Centers for Medicare & Medicaid Services, HHS § 494.170

(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 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.

§ 494.160 [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.
§ 494.180  Condition: Governance.

The ESRD facility is under the control of an identifiable governing body, or designated person(s) with full legal authority and responsibility for the governance and operation of the facility. The governing body adopts and enforces rules and regulations relative to its own governance and to the health care and safety of patients, to the protection of the patients’ personal and property rights, and to the general operation of the facility.

(a) Standard: Designating a chief executive officer or administrator. The governing body or designated person responsible must appoint an individual who serves as the dialysis facility’s chief executive officer or administrator who exercises responsibility for the management of the facility and the provision of all dialysis services, including, but not limited to—

(1) Staff appointments;
(2) Fiscal operations;
(3) The relationship with the ESRD networks; and
(4) Allocation of necessary staff and other resources for the facility’s quality assessment and performance improvement program as described in §494.110.

(b) Standard: Adequate number of qualified and trained staff. 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;
(2) A registered nurse, who is responsible for the nursing care provided, is present in the facility at all times that in-center dialysis patients are being treated;
(3) All staff, including the medical director, have appropriate orientation to the facility and their work responsibilities; and
(4) All employees have an opportunity for continuing education and related development activities.

(c) Standard: Medical staff appointments. The governing body—

(1) Is responsible for all medical staff appointments and credentialing in accordance with State law, including attending physicians, physician assistants, nurse practitioners, and clinical nurse specialists; and
(2) Ensures that all medical staff who provide care in the facility are informed of all facility policies and procedures, including the facility’s quality assessment and performance improvement program specified in §494.110.

(3) Communicates expectations to the medical staff regarding staff participation in improving the quality of medical care provided to facility patients.

(d) Standard: Furnishing services. The governing body is responsible for ensuring that the dialysis facility furnishes services directly on its main premises or on other premises that are contiguous with the main premises and are under the direction of the same