(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 communication and varied interpersonal skills, including patient sensitivity training and care of difficult patients. The training program must include the following subjects:

(i) Principles of dialysis.
(ii) Care of patients with kidney failure, including interpersonal skills.
(iii) Dialysis procedures and documentation, including initiation, proper cannulation techniques, monitoring, and termination of dialysis.
(iv) Possible complications of dialysis.
(v) Water treatment and dialysate preparation.
(vi) Infection control.
(vii) Safety.
(viii) Dialyzer reprocessing, if applicable.

(4) Be certified under a State certification program or a national commercially available certification program, as follows—

(i) For newly employed patient care technicians, within 18 months of being hired as a dialysis patient care technician; or
(ii) For patient care technicians employed on October 14, 2008, within 18 months after such date.

(f) Standard: Water treatment system technicians. Technicians who perform monitoring and testing of the water treatment system must complete a training program that has been approved by the medical director and the governing body.

§ 494.150 Condition: Responsibilities of the medical director.

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. Medical director responsibilities include, but are not limited to, the following:

(a) Quality assessment and performance improvement program.
(b) Staff education, training, and performance.
(c) Policies and procedures. The medical director must—
(1) Participate in the development, periodic review and approval of a "patient care policies and procedures manual" for the facility; and
(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).

§ 494.160 [Reserved]

§ 494.170 Condition: Medical records.

The dialysis facility must maintain complete, accurate, and accessible records on all patients, including home patients who elect to receive dialysis supplies and equipment from a supplier that is not a provider of ESRD services and all other home dialysis patients whose care is under the supervision of the facility.

(a) Standard: Protection of the patient’s record. The dialysis facility must—

(1) Safeguard patient records against loss, destruction, or unauthorized use; and
(2) Keep confidential all information contained in the patient's record, except when release is authorized pursuant to one of the following:

(i) The transfer of the patient to another facility.
(ii) Certain exceptions provided for in the law.
(iii) Provisions allowed under third party payment contracts.

(iv) Approval by the patient.
(v) Inspection by authorized agents of the Secretary, as required for the administration of the dialysis program.

(3) Obtaining written authorization from the patient or legal representative before releasing information that is not authorized by law.