

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.

(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 non-referral as a transplantation candidate as documented in accordance with § 494.80(a)(10).

(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.

(b) *Standard: Implementation of the patient plan of care*. (1) The patient's plan of care must—

(i) Be completed by the interdisciplinary team, including the patient if the patient desires; and

(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.

(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).

(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—

(i) Adjust the plan of care to reflect the patient's current condition;

(ii) Document in the record the reasons why the patient was unable to achieve the goals; and

(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.

(c) *Standard: Transplantation referral tracking*. 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.

(d) *Standard: Patient education and training*. 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.

§ 494.100 Condition: Care at home.

A dialysis facility that is certified to provide services to home patients must ensure through its interdisciplinary

team, that home dialysis services are at least equivalent to those provided to in-facility patients and meet all applicable conditions of this part.

(a) *Standard: Training.* The interdisciplinary team must oversee training of the home dialysis patient, the designated caregiver, or self-dialysis patient before the initiation of home dialysis or self-dialysis (as defined in § 494.10) and when the home dialysis caregiver or home dialysis modality changes. The training must—

(1) Be provided by a dialysis facility that is approved to provide home dialysis services;

(2) Be conducted by a registered nurse who meets the requirements of § 494.140(b)(2); and

(3) Be conducted for each home dialysis patient and address the specific needs of the patient, in the following areas:

(i) The nature and management of ESRD.

(ii) The full range of techniques associated with the 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 administration of erythropoiesis-stimulating agent(s) (if prescribed) to achieve and maintain a target level hemoglobin or hematocrit as written in patient's plan of care.

(iii) How to detect, report, and manage potential dialysis complications, including water treatment problems.

(iv) Availability of support resources and how to access and use resources.

(v) How to self-monitor health status and record and report health status information.

(vi) How to handle medical and non-medical emergencies.

(vii) Infection control precautions.

(viii) Proper waste storage and disposal procedures.

(b) *Standard: Home dialysis monitoring.* The dialysis facility must—

(1) Document in the medical record that the patient, the caregiver, or both received and demonstrated adequate comprehension of the training;

(2) Retrieve and review complete self-monitoring data and other information from self-care patients or their des-

ignated caregiver(s) at least every 2 months; and

(3) Maintain this information in the patient's medical record.

(c) *Standard: Support services.* (1) A home dialysis facility must furnish (either directly, under agreement, or by arrangement with another ESRD facility) home dialysis support services regardless of whether dialysis supplies are provided by the dialysis facility or a durable medical equipment company. Services include, but are not limited to, the following:

(i) Periodic monitoring of the patient's home adaptation, including visits to the patient's home by facility personnel in accordance with the patient's plan of care.

(ii) Coordination of the home patient's care by a member of the dialysis facility's interdisciplinary team.

(iii) Development and periodic review of the patient's individualized comprehensive plan of care that specifies the services necessary to address the patient's needs and meets the measurable and expected outcomes as specified in § 494.90 of this part.

(iv) Patient consultation with members of the interdisciplinary team, as needed.

(v) Monitoring of the quality of water and dialysate used by home hemodialysis patients including conducting an onsite evaluation and testing of the water and dialysate system in accordance with—

(A) The recommendations specified in the manufacturers' instructions; and

(B) The system's FDA-approved labeling for preconfigured systems designed, tested, and validated to meet AAMI quality (which includes standards for chemical and chlorine/chloramine testing) water and dialysate. The facility must meet testing and other requirements of AAMI RD52:2004. In addition, bacteriological and endotoxin testing must be performed on a quarterly, or more frequent basis as needed, to ensure that the water and dialysate are within the AAMI limits.

(C) The dialysis facility must correct any water and dialysate quality problem for the home hemodialysis patient, and if necessary, arrange for backup dialysis until the problem is corrected if—

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(1) Analysis of the water and dialysate quality indicates contamination; or

(2) The home hemodialysis patient demonstrates clinical symptoms associated with water and dialysate contamination.

(vi) Purchasing, leasing, renting, delivering, installing, repairing and maintaining medically necessary home dialysis supplies and equipment (including supportive equipment) prescribed by the attending physician.

(vii) Identifying a plan and arranging for emergency back-up dialysis services when needed.

(2) The dialysis facility must maintain a recordkeeping system that ensures continuity of care and patient privacy. This includes items and services furnished by durable medical equipment (DME) suppliers referred to in § 414.330(a)(2) of this chapter.

§ 494.110 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.

(a) *Standard: Program scope.* (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:

(i) Adequacy of dialysis.

(ii) Nutritional status.

(iii) Mineral metabolism and renal bone disease.

(iv) Anemia management.

(v) Vascular access.

(vi) Medical injuries and medical errors identification.

(vii) Hemodialyzer reuse program, if the facility reuses hemodialyzers.

(viii) Patient satisfaction and grievances.

(ix) Infection control; with respect to this component the facility must—

(A) Analyze and document the incidence of infection to identify trends and establish baseline information on infection incidence;

(B) Develop recommendations and action plans to minimize infection transmission, promote immunization; and

(C) Take actions to reduce future incidents.

(b) *Standard: Monitoring performance improvement.* The dialysis facility must continuously monitor its performance, take actions that result in performance improvements, and track performance to ensure that improvements are sustained over time.

(c) *Standard: Prioritizing improvement activities.* The dialysis facility must set priorities for performance improvement, considering prevalence and severity of identified problems and giving priority to improvement activities that affect clinical outcomes or patient safety. The facility must immediately correct any identified problems that threaten the health and safety of patients.

§ 494.120 Condition: Special purpose renal dialysis facilities.

A special purpose renal dialysis facility is approved to furnish dialysis on a short-term basis at special locations. Special purpose dialysis facilities are divided into two categories: vacation