, and ultimately preventing it.

Please add the definition for "Nursing Facility. Is this referring only to long-term facilities, or does it also include hospital setting?

Infection Control

494.30 I am disappointed with the Proposed Rule in regards to Hepatitis C Screening. It seems to be based on Medicare reimbursement issues rather than the establishment of prudent and good policy for beneficiaries. I recommend screening at least on admission to a facility and semi-annually.

In order to assure oversight of infection control practices, the actual designation of a registered nurse as the infection control or safety officer is a prudent recommendation. Actually designating someone as accountable is the first step to making it happen.

Water Quality

I am in agreement with CMS that AAMI should be used as the appropriate authority on water quality. I encourage the change in reduction in the allowable dialysate colony counts from 2000 cfu/ml to 200cfu/ml moving toward a more pure dialysate as current evidence has demonstrated that this improves patient outcomes

Physical Environment

494.60
The proposed conditions do not define what "sufficient space" is for providing needed care. I do believe a minimum recommendation is needed. I believe not defining this will lead to "cramming- in" patient stations to increase census for financial gains. The current

existing recommendation has prevented this. The proposed conditions state that "this detail is better left to the judgment of the facility staff". I can assure you the "facility staff" is not currently and will not in the future be asked their opinion on this subject.

494.60 (c) (2) (i): I do not think that the conditions of coverage should propose that the temperature be maintained that is comfortable for the majority of patients. I believe dialysis facilities do make reasonable accommodations for their patients, sometimes at the expense of the staff. The cause of the patient feeling cold is not as simple as outlined in the proposal. The dialysis patient is "cold" related to numerous physiological factors, i.e. anemia, uremia has affected their metabolic rate, they are immunosuppressed, they are mainly inactive during the process. The basic dialysis procedure is not programmed to decrease the patient's temperature, but it is to maintain a constant temperature. As fluid is removed from the patient their temperature is rising- Not falling as the proposal suggest, and if the dialysate temperature is greater than the patient's temperature- both factors leads to vasodilatation, and ensuing intradialytic symptoms. Thermal control – maintaining the dialysate temperature no higher than 36 C is a well documented principle of dialysis. This is done in order to keep the patient's temperature the same as the pre-temperature. If not done adequately, the patient's post temperature will be higher than his pre-temperature, and the patient will have an increased risk of all related dialysis symptoms. References include K/DOQI guidelines 15-16 in the adequacy section. If patients are cold, it is important to warm them from outside the body thru appropriate dress and blankets to keep their own body heat in. Encouraging exercise during dialysis may also be recommended to increase their comfort. Increasing the room temperature would often require temperatures that cause the dialysis staff (who are wearing their appropriate personal protective gowns) to become overheated and most likely would still NOT keep the patient's warm. Basic education with the patient on the causes of feeling cold and appropriate means to prevent it are actually what is needed and should be proposed. This is the number one complaint of patients- and the causes need to be addresses appropriately. The answer is not to increase the room or dialysate temperatures. The recommended proposal will not only Not solve the issue, but it has the potential of creating more conflict in the dialysis environment.

494.60(d) (3): I am in agreement that AEDs should be required in all dialysis facilities that are not located in a facility that has its own emergency team. AEDs have been around long enough, and have been made simple enough that they should now be a standard safety requirement.

The existing 405.2140(b) (3) specifies that the facility have a nursing / monitoring station from which adequate surveillance of patients receiving services can be made. I recommend not eliminating this – it is not only a physical environment issue- but a safely issue. It is imperative that the patients be in full view of the staff at all times- and there are manly non-interactive moments in dialysis. This is consistent with what is stated on page 71, under proposed 494.70(a) (3) and (4) concerning privacy: "we are not

necessarily advocating physical barriers in dialysis .....because patients should be in view of staff at all times during the treatment to ensure safety".

Patient Assessment

494.80
I am in agreement that a systematic patient assessment is essential to improving quality of patient care and outcomes. However, in proposed 494.80(a) I would like to add the evaluation of intradialytic symptoms- frequency, causes, treatment, and mostly preventative plan. As stated earlier under "patient reactions", these symptoms are not being tracked on a routine basis, often are considered a "normal" part of dialysis, and usually are only band aided (administration of saline or a hypertonic medication- often unnecessarily) versus identifying the cause and preventative plan of care. Evidence is now showing that these are not just transient events- but are causing long –term effects on the patient (i.e. cardiovascular as well as cerebral effects). Assessment can be easily done thru a simple facility occurrence or variance reporting system.

I recommend that a definition on "new" patient needs to be clarified as stated in Definitions above.

I recommend that the initial assessment be done by a number of dialysis days (9) versus 20 calendar days- whichever comes first.

494.80(c) Along with ensuring that patients receive a sufficient dialysis treatment by monitoring the dose in terms of Kt/V, monitoring fluid status is equally important. The Hemo study concluded that Kt/V above standard does not substantially reduce mortality or morbidity on our patients. Dialysis treatments should not be considered as only "rinsing" treatments. Appropriate fluid removal is also part of adequate treatments and should be reviewed on a monthly basis as well. In the adequacy section of the K/DOQI guidelines, guideline 15-16 , the work group suggests that efforts be undertaken to develop accurate methods of measuring intravascular volume and relate these changes to BP measurements/ and prevention of intradialytic complications. I recommend that not only intradialytic symptoms be monitored and recorded every treatment as stated above, and re-assessesed for improvements on a monthly basis , but pre-post BPs, and the Number and type of antihypertensives be monitored on a monthly basis as well.

In accordance with the K/DOKI recommendation that methods of measuring intravascular volume need to be developed, the use of current Blood volume monitoring technologies that are in existence need to be encouraged.

Along with a comprehensive annual reassessment, I recommend a monthly summary be done for all patients to ensure stability is maintained. A very simple tool can be devised

that would not cause unnecessary burdens to the facility staff, yet quickly assess that quality outcomes are being achieved.

The definition of unstable needs to include the assessment of intradialytic symptoms.

Inadequate dialysis needs to also include an assessment of volume status-minimally Pre and Post BP, as well as the number and type antihypertensive meds, Dry weight changes, and intradialytic symptoms, admissions for CHF. Fluid overload as well as hypovolemia has been associated with negative outcomes in mortality, hospitalization, and quality of life. The effects of both on the Cardiovascular system have been well documented.

Since the definition of unstable is somewhat subjective, and can not be made without assessment- I do not believe that a simple monthly summary is unreasonable. Minimally, it would identify those who are not clinically stable and lead to changes in the Plan of Care proactively. Unfortunately, in the current proposal, an unstable patient might be missed- and the assessment be delayed

Plan of Care

494.90 As stated above, I feel a simple tool can be developed for monthly summary.

As well as including the performance measures for intradialytic symptoms, Volume status (Pre/post BPs, number and type of antihypertensives, dry wt changes, admissions for CHF), I also recommend that bone disease management performance measures should be incorporated more specifically into the patient plan of care.

Since fluid status has been associated with increased morbidity, mortality, and hospitalizations, I recommend that each facility designate a registered nurse as a Fluid Manager.

The definition of adequacy must include not only Kt/V but also volume status as stated. Under Patient Assessment.

494.90(b) (2): The Plan of care timeline for implementation should be measured by the number of treatments rather than number of days i.e.: 21 days or 9 treatments whichever cones first

494.90(a) (4) I agree that routine monitoring of the vascular access needs to occur monthly. Reimbursement of facilities for access blood flow measurements thru the current methods of Delta H, TQA, or transonic flow measurements needs to also occur in order for this service to be routinely performed.

I recommend that each facility have a registered nurse as the vascular access coordinator on the interdisciplinary team.

494.90(b) (4) I am surprised by the rule that associates a higher payment to a physician who provides more visits within each month to an ESRD patient.
I would like to suggest that a payment incentive be considered for more frequent patient assessments from the facility team as well. Perhaps that would override any additional burden for more than annual patient assessments and promote proactive assessment of the "stable" patient.
I agree that physicians should periodically see their patients while they are undergoing dialysis and would like to see a required recommendation.

Condition: Care at Home
494.100
Dialysis of ESRD Patients in Nursing and Skilled Nursing Facilities

I am not sure I understand the definition of Nursing facility- is this referring to patients being dialyzed in a hospital setting???

494.180(b) (2): I agree that a registered nurse needs to be on premise whenever in-center patients are being treated. In addition, clarification needs to include that this is an experienced dialysis nurse. Experienced needs to be defined as more than just receiving an in-service. If the procedure is delegated to the LPN or PCT, then direct and immediate supervision should also be required for hemodialysis to ensure patient health and safety.

I do believe a statement concerning patient to caregiver ratios should be addressed.

e. Monitoring: I agree that the proposal require that a certified ESRD facility be responsible for monitoring the care of the ESRD patient in the NF or SNF.

I also agree that it is imperative that the trained caregivers not only be present in the room at all times during hemodialysis, but the if the procedure is being delegated by the RN to a PCT or LPN, that the experienced dialysis RN provide direct and immediate supervision of this treatment. I have observed too often that unlicensed personnel are delivering a hemodialysis treatment in a patient room, with no experienced RN on premise. I have also observed them administrating blood products, Epogen, and other medications. They believe they are covered under the facility RN covering the floor – who is not experienced in dialysis. The facility RNs many times are not even aware of the status of the caregiver, and assume that they are performing to their limitations only. They are overwhelmed and unable to quickly and competently handle patient complications.
This needs to be specifically clarified for all facilities discussed to ensure that the health and safety of NF and SNF hemodialysis patients is protected.

QAPI

A definition for medical injuries needs to be clarified. Does this include the intradialytic morbidities that I have discussed in previous sections? I suggest that a tracking system for each of these events be developed in order to identify incidents, causes, and preventative measures. Currently these are not routinely tracked unless a severe adverse outcome occurred. Numerous caregivers have come to believe that these are acceptable and transient, partly because they are not monitored. Adding these to the facility variance or occurrence report may be all that is needed.
I agree with the OIG findings stated on page 135 that medical injuries are not systematically monitored in dialysis facilities – the facility variance report could be the first step in correcting this issue.

A patient satisfaction survey is a reasonable and should include their satisfaction with the prevention of intradialytic symptoms and effects of the treatment on quality of life.

I agree that the facility needs to collect and analyze clinical data about the components of their care processes. Along with the clinical performance measures sited in the 2002 OIG report, Fluid -Volume status of their patients, and the occurrence of intradialytic morbidities, as described in previous sections, needs to be added. In accordance with the K/DOKI recommendation that methods of measuring intravascular volume need to be developed, the use of current Blood volume monitoring technologies that are in existence that would meet this requirement, need to be encouraged.

494.110(a) Program scope

As stated previously as well as adding Fluid- volume status as part of adequacy, and defining Medical injuries to include intradialytic morbidities, I would also include infection control and bone disease management in this area. The addition of these performance measures would add to the achievement of improved patient outcomes, patient safety and patient satisfaction.

Personnel Qualifications

494.140(b) (3) (i): Since the Registered nurse holds the license for independent practice, and delegates to the PCT and LPN, the conditions can not permit the LPN/ LVN to be in charge. LPNs in most states are limited to observing, documenting and reporting to the RN and are not giving the necessary training for assessing patient conditions. In addition, in the the United Stated, there is no state in which an LPN can supervise an RN.
As discussed in VI.A.2 –a registered nurse has the necessary professional training and expertise to coordinate care in the unit… In agreement with this statement- only the RN can be in charge.

494.140(e) Dialysis Technicians

I would encourage the wording of care provided under the supervision of the registered nurse to change to the "ongoing, immediate and direct" supervision.

I strongly believe that to ensure patient safety, it would be prudent to recommend that patient care technicians should be certified through a nationally recognized certification program in order to ensure that the minimum level of education and competency is completed.

I agree with the 3 month experience (but redefine as "clinical" experience) after the facility training program. It takes this amount of time minimally to go from orientee to novice to experienced with this complicated treatment and delicate patient population. I would also consider defining more time for hands-on direct care prior to working with the acute care hemodialysis patients.

I agree that it should be under the direct supervision of the registered nurse since that is who is ultimately accountable to ensure that they are delegating activities that the PCT has the knowledge, skill level and competency to complete.

494.80(a) (3) I do recommend that there should be a requirement within the proposed conditions for coverage that each dialysis facility ensure a routine assessment of patient medications by a pharmacist. We have poly-pharmacy in dialyis. Many of the adverse effects that occur during treatments are related to the numerous meds, and their combinations. Numerous providers are prescribing the medications. A pharmacist as part of the team could assist in identifying potentially harmful combinations, and help relate the patient's symptomology to their medications. With so many new medications on the market, and the amounts prescribed to our patients, a pharmacist could be an invaluable addition to the team. Currently the facility staff have barely enough time to make sure they document what the patient is taking. We need someone to help the staff decide what the patient needs- and most importantly what can be discontinued.

Governance

494.180(b)(1) A requirement for an acuity-based staffing plan to assure adequate staffing and appropriate staff –to –patient ratios would be highly desirable- and not that difficult to create. It is much needed. I see Pct ratios between 3-6 and RN ratios anywhere from 6 to 24. A minimal standard ratio should also be recommended.

494.180(b) (2) Please add a dialysis experienced registered nurse bust be present in the facility at all times that patients are being treated.

494.18(b) (4) I applaud your decision to retain the existing requirement that all employees have an opportunity for continuing education. This is very lacking and much needed, even with the current requirement.

Thank you for the opportunity to comment on the Proposed Conditions of Coverage,

Diana Hlebovy, BSN, RN, CHN, CNN

Submitter : Ms. Tammy Gargis **Date:** 05/04/2005

Organization : Hattiesburg Clinic

Category : End-Stage Renal Disease Facility

Issue Areas/Comments

GENERAL

GENERAL

Fire safety- CMS proposal to adopt chapters 20 and 21 of the National Fire Protection Association Life Safety codes for all outpatient dialysis units would be extremly burdensome for dialysis units. I manage 10 units, which all adhere to local fire codes. The design of dialysis units, the staffing ratios, and the out patient status of these patients, and the current guidelines would allow for a timely evacuation of patients if needed in the event of a fire. You state that you recognize that "older" dialysis units may have difficulty satisfying all of the LSC requirements and could apply for a waiver from particular requirements on a case by case basis, if it would not adversely affect patient health and safety, through the unit's State agency; and that the state agency would recommend approval or disapproval of the request. This proposal would create an extreme burden for most all exisiting dialysis units and the waiver process is not acceptable. The current fire safety regulations have been very effective in providing a safe environment for patients. I know of no deaths/ injuries related to fire in dialysis units.

Thank you for the opportunity to comment,
Tammy Gargis

Submitter : Dr. Marilyn Speedie **Date:** 05/04/2005

Organization : U, Minnesota College of Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

May 3, 2005

Mark B. McClellan, MD, PhD
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention File code CMS-3818-P

Dear Dr. McClellan:

I am writing to offer comments regarding the proposed revisions to the Conditions for Coverage for End Stage Renal Disease Facilities. Specifically, I wish to comment on Proposed rule 494.140 (?Personnel Qualifications?) which addresses the possible role of a pharmacist within the dialysis facility. The proposed rule acknowledges the contributions a pharmacist can make to the safe and effective use of medications in the dialysis patient population and invites comments regarding what role the pharmacist should play. I wish to provide support for the routine use of pharmacists as part of multidisciplinary teams in dialysis facilities.

I am dean of the College of Pharmacy at the University of Minnesota. Our College of Pharmacy is proud to have been associated for many years with pharmacists who provide medication therapy management to patients in dialysis units; several of these pharmacists have served on our faculty. Our Doctor of Pharmacy students receive excellent education in nephrology and the use of medications in patients with renal disease, and are fully qualified to provide care for dialysis patients. In addition to didactic material in the curriculum, some students choose to complete clinical rotations in dialysis facilities where they receive additional clinical training in providing this care.

I recommend that pharmacists be a required part of the multidisciplinary team that provides care to dialysis patients. Routine care should include a medication review that is conducted at least monthly and pharmacists should work as part of a team to help manage medication problems that arise and to advise on selection of specific medications and manage changes in medication dosage when needed. Pharmacists also should participate in development and implementation of medication-related protocols in order to assure cost-effective use of medications. Finally, pharmacists should develop and maintain policies for the safe storage, preparation and administration of medications within the facility.

The benefit of such a role will be better patient care and lower medical costs for these patients. Dialysis patients receive an average of 10-12 medications a day. Kidney disease often requires patient specific medication dosing and most dialysis patients have multiple comorbid conditions that complicate their treatment and increase risk for adverse drug events. Yet, despite many studies that document the ability of pharmacists to improve patient care and prevent medication-related adverse events, the majority of patients receive dialysis in free-standing facilities in which no pharmacists are present. I strongly urge you to provide these patients the benefit of a regular systematic medication review by pharmacists. You will find an improvement in their health and a lowering of medical costs associated with their care.

Thank you for your consideration.

Sincerely,

Marilyn K. Speedie, Ph.D.
Dean

Submitter : Mrs. PAMELA DAVIES **Date:** 05/04/2005

Organization : ADIRONDACK MEDICAL CENTER

Category : Nurse

Issue Areas/Comments

Issues 1-10

Plan of Care

The 30 day total time frame for patient assessment and development of a plan of care would be more reasonable if it were made to be 45 days. Patients are often overwhelmed when they first start dialysis and it is difficult to complete a full assessment process when they are uremic, trying to adjust to dialysis, and receiving more info than they can handle. A 45 day timeframe for assessment/care planning allows time for a comprehensive assessment by all disciplines, and allows some time for stabilization on dialysis so appropriate goals can be established.

By establishing the tight time frame of 30 days, it will be difficult to involve the patient properly in the process-- due to time limitations for conferences and the need to coordinate several disciplines.

Under paragraph 494.90(a)(2): the statement "require the interdisciplinary team to provide the necessary care and services to achieve and sustain an effective nutritional status"-- that wording is really tight, and doesn't take into account the myriad of reasons that a patient may not be achieving the goals-- patient results are not cut and dried based on the team's intervention, but that statement puts an onus on the team to guarantee that the patient reaches goal!

Likewise, paragraph 494.90(a)(3) "assist and support the hemodialysis and peritoneal dialysis patient in achieving and maintaining the expected hemoglobin/hematocrit level"-- that wording is too vague; what is meant by 'assist and support'? And again, there can be many reasons why the patient is not meeting goal.

Under paragraph 494.90(a)(6)regarding rehab: this proposed requirement seems to add a lot of work onto the team, but there is no provision made to add support (i.e. rehab) staff to accomplish it. We are a very small unit, with a very small staff-- I don't know how we would be able to meet this, who would do it, and how the cost of doing it would be supported considering the reimbursement we receive in light of all the other things we need to provide for the patient.

Submitter : Mrs. PAMELA DAVIES **Date:** 05/04/2005

Organization : ADIRONDACK MEDICAL CENTER

Category : Nurse

Issue Areas/Comments

Issues 11-20

Cross-reference Changes

Regulatory Impact Analysis: "Since this rule applies only to dialysis facilities, it has not impact on small rural hospitals".

We are a dialysis facility in a small rural hospital– there is impact because of the small number of staff we have to implement these changes. Many of the items are already in place, but formalizing the reporting and some of the other issues I've commented on, will definitely impact the cost of our personnel resources.

Responsibilities of the Medical Director

There seems to be a high degree of direct responsibility placed on the medical director in this section. The wording appears to be based on how a large unit with a full time medical director would function and the issues therein, however, we are a small unit. Our medical director is also the only attending, and has his own internal med practice. Adding additional responsibility to the extent proposed would be very difficult for our 'one man band' to meet, and our volume does not financially support adding additional medical staff.

Governance

Electonic Data Submission: paragraph 494.180(h)
I have a hard time believing that all this added data collection, collating, and submission will not add on significant time to reporting. We are a small unit, do not have clerical support staff, so this burden would fall to higher paid employees, thereby adding significantly to the cost of the program, without change in reimbursement.
I am currently utilizing a reporting program via ESRDNY for vascular access data. Because the program is improperly set up, I have to re-enter the same patient demographic data monthly-- a repetitive waste of time. If the CMS proposal comes to fruition, the programs need to avoid this type of error in their systems.

Submitter :

Date: 05/04/2005

Organization : **Nephrology Pharmacy Associates**

Category : **Health Care Industry**

Issue Areas/Comments

Issues 11-20

Personnel Qualifications

See attachment

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

Organization : **Nephrology Pharmacy Associates**

Category : **Health Care Industry**

Issue Areas/Comments

Issues 11-20

Personnel Qualifications

See attachment

CMS-3818-P-184-Attach-1.DOC

3809 Denear Court
Brooklyn Park, MN 55443

NPA
Nephrology Pharmacy Associates
Dedicated to the optimal use of medications in patients with kidney disease

phone/fax (763) 315-6581
www.nephrologypharmacy.com

Attachment #184
May 3, 2005

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

Dear Dr. McClellan,

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

Our company, Nephrology Pharmacy Associates (NPA), is devoted to improving medication management in patients with chronic kidney disease. As nephrology pharmacists ourselves, we strongly believe that pharmacists should be integral members of the health care team serving the ever-increasing complex drug-related needs of dialysis patients.

We believe that pharmacists should be recognized as an integral part of the dialysis health care team due to the:

- large number of concurrent diseases in this patient population,
- huge number of prescription and over-the-counter medications prescribed,
- increased risk for adverse medication-related outcomes,
- pharmacodynamic and pharmacokinetic changes in drug disposition due to kidney disease
- pharmacokinetic variability of drugs during various dialytic procedures,
- the need for cost effective drug therapy,
- complex nature of drug dosage regimens in dialysis patients,
- training of pharmacists that prepares them to serve as consultants to dialysis facilities,
- need for storage, preparation, and administration of medications within the dialysis unit,
- changing nature of drug therapy that will arise due to the Medicare Modernization Act and Medicare Part D implementation

George R. Gallie, Pharm.D., Ph.D.
(518) 477-9199

Curtis A. Johnson, Pharm.D.
(608) 848-3634

Nancy A. Mason, Pharm.D.
(734) 944-0602

Wendy L. St. Peter, Pharm.D.
(763) 315-6581

Specifically, we would like to make the following recommendations:

1. The multidisciplinary dialysis team should include a pharmacist with experience or training in nephrology pharmacotherapy.
2. The routine patient care of dialysis patients should include a comprehensive pharmacotherapy assessment by a pharmacist at initiation of dialysis, including the identification of drug-related problems.
3. Pharmacotherapy follow-up evaluations including documentation of progress in achieving goals of therapy should be conducted at least monthly. This frequency is consistent with what is required in skilled nursing and intermediate care nursing facilities.
4. Pharmacists should participate in the development and implementation of medication-related protocols within dialysis units or programs 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.

Medication therapy management services have been demonstrated to save substantial health care resources, while ensuring that individual patients receive effective and safe drug therapies. Because medications play such a vital role in the care of patients with end-stage renal disease, inclusion of a pharmacist as part of the dialysis health care team is essential.

Best regards,

George R. Bailie, Pharm.D., Ph.D Nancy A. Mason, Pharm.D.

Curtis A. Johnson, Pharm.D. Wendy L. St. Peter, Pharm.D., FCCP

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

Organization : DaVita, Inc.

Category : Dietitian/Nutritionist

Issue Areas/Comments

Issues 1-10

Basis

I wish to submit a comment on the ratio of patient to dietitian in the facility setting. The trend across the country is to decrease the number of patients per dietitian.

Renal Dietitians, as clinicians, are being burdened with an increasing amount of paperwork, including reports and forms which decrease time with individual patients. While I understand the need for some of the paperwork, the increase means that a greater amount of time is spent behind a desk than in the facility with patients.

New patients, in particular, are needy of reassurance, support, practical application of diet, medicine, and active encouragement that they can endure dialysis and that their life has a chance to continue.

Often, they do not remember what they were taught during the first one or two treatments due to stress, fear of dialysis, and the physical symptoms of chronic illness, so follow-up is needed to reinforce what was previously taught, deepen the patient knowledge base, and answer questions of patients and family members.

To do the job well, additional dietitians need to be added to facilities so patients have more time with dietitians and the paper burden can be shared. Since our dietitians do not receive overtime for any hours greater than 40 per week, work is taken home, longer hours are spent in the office, and Renal Dietitians are not as effective due to fatigue. I don't know of a single dietitian who isn't in this situation, and still needing more hours per day to do an effective job. Thank you for the opportunity to comment.

Submitter : Ms. Valerie Takai **Date:** 05/04/2005

Organization : Ms. Valerie Takai

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

A single attachment includes general comments and comments on issues 1-10 and 11-20

CMS-3818-P-186-Attach-1.DOC

CMS-3818-P-186-Attach-2.DOC

Attachment #186

Docket: CMS-3818P – End Stage Renal Disease (ESRD) Conditions for Coverage

Valerie Takai OTR
May 4, 2005

Introduction and General Comments

I am grateful to have this opportunity to comment on the Proposed Rule for the first major revision since 1976 of the Medicare Program: Conditions for Coverage for End Stage Renal Disease. My comments are honest and frank. My goal is simply to promote a better life for this population with improved care.

My unique perspective as an occupational therapist with over 20 years of experience in acute care, rehabilitation, and chronic disease facilities as well as in home care along with my present role as an ESRD caregiver for 5 years spending extensive time observing and interacting with patients and staff at the Yorkville Dialysis Unit in New York City have helped me formulate my responses to the Proposed Rule.

I have been a very involved caregiver for my husband, an insulin dependent diabetic for over 40 years, who, in addition to having ESRD, has undergone a colonectomy for colon cancer and has a dementia and gait disorder from a constellation of neurologic conditions. I accompany him three times a week to dialysis and serve as his advocate.

From rehabilitation I learned that the patient centered team approach is essential for quality care and good treatment outcome. Over several years I treated over 1,000 patients as a member of an interdisciplinary team in a special clinic for patients with amyotrophic lateral sclerosis seen throughout the course of their terminal illness. Quality of life as well as improved physical and psychological function for the disabled has been an important focus of my career.

Issues 1 – 10

Physical Environment
(Proposed 494.60)

An early concern of mine when my husband started dialysis was the problem of safety for an individual patient leaving the dialysis unit alone taking the elevator downstairs to the lobby to await transportation home. I have witnessed that approximately half of the patients in the dialysis unit have limited ambulation and problems with balance and endurance due to a wide range of factors which often worsen immediately following dialysis treatment. Many use canes or rolling walkers, and some wear orthotics or prostheses. There is no phone or intercom between the lobby and the dialysis unit on the second floor and at that time once a patient walked out of the Unit he or she was essentially on his own.

While I had to escort my husband in his wheelchair to the lobby I also found myself assisting other patients and on at least two occasions prevented patients from falling. Staff appeared oblivious to the problem. After letters to Administration at Beth Israel Medical Center and the Yorkville Dialysis Unit, one of which described an incident where I found a stranger urinating in the downstairs lobby and going through the trash, a security guard was finally hired. He can watch out for the safety of the dialysis unit as well as the safety of individual patients and when necessary procure a wheelchair or physically escort a patient.

494.60(e) Dialysis centers in New York City are often located on the 2nd floor of small office buildings some with only one small elevator and one staircase. A large and growing population of patients has impaired ambulation and some patients are wheelchair bound. I propose that as part of standard equipment for such facilities an emergency EVAC chair (commonly used by firefighters and others) be standard equipment available to assist staff in evacuating patients in the case of fire or in the case of an elevator being out of order (a not unusual occurrence).

Patients' Rights

494.70 (a) Proposals emphasizing the right to be treated as an individual with dignity, and respect are essential. It has been my

experience that many staff in daily contact with dialysis patients are not trained to consider the psychosocial needs of ESRD patients. It is important for all staff including receptionists and dialysis technicians as well as physicians, nurses, social workers, and dieticians be expected to treat ESRD patients with respect.

Regarding the proposal to inform patients of their right to establish an advance directive this is critical. Just leaving healthcare proxy forms and living wills on a display table is not enough. It has been my experience that staff at the dialysis center treating my husband is uncomfortable dealing with end of life discussions and there is no policy for handling the topic. Patients need to have a knowledgeable person on staff comfortable communicating with patients on advanced directives and initiating discussion. Patients learn of other patients' deaths and express their own anxiety when they wonder how they died, was there any pain and suffering, and do not learn the answer. It should not fall into the lap of the social worker because the nephrologists or nurse practitioners do not wish to handle the issue. Sensitivity to medical ethical issues is critical. Patients need to be made aware of hospice and palliative care should it be needed.

I quote from the AAHPM Bulletin, Quarterly Newsletter of the American Academy of Hospice and Palliative Medicine Vol 3. No 1 Fall 2002 article "Discontinuation of Dialysis: The Role of Hospice and Palliative Care," "If ever a subgroup of dying patients deserved palliative care, it is the growing group of patients whose dialysis has been discontinued and who face a mean of only eight days to live." The article mentioned that in the United States more than 20,000 end-stage ESRD patient deaths followed dialysis discontinuation between 1990 and 1995. In New England patient deaths preceded by decisions to terminate death rose from 10% to 28% in the past decade covered in the article. The article mentions a Bayside Medical Center prospective study which examined all ERSD deaths not just those preceded by dialysis termination and found that 57% of respondents were unsure or believed that the patient died with pain and 24% thought the death was not peaceful while 43% regretted that the patient had not fulfilled his or her final wishes at the end of life.

Patient Assessment

(Proposed 494.80) The initial period of dialysis was a terrifying experience as my husband had been hospitalized for six weeks for a subtotal colonectomy and started on hemodialysis just prior to coming to the dialysis center. He had to travel by ambulance from home for the first four and a half months. He was very frail and disoriented. On his second visit on the evening shift he stood up and his permacatheter got disconnected. I was informed in the waiting room of the dialysis center that there was an emergency and that he had been taken to the ER and that he would be alright. I met him in the ER just as the nurse was in the midst of taking his blood pressure with the tightened cuff placed over his new fistula. He had to be hospitalized then to repair the permacatheter and have another surgery for a fistula. I only learned what actually happened several months later from an ambulance driver who caught him as he came to standing and from a patient receiving dialysis situated in a chair next to him at the time. This incident was to be one of several emergencies occurring in the dialysis unit over the course of almost five years resulting in hospitalization.

Our first impression of the dialysis unit was to have a lasting effect. In the waiting room I remember handouts delineating regulations about bringing weapons and signs posted for how to file grievances and some pamphlets relating to diet. The receptionist was cold and curt and sat behind a closed window with a lock which she opened reluctantly. There were doors everywhere which had to be opened. Healthcare proxy and living will forms I discovered much later on a counter in the dialysis unit.

As a new patient neither my husband nor myself received psychological support and the assessment by the nurse practitioner merely sought verification of his complicated medical history. The only person who involved us in the assessment was the nutritionist who called me at home prior to the initial visit to the dialysis unit and who spent much time introducing me in detail to the new diet taking into consideration my husband's individual cultural as well as physical needs. I relied on my own skills as an occupational therapist to anticipate his rehabilitation needs as he gained strength and fortunately through my initiative he was able to receive physical therapy through Visiting Nurse home care.

His nephrologist never saw him in the dialysis unit but instead he had to be brought by ambulance from home to his office (only 4 blocks

from the dialysis unit) at great inconvenience to the patient (and at a large expense to Medicare) who had to travel another three other days in the same week by ambulance to dialysis.

Approximately a year later when his condition was stable and he was traveling by car service, I was asked to sign a copy of the treatment plan. There had been no prior discussion or input from the patient or myself. It was the first time that we actually saw a plan which had almost no comments.

The initial assessment sets the groundwork for the patient's introduction to dialysis and the many changes taking place. Patients have questions but when there is no orientation and minimal discussion with staff and no input from the patient dialysis is overwhelming. It would have been very helpful to know what to anticipate in the gradual adjustment of the body to dialysis and relieved much of the discomfort of some of the side effects and medical complications. A three month time frame for reassessment of new patients and if necessary in special cases a six month time frame would help to alleviate many of the physical discomforts and reduce much of the anxiety and stress that new patients feel. It could also help to focus on such issues as depression and clarify further treatment goals, confront noncompliance and give patients the opportunity to ask and receive answers to their concerns about treatment.

It should be emphasized that the assessment be done by an interdisciplinary team so that staff can have a clear unified vision of treatment goals and thus can work together to promote optimal patient care, and, that the patient be involved from the very beginning. An important benefit to the team approach is the learning that staff from different disciplines gain from each other as well as from the patient.

Patient Plan of Care

(Proposed) 494.90 A single patient plan developed by input from the interdisciplinary team in the assessment should include the patient's nephrologist, nurse or nurse practitioner, nutritionist, and social worker. Additional members to consider adding are a physical therapist and a consulting psychiatrist if indicated. When staff work together to promote treatment goals it gives patients a strong sense of support and a more

hopeful yet realistic outlook for the future. When the patient has input there is a better chance that he or she will be more motivated to take better responsibility for his or her own care.

Rehabilitation Status (Proposed) 494.90 (a) (6) (7)

Renal rehabilitation has not forcefully addressed on a widespread basis the potential for physical restoration, employment, and the pursuit of an active life. Rehabilitation promotes maximum physical function and emotional wellbeing. It is concerned with overall quality of life.

I heartily agree with the contents of this section and emphasis on rehabilitation as a distinct plan of care category and its essential role in treatment and recovery and its emphasis on an ongoing process. Rehabilitation should be addressed when possible before the patient even begins dialysis. Nephrologists tend to underestimate the potential of rehabilitation and the benefits that can be realized by their patients with focus on exercise, basic skills for living, education, and vocational evaluation and training. Rehabilitation looks at the total patient and seeks to enhance physical and psychological function.

We all know that exercise is beneficial for us, but it is especially beneficial for dialysis patients, who suffer from various co-morbidities, including hypertension, diabetes, and cardiovascular diseases. In addition, patient may suffer from bone disease, cancer, progressive neurological disorders, etc. Their deconditioned status is further exacerbated by the fact that they are required to remain stationary for over 12 hours a week. Rehabilitation when it involves medical needs is required to be through referral of a physician and not under social service.

My husband was fortunate to receive physical therapy at the Yorkville Dialysis Unit for progressive lower extremity exercise while undergoing dialysis and at home following acute hospitalizations under Visiting Nurse homecare. Without physical therapy he would be in a nursing home. It was essential for me to be able to walk him up steps at the entrance and lobby of our apartment building and get him in and out of a car by myself, otherwise, I could not bring him to dialysis. Ambulette is out of the question due to the high cost of private pay. A slight

decrease in his ability to ambulate means I am not able to care for him at home.

Physical activity and rehabilitation programs can benefit patients by improving strength, coordination, flexibility, endurance, and reducing depression. Individually tailored physical therapy programs are easily accomplished through resistance training and/or hand weights, a stationary cycle, or recumbent stair climber. An on-site physical therapist can assist with home programs of exercise as well as in-center exercise. Groups of patients can be doing exercise at the same time while on dialysis machines.

Formal guidelines need to be established to integrate physical activity and exercise training into the routine care of dialysis patients. Exercise programs are an easy way to help patients maintain their functional independence while living at home and taking care of themselves. The preventative attitude can stop the downward spiral of physical deterioration which occurs in renal patients, reducing not only their suffering but also costs, and resulting in positive benefits for patients, the healthcare system, and society.

494.90g. **Social Services**

It is my feeling that the social worker has a tremendous burden handling a difficult caseload alone without support, and, in addition counseling staff. The social worker counsels and educates patients and provides much needed specific information and referrals to outside agencies assisting with obtaining Medicare and Medicaid benefits and so forth.. Many patients are extremely angry and often belligerent and depressed. Staff also can be frustrated, angry, and depressed by their caseload. The first year at the dialysis unit my husband and I were confronted with a burned out staff who resented coming to work and treating dialysis patients. The patients were also angry. When we greeted staff there was often no response. Often there was no conversation between a nurse or technician and the patient during the entire course of treatment. There were many staff arguments and complaints in front of patients and many patients were highly anxious and depressed. There were battles between ambulance and ambulette drivers and individual staff in front of everyone. If only there had been a psychiatrist available to help the social worker and staff deal with staff

burnout and to treat patients who were suffering moderate to severe depression.

I strongly recommend the availability of a consulting psychiatrist to work with staff individually or in a group to help them deal with their own individual feelings about patients and to also help prescribe medication for patients when needed consulting with the patient's nephrologist. Staff burnout is detrimental to patient care and should be dealt with directly and without delay. Good staff leave if burnout is not handled properly. Dialysis patients are a challenging group to treat and their treatment outcome can be rewarding to all if staff and patients can work together.

Implementation of the Patient Plan of Care

(Proposed 494.90 (b) (4)) It has been many months since my husband has been seen by his nephrologist providing the ESRD care but his record has been reviewed by the nurse practitioner and conveyed to him. His nephrologist is an extremely competent dedicated knowledgeable overworked physician who while not seen often in person by patients is available 24/7 for their care. It is rare that his physician or other nephrologists see their patients in the Yorkville dialysis unit. His physician cares for over half of the patients in the dialysis unit who must schedule a separate appointment in order to see him. This kind of scheduling makes it difficult for patients who work or going to school or who are frail and essentially homebound who have to sacrifice enough of their free time just to receive dialysis and then have to make an additional trip to the doctors office which generally involves a long wait. To me this refutes the idea of patient centered care. Patients benefit from individual contact with their physicians and not just through an intermediary. Dialysis staff also benefit from seeing the physicians in the unit from time to time.

Patient Education and Training

(Proposed 494.90 (d)) Because of so many unanticipated physical changes in the patient and major life changes and decisions to be made the patient and family especially need support during the early transition onto dialysis and education and training in the regime they need to follow and a chance to ask many questions and have them answered. Much

time and concentration on the patient during the first few months will contribute significantly to the outcome. My experience with my husband was minimal education and no goal setting with the patient and family. The major way of learning about dialysis was from other patients, technicians and nurses who would merely answer questions posed by patients rather than initiate any training.

Docket Number: CMS-3818P – End Stage Renal Disease (ESRD) Conditions for Coverage

Issues 11-20

Condition: Quality Assessment and Performance Improvement (Proposed 494.110)

QAPI

I would like to stress the importance of establishing internal systems for identifying and analyzing causes of medical injuries and medical errors. The overall goal should be to improve quality care. It has been my experience at the Dialysis Unit medical injuries are often not documented and that injuries are frequent. I have found that certain technicians do not report possible injuries to their supervisors or nurses on duty and that little information is shared by staff when a problem arises. Just one small example occurred with my husband when a technician used plastic tape to secure the needles in the new graft site in his leg. When he removed the tape he removed large pieces of skin with it. When we arrived at the dialysis center the next scheduled appointment we became aware that the technician never even conveyed the incident to the nurse supervising him. Fortunately my husband still had a functioning permacatheter as he had to wait over six weeks before the skin over the graft site had healed sufficiently for the graft to be used again. To this day technicians have to be told to use paper tape and what direction to insert the needles in the graft in his leg. Better training of technicians is needed.

There needs to be a positive supportive atmosphere where staff is willing to come forward with information about possible injuries and are free to question.

Just two months ago my husband had an emergency hospitalization for blood transfusions when a needle became dislodged and appropriate help was delayed due to technicians not responding to three signals for assistance. The technician who finally responded gave extra saline without checking the graft site while the dialysis machine was pulling blood out of his body but not returning it. The ambulance to the hospital a few blocks away cost 1,400 dollars and the hospitalization several thousand dollars.

Personnel Qualifications

Medical Director

(Proposed 494.140 (a) and Proposed 494.150) This is an extremely important position and demands direct involvement with staff and responsibility for the direction of medical care and quality of staff. The Medical Director's name and title should be posted so that staff and patients know who the Director is. Recently posing the question of the name of the Medical Director to the receptionist, several patients, and staff no one was able to name the Director. It indicates that the Medical Director is not very involved with the Dialysis Unit and its focus on patient care. For five years there has been no posting of the Medical Director's name and no dissemination of information regarding his or her name. I strongly support that the proposal that the medical director should be on-site and directly responsible for the quality of care delivered and have the authority to develop and monitor quality improvements, serve as a much needed educational resource for all medical and nursing staff, and when necessary terminate or report to the appropriate authority those who are not performing according to acceptable standards of care.

Social Worker

(Proposed 494.140 (d) I strongly support the proposal of the requirement for an MSW and the strengthening of the social service role by freeing up the social worker using nonprofessional staff to perform the clerical duties involved with information on Medicaid, Medicare, medication, and transportation. Psychosocial evaluations and counseling are critical for patient care. I would like to stress again the importance of access to a psychiatrist to assist the social worker when referrals are indicated for medication for treatment of depression in

consultation with the nephrologists and provide support for working with staff to deal with their own feelings in handling a complex and difficult caseload.

Dialysis Technician

(Proposed 494.140 (e)) In reviewing the 72 page Proposed Rules document I was shocked but I must admit not surprised by the limited training of the dialysis technicians, the frontline deliverers of patient care. It is amazing to me that there is no uniform national credentialing, licensing, or minimal qualification requirements and yet these individuals with sometimes less than a high school degree and three months education and three months on the job training by a nurse have such tremendous responsibility. It is no wonder to me that there are many problems with preservation of working fistulas and grafts many of which are preventable. My experience is that the skill of individual technicians is highly variable and that incompetent technicians are kept on staff. A chain is as strong as its weakest link and one incompetent technician rotated amongst many patients can cause tremendous harm and directly affect the overall quality of care of patients in the dialysis unit. Patients are most troubled by the lack of skill of individual technicians and the harm done to their fistulas and grafts by those initiating cannulation and venipuncture with large gauge needles without the necessary fine hand skills and training. The emotional cost to patients and their families as well as the physical suffering and the expense of additional surgeries and hospitalizations is high. I learned that in Japan physicians insert the needles. A Japanese nephrologist told me that Asian patients have smaller blood vessels and are started out on finer gauge needles than are available here and that there are fewer complications with fistulas.

Concentration on upgrading dialysis technician qualification and working toward a national certification system is critical to improving patient care and in the long term should reduce hospitalizations caused by medical injuries.

Medical Records

(494.170) Medical records should be up to date and accurate. When incidents occur they need to be reported without fear of retribution. Medical emergencies need to be reported immediately and

need to be tracked to prevent future incidents. Patients need to keep the nurse in charge of their care updated on changes in medications so that they can be entered in the record. Phone numbers and emergency contact information of patients need to be up to date. Consideration should be given to the entering of healthcare proxies into the medical record as is done when patients are hospitalized.

Ownership of Dialysis Facility

Existing 405.2136 (a) covers the full disclosure of ownership for facilities that are independently owned, controlled by a partnership, or wholly owned by corporate entities. It is not transparent to patients or staff who owns the Yorkville Dialysis Unit and the exact relationship of Fresenius and Beth Israel Hospital. With the sudden closing of the Singer Division of Beth Israel Hospital last July due to severe financial problems and rumored accounting irregularities it is an especially important issue. There is no sign at the entrance and only in the last month was a sign put up with Beth Israel North Division posted in the hallway and names without titles with arrows pointing in the direction of their offices.

(Proposed 494.180) This proposal is critical to resolve the lack of transparency regarding legal ownership with an identifiable governing body. The proposal 494.180g stipulating that the governing body be responsible for emergency coverage and for written instructions to staff and patients for obtaining emergency medical care is essential. Medical emergencies arise suddenly without warning and patients need to know before an emergency arises what hospital emergency room will accept them and how their records will be transferred to and from the dialysis unit to the accepting hospital.

Submitter : Mr. Rosario (Russ) Lazzaro **Date:** 05/04/2005

Organization : Holy Name Hospital

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

Thanks!

Submitter : Mr. Rosario (Russ) Lazzaro **Date:** 05/04/2005

Organization : Holy Name Hospital

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

Thanks!

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

Organization :

Category : **Dietitian/Nutritionist**

Issue Areas/Comments

GENERAL

GENERAL

1. RD must be registered with 1 year clinical experience -
Recommend "preferably" vs. must be registered with 1 yr clinical experience, as we have had exceptional dietitians right out of school, with strong renal clinical background that did a great job. Davita also has an outstanding training program for new hires. If it's a stand alone dialysis unit, I would agree.
2. Initial nutrition assessment in 20 calendar days.
Recommend make it as a range "within 20 - 30 days," as pt. may not be mentally ready or physically stable for complete assessment by that time. It leaves a grace period, yet states the ideal.
3. Care plan due 10 days following the initial assessment
Recommend "30 days from patient admission date" as care plan meetings are coordinated monthly between a minimum of 4 - 7 disciplines, patient and family members, and cannot be given such an astringent timeline. Wouldn't be practical or feasible.
4. Comprehensive nutrition reassessment in 3 months
An annual nutrition reassessment on a comprehensive level would be sufficient and practical. We automatically address nutrition status and evaluate nutrition needs on a monthly basis.
5. Patient Care Plan must address 5 specific areas with expected outcomes and timeline
Addressing goals (or outcomes) is valuable, for e.g. anemia and osteodystrophy management, etc. Setting a timeline is sensible, although may not necessarily reach goal within stated timeline.
6. Comprehensive reassessments at least annually is valuable and reasonable.
7. CQI must address nutritional status, i.e. albumin is valuable.

Appreciate CMS for allowing clinicians to give feedback on their conditions of coverage. We are here to give the best care to our patients.