



Ohio Administrative Code

Rule 3701-83-23.1 Services standards- freestanding dialysis centers.

Effective: July 1, 2016

(A) Each dialysis center shall:

(1) Develop and follow policies and procedures for the provision of care consistent with national standards of care or guidelines;

(2) Develop and follow protocols for the prevention of disease and infection transmission utilizing standards of care or guidelines for dialysis patients that comply with the regulations for end stage renal disease services contained in 42 C.F.R. 494.30 (October 1, 2009);

(3) Provide services in accordance with the clinical capabilities of the facility;

(4) Develop and follow policies and procedures for the administration of medication;

(5) Develop and follow policies and procedures for the provision of water and dialysate that comply with the regulations for end stage renal disease services contained in 42 C.F.R. 494.40 (October 1, 2009) and are consistent with the association for advancement of medical instrumentation (AAMI) standards, including criteria for the biological and chemical composition of the water;

(6) Develop and follow policies and procedures for the re-use of hemodialyzers that comply with the regulations for end stage renal disease services contained in 42 C.F.R. 494.50 (October 1, 2009) and are consistent with the association for advancement of medical instrumentation (AAMI) standards;

(7) Develop and follow policies and procedures for direct care staff to notify appropriate health care professionals of problems related to the provision of dialysis care;

(8) Develop and follow emergency plans to include patient self disconnect;

(9) Provide each patient with both verbal and written instructions for post treatment care and



procedures for obtaining emergency care; and

(10) Develop and follow policies and procedures for documenting and responding to adverse events. The policies and procedures shall include the course of action to be taken by staff to respond to adverse events, including patient care and evaluation of equipment, water, or dialysate solution. Each dialysis center shall report to the director all adverse events involving the following:

- (a) An event requiring emergency treatment, or hospitalization;
- (b) An involuntary discharge of a patient;
- (c) Contamination of the water or dialysate;
- (d) Development of infection or communicable disease; and
- (e) An event having a direct or immediate impact on the health, safety, or security of a patient or staff member.

(B) Each dialysis center shall utilize a coordinated and integrated interdisciplinary team working in conjunction with the patient, to develop and implement a written, individualized, comprehensive patient care plan. The care plan shall:

- (1) Be based upon an evaluation of the nature of the patient's illness, the treatment modality prescribed, and an assessment of the patient's needs;
- (2) Address the patient's physical, medical, dietary, psychosocial, functional, and rehabilitation needs
- (3) Be reviewed at least semi-annually if the patient is stable and monthly if the patient is not stable.

(C) Each dialysis center shall provide the necessary ancillary and support services to meet the dialysis needs of patients and in accordance with the patients' care plans.

(D) No dialysis center may set up dialysis stations for patient use which exceed the authorized



maximum number of licensed dialysis stations.

(E) No dialysis center shall provide dialysis services for hepatitis B positive patients unless the facility has an in-house isolation room, a designated station or area.

(F) Each dialysis center shall provide the patient or the patient's representative in writing the following:

(1) Information regarding the policies, procedures, and mission statement of the dialysis center and the services provided at the facility;

(2) Information concerning the services to be performed;

(3) Information about the complaint policies and procedures required by rule 3701-83-13 of the Administrative Code; and

(4) Information regarding the center's policy on advanced directives and do-not-resuscitate orders, if applicable.

(G) Each dialysis center shall maintain operational records for:

(1) The dialysate solution delivery system;

(2) The reuse of hemodialyzers and bloodlines;

(3) The reprocessing system;

(4) The water treatment system; and

(5) The water treatment quality.

(H) Each dialysis center shall maintain records of water test results and necessary treatment for two years.



(I) Each dialysis center shall maintain an appropriately stocked emergency tray or cart consistent with the types of services being provided.

(J) Each dialysis center shall ensure that all drugs and supplies have not exceeded the expiration date.

(K) Each dialysis center shall develop and follow procedures to respond to medical emergencies that may arise in the provision of services to patients, including emergency cardiac care.