



## **Psychosocial Aspects of the 2008 Dialysis Conditions for Coverage LONG VERSION**

*Including information from the preamble of the document*

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To go into effect October 14, 2008 in every U. S. dialysis unit

You can find the entire conditions for coverage at: <http://edocket.access.gpo.gov/2008/pdf/08-1102.pdf>

*This packet was put together by the Council of Nephrology Social Workers (CNSW) to help inform and educate the kidney community about the psychosocial aspects of the new conditions. The implementation and interpretation of the new Conditions of Coverage for End-stage Renal Disease Facilities is anticipated to be a dynamic process. This document reflects the information available to the kidney community as of its version date. Please confirm with CNSW whether further information, resources, or guidance has been provided on this subject. Information provided by CNSW is not intended to establish or replace policies and procedures provided by dialysis providers to their facilities. Please check with your dialysis facility management before implementing any information provided here.*

**To best stay informed and up-to-date about the new conditions,  
we encourage you to be a national member of CNSW-  
Go to [www.kidney.org](http://www.kidney.org), or Call (800) 622-9010 to join today!  
<http://www.kidney.org/professionals/pdf/cnswform.pdf>**

Location	Condition	Standard	Language	Key Points, Background and More Information From Preamble
Subpart B Patient Safety	494.60 Physical Environment	(c) Patient care environment	<p>The dialysis facility must:</p> <p>(i) Maintain a comfortable temperature within the facility; and</p> <p>(ii) Make reasonable accommodations for the patients who are not comfortable at this temperature.</p> <p>(3) The dialysis facility must make accommodations to provide for patient privacy when patients are examined or treated and body exposure is required.</p>	<ul style="list-style-type: none"> <li>• <i>Room temperature is a source of frequent tension in a hemodialysis facility. Generally, the sedentary patients undergoing treatment prefer a warmer room temperature, while staff who are engaged in activity and wearing protective coverings prefer a cooler room temperature.</i></li> <li>• The intent of the new requirement is to have facilities arrive at a middle ground so that the room temperature is at least marginally acceptable to both patients and staff. Patients who continue to feel cold could use coverings or blankets. Regardless of the room temperature, patients should not be deprived of the ability to use covers or blankets. The dialysis facility may allow patients to bring their own blanket or may opt to provide a cover. In either case, adequate infection control precautions must be taken considering the risk of blood spatter. Additionally, the access sites and line connections should remain uncovered to allow staff to visually monitor these areas to ensure patient safety.</li> <li>• We also pointed out that in situations when there was patient body exposure, the staff would be instructed to provide temporary screens, curtains, or blankets to protect patient privacy. To respond to these comments and to further strengthen the patient's right to physical privacy, we have added a new provisions at § 494.60(c)(d)...</li> </ul>
Subpart C Patient Care	494.70 Patients' rights	(a) Patients' rights	<p>The dialysis facility must inform patients (or their representatives) of their rights (including their privacy rights) and responsibilities when they begin their treatment and must protect and provide for the exercise of those rights.</p> <p>(a) Standard: Patients' rights. The patient has the right to—</p> <p>(1) Respect, dignity, and recognition of his or her individuality and personal needs, and sensitivity to his or her psychological needs and ability to cope with ESRD;</p> <p>(2) Receive all information in a way that he or she can understand;</p> <p>(3) Privacy and confidentiality in all aspects of treatment;</p> <p>(4) Privacy and confidentiality in personal medical records;</p> <p>(5) Be informed about and participate, if desired, in all aspects of his or her care, and be informed of the right to refuse treatment, to discontinue treatment, and to refuse to participate in experimental research;</p> <p>(6) Be informed about his or her right to execute advance directives, and the</p>	<ul style="list-style-type: none"> <li>• <i>Patients are entitled to be informed of their rights at the start of care, meaning within the first 3 treatments in the facility, which, we believe, will allow patients to exercise their rights and make choices regarding their care immediately. We are not prescribing the level of detail for a patient's rights review, nor which facility staff members must perform the review. The facility has flexibility in meeting the intent of this provision, so long as the facility sufficiently informs the patient so that he or she may exercise his or her rights early in dialysis care. The professionals at the dialysis facility should determine the most appropriate time for a more detailed review of patient's rights (including discharge policy information) according to individual patient's needs.</i></li> <li>• Patients must also be informed of dialysis facility discharge policies as required at § 494.70(b)(1), and we expect all information would be provided at one time. We believe requiring a facility to provide patient's rights information within 3 treatments is reasonable, given that dialysis is normally performed 3 times per week for approximately 3 to 4 hours per session.</li> <li>• <b>Comment:</b> <i>We received several comments regarding possible misinterpretations by State surveyors as to what is meant by patients being "informed" of facility policies. Response: The word "inform" simply means to communicate knowledge. We have not dictated the mode of communication. Patient rights information may be presented to patients in writing, orally, in audiovisual form, etc. Since the means by which information is communicated to the patient is not specified, facilities and their staff have the necessary flexibility to comply within the intent of the condition. Response: At § 494.70(a)(1) patients have the right to receive respect for their personal needs. The intent of this standard is that all facilities must respect patients and their individual characteristics or unique needs. For instance, facilities may want to develop policies for a variety of situations, such as patient restroom use during a dialysis session, to ensure that their patients' rights are protected. We do not expect that patient signatures</i></li> </ul>

<p>494.70 Patients' rights CON'T</p>	<p>facility's policy regarding advance directives; (7) Be informed about all treatment modalities and settings, including but not limited to, transplantation, home dialysis modalities (home hemodialysis, intermittent peritoneal dialysis, continuous ambulatory peritoneal dialysis, continuous cycling peritoneal dialysis), and in-facility hemodialysis. The patient has the right to receive resource information for dialysis modalities not offered by the facility, including information about alternative scheduling options for working patients; (8) Be informed of facility policies regarding patient care, including, but not limited to, isolation of patients; (9) Be informed of facility policies regarding the reuse of dialysis supplies, including hemodialyzers; (10) Be informed by the physician, nurse practitioner, clinical nurse specialist, or physician's assistant treating the patient for ESRD of his or her own medical status as documented in the patient's medical record, unless the medical record contains a documented contraindication; (11) Be informed of services available in the facility and charges for services not covered under Medicare; (12) Receive the necessary services outlined in the patient plan of care described in § 494.90; (13) Be informed of the rules and expectations of the facility regarding patient conduct and responsibilities; (14) Be informed of the facility's internal grievance process; (15) Be informed of external grievance mechanisms and processes, including how to contact the ESRD Network and the State survey agency; (16) Be informed of his or her right to file</p>	<p><i>on liability waivers are necessary or appropriate in most cases.</i></p> <ul style="list-style-type: none"> <li>• When a patient needs to use the restroom, that time should not be deducted from the dialysis treatment session. Facilities should schedule patients in such a way so that patients are not forced to give up prescribed services for which Medicare provides payment. In addition, CMS considers facilities that fail to schedule patients appropriately and thus, force patients to give up prescribed services, to be a serious matter of program integrity.</li> <li>• <i>The intent of the proposed rule language was to provide the facility with flexibility in meeting the requirement that it provide information in a way the patient understands. If a facility needs to obtain the use of a translator service to provide information to a patient and respond to questions, then we expect the facility to obtain that service....The information required to be provided under § 494.70 would include all the information patients need to understand their rights and participate in their care if they choose (see § 494.70(a)(5)).</i></li> <li>• <b>Comment:</b> One commenter suggested that specific language be added to state that a social worker should have the ability to assess a patient's psychological needs in a private environment. <b>Response:</b> The intention of § 494.70(a)(3) and § 494.70(a)(4) is that all facilities must respect privacy and confidentiality for all patients; therefore social worker-patient interactions that require privacy should be conducted in private.</li> <li>• <i>It may be desirable that patients participate fully in their care; however, neither CMS nor a facility can demand full patient participation. Additionally, we cannot mandate the involvement of patient representatives in the care of patients. We do require that patients have the opportunity to participate in their care. Patients have the right to accept or decline to participate. Patients have the right to be involved in their care planning as part of the interdisciplinary team, which is defined at § 494.80 and § 494.90. Because patients have the right to be part of the interdisciplinary team, they have the opportunity to participate in all aspects of care, which includes, but is not limited to, care planning. The language in the final rule allows for flexibility in the way a facility demonstrates that a patient has had sufficient opportunity to participate as part of the team. Care plan meetings or conference calls that allow the patient to call in from home would allow the patient to participate. The dialysis facility must encourage patient participation in care planning.</i></li> <li>• The large number of supportive comments regarding advance directives is appreciated. We believe that it is important to include this language in the final regulation for several reasons, not the least of which is that while ESRD treatment has prolonged life, the typical patient receiving dialysis treatment is often afflicted with multiple co-morbidities. We are not mandating that facilities discuss "end of life" options, requiring units to provide advance directives planning assistance, or requiring patients to complete advance directive documents. We are requiring in the final rule at § 494.70(a)(6) that facilities inform patients of their right to have advance directives and inform patients of the facility's policies regarding advance directives. Patients requiring assistance in advance directive preparation should look to the facilities' social workers for guidance, as social work professionals are trained to use their clinical judgment to evaluate, provide information and make referrals if necessary. The facility should address advance directives in their policies and procedures, which must be available to</li> </ul>
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	<p>494.70 Patients' rights CONT</p>		<p>internal grievances or external grievances or both without reprisal or denial of services; and (17) Be informed that he or she may file internal or external grievances, personally, anonymously or through a representative of the patient's choosing.</p>	<p>patients as required in the "Patients' rights" condition. We expect facilities to make patients aware of their policies regarding honoring properly executed advance directives. If a facility does not honor advance directives, we expect it to make the patient aware of that policy. In addition, we believe that the facility should develop a protocol for patient transfer, if a facility does not intend to honor advance directives.</p> <ul style="list-style-type: none"> <li>• <i>Individual patients always have the choice to not seek treatment. As indicated at proposed §494.70(a)(5), patients have the right to refuse treatment. If an individual is a patient of an ESRD facility, then he or she has likely made the decision to treat his or her illness. However, the patient's medical condition may change in later months or years and there could be a time when the patient decides that dialysis treatment is no longer appropriate. Therefore, in response to this comment, we have modified our requirement so that a patient must be informed of the right to discontinue as well as refuse treatment.</i></li> <li>• Patients have the right to receive resource information for modalities not offered in their facilities. The facility may wish to create a resource information packet or provide patients with an existing list from Medicare's DFC Web site. This resource information may include giving the patient a handout, or the DFC Web site information. Doing any of these things would meet the requirement to provide the patient with resource information on where they may obtain alternate care options.</li> <li>• <i>Patients currently are allowed to self- cannulate upon receiving the proper training and demonstrating competency. The patient's right to participate in aspects of his or her care is addressed at § 494.70(a)(5), and as written, is flexible enough to include self-cannulation as well as other forms of in- center self-care and home dialysis.</i></li> <li>• Dialysis patients who work or attend school should be encouraged to continue doing so and dialysis facilities should recommend the most appropriate modality and setting for dialysis. While we are not requiring a facility to provide every modality or schedule to accommodate patients' unique schedules, we are now requiring that facilities inform the patient where such accommodations may be obtained. We have added new language at § 494.70(a)(7), giving the patient the right to receive resource information about dialysis modalities not offered by that facility, including alternative scheduling options for working patients. Accommodations for working patients may include, for example, home hemodialysis, peritoneal dialysis, or extended facility hours.</li> <li>• <i>Reuse is a care decision that is to be made between the patient and his or her physician. Patients also have the option to seek treatment in a facility that exclusively uses new dialyzers.</i></li> <li>• <b>Comment:</b> A few commenters suggested that regulatory language require that patients be given access to social work and psychological services, psychosocial counseling, and nutritional counseling. Some commenters suggested that language be added to the "Patients' rights" condition that specifies that patients would have access to, and receive counseling from, a qualified social worker and a dietitian. Some commenters recommended that patients have the right to receive a referral for mental health services, physical or occupational therapy and/or vocational rehabilitation, as needed. <b>Response:</b> The "Patient assessment" and the "Patient plan of care" conditions for coverage (§ 494.80 and § 494.90, respectively), require input by an interdisciplinary team. This team of professionals includes, at minimum, a registered nurse, physician,</li> </ul>
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	<p>494.70 Patients' rights CONT</p>			<p>social worker and dietitian. The team is responsible for properly assessing and treating the patient, which would include identifying additional treatment needs, such as psychosocial counseling, etc. Therefore, we believe that expanding the language at § 494.70(a)(12) to include social work and psychological services, psychosocial counseling and nutritional counseling, as suggested by these public comments, would be redundant under the final rule. Under the final rule, following the comprehensive assessment required at § 494.80, a plan of care for each patient must be implemented, which must include care and services deemed necessary by the interdisciplinary team. The requirements for the provision of services under the "Plan of care" condition at § 494.90, do include nutritional and social services, such as psychosocial and nutritional counseling. Furthermore, the "Patients' rights" condition at § 494.70(a)(11) requires facilities to inform patients of their right to be informed of services available in the facility and the charges for services not covered under Medicare. At § 494.70(a)(12), patients have the right to receive the necessary services outlined in the patient plan of care.</p> <ul style="list-style-type: none"> <li> <p><b>Comment:</b> Some commenters suggested adding language to specify that facilities must inform patients of their responsibilities, including punctuality, following dietary/fluid restrictions, following treatment regimens, exhibiting appropriate personal behavior, informing the team of scheduling problems, and issues in filling prescriptions. Other commenters stated that facilities should inform patients that the patients have a responsibility to listen and ask questions when they do not fully understand their rights or responsibilities. Another commenter stated that CMS should clarify patient responsibilities in the standard for patient rights. <b>Response:</b> Patient responsibilities are addressed at § 494.70(a)(13). We have retained the existing requirement found at § 405.2138(a)(1), which states that patients must be informed of the rules and expectations of the facility regarding patient conduct and responsibilities. The proposed language has been retained in the final rule. It is essential to recognize that positive patient behavior may be encouraged but cannot be regulated.</p> </li> <li> <p>Patients are to be reassessed by the interdisciplinary team, including a Master's degree social worker (MSW) at least monthly when a patient exhibits significant changes in psychosocial needs (as required at § 494.80(d)(2)(iii)), manifested by, for example, issues such as disruptive behavior, that could result in discharge... As stated in the proposed rule preamble, we do not expect that a patient should be involuntarily discharged from a dialysis facility merely for failure to follow the instructions of a facility staff member. However, we recognize it may be necessary to discharge a disruptive patient in order to protect the rights and safety of other patients and staff in the facility. If, for instance, a patient physically harms or threatens other patients and/or staff, brings weapons or illegal drugs into a facility, or verbally abuses and disrupts the facility to a degree that the facility is unable to operate effectively, then the 30-day discharge notice policy could be abbreviated pursuant to § 494.180(f)(5).</p> </li> <li> <p><b>Comment:</b> One commenter recommended that we require posted patient rights to be written in English at a 7th to 9th grade level and translated into a patient's native language if possible. Many other comments suggested that we require facilities to have an "alternate method" to inform patients who cannot read posted information. <b>Response:</b> The concerns raised in these comments have already been addressed at §</p> </li> </ul>
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**2008 Dialysis Conditions for Coverage- CONDITIONS WITH PSYCHOSOCIAL RELEVANCE**

				<p>494.70(a)(2). The “Patients’ rights” condition requires that all patients receive information in a way they can understand. Facilities have the flexibility to provide information to patients in the most appropriate manner based upon patient needs. The qualified professionals at the facility are capable of evaluating an individual patient’s level of understanding and making a determination regarding the needs of that patient.</p>
Subpart C Patient Care	494.70 Patients’ rights	(b) Standard: Right to be informed regarding the facility’s discharge and transfer policies	(b) Standard: Right to be informed regarding the facility’s discharge and transfer policies. The patient has the right to— (1) Be informed of the facility’s policies for transfer, routine or involuntary discharge, and discontinuation of services to patients; and (2) Receive written notice 30 days in advance of an involuntary discharge, after the facility follows the involuntary discharge procedures described in § 494.180(f)(4). In the case of immediate threats to the health and safety of others, an abbreviated discharge procedure may be allowed.	<p><b>Comment:</b> One commenter requested additional clarification regarding what would constitute “discharge” (for example, “30 days after departure from a facility for any reason”). <b>Response:</b> Our intent was to describe the cessation or end of patient care services for patients who either voluntarily leave the facility or for patients who are discharged for reasons listed at § 494.180(f). To address the commenter’s concern, we have added clarifying language at § 494.10 to read, “Discharge means the termination of patient care services by a dialysis facility or the patient voluntarily terminating dialysis when he or she no longer wants to be dialyzed by that facility.”</p>
Subpart C Patient Care	494.70 Patients’ rights	(c) Standard: Posting of rights	The dialysis facility must prominently display a copy of the patient’s rights in the facility, including the current State agency and ESRD network mailing addresses and telephone complaint numbers, where it can be easily seen and read by patients.	<p><b>Comment:</b> We received many comments in support of more patient protection requirements regarding facility internal grievance processes. Commenters supported the proposed requirement for facilities to post information on how to file a grievance. Some commenters specifically supported requiring the posting of Network and State Agency phone numbers and/or mailing addresses. <b>Response:</b> We agree that it would be in the best interest of patients that Network and State Agency mailing addresses and phone numbers be posted. Posting the additional patient rights information will not be a significant burden upon facilities. We have revised § 494.70(c) to include ‘mailing addresses.</p>
Subpart C Patient Care	494.80 Patient assessment	(a) Standard: Assessment criteria	The facility’s interdisciplinary team consists of, at a minimum, the patient or the patient’s designee (if the patient chooses), a registered nurse, a physician treating the patient for ESRD, a social worker, and a dietitian. The interdisciplinary team is responsible for providing each patient with an individualized and comprehensive assessment of his or her needs. The comprehensive assessment must be used to develop the patient’s treatment plan and expectations for care. (a) Standard: Assessment criteria. The patient’s comprehensive assessment must include, but is not limited to, the following: (1) Evaluation of current health status and medical condition, including co- morbid	<ul style="list-style-type: none"> <li>The entire interdisciplinary team is responsible for ensuring that each patient is individually assessed and his or her needs identified, as required at § 494.80. We expect all professional members of the interdisciplinary team to complete the portions of the comprehensive patient assessment that are within their respective scopes of practice. It is not necessary for each professional team member to individually complete the entire comprehensive assessment and thereby duplicate efforts. Professional interdisciplinary team members might choose to conduct one-on-one interviews with patients to complete the assessments. The team may also opt to set up team meetings, which would include the patient, in order to collect the appropriate assessment information. We expect facilities to determine the best way to manage this process, and create policies and procedures to accurately and effectively collect patient assessment information. The assessment information is used to develop the patient’s treatment plan and expectations for care, and thus it is critical for the members of the interdisciplinary team to participate.</li> </ul>

	<p>494.80 Patient assessment CONT</p>	<p>(a) Standard: Assessment criteria</p>	<p>conditions. (2) Evaluation of the appropriateness of the dialysis prescription, blood pressure, and fluid management needs. (3) Laboratory profile, immunization history, and medication history. (4) Evaluation of factors associated with anemia, such as hematocrit, hemoglobin, iron stores, and potential treatment plans for anemia, including administration of erythropoiesis- stimulating agent(s). (5) Evaluation of factors associated with renal bone disease. (6) Evaluation of nutritional status by a dietitian. (7) Evaluation of psychosocial needs by a social worker. (8) Evaluation of dialysis access type and maintenance (for example, arteriovenous fistulas, arteriovenous grafts, and peritoneal catheters). (9) Evaluation of the patient's abilities, interests, preferences, and goals, including the desired level of participation in the dialysis care process; the preferred modality (hemodialysis or peritoneal dialysis), and setting, (for example, home dialysis), and the patient's expectations for care outcomes. (10) Evaluation of suitability for a transplantation referral, based on criteria developed by the prospective transplantation center and its surgeon(s). If the patient is not suitable for transplantation referral, the basis for nonreferral must be documented in the patient's medical record. (11) Evaluation of family and other support systems. (12) Evaluation of current patient physical activity level. (13) Evaluation for referral to vocational and physical rehabilitation services.</p>	
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<p>Subpart C Patient Care</p>	<p>494.80 Patient assessment</p>	<p>(b) Standard: Frequency of assessment for patients admitted to the dialysis facility.</p>	<p>(1) An initial comprehensive assessment must be conducted on all new patients (that is, all admissions to a dialysis facility), within the latter of 30 calendar days or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session. (2) A follow up comprehensive reassessment must occur within 3 months after the completion of the initial assessment to provide information to adjust the patient's plan of care specified in § 494.90.</p>	<p><i>Comment:</i> A few commenters sought clarification on the meaning of the phrase “new patient” at proposed § 494.80(b), “Frequency of assessment for new patients.” The commenters asked whether “new patient” meant a patient new to dialysis or a patient new to a particular dialysis unit. Another commenter asked if “new patient” referred to a patient receiving his or her first treatment in an outpatient dialysis unit.</p> <p><i>Response:</i> In order to clarify the meaning of “new patient,” we have modified the title of § 494.80(b), so that it now reads: “Frequency of assessment for patients admitted to the dialysis facility.” We intend for all dialysis patients new to any particular outpatient dialysis facility be categorized as “new patients” and have a comprehensive assessment within the specified 30-day timeframe even if they are transferring from another dialysis facility. This means a comprehensive assessment must be done on all transfer patients, as well as those new to dialysis, within the first 30 days.</p>
<p>Subpart C Patient Care</p>	<p>494.80 Patient assessment</p>	<p>(d) Standard: Patient reassessment</p>	<p>In accordance with the standards specified in paragraphs (a)(1) through (a)(13) of this section, a comprehensive reassessment of each patient and a revision of the plan of care must be conducted— (1) At least annually for stable patients; and (2) At least monthly for unstable patients including, but not limited to, patients with the following: (i) Extended or frequent hospitalizations; (ii) Marked deterioration in health status; (iii) Significant change in psychosocial needs; or (iv) Concurrent poor nutritional status, unmanaged anemia, and inadequate dialysis.</p>	<p>Unstable patients must be reassessed in accordance with § 494.80(d), which specifies use of the assessment criteria at § 494.80(a)(1) through § 494.80(a)(13). While a comprehensive reassessment for patients classified as unstable is required, it is possible that patient status may not change in all parts of the assessment. Patient status, whether changed or unchanged, should be clearly reflected in the new assessment.</p>

<p>Subpart C Patient Care</p>	<p>494.90 Patient plan of care</p>		<p>The interdisciplinary team as defined at § 494.80 must develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and must include measurable and expected outcomes and estimated timetables to achieve these outcomes. The outcomes specified in the patient plan of care must be consistent with current evidence-based professionally-accepted clinical practice standards.</p>	<ul style="list-style-type: none"> <li>• We recognize that patient outcomes are determined in part by factors outside of the dialysis facility's control, such as demographics, the systemic effects of the underlying renal disease, and patient preferences and adherence. Further, we recognize that health care delivery is dynamic and that not all patients may be achieving, for example, the expected delivered dose of dialysis at any specific point in time. If the patient is unable to achieve the desired health outcomes, the plan of care should be adjusted to reflect the patient's condition along with an explanation, and any opportunities for improvement in the patient's health should be identified. If the patient is unable to achieve the desired health outcomes, the plan of care should be adjusted to reflect the patient's condition along with an explanation for the patient's inability to achieve the desired outcomes, and the team must identify any opportunities to improve the patient's health....The patient is part of the team and should be working to meet the plan of care goals. We are requiring the interdisciplinary team to adjust the patient's plan of care to achieve revised goals if initial outcomes are not achieved. If a Therapeutic goal is not met due to patient non-compliance, then interventions must be implemented to achieve better patient compliance. If reasonable measures have been taken and lack of patient compliance still prevents the goal from being met, the facility must document the interventions, the results of the interventions, and the plan to preserve patient health and safety within the limitations of poor patient compliance. Patient choices that create barriers to meeting the targets should be documented and addressed to a reasonable extent by the team. We are not requiring patients to meet plan of care goals as a condition for coverage of facility services.</li> <li>• <i>The introductory language to the "Patient plan of care" condition calls for the Establishment of "measurable and expected outcomes and estimated timetables to achieve these outcomes." This requirement will allow for individualized plans that lead to desirable outcomes for patients in all care areas listed in the patient's plan of care, including rehabilitation. Outcomes listed in the plan of care could include such targets as the return of the patient to a former occupation, attainment of a certification of education, return to normal activities within the patient's household, a certain level of functionality, or any another outcome that the team has determined is appropriate for the patient. Dialysis facilities have the flexibility to choose appropriate rehabilitation outcome targets, and we will not narrowly define them in this final rule.</i></li> <li>• Advance directives were added under the "Patient's rights" and "Medical records" conditions and therefore we will not require advance directives within the plan of care. Facilities have the flexibility to address advance directives within the plan of care when they deem it appropriate.</li> <li>• <i>Comment: One commenter believes that education for all life changes associated with dialysis is an unfunded mandate that will require additional personnel skilled in this training. The commenter also stated that patient education regarding employment, rehabilitation and transplantation is beyond the scope of the dialysis center nurses and technicians. Response: Patient education is included in the Medicare composite rate paid for dialysis. We expect that the interdisciplinary team has the skills and expertise needed to educate dialysis patients about aspects of the dialysis experience, dialysis management, quality of life, rehabilitation, and transplantation.</i></li> </ul>
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<p>Subpart C Patient Care</p>	<p>494.90 Patient plan of care</p>	<p>(a) Standard: Development of patient plan of care.</p>	<p>The interdisciplinary team must develop a plan of care for each patient. The plan of care must address, but not be limited to, the following: (6) Psychosocial status. The interdisciplinary team must provide the necessary monitoring and social work interventions. These include counseling services and referrals for other social services, to assist the patient in achieving and sustaining an appropriate psychosocial status as measured by a standardized mental and physical assessment tool chosen by the social worker, at regular intervals, or more frequently on an as-needed basis.</p>	<ul style="list-style-type: none"> <li> <p><i>Comment:</i> Although most comments recommended that social services be part of the plan of care, two commenters disagreed, stating that social workers have too big a caseload and are not capable of providing professional counseling services. One commenter stated that until there is consensus on outcomes, CMS should not include an outcomes-based social service requirement in the plan of care. Commenters supporting social services in the plan of care submitted a lengthy list of references that highlight the importance of social services as related to improved patient outcomes. <i>Response:</i> In the previous conditions (§ 405.2162) as well as in this final rule (§ 494.180(b)), dialysis facilities are required to have adequate staff available to meet the care needs of their dialysis patients. This requirement applies to the provision of social services as well. Facilities may want to assess the caseloads of social workers to ensure there are adequate staff to provide the appropriate level of social services, including counseling. Social workers who meet the qualifications at § 494.140(d) are capable of providing counseling services to dialysis patients. Furthermore, Medicare payment for social worker counseling services is included in the dialysis facility composite rate.</p> </li> <li> <p><b>Comment:</b> We received many comments regarding whether a social services component should be required in the “Patient plan of care” condition. Most of the comments recommended that social services be part of the plan of care and referred to current research regarding social work services. Commenters stated that studies have shown that social work intervention improves patients’ quality of life, their adherence to the ESRD treatment regimes and fluid restrictions, and improves medication compliance. Another example of improved outcomes provided by a commenter is that social work interventions can reduce patients’ blood pressure and anxiety levels. Commenters suggested including emotional and social well-being criteria in the final rule. Some commenters recommended including functional status measures that they believe correlate with better survival and hospitalization rates. Other commenters recommended requirements that would specify psychosocial criteria along with MSW tasks and responsibilities, and which would require that MSWs provide information and training to patients. Some commenters suggested adding specific language that would address measurable improvement in physical, mental, and clinical health outcomes,” “psychosocial status and appropriate referral for services,” and would “provide the necessary care and services to achieve and sustain effective psychosocial status.” Many commenters suggested that we require use of a tool to assist in measuring psychosocial status. Tools suggested include the Zung Self- Assessment Depression Scale or Hamilton Anxiety Scale, and a quality- of-life tool such as the SF-36, or SF-12 (version 2.0 tool), that commenters state are used to measure depression, functional status, and predict mortality and morbidity. Commenters cited research supporting social work interventions that they believe would contribute to meeting patient care team goals. <b>Response:</b> In response to the large number of comments, and in light of current academic research supporting social service interventions to improve patient care, we are adding a social services component, called “psychosocial status” to the plan of care requirements at § 494.90(a)(6). We are requiring that a standardized tool, chosen by the social worker, be used to monitor patient status, and</p> </li> </ul>
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	<p>494.90 Patient plan of care CON'T</p>		<p>(6) Psychosocial status CON'T</p>	<p>that counseling be provided and referrals be made as appropriate. This new requirement reads, "The interdisciplinary team must provide the necessary monitoring and social work interventions, including counseling and referrals for social services, to assist the patient in achieving and sustaining an appropriate psychosocial status as measured by a standardized mental and physical assessment tool chosen by the social worker, at regular intervals, or more frequently on an as-needed basis." The standardized tool should be a professionally accepted, valid, reliable tool, such as the SF-36, and should relate to the patient's functional health and well-being. The tool must be used as a monitoring aid that assists in determining the patient's psychosocial status. The SF-36 model uses metrics that measure physical health as related to functional level and presence of pain, and mental health as related to social functioning, emotional and mental health. Reliability and validity studies have been performed for this instrument. More information about the SF-36 may be found in numerous articles or on the Web at <a href="http://www.sf-36.org/tools/sf36.shtml">http://www.sf-36.org/tools/sf36.shtml</a>. The SF-12 survey form was derived from the SF-36 form and scales the 36 question survey down to a 1-page, 2-minute version. However, we are not specifying which tool must be used in order to allow flexibility and to limit the amount of burden. The choice of which standardized tool to use is best left to the facility social worker.</p> <ul style="list-style-type: none"> <li>At § 494.80(a)(7), a social worker is required to assess the psychosocial needs of patients, and § 494.90(a)(6) of the final rule requires the plan of care to address psychosocial status using a standardized mental and physical assessment tool, chosen by the qualified social worker. As discussed previously, we are not requiring facilities to use any specific assessment tool.</li> </ul>
<p>Subpart C Patient Care</p>	<p>494.90 Patient plan of care</p>	<p>(a) Standard: Development of patient plan of care.</p>	<p>The interdisciplinary team must develop a plan of care for each patient. The plan of care must address, but not be limited to, the following: (7) Modality. (i) Home dialysis. The interdisciplinary team must identify a plan for the patient's home dialysis or explain why the patient is not a candidate for home dialysis. (ii) Transplantation status. When the patient is a transplant referral candidate, the interdisciplinary team must develop plans for pursuing transplantation. The patient's plan of care must include documentation of the— (A) Plan for transplantation, if the patient accepts the transplantation referral; (B) Patient's decision, if the patient is a transplantation referral candidate but declines the transplantation referral; or (C) Reason(s) for the patient's nonreferral as a transplantation candidate as</p>	<ul style="list-style-type: none"> <li>The patient must be assessed at least annually for modality choice and level of participation in the dialysis care process...The interdisciplinary team must identify a plan for home dialysis or explain why the patient is not a candidate for home dialysis." This provision requires that, based on the most recent assessment, the plan of care must be revised to reflect modalities for which the patient is a candidate and the patient's preferences regarding modality.</li> <li>Our intent is to ensure that the interdisciplinary team is aware of where the patient is in the referral and transplant evaluation process so that patients do not get "lost" along the way. We do not expect that the transplant referral tracking responsibilities borne by the dialysis facilities would be redundant with the responsibilities of the transplant center. We would expect the interdisciplinary team to be aware of whether the patient has completed the evaluation process, is wait-listed, ineligible for wait listing, or is awaiting living donation. Moreover, the dialysis facility is expected to alert the transplant center about changes in the patient's condition that would affect whether a patient was able to receive kidney transplantation. The transplantation center conditions of participation published on March 30, 2007 (72 FR 15198) require kidney transplant centers to communicate transplant patient status to the dialysis facility at § 482.94(c)(1) and § 482.94(c)(2) so that there is two-way communication.</li> </ul>

			documented in accordance with § 494.80(a)(10).	
Subpart C Patient Care	494.90 Patient plan of care	(a) Standard: Development of patient plan of care.	The interdisciplinary team must develop a plan of care for each patient. The plan of care must address, but not be limited to, the following: (8) Rehabilitation status. The interdisciplinary team must assist the patient in achieving and sustaining an appropriate level of productive activity, as desired by the patient, including the educational needs of pediatric patients (patients under the age of 18 years), and make rehabilitation and vocational rehabilitation referrals as appropriate.	<ul style="list-style-type: none"> <li>This final rule makes the interdisciplinary team responsible for the patient plan of care, including rehabilitation. Referrals may be made by the appropriate team member, which may be the physician and/or the nurse or social worker. The role of the medical director, as described in § 494.150, is to be responsible for the delivery of patient care and outcomes in the facility; this would include rehabilitation outcomes.</li> <li><i>The patient is a member of the interdisciplinary team and, as such, should participate in team discussions regarding rehabilitation potential and goals.</i></li> </ul>
Subpart C Patient Care	494.90 Patient plan of care	(b) Standard: Implementation of the patient plan of care.	<p>(1) The patient's plan of care must—</p> <p>(i) Be completed by the interdisciplinary team, including the patient if the patient desires; and</p> <p>(ii) Be signed by team members, including the patient or the patient's designee; or, if the patient chooses not to sign the plan of care, this choice must be documented on the plan of care, along with the reason the signature was not provided.</p> <p>(2) Implementation of the initial plan of care must begin within the latter of 30 calendar days after admission to the dialysis facility or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session. Implementation of monthly or annual updates of the plan of care must be performed within 15 days of the completion of the additional patient assessments specified in § 494.80(d).</p> <p>(3) If the expected outcome is not achieved, the interdisciplinary team must adjust the patient's plan of care to achieve the Specified goals. When a patient is unable to achieve the desired outcomes, the team must—</p> <p>(i) Adjust the plan of care to reflect the patient's current condition;</p> <p>(ii) Document in the record the reasons why the patient was unable to achieve the goals; and</p>	<ul style="list-style-type: none"> <li><i>We have designated the patient as a member of the interdisciplinary team (if the patient desires) and expect that the patient would share in the goal-setting team decisions.</i></li> <li>The interdisciplinary team definition specifically includes the patient, and has been added to the first paragraph of this condition. We have added the phrase "including the patient if the patient desires" to § 494.90(b)(1)(i) to clarify that we expect that the patient will want to participate in devising the plan of care</li> <li><i>The role of the patient is central to providing quality dialysis care. Paper compliance without substantive compliance is unproductive. Specifically, the patient member of the interdisciplinary team has a role in converting the comprehensive assessment into a meaningful plan of care. Whenever possible, the patient (or designee) should assist in the identification of goals and in formulating the action plan to achieve these goals. The patient must be involved in care planning and actively participate in care plan development and review. Survey tag V174, referred to by the commenter, required regularly scheduled conferences, with participation by the staff involved in the patient's care, to evaluate the progress each patient is making towards the goals in their long-term care program and patient care plan. However, this final rule also allows the facility flexibility to choose the methods to ensure patient participation. One means of providing an opportunity for participation is to have the patient attend the meeting in which the plan of care is developed and updated. This final rule makes very clear that the patient is part of the care team and can participate in the assessment and the plan of care activities if the patient desires to do so. While we have not required monthly care plan meetings specifically, the facility must demonstrate that there is an opportunity for patient involvement and participation. The facility has the flexibility to design a process. The patient signature on the plan of care is not sufficient to demonstrate patient participation. The new interpretive guidelines for this regulation will include direction to surveyors regarding enforcement of this provision.</i></li> <li>We agree that as long as the patient has been provided sufficient opportunity to participate with the interdisciplinary team, the dialysis facility should not receive a citation for non-compliance with these conditions when the patient has refused to participate or sign the plan of care. We have modified the language at § 494.90(b)(1)(ii)</li> </ul>

	<p>494.90 Patient plan of care CON'T</p>	<p>(b) Standard: Implementation of the patient plan of care. CON'T</p>	<p>(iii) Implement plan of care changes to address the issues identified in paragraph (b)(3)(ii) of this section. (4) The dialysis facility must ensure that all dialysis patients are seen by a physician, nurse practitioner, clinical nurse specialist, or physician's assistant providing ESRD care at least monthly, as evidenced by a monthly progress note placed in the medical record, and periodically while the hemodialysis patient is receiving in-facility dialysis.</p>	<p>to indicate that the facility must document a patient's refusal to sign the plan of care, along with the reason the signature was not provided.</p> <ul style="list-style-type: none"> <li> <p><b>Comment:</b> Many comments addressed proposed § 494.90(b)(4), which would require the dialysis facility to ensure that the patients are seen at least monthly by a physician providing ESRD care. Some commenters supported this provision and a few suggested that the visit could take place in the physician's office. Other commenters disagreed with the requirement but agreed with the intent, saying that physicians should see their dialysis patients at least monthly. Many commenters strongly disagreed with the provision, stating that the facility should not be accountable for physician visits. A few commenters stated that the payment G-codes provided enough incentive for facilities and that therefore this physician visit requirement was not needed. Other commenters suggested there was no evidence of any benefits that could be linked to monthly visits, and this would be especially burdensome for rural dialysis facilities. One commenter recommended that an exception be available for facilities in the Pacific Islands. Two commenters suggested that CMS had no authority to mandate these monthly physician visits according to section 1801 of the Social Security Act, which prohibits the federal government from exercising any supervision or control over the practice of medicine. <b>Response:</b> We believe that it is in the best interest of the patient for dialysis facilities to ensure that a physician (or other practitioner, such as a PA, nurse practitioner, or clinical nurse specialist) visits each month. The Dialysis Outcomes and Practice Patterns Study (DOPPS) data demonstrate that physician contact correlates with the quality of care. The G-codes, established in the final rule, "Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2004" published November 7, 2003 (68 FR 63196, 63216), provide payment to physicians in incremental amounts depending on whether the patient was seen 1, 2-3, or 4 times during a given month. Although the payment G-codes provide some incentive for attending physicians to see their dialysis patients more often, physicians may still choose not to see their patients for a month or more. In this case, the patient still receives dialysis for which the facility receives payment. We do not believe that requiring monthly visits infringes on how physicians practice medicine and note that physician organizations that provided comment on the proposed rule supported the provision. We are retaining the proposed provision at § 494.90(b)(4) to ensure that patients receive face-to-face physician (or, as discussed below, "physician extender") visits at least monthly.</p> </li> <li> <p><b>Comment:</b> A few commenters suggested that physician assistants be allowed to perform monthly visits, while one commenter favored allowing a nurse practitioner to perform monthly visits. <b>Response:</b> In response to comments, we have added nurse practitioners, clinical nurse specialists, and physician assistants as options for compliance with the provision requiring monthly visits by a physician. CMS has previously issued instructions regarding physician visits and payment via Gcodes and these instructions clarify that a physician assistant, clinical nurse specialist, or a nurse practitioner may provide visits to dialysis patients instead of a physician. Physicians may use nurse practitioners, physician assistants, and clinical nurse specialists, who are able under the Medicare statute to furnish services that would be physician services if furnished by a physician and who are eligible to enroll in the Medicare</p> </li> </ul>
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<p>Subpart C Patient Care</p>	<p>494.90 Patient plan of care</p>	<p>(c) Standard: Transplantation referral tracking</p>	<p>The interdisciplinary team must— (1) Track the results of each kidney transplant center referral; (2) Monitor the status of any facility patients who are on the transplant wait list; and (3) Communicate with the transplant center regarding patient transplant status at least annually, and when there is a change in transplant candidate status.</p>	<p>program, to deliver some of the visits during the month.</p>
<p>Subpart C Patient Care</p>	<p>494.90 Patient plan of care</p>	<p>(d) Standard: Patient education and training</p>	<p>The patient care plan must include, as applicable, education and training for patients and family members or caregivers or both, in aspects of the dialysis experience, dialysis management, infection prevention and personal care, home dialysis and self-care, quality of life, rehabilitation, transplantation, and the benefits and risks of various vascular access types.</p>	<ul style="list-style-type: none"> <li> <p>• <b>Comment:</b> We received several comments supporting inclusion of the “Patient education and training” standard at § 494.90(d). Some commenters recommended the addition of other training topics, including patient education regarding arteriovenous fistulas, advance directives, and more. A commenter recommended that we require documentation in the medical record that patients were informed of the risks and benefits of various types of vascular access consistent with “Fistula First”, and provide funding for this if needed. <b>Response:</b> We agree that it is a reasonable expectation that dialysis patients be educated regarding the risks and benefits of various access types due to the impact of a vascular access on the patient’s morbidity and mortality risks. Comments on this and other sections of these conditions strongly support adding a requirement ensuring that patients must be educated regarding the risks, benefits, and outcomes of various access types. These comments are in keeping with the National “Fistula First” quality initiative. Additionally, the Institute of Medicine (IOM) has encouraged the empowerment of patients to improve the quality of the healthcare system. Therefore, we have added new language to the “Patient plan of care” condition at § 494.90(d), Patient education and training, requiring that the plan of care include education and training on the benefits and risks of various vascular access types. We have also added infection prevention and personal care, and home dialysis and self-care training to this provision in response to comments as discussed under the “Infection control” and “Care at home” sections of the preamble.</p> </li> <li> <p>• <b>Comment:</b> <i>One commenter believes that education for all life changes associated with dialysis is an unfunded mandate that will require additional personnel skilled in this training. The commenter also stated that patient education regarding employment, rehabilitation and transplantation is beyond the scope of the dialysis center nurses and technicians.</i> <b>Response:</b> <i>Patient education is included in the Medicare composite rate paid for dialysis. We expect that the interdisciplinary team has the skills and expertise needed to educate dialysis patients about aspects of the dialysis experience, dialysis management, quality of life, rehabilitation, and transplantation.</i></p> </li> </ul>

<p>Subpart C— Patient Care</p>	<p>494.110 Condition: Quality assessment and performance improvement.</p>		<p>Condition: Quality assessment and performance improvement. The dialysis facility must develop, implement, maintain, and evaluate an effective, data-driven, quality assessment and performance improvement program with participation by the professional members of the interdisciplinary team. The program must reflect the complexity of the dialysis facility's organization and services (including those services provided under arrangement), and must focus on indicators related to improved health outcomes and the prevention and reduction of medical errors. The dialysis facility must maintain and demonstrate evidence of its quality improvement and performance improvement program for review by CMS.</p>	<p>We are also requiring at § 494.110 that the interdisciplinary team, which includes the RN, social worker, and dietitian, play an active role in the QAPI program. This final rule requires that the interdisciplinary team provide appropriate care to dialysis patients and improve patient care on an ongoing basis. The dialysis facility may need to evaluate staffing levels as part of their action plan for the QAPI program. In order to clarify that the adequate staffing standard applies to all clinical staff, we have added language to the requirement at § 494.180(b)(1), requiring that the RN, social worker and the dietitian be available to meet patient clinical needs.</p>
<p>Subpart C— Patient Care</p>	<p>494.110 Condition: Quality assessment and performance improvement</p>	<p>(a) Standard: Program scope.</p>	<p>(2) The dialysis facility must measure, analyze, and track quality indicators or other aspects of performance that the facility adopts or develops that reflect processes of care and facility operations. These Performance components must influence or relate to the desired outcomes or be the outcomes themselves. The program must include, but not be limited to, the following: (viii) Patient satisfaction and grievances</p>	<ul style="list-style-type: none"> <li>• We have modified this requirement in the final rule to make clear that the professional members of the interdisciplinary team (physician, RN, social worker, and dietitian) must participate in the QAPI program. The facility has the option of including facility patients when appropriate.</li> <li>• <i>Facilities may use indicators and measures of their choice as appropriate and necessary to implement the data driven QAPI program. We may update the QAPI topics as needed in future revisions of the ESRD conditions for coverage. Facilities may add topics to their QAPI program as needed to meet the unique needs of their facility.</i></li> <li>• The facility has the flexibility to develop and implement QAPI via processes of their own choosing, as long as the efforts result in a multidisciplinary, data-driven QAPI program that achieves improvement and meets the criteria stated in § 494.110. This might include face-to-face meetings or additional and alternate activities. We have not modified the regulatory language to specify processes or face-to-face meetings.</li> <li>• <i>We are requiring that dialysis facilities include patient satisfaction as a component of their QAPI program. At this point in time we are strongly encouraging facilities to use the standardized ICH CAHPS tool to assess in-center hemodialysis patient experience of care, but we are not requiring use of this instrument. As the renal community becomes more experienced with using the ICH CAHPS instrument and recognizes benefits associated with its use, we would expect to see widespread voluntary use. The IOM dimensions of patient-centered care include respect for patients' values, preferences, and expressed needs; coordination and integration of care; information, communication, and education; physical comfort; emotional support; involvement of family and friends; continuity and transition; and access to care. The ICH CAHPS survey instrument addresses all these areas in either the Core Instrument or supplemental questions. The ICH CAHPS core instrument and supplemental questions have been placed in the public domain. Any hemodialysis facility interested in using the survey should contact Charles</i></li> </ul>

<p>Subpart C Patient Care</p>	<p>494.110 Quality assessment and performance improvement</p>	<p>(a) Standard: program scope</p>	<p>The dialysis facility must develop, implement, maintain, and evaluate an effective, data-driven, quality assessment and performance improvement program with participation by the professional members of the interdisciplinary team. The program must reflect the complexity of the dialysis facility's organization and services (including those services provided under arrangement), and must focus on indicators related to improved health outcomes and the prevention and reduction of medical errors. The dialysis facility must maintain and demonstrate evidence of its quality improvement and performance Improvement program for review by CMS. (1) The program must include, but not be limited to, an ongoing program that achieves measurable improvement in health outcomes and reduction of medical errors by using indicators or performance measures associated with improved health outcomes and with the identification and reduction of medical errors. (2) The dialysis facility must measure, analyze, and track quality indicators or other aspects of performance that the facility adopts or develops that reflect processes of care and facility operations. These performance components must influence or relate to the desired outcomes or be the outcomes themselves. The program must include, but not be limited to, the following: (viii) Patient satisfaction and grievances.</p>	<p>Darby at <a href="mailto:Charles.Darby@ahrq.hhs.gov">Charles.Darby@ahrq.hhs.gov</a>.</p>
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<p>Subpart D Administration</p>	<p>494.140 Personnel qualifications</p>		<p>All dialysis facility staff must meet the applicable scope of practice board and licensure requirements in effect in the State in which they are employed. <i>The dialysis facility's staff (employee or contractor) must meet the personnel qualifications and demonstrated competencies necessary to serve collectively the comprehensive needs of the patients. The dialysis facility's staff must have the ability to demonstrate and sustain the skills needed to perform the specific duties of their positions.</i></p>	
<p>Subpart D Administration</p>	<p>494.140 Personnel qualifications</p>	<p>(d) Social Worker</p>	<p>The facility must have a social worker ho—                  (1) Holds a master's degree in social work with a specialization in clinical practice from a school of social work accredited by the Council on Social Work Education; or                  (2) Has served at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who qualifies under § 494.140(d)(1).</p>	<ul style="list-style-type: none"> <li>• <i>Some commenters stated that it would be helpful if clinical social worker responsibilities were listed in regulation; they state that social workers are unable to provide clinical social services to patients because they are often tasked with clerical work that fills the majority of their time. Response: We have sought to be less prescriptive in this rule in order to allow dialysis facilities flexibility in meeting Medicare requirements. We expect that as professional caregivers, members of the interdisciplinary team are aware of their discipline's professional standards of practice and provide quality care to their patients in keeping with those standards. Under the "Patient assessment" and "Patient plan of care" conditions (§ 494.80 and § 494.90), we require that members of the interdisciplinary team complete a comprehensive assessment followed by a plan of care that identifies goals for patient care and the services that will be provided in order to meet those goals. This includes psychosocial and nutrition services to be provided by the social worker and the registered dietitian. The assessment and plan of care requirements necessitate that the RN, social worker, and dietitian provide appropriate professional care to each patient. Specifically, the dialysis facility must ensure that the social worker provides timely psychosocial assessments and social work interventions in accordance with the plan of care in order to meet these conditions for coverage. We are also requiring at § 494.140 that the interdisciplinary team, which includes the RN, social worker, and dietitian, play an active role in the QAPI program This final rule requires that the interdisciplinary team provide appropriate care to dialysis patients and improve patient care on an ongoing basis. We do not agree that all the responsibilities of the entire interdisciplinary team need to be enumerated in regulation.</i></li> <li>• <b>Comment:</b> We received more than 70 comments regarding social worker qualifications. The vast majority of commenters supported the proposed social worker qualifications, which require a master's degree in social work from a school of social work accredited by the Council on Social Work Education. Commenters stated that dialysis patients have highly complex needs and require care from an MSW who has a "specialization in clinical practice" education. Commenters made the following statements in support of an MSW with a specialization in clinical practice. They stated that the nephrology social workers must be skilled in</li> </ul>

	<p>494.140 Personnel qualifications CON'T</p>	<p>(d) Social Worker CON'T</p>		<p>assessing for psychosocial influences and their interrelatedness in predicting treatment outcomes, and must be able to design interventions with the patient, the family, the medical team, and community systems at large to maximize the effectiveness of ESRD treatment. The additional training received by MSWs enables them to perform these complex professional tasks and ensure effective outcomes that have a direct relationship to morbidity and mortality. Masters-prepared social workers are trained to use validated tools, such as the SF36 (the Medical Outcomes Study 36-item short-form health survey) and the KDQOL (Kidney Disease Quality of Life), to improve care and to monitor the outcomes of directed interventions. Most nephrology social workers provide psychosocial services autonomously as primary providers without social work supervision or consultation, using highly developed social work intervention skills obtained in a master's level curriculum. The masters in social work degree provides an additional 900 hours of specialized training beyond a baccalaureate degree in social work. An MSW curriculum is the only curriculum that offers additional specialization in the Bio-Psycho-Social-Cultural, Person-in- Environment model of understanding human behavior. Undergraduate degrees or other mental health credentials do not offer this specialized and comprehensive training. The National Association of Social Workers Standards of Classification considers the baccalaureate degree as a basic level of practice, while the masters degree is considered a specialized level of professional practice and requires a demonstration of skill or competency in performance. These commenters provided references and citations along with these comments. A few commenters suggested that the master's degree qualification be eliminated because it is difficult to recruit MSWs in some rural areas. A commenter stated that in California a licensed clinical social worker requires 2 years of supervision and two examinations, which makes it difficult to get a licensed clinical social worker license. Another commenter suggested that we keep the MSW requirement but include an "exceptions process" for units that cannot hire an MSW. Some commenters stated that bachelor's prepared social workers are competent as long as they are supervised by an MSW. <b>Response:</b> We appreciate the large degree of support for the MSW qualification for social workers. We have revised the MSW requirement in § 494.140(d)(1) by adding "specialization in clinical practice," as specified in part 405, subpart U, as the majority of comments supported this. The consensus among the commenters is that this level of knowledge and skill is needed to deal with an increasingly older, sicker, more complex dialysis patient population.</p> <ul style="list-style-type: none"> <li>• <b>Comment:</b> One commenter recommended that we delete § 494.140(d) in its entirety or delete any preamble references to MSWs performing counseling, long-term behavioral and adaptation therapy, and grieving therapy. The commenter stated that such counseling exceeds the expertise of MSWs, and that patients should be referred outside the units for this service. The commenter also claimed that an "expansion" of counseling requirements represents a potential \$18 million burden to his large dialysis organization. <b>Response:</b> The "Personnel qualifications" condition for coverage at § 494.140 does not specify tasks or</li> </ul>
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	<p>494.140 Personnel qualifications CON'T</p>	<p>(d) Social Worker CON'T</p>		<p>responsibilities for dialysis facility social workers, but only their education and qualifications. The proposed rule preamble discussion provided examples of social worker services that facilities might offer, including counseling services, long-term behavioral and adaptation therapy, and grieving therapy (70 FR 6222) that would require the education and training of an MSW. The proposed rule's preamble discussion is consistent with part 405, subpart U social worker requirements at § 405.2163(c), which state that "Social services are provided to patients and their families and are directed at supporting and maximizing the social functioning and adjustment of the patient." Social services needed for each patient should be determined during the assessment and identified in the plan of care. Only one commenter suggested § 494.140(d) be deleted in its entirety, while very large number of comments supported this requirement, and the consensus was to retain MSWs in dialysis units. MSWs are trained and competent to counsel patients. The social worker professional standards of practice (<a href="http://www.socialworkers.org/practice/standards/NASWHealthCareStandards.pdf">http://www.socialworkers.org/practice/standards/NASWHealthCareStandards.pdf</a>) do include patient and family counseling within the scope of services provided by a social worker. MSW services, which include counseling, is incorporated into the Medicare composite payment rate and should not be outsourced or separately billed.</p> <ul style="list-style-type: none"> <li> <p><b>Comment:</b> We received a large number of comments regarding our proposed deletion of the master's degree "grandfather clause" for social workers. Many commenters agreed with eliminating the "grandfather clause" because "30 years was more than enough time for dialysis social workers to obtain masters degree." Commenters stated that MSW and BSW tasks could be broken out into separate job descriptions so that BSWs may assist MSWs. Commenters said that there was no MSW shortage. A larger number of commenters suggested that we retain the "grandfather clause" for non-MSWs so that currently employed non-MSWs working as dialysis social workers do not lose their jobs. Some commenters suggested that experienced non-MSW social workers were competent and had much to offer dialysis patients. A few commenters recommended that we continue the grandfather clause until the year 2015 to allow current non- MSWs who met the subpart U requirements to finish out their careers. <b>Response:</b> According to the definition of "Qualified personnel" at § 405.2102, a non-masters degree social worker may serve as an ESRD social worker (under § 405.2102(f)(2), qualified personnel) when he or she "has served for at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who qualifies under paragraph (f)(1) of this definition" (that is, has completed a course of study with specialization in clinical practice at, and holds a masters degree from a graduate school of social work). This subpart U grandfather clause only applies to non- MSWs who have been practicing social work since 1974, and any ESRD social workers who do not have 2 years of experience prior 1976 must have a masters degree. While we believe the number of non- masters-degree social workers still practicing over the past 32 years is small, we do not intend that these long- time employees should become unqualified for their jobs because of deletion</p> </li> </ul>
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	<p>494.140 Personnel qualifications CON'T</p>	<p>(d) Social Worker CON'T</p>		<p>of the “grandfather clause.” ...The grandfather clause may not be applied to social workers who do not meet the 1976 experience criterion. Bachelors-prepared social workers may function as assistants to the MSW. The MSW is the staff member who must satisfy these conditions for coverage.</p> <ul style="list-style-type: none"> <li> <p>• <b>Comment:</b> A few commenters suggested that we eliminate the proposed § 494.140(d)(2) requirement, “Meets the practice requirements for social services in the State in which he or she is employed.” <b>Response:</b> Adherence to State scope-of-practice requirements is an appropriate minimum requirement for a federal health and safety regulation. This final rule supports compliance with State regulations. The final rule provision for meeting applicable scope- of-practice board and licensure requirements for dialysis facility personnel has been moved to the beginning of § 494.140 to avoid redundancy within the standards for each of the dialysis facility staff members.</p> </li> <li> <p>• <b>Comment:</b> Several commenters suggested that we add a social worker licensure requirement to § 494.140(d)(2). <b>Response:</b> The proposed rule at § 494.20 required licensure for all staff. To prevent confusion regarding whether licensure is required under personnel qualifications, we have moved the requirement to the beginning of § 494.140, to read: “All dialysis facility staff must meet the applicable scope of practice board and licensure requirements in effect in the State in which they are employed.”</p> </li> <li> <p>• <b>Comment:</b> Many social workers as well as some commenters who are not social workers suggested that a new social worker aide personnel standard be added to the final rule. The rationale given was that this new staff member could perform many of the clerical tasks (admissions, billing, transportation, transient patient paperwork, determining insurance coverage) often assigned to social workers, so that the social worker would be freed up to perform clinical social services, such as counseling, that would result in improved patient care and better outcomes. Many commenters stated this position should be required for dialysis facilities with more than 75 patients. <b>Response:</b> This final rule requires each facility to have adequate staff to meet patient needs. Paragraph § 494.180(b)(1) applies to all dialysis staff, including social workers. The use of ancillary staff is not precluded by this regulation. Some dialysis facilities do employ staff to assist the social worker with clerical tasks, while other facilities may employ more than one social worker. Each facility should assess their staffing needs and determine appropriate staffing levels. While we agree that using an MSW to perform clerical tasks and manage patient financial information may not be the most effective or efficient use of trained and licensed professional clinical staff, we are not requiring that dialysis facilities employ social worker aides. We encourage dialysis facilities to use staff resources in the most effective and efficient manner to provide quality care to dialysis patients.</p> </li> <li> <p>• <b>Comment:</b> Many commenters suggested that the final rule state that MSWs could not be assigned non-MSW tasks. These commenters object to the number of clerical tasks that are assigned to social workers. <b>Response:</b> Dialysis facilities have the flexibility to assess facility-staffing needs and use staff as necessary. This final rule requires social workers to provide appropriate clinical services to</p> </li> </ul>
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	<p>494.140 Personnel qualifications CON'T</p>	<p>(d) Social Worker CON'T</p>		<p>dialysis patients under the “Patient assessment” and “Patient plan of care” conditions for coverage (§ 494.80 and § 494.90 respectively). The social worker must also participate in the facility QAPI program (§ 494.110). The facility must have a sufficient social services staff to meet dialysis patient needs as required at § 494.180(b)(1), which applies to all dialysis staff, including social workers. We would expect that any tasks assigned to the social worker would not compromise the social worker’s ability to meet his or her obligations to patients and these conditions for coverage. We have not added restrictions regarding staff assignments to this final rule.</p> <ul style="list-style-type: none"> <li> <p>• <b>Comment:</b> Many commenters recommended that we specify a maximum MSW caseload or an MSW- to-patient ratio. <b>Response:</b> As discussed above, adequate staffing is addressed under the “Governance” condition for coverage at § 494.180(b). Some states have implemented staff-to-dialysis patient ratios, and we defer to State provisions on this issue. Nephrology social workers should adhere to the professional standards of practice for social workers. The National Association of Social Workers published “NASW Standards for Social Work Practice in Health Care Settings” in 2005. These professional practice standards may be found at <a href="http://www.socialworkers.org/practice/standards/NASWHealthCareStandards.pdf">http://www.socialworkers.org/practice/standards/NASWHealthCareStandards.pdf</a>. The National Association of Social Workers and Council of Nephrology Social Workers jointly published “NASW/NKF Clinical Indicators for Social Work and Psychosocial Service in Nephrology Settings” in October 1994, which may be found at <a href="http://www.socialworkers.org/practice/standards/nephrologysettings.asp">http://www.socialworkers.org/practice/standards/nephrologysettings.asp</a>. In addition, the NKF has published the 2003 Council of Nephrology Social Workers “Standards of Practice for Nephrology Social Work.” These standards of practice include guidelines for clinical practice, a description of the nephrology social work role, as well as staffing information.</p> </li> <li> <p>• <b>Comment:</b> A commenter suggested that the final rule state that different facilities can share the same renal dietitian or social worker. <b>Response:</b> Neither part 405, subpart U nor the proposed rule precludes facility sharing of renal dietitians and social workers, as long as each facility has adequate staff and staff hours to meet patient needs and provide care consistent with professional practice standards. Please refer to § 494.180(b)(1), which applies to all dialysis staff.</p> </li> <li> <p>• We appreciate the large degree of support for the MSW qualification for social workers. We have revised the MSW requirement in § 494.140(d)(1) by adding “specialization in clinical practice,” as specified in part 405, subpart U, as the majority of comments supported this. The consensus among the commenters is that this level of knowledge and skill is needed to deal with an increasingly older, sicker, more complex dialysis patient population.</p> </li> </ul>
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<p>Subpart D Administration</p>	<p>494.140 Personnel qualifications</p>	<p>(e) Patient care dialysis technicians</p>	<p>Patient care dialysis technicians must—                  (3) Have completed a training program that is approved by the medical director and governing body, under the direction of a registered nurse, focused on the operation of kidney dialysis equipment and machines, providing direct patient care, and <b>Communication and interpersonal skills, including patient sensitivity training and care of difficult patients.</b></p>	<ul style="list-style-type: none"> <li>• The proposed PCT training program (proposed at § 494.180(b)(5)) included the “care of patients with kidney failure, including interpersonal skills” and “possible complications of dialysis.” “Care of patients with kidney failure” (proposed § 494.180(b)(5)(ii)) would include psychosocial and nutritional aspects of care. The “interpersonal skills” training would include professional conduct and interactions during challenging situations.</li> </ul>
<p>Subpart D Administration</p>	<p>494.150 Responsibilities of the medical director</p>		<p>The dialysis facility must have a medical director who meets the qualifications of § 494.140(a) to be responsible for the delivery of patient care and outcomes in the facility. The medical director is accountable to the governing body for the quality of medical care provided to patients.                  (b) Staff education, training, and performance.                  (2) Ensure that--                  (i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; and                  (ii) The interdisciplinary team adheres to the discharge and transfer policies and procedures specified in § 494.180(f).</p>	<ul style="list-style-type: none"> <li>•</li> </ul>

<p>Subpart D Administration</p>	<p>494.180 Governance</p>	<p>(b) Standard: Adequate number of qualified and trained staff.</p>	<p>The governing body or designated person responsible must ensure that— (1) An adequate number of qualified personnel are present whenever patients are undergoing dialysis so that the patient/staff ratio is appropriate to the level of dialysis care given and meets the needs of patients; and the registered nurse, social worker and dietitian members of the interdisciplinary team are available to meet patient clinical needs; (4) All employees have an opportunity for continuing education and related development activities.</p>	<ul style="list-style-type: none"> <li>• Many commenters suggested a 1:75 MSW-to-patient ratio, and stated that it was impossible for MSWs to do case review and counseling with high patient ratios. Commenters stated that MSWs were assigned large caseloads of between 125 and 300 patients each, and cited a 2005 study (Bogatz, Colasanto, and Sweeney) in support of this contention. Some commenters recommended that we require use of a standardized acuity-based formula for adequate staff, such as the NKF Council of Nephrology Social Workers’ “Professional Advocacy for the Nephrology Social Worker, First Edition 2002” (pages 9–11). One social worker stated she had 150 patients in 3 units and could therefore only triage and “put out fires.” <b>Response:</b> We solicited public comment in the proposed rule regarding whether we should include a requirement for an acuity-based staffing plan. The public comments were split on the acuity-based staffing plan issue. Clearly staffing is of concern to many commenters. While commenters agreed with the intent of the proposed adequate staff provision at § 494.180(b)(1), there was discontent related to how this provision would be interpreted and enforced. First, we would like to clarify that the adequate staff standard applies to all clinical patient care staff, including nurses, technicians, social workers, and dietitians who provide services to the dialysis patients. Appropriate staffing ratios are affected by a number of factors. These factors include patient acuity, level of staff expertise and skill mix, presence or absence of support staff/unlicensed personnel, available technology, distances between groups of patients served, efficiency of systems in place, scope of staff duties, degree of team work, State requirements, practice board-imposed limitations, number of meetings in which staff participation is required, paperwork demands, etc. We do not have a method available to identify and account for all of these types of characteristics in determining staff ratios that balance staff time to provide quality care and meet patient needs with the economic factors associated with dialysis facility labor costs. We are also concerned that any mandated minimum staffing ratios would be interpreted as the “maximum ceiling” that must be complied with which could lead to a decline in the number of patient care staff available. “Adequate staff” means staffing must be sufficient so that quality care is provided to dialysis patients that is consistent with the patient plan of care and professional practice standards. We are requiring under the “Patient assessment” and “Patient plan of care” conditions (§ 494.80 and § 494.90 respectively) that members of the interdisciplinary team complete a comprehensive assessment, followed by a plan of care that identifies goals for patient care and the services that will be provided in order to meet those goals. This includes psychosocial and nutrition services to be provided by the social worker and the dietitian. The assessment and plan of care requirements necessitate that the RN, social worker, and dietitian provide appropriate professional care to each patient. We are also requiring at § 494.110 that the interdisciplinary team, which includes the RN, social worker, and dietitian, play an active role in the QAPI program. This final rule requires that the interdisciplinary team provide appropriate care to dialysis patients and improve patient care on an ongoing basis. The dialysis facility may need to evaluate staffing levels as part of their action plan for the QAPI program. In order to clarify that the adequate staffing standard applies to all clinical staff, we</li> </ul>
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				<p>have added language to the requirement at § 494.180(b)(1), requiring that the RN, social worker and the dietitian be available to meet patient clinical needs.</p>
<p>Subpart D Administration</p>	<p>494.180 Governance</p>	<p>(e) Standard: Internal Grievance Process</p>	<p>The facility's internal grievance process must be implemented so that the patient may file an oral or written grievance with the facility without reprisal or denial of services. The grievance process must include: (1) A clearly explained procedure for the submission of grievances. (2) Timeframes for reviewing the grievance. (3) A description of how the patient or the patient's designated representative will be informed of steps taken to resolve the grievance.</p>	<p><i>Comment:</i> One commenter suggested the final rule state (at § 494.180(e)) that the facility must accept a grievance in any form (oral or written) presented.</p> <p><i>Response:</i> We agree that facilities should not limit acceptance of grievances to written grievances, and therefore, we have added the words "oral or written" at § 494.180(e) to allow patients more flexibility in how they communicate a grievance. The sentence now reads, "The facility's internal grievance process must be implemented so that the patient may file an oral or written grievance with the facility without reprisal or denial of services."</p> <p><i>Comment:</i> Two commenters suggested we require the internal grievance process to be posted. Another commenter recommended patient involvement in the design and administration of internal grievance process.</p> <p><i>Response:</i> We are not prescribing the manner in which a facility must make its grievance process known. The facility has the flexibility to inform patients of the grievance process as required under the "Patients' rights" condition at § 494.70(a)(14), using the methods of its choice.</p> <p><i>Comment:</i> One commenter recommended that we require routine reporting to the ESRD Network on the number and topics of complaints. A second commenter supported the concept of an internal grievance process, but suggested the addition of an expectation of timely investigation, documentation, and resolution, along with a quality assurance requirement to prevent any recurrences.</p> <p><i>Response:</i> Grievances resolved at the facility level might not need to be escalated to the ESRD Network level. Grievances are to be addressed in a reasonable fashion in a reasonable period of time. The grievance process must include a clearly explained procedure for the submission of grievances, timeframes for reviewing the grievance, and a description of how the patient or the patient's designated representative will be informed of steps taken to resolve the grievance. Dialysis facilities must track grievances and patient satisfaction as part of the QAPI program in which trending and quality improvement efforts are expected (§ 494.110(a)(2)(viii)).</p>

<p>Subpart D Administration</p>	<p>494.180 Governance</p>	<p>(f) Standard: Involuntary discharge and transfer policies and procedures</p>	<p>The governing body must ensure that all staff follow the facility's patient discharge and transfer policies and procedures. The medical director ensures that no patient is discharged or transferred from the facility unless—</p> <ul style="list-style-type: none"> <li>(1) The patient or payer no longer reimburses the facility for the ordered services;</li> <li>(2) The facility ceases to operate;</li> <li>(3) The transfer is necessary for the patient's welfare because the facility can no longer meet the patient's documented medical needs; or</li> <li>(4) The facility has reassessed the patient and determined that the patient's behavior is disruptive and abusive to the extent that the delivery of care to the patient or the ability of the facility to operate effectively is seriously impaired, in which case the medical director ensures that the patient's interdisciplinary team—             <ul style="list-style-type: none"> <li>(i) Documents the reassessments, ongoing problem(s), and efforts made to resolve the problem(s), and enters this documentation into the patient's medical record;</li> <li>(ii) Provides the patient and the local ESRD Network with a 30-day notice of the planned discharge;</li> <li>(iii) Obtains a written physician's order that must be signed by both the medical director and the patient's attending physician concurring with the patient's discharge or transfer from the facility;</li> <li>(iv) Contacts another facility, attempts to place the patient there, and documents that effort; and (v) Notifies the State survey agency of the involuntary transfer or discharge.</li> </ul> </li> <li>(5) In the case of immediate severe threats to the health and safety of others, the facility may utilize an abbreviated involuntary discharge procedure.</li> </ul>	
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