

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/05-1622.pdf
494.10 Definitions Dialysis facility NEW Staff assisted skilled nursing home dialysis	Add: A new category for dialysis provided in a nursing home setting Rationale: Nursing home dialysis is typically provided by staff. Home dialysis (PD or home hemodialysis) is typically performed by a trained <i>patient</i> and/or a helper. Making these treatments equivalent ignores the important differences between them, including the staff training/supervisory needs of nursing home dialysis patients. Reference: Tong & Nissenson, 2002
494.20. Condition Compliance with Federal, State, and local laws and regulations	Add: "Facilities must accommodate mobility, hearing, vision, or other disabilities or language and communication barriers" Rationale: Healthcare settings are covered entities under the Americans with Disabilities Act. References: ADA
494.60 Condition Physical Environment. (c) Patient care environment	Add to c1: Require facilities to be accessible to people with disabilities. Rationale: Americans with Disabilities Act Reference: ADA Add to c1: Require facilities to have a place for confidential interviews with patients and families and to provide for privacy during body exposure. Rationale: HIPAA privacy Reference: <i>Protecting the Privacy of Patients' Health Information</i> 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 <i>demonstrate understanding</i> of information provided. Rationale: Without this requirement, it would be very easy for staff to believe that they had informed a patient without realizing that, in fact, the patient did not understand the information. References: Johnstone, 2004; Juhnke & Curtin, 2000; Kaveh & Kimmel, 2001 Comment & Addition to a6: CNSW supports the language of a6 with the recommended addition of requiring facilities to inform patients of all available treatments (in-center hemodialysis, CAPD, CCPD, conventional home hemodialysis, daily home hemodialysis, nocturnal home hemodialysis, transplant), and to provide a list of facilities where treatments are offered within 120 miles if the facility does not offer that treatment. Rationale: We propose to require that a facility inform patients about all available treatment modalities

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

Comment: CNSW supports the language of a5

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

Add: (new 17) "Have access to a qualified social worker and dietitian as needed"

Rationale: Social workers and dietitians often have large caseloads, cover multiple clinics and/or work part-time, and patients often do not know how to contact them when needed.

References: Bogatz, Colasanto, Sweeney, 2005; Forum of ESRD Networks, 2003; Merighi & Ehlebracht, 2004a

Add: (new 18) "Be informed that full- or part-time employment and/or schooling is possible on dialysis"

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

References: Curtin et al, 1996; Rasgon et al, 1993, 1996

Add: (new 19) "Have a work-friendly modality (PD or home hemodialysis) or schedule that accommodates work or school"

Rationale: Same as above for new 18.

References: Same as above for new 18, plus: Mayo 1999

Add: (new 20) "Receive referral for physical or occupational therapy, and/or vocational rehabilitation as needed"

Rationale: These interventions have been shown to improve patient rehabilitation outcomes.

References: Beder, 1999; Dobrof et al., 2001; Witten, Howell & Latos, 1999.

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

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

Add: (new 22) “Request an interdisciplinary conference with the care team, medical director and/or nephrologists.”

Rationale: Patients don’t realize that they can convene a care conference, and this is one way to obtain feedback from the team outside of the normal care planning meeting, which might only be done once/year.

Add: (new 23) “Refuse cannulation by a nurse or technician if access problems occurred with that staff member in the past until evidence of retraining is provided. Patients may also request another staff person to observe cannulation.”

Rationale: Patients have only a limited number of potential vascular access sites, and if a staff person was responsible for causing access damage or hospitalization in the past, patients must have the right to protect themselves by refusing care from that staff person. Despite the obvious interpersonal and convenience issues this will cause for facilities, this is a patient safety issue that also has the potential to reduce cost to the system of hospitalization from vascular access problems. This will also encourage clinics to help their staff improve their cannulation skills and teach patients to self-cannulate.

Add: (new 24) “Be informed that self-cannulation is possible and be offered training to self cannulate.”

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

Add: (new 25) “Be informed of topical analgesics for needle pain and how to obtain them”

Rationale: Needle fear and needle pain are largely unaddressed issues in hemodialysis, despite the large (14-15 gauge) needles that must be used at each treatment. Patients should be able to undergo a painless treatment, and low-cost, over-the-counter, 4% lidocaine preparations are available that will not harm the access and will provide pain relief. Patients should be told that these products exist and where to obtain them.

Reference: McLaughlin et al., 2003

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

Rationale: Patients are faced with numerous adjustment issues due to ESRD and its treatment regimes. Master’s level social workers are trained to intervene within areas of need that are essential for optimal

	<p>patient functioning and adjustment References: McKinley & Callahan, 1998; Vourlekis & Rivera-Mizzoni, 1997</p>
<p>494.70 Condition Patients' Rights (b) Standard: Right to be informed regarding the facility's discharge and transfer policies.</p>	<p>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</p> <p>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</p> <p>Change: (renumbered 3) Delete or define "reducing...ongoing care." Rationale: This phrase is unclear.</p>
<p>494.70 Condition Patients' Rights (c) Standard: Posting of rights.</p>	<p>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</p>
<p>494.80 Condition Patient assessment (a) Standard: Assessment criteria.</p>	<p>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.</p> <p>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."</p>

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 & Chewing, 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

	<p>basis for non-referral.”</p> <p>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.</p> <p>Comment: CNSW supports the language of a10, a11, a12, a13</p>
<p>494.80 Condition Patient assessment (b) Standard. Frequency of assessment for new patients</p>	<p>Change: (b1) to “An initial comprehensive assessment and patient care plan must be conducted within 30 calendar days after the first dialysis treatment.”</p> <p>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.</p> <p>Comment: CNSW supports the language of b2</p>
<p>494.80 Condition Patient assessment (d) Standard: Patient reassessment</p>	<p>Change: (d2iii) to “significant change in psychosocial needs as identified in 494.80 a7.”</p> <p>Rationale: Referring back to the specific psychosocial issues recommended to be added to 494.80 a7 will eliminate any ambiguity of needs to reassess</p> <p>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.”</p> <p>Rationale: Low PCS scores predict higher morbidity and mortality in research among ESRD patients.</p> <p>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</p> <p>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.”</p> <p>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.</p> <p>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</p> <p>Add: (new vii) “Depression per patient report, staff observation or validated depression screening survey”</p> <p>Rationale: Multiple studies report a high prevalence of untreated depression in dialysis patients; depression is an independent predictor of death.</p> <p>References: Andreucci et al., 2004.; Kimmel, 1993; Kimmel, 1998; Kutner et al., 2000.; Wuerth, Finklestein & Finklestein, 2005</p> <p>Add: (new viii) “Loss of or threatened loss of employment per patient report”</p>

	<p>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.</p> <p>References: Blake, Codd, Cassidy & O'Meara, 2000; Lowrie, Curtin, LePain & Schatell, 2003; Mapes et al., 2004; Witten, Schatell & Becker, 2004</p>
<p>494.90 Condition Patient plan of care. (a) Standard: Development of patient plan of care.</p>	<p>Add: (a) the <i>patient</i> 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."</p> <p>Rationale: The patient must be explicitly listed as part of the care planning process</p> <p>Add: (new 3) "<i>Psychosocial status</i>. The interdisciplinary team must provide the necessary care and services to achieve and sustain an effective psychosocial status."</p> <p>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.</p> <p>Add: (new 6) Home dialysis status. All patients must be informed of <i>all</i> 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</p> <ul style="list-style-type: none"> (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. <p>Rationale: Home therapies allow greater flexibility, patient control, fewer dietary and fluid restrictions, need for fewer medications, potential for improved dialysis adequacy, and improved likelihood of employment. CMS has stated encouragement of home dialysis as a goal. Every patient must be informed of home dialysis options, evaluated for candidacy for home dialysis, and, if not a candidate, the reason(s) why not should be reported. This allows quality assessment and improvement activities to be undertaken</p>

	<p>in the area of home dialysis.</p> <p>Add: (renumbered 8) “Rehabilitation status. The interdisciplinary team must provide the necessary care and services to:</p> <ul style="list-style-type: none"> (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.” <p>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.</p>
<p>494.90 Condition Patient plan of care. (b) Standard: Implementation of the patient care plan.</p>	<p>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.”</p> <p>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.</p>
<p>494.90 Condition Patient plan of care. (c) Standard: Transplantation referral tracking</p>	<p>Comment: CNSW supports the language of (c) and recommends its inclusion in the final conditions. In addition, we would also like to see language which would outline the responsibilities of transplant centers and their responsibilities for following up and informing dialysis units of the transplant status of patients referred for transplant.</p>
<p>494.90 Condition Patient plan of care. (d) Standard: Patient education and training.</p>	<p>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:</p> <ul style="list-style-type: none"> (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

	<p>least 11 gm/dL</p> <p>(iii) How to follow the renal diet, fluid restrictions, and medication regimen</p> <p>(iv) How to read, understand, and use lab tests to track clinical status</p> <p>(v) How to be an active partner in care</p> <p>(vi) How to achieve and maintain physical, vocational, emotional and social well-being</p> <p>(vii) How to detect, report, and manage symptoms and potential dialysis complications</p> <p>(viii) What resources are available in the facility and community and how to find and use them</p> <p>(ix) How to self-monitor health status and record and report health status information</p> <p>(x) How to handle medical and non-medical emergencies</p> <p>(xi) How to reduce the likelihood of infections</p> <p>(x) How to properly dispose of medical waste in the dialysis facility and at home</p> <p>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.</p> <p>References: Curtin, et al. 2002; Curtin, Klag, Bultman & Schatell, 2002; Curtin, Sitter, Schatell & Chewning, 2004; Johnstone, et al., 2004</p>
<p>494.100 Condition Care at home.</p>	<p>Comment: CNSW agrees that services to home patients should be at least equivalent to those provided to in-center patients.</p> <p>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.</p> <p>Add: (new 3iv) "Implementation of a social work care plan"</p> <p>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.</p>
<p>494.100 Condition Care at home. (c) Standard: Support services.</p>	<p>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."</p> <p>Rationale: Members of the interdisciplinary team can offer better care to patients after seeing the patient</p>

	<p>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?)</p> <p>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</p>
<p><i>NEWCONDITION</i> Staff assisted skilled nursing home dialysis</p>	<p>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</p> <p>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.</p>
<p>§494.110 Condition Quality assessment and performance improvement. (a) Standard: Program scope.</p>	<p>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</p>

	<p>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.</p> <p>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”</p> <p>Rationale: These scores provide a baseline and ongoing basis for QAPI activities to improve patient rehabilitation outcomes.</p> <p>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.</p>
<p>494.140 Condition Personnel qualifications</p>	<p>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.</p> <p>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</p>

	<p>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, <u>End-Stage Renal Disease Workgroup Recommendations to the Field</u>, 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:</p> <ul style="list-style-type: none"> • 94% of social workers did clerical tasks, and that 87% of those respondents considered these tasks to be outside the scope of their social work training. • 61% of social workers were solely responsible for arranging patient transportation. • 57% of social workers were responsible for making travel arrangements for patients who were transient, which required 9% of their work time. • 26% of social workers were responsible for initial insurance verification. • 43% of social workers tracked Medicare coordination of benefit periods. • 44% of social workers were primarily responsible for completing patient admission paperwork. • 18% of social workers were involved in collecting fees from patients. (Respondents noted that this could significantly diminish trust and cause damage to the therapeutic relationship). • Respondents spent 38% of their time on insurance, billing and clerical tasks vs. 25% of their time spent assessing and counseling patients. • Only 34% of the social workers thought that they had enough time to sufficiently address patients’ psychosocial needs. <p>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).</p>
<p>494.140 Condition Personnel qualifications (d) Standard: Social</p>	<p><i>Change the language of d to:</i> <i>Social worker.</i> 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</p>

worker.

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

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

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

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

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

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

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

	<p>adherence.</p> <ul style="list-style-type: none"> • 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). <p>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.</p>
<p>494.140 Condition Personnel qualifications</p>	<p>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.</p> <p>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</p>

	<p>survey were responsible for making dialysis transient arrangements (which involved copying and sending patient records to out-of-town units), yet only 20% were able to do patient education. In the Promoting Excellence in End-of-Life Care’s 2002 report, <u>End-Stage Renal Disease Workgroup Recommendations to the Field</u>, workgroup members recommended that dialysis units discontinue using master’s level social workers for clerical tasks to ensure that they will have sufficient time to provide clinical services to their patients and their families. Merighi and Ehlebracht (2004b; 2004c; 2005), in a survey of 809 randomly sampled dialysis social workers in the United States, found that:</p> <ul style="list-style-type: none"> • 94% of social workers did clerical tasks, and that 87% of those respondents considered these tasks to be outside the scope of their social work training. • 61% of social workers were solely responsible for arranging patient transportation. • 57% of social workers were responsible for making travel arrangements for patients who were transient, taking 9% of their time. • 26% of social workers were responsible for initial insurance verification. • 43% of social workers tracked Medicare coordination periods. • 44% of social workers were primarily responsible for completing admission packets. • 18% of social workers were involved in collecting fees from patients. Respondents noted that this could significantly diminish therapeutic relationships and decrease trust. • Respondents spent 38% of their time on insurance, billing and clerical tasks vs. 25% of their time spent counseling and assessing patients. • Only 34% of the social workers thought that they had enough time to sufficiently address patient psychosocial needs. <p>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.</p>
<p>§494.180 Condition Governance. (b1) Standard. Adequate number of qualified and trained staff.</p>	<p>Add: (1i) No dialysis clinic should have more than 75 patients per one full time social worker.</p> <p>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</p>

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

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

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

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

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

	<p>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.</p> <p>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.</p>
<p>§494.180 Condition Governance. (b4) Standard. Adequate number of qualified and trained staff.</p>	<p>Comment: CNSW agrees that all employees must have an opportunity for continuing education and related development activities.</p>
<p>§494.180 Condition Governance. (b5) Standard. Adequate number of qualified and trained staff.</p>	<p>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.</p>
<p>§494.180 Condition Governance. (h) Standard: Furnishing data and information for ESRD program administration.</p>	<p>(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.</p>

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