This proposal repeals the existing rules in Texas Administrative Code (TAC) [Title 25, Chapter 117, End Stage Renal Disease Facilities](https://texreg.sos.state.tx.us/public/readtac%24ext.ViewTAC?tac_view=4&ti=25&pt=1&ch=117), and replaces them with new rules in 26 TAC, Chapter 507, End Stage Renal Disease Facilities. The proposal updates the end stage renal disease facility rules to:

* ensure patient safety;
* incorporate guidelines on new treatment modalities and technologies;
* communicate important Texas Health and Human Services Commission organizational changes;
* make necessary changes to inspection, investigation, and enforcement procedures; and
* reflect current industry standards and terminology.

TITLE 26 HEALTH AND HUMAN SERVICES

PART 1 HEALTH AND HUMAN SERVICES COMMISSION

CHAPTER 507 END STAGE RENAL DISEASE FACILITIES

SUBCHAPTER A GENERAL PROVISIONS

§507.1. Purpose.

(a) The purpose of this chapter is to implement Texas Health and Safety Code, Chapter 251, which requires an end stage renal disease facility providing routine, repetitive, outpatient dialysis to be licensed by the Texas Health and Human Services Commission.

(b) This chapter provides minimum standards for the equipment used by the facility; water treatment and reuse; sanitary and hygienic conditions; quality assessment and performance improvement; indicators of quality of care; provision and coordination of treatment and services; qualifications and supervision of the professional staff, including physicians and other personnel; clinical records; curricula, and instructors used to train dialysis technicians; the competency evaluation of dialysis technicians; and enforcement standards.

(c) Compliance with this chapter does not constitute release from the requirements of other applicable federal, state, or local laws, codes, standards, rules, regulations, and ordinances. The more stringent standard, code, or requirement shall apply when a difference in requirements exists.

§507.2. Definitions.

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

 (1) Action level--The point at which steps shall be taken to interrupt the trend towards unacceptable levels.

 (2) Administrator--A person who is delegated the responsibility for the implementation and proper application of policies, programs, and services established for the end stage renal disease facility.

 (3) Advanced practice registered nurse (APRN)--A registered nurse who is currently licensed and authorized to practice by the Texas Board of Nursing.

 (4) Adverse event--An event that results in unintended harm to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient or those events affecting patient's family members, visitors, or staff.

 (5) Applicant--The person legally responsible for the operation of the facility, whether by lease or ownership, who seeks a license from HHSC.

 (6) Biofilm--A coating on surfaces consisting of microcolonies of bacteria embedded in a protective extracellular matrix. The matrix, a slimy material secreted by the cells, protects the bacteria from antibiotics and disinfectants.

 (87) Business day--Any day between and including Monday through Friday and does not include public holidays and weekends.

 (7) Calendar day--All days in a month, including weekends and holidays.

 (8) Caregiver--A person trained, qualified, and competent in the use of a device for the selected modality prescribed by the physician.

 (9) Change of ownership--A change to the legal entity on record, which also results in a change to the Employee Identification Number (EIN) of the legal entity.

 (10) Charge nurse--A registered nurse practicing nursing in accordance with applicable provisions of law who is responsible for making daily staff assignments based on patient needs, providing immediate supervision and support of patient care, monitoring patients for changes in condition, and communicating with the physician, dietician, and social worker regarding patient needs.

 (11) Closed system--A dialysis system, hemodialysis or peritoneal dialysis, that uses sterile manufactured bagged dialysate, or dialysate solution.

 (12) CMS--Centers for Medicare and Medicaid Services.

 (13) Commissioner--The commissioner of the Texas Health and Human Services Commission.

 (14) Competency--The demonstrated ability to carry out specified tasks or activities with reasonable skill and safety that adheres to the prevailing standard of practice.

 (15) Conditions for Coverage (CfCs)--The minimum health and safety rules that all Medicare and Medicaid participating dialysis facilities shall meet. The basic health and safety requirements that an ESRD supplier of services must meet to receive payment from the Medicare program.

 (16) Conventional dialysis system--The facility's water treatment components and single pass dialysis machines.

 (17) Core staff members--The facility's medical director, supervising nurse, dietitian, social worker, administrator, and approved biomedical representative.

 (18) Corrective action plan--An alternative to enforcement action as outlined in Texas Health and Safety Code §251.061 (Corrective Action Plan).

 (19) Delegation--The transfer of the authority to perform a selected task or activity in a selected situation to a qualified and properly trained individual.

 (20) Dialysate--An aqueous fluid containing electrolytes and usually dextrose, which is intended to exchange solutes with blood during hemodialysis. The word "dialysate" is used throughout this document to mean the fluid made from water and concentrate that is delivered to the dialyzer by the dialysate supply system. Such phrases as "dialyzing fluid" or "dialysis solution" may be used in place of dialysate. The term “dialysate” does not include peritoneal dialysis fluid.

 (21) Dialysate supply system--Devices that prepare dialysate on line from water and concentrates, or store and distribute premixed dialysate; circulate the dialysate through the dialyzer; monitor the dialysate for temperature, conductivity, pressure, flow, and blood leaks; and prevent dialysis during disinfection or cleaning modes. The term includes reservoirs; conduits; proportioning devices for the dialysate; and monitors, associated alarms, and controls assembled as a system for the characteristics listed above. The dialysate supply system is often an integral part of single-patient dialysis machines.

 (22) Dialysis--A process by which dissolved substances are removed from a patient's body by diffusion, osmosis, and convection (ultrafiltration) from one fluid compartment to another across a semipermeable membrane.

 (23) Dialysis technician--An individual who is not a registered nurse or physician and who provides dialysis care under the supervision of a registered nurse or physician. This individual may also be known as a Patient Care Technician (PCT) or Certified Clinical Hemodialysis Technician (CCHT).

 (24) Dietitian--A person who is currently licensed under the laws of this state to use the title of licensed dietitian, is a registered dietitian, and has one year of experience in clinical dietetics after becoming a registered dietitian.

 (25) Direct care staff--Staff who provide hands-on dialysis care to specifically assigned patients during their dialysis treatment (e.g., registered nurse, licensed vocational nurse, patient care technician). These staff members fulfill the patient to staff ratio requirement. This does not include the Charge Nurse, as demonstrated in Figure: 26 TAC §507.106.

 (26) Education--The presentation and teaching of informative materials to persons, including patients of the licensed ESRD facility, regarding treatment modalities, options, and overall health literacy. Education may be conducted individually or in a group setting.

 (27) Empty bed contact time (EBCT)--A measure of how much contact occurs between particles, such as activated carbon, and water as the water flows through a bed of the particles. EBCT = (7.48 x V)/Q where V is the volume of particles in the bed (feet), Q is the flow rate of the water through the bed (gallon/minute), and 7.48 is the conversion factor for gallons to feet.

 (28) End stage renal disease (ESRD)--The stage of renal impairment or acute kidney injury that appears irreversible and permanent and that requires a regular course of dialysis or kidney transplantation to maintain life (also known as chronic kidney disease stage V).

 (29) End stage renal disease facility--A facility that provides dialysis treatment or dialysis training and support to individuals with end stage renal disease.

 (30) Endotoxin--Lipopolysaccharides consisting of a polysaccharide chain covalently bound to lipid A and the major component of the outer cell wall of gram-negative bacteria.

 (31) Endotoxin-retentive filter--Membrane filter specifically proven to remove bacteria and endotoxins.

 (32) EOC--Emergency Operations Center in local jurisdictions.

 (33) Facility--A contiguous, identifiable location. The location shall be either a freestanding building or in one distinct contiguous space of a multi-tenant building.

 (34) Full-time--The time period established by a facility as a full working week, as defined and specified in the facility's policies and procedures.

 (35) Full-time equivalent--Work time equivalent to 2,080 hours per 12 consecutive months.

 (36) Governing body--The governing authority of a licensed ESRD that is responsible for organization, management, control, operation, and appointment of medical staff. The governing authority includes the medical director and representatives of the ESRD’s owner, with full legal authority and responsibility for the governance and operation of the facility. The governing body has the overall legal responsibility for the operation of a health care facility.

 (37) Health care facility--Any type of facility or home and community support services agency licensed to provide health care in any state or certified for Medicare (Title XVIII) or Medicaid (Title XIX) participation in any state.

 (38) HHSC--The Texas Health and Human Services Commission.

 (39) Home dialysis service--Dialysis performed at home by an end stage renal disease patient or caregiver who has completed an appropriate course of training, as described in §507.45(j) of this chapter (relating to Provision and Coordination of Treatment and Services).

 (40) Hospital--A facility that is licensed under Texas Health and Safety Code, Chapter 241, or if exempt from licensure, certified by the United States Department of Health and Human Services as in compliance with conditions of participation for hospitals in Title XVIII, Social Security Act (42 United States Code, §1395 et seq.).

 (41) Incident--Death of a dialysis patient, which occurs in the facility, at home, or in a hospital; hospital transfers; conversion of staff or a patient to hepatitis B surface antigen (HbsAg) positive; involuntary transfer or discharge of a patient; and a fire in the ESRD facility.

 (42) In-center dialysis--Dialysis provided within the facility’s licensed patient care area.

 (43) Inspection--A survey conducted by a representative of HHSC to determine if an applicant or licensee is in compliance with this chapter.

 (44) Integrated hemodialysis system--A preconfigured hemodialysis system, as designated by the Federal Drug Administration (FDA), is one in which dialysis-quality water and concentrate is prepared and used at the patient’s station in the approved and licensed dialysis unit. In licensed facilities that use this modality of delivery of dialysis services, the conventional water distribution system may not be necessary, as each unit contains its own water purification system, produces dialysate, and makes individualized appropriate adjustments as needed.

 (45) Interdisciplinary team (IDT)--A group composed of the primary dialysis physician, the registered nurse, the dietitian, and the social worker who are responsible for planning care for the patient.

 (46) Intermediate-level disinfection--A surface treatment using chemical germicides or disinfectants which are capable of inactivating various classes of microorganisms including viruses (primarily medium to large viruses and lipid-containing viruses), fungi, and actively growing bacteria (including tubercle bacteria) when such chemical germicides or disinfectants are used in accordance with the manufacturer's directions for use or per established guidelines. Intermediate-level disinfection is generally not effective in inactivating or eliminating bacterial endospores. Examples of intermediate-level disinfectants include bleach, 70 - 90 percent ethanol or isopropanol, and certain phenolic or iodophor preparations.

 (47) Licensed nurse--A registered nurse or licensed vocational nurse.

 (48) Licensed vocational nurse (LVN)--A person who is currently licensed under the Nursing Practice Act by the Texas Board of Nursing as a licensed vocational nurse, or who holds a valid vocational nursing license with multi-state licensure privilege from another compact state, and who may provide dialysis treatment after meeting the competency requirements specified for dialysis technicians.

 (49) Medical director--A physician who:

 (A) is board certified in internal medicine, by the American Board of Internal Medicine, or pediatrics, by the American Board of Pediatrics, has completed a board-approved training program in nephrology, and has at least 12 months of experience providing care to patients receiving dialysis; or

 (B) is board certified in nephrology or pediatric nephrology and has at least 12 months of experience providing care to patients receiving dialysis.

 (50) Medical review board--A medical review board that is appointed by a renal disease network organization, which includes this state, with the network having a contract with the Centers for Medicare and Medicaid Services of the United States Department of Health and Human Services, under 42 United States Code §1395rr.

 (51) Modality--Different treatment options and settings for patients with end stage renal disease, for example, in-center hemodialysis, home hemodialysis, home peritoneal dialysis, self-care dialysis, nocturnal dialysis, and transplantation.

 (52) Owner--Legal entity who holds or will hold a license issued under Texas Health and Safety Code, Chapter 251.

 (53) Patient--An individual receiving dialysis treatment or training from an end stage renal disease facility.

 (54) Patient plan of care--Documentation of the interactive process whereby the interdisciplinary team and the patient and family members or guardian develop and implement a plan, based on the assessments performed by the interdisciplinary team members, to assist the end stage renal disease patient in managing the disease and its complications.

 (55) Pediatric patient--An individual from birth and continuing through 18 years of age.

 (56) Person--An individual, corporation, or other legal entity.

 (57) Physician--A physician licensed by the Texas Medical Board who meets the requirements set forth in the CMS Conditions for Coverage.

 (58) Physician assistant--A person licensed as a physician assistant by the Texas Medical Board.

 (59) Physician extender--A health care provider (advanced practice registered nurse or physician assistant) who is not a physician but who performs medical activities typically performed by a physician, as outlined in §507.45(i)(3) of this chapter (relating to Provision and Coordination of Treatment and Services).

 (60) Plan of Correction (POC)--A written plan developed by the facility that lists specific actions to be taken to correct specific deficiencies of state licensing regulations.

 (61) Prelicensure conference--A conference held with HHSC staff and the administrator or licensed professional who is listed on the license application to review licensure standards and inspection documents and provide consultation prior to the issuance of the license. The prelicensure conference is not equal to or a substitution for the physical plant feasibility conference.

 (62) Product water--Water produced by a water treatment system or by an individual component of a system.

 (63) Progress note--A record of an event dated and signed by facility staff, which summarizes facts about the patient's care and the patient's response during a given time period. Progress notes may be maintained electronically and shall be provided to HHSC within the timeframe requested by HHSC.

 (64) Pyrogen--A fever producing substance. Pyrogens are most often lipopolysaccharides of gram-negative bacterial origin.

 (65) Quality assessment and performance improvement (QAPI)--An ongoing program that measures, analyzes, and tracks quality indicators related to improve health outcomes. The program implements improvement plans and evaluates the implementation until resolution is achieved.

 (66) Registered nurse (RN)--A person who is currently licensed by the Texas Board of Nursing as a registered nurse, or who holds a valid registered nursing license with multi-state licensure privilege from another compact state.

 (67) Second-chance patient--A patient who has voluntarily or involuntarily discharged from a facility or is pending involuntary discharge due to behavioral or compliance issues, who the ESRD Network has chosen to participate in the second chance program set forth by the ESRD Network and agrees to receive treatment at another licensed ESRD facility. The patient will have specific behavioral and or compliance expectations that shall be achieved and maintained to successfully participate in the second chance program and remain a patient at the accepting facility.

 (68) Self-care services/transitional care--A service where patients participate in their self-care, which is supervised by a qualified Registered Nurse as approved and delegated by the Medical Director.

 (69) Self-care patients--In-center patients who perform all or part of their dialysis treatments. Patients may perform a variety of tasks associated with in-center hemodialysis if they are comfortable and have been deemed competent to perform the tasks using a checklist with a goal of total self-care and limited supervision and support. At a minimum, a self-care patient should demonstrate the ability to set up and tear down the machinery used in the patient’s treatment, be able to hold their own site at termination of treatment and be able to take and record their own vital signs prior to initiation of the day's treatment and at its termination.

 (70) Single patient device--An alternate method of providing hemodialysis, as designated by the FDA and prescribed to a patient for their individual use, during their need for dialysis. Single patient devices, once the designated patient no longer needs the device, can be processed, disinfected, and prepared for another designated patient’s use, per manufacturer’s directions for use.

 (71) Social worker--A person who:

 (A) is currently licensed as a social worker under Texas Occupations Code, Chapter 505, and holds a master's degree from a graduate school of social work accredited by the Council on Social Work Education; or

 (B) has worked for at least two years as a social worker, one year of which was in a dialysis facility or transplantation program prior to September1, 1976, and has established a consultative relationship with a social worker who has a master's degree from a graduate school of social work accredited by the Council on Social Work Education.

 (72) Sorbent regeneration system--A system that regenerates dialysate by passing the dialysate through substances that restore the dialysate to a condition comparable to fresh dialysate.

 (73) Station--An area in the facility in which a patient receives in-center hemodialysis treatment, or dialysis instruction, such as home hemodialysis training or home peritoneal dialysis training.

 (74) Statute--Texas Health and Safety Code, Chapter 251.

 (75) Supervising nurse (Director of Nursing)--A registered nurse who:

 (A) has at least 18 months experience as an RN, which includes at least 12 months experience in dialysis that has been obtained within the last 24 months; or

 (B) has at least 18 months experience as an RN and holds a current certification from a nationally recognized board in nephrology nursing or hemodialysis.

 (76) Supervision--Authoritative procedural guidance by a qualified person for the accomplishment of a function or activity with initial direction and periodic inspection of the actual act of accomplishing the function or activity.

 (a) Immediate supervision--The supervisor is observing the task or activity as it is performed.

 (b) Direct supervision--The supervisor is on the premises but not necessarily immediately physically present where the task or activity is being performed.

 (c) Indirect supervision-- The supervisor is not on the premises but is accessible by two-way communication, able to respond to an inquiry when made, and readily available for consultation.

 (77) TAC--Texas Administrative Code.

 (78) Technical supervisor--The supervisor of the facility's mechanical, reuse, and water treatment systems.

 (79) Training (Patient)--The process of developing, practicing and maintaining specific skills with an individual patient regarding the patient's treatment modality, including self-care, home hemodialysis, peritoneal dialysis, and other modalities.

 (80) Training (Staff)--The learning of tasks through on-the-job experience or instruction by an individual who has the capacity through education or experience to perform the task or activity to be delegated.

 (81) Ultrafilter--A membrane filter with a pore size in the range 0.001 to 0.05 micron (µm). Performance is usually rated in terms of a nominal molecular weight cut off (MWCO), which is defined as the smallest molecular weight species for which the filter membrane has more than 90 percent rejection. Ultrafilters with a nominal MWCO of 20,000 or less are generally adequate for endotoxin removal.

 (82) Water distribution systems--Components may include any storage tanks and piping used to distribute the product water from the purification cascade to or from its point of use, including individual hemodialysis machines, dialyzer reprocessing equipment, and dialysate concentrate preparation systems.

 (83) Water treatment system--A collection of water purification devices and associated piping, pumps, valves, gauges, and other related components that together produce purified water for hemodialysis applications and deliver it to the point of use.

TITLE 26 HEALTH AND HUMAN SERVICES

PART 1 HEALTH AND HUMAN SERVICES COMMISSION

CHAPTER 507 END STAGE RENAL DISEASE FACILITIES

SUBCHAPTER B LICENSING REQUIREMENTS

§507.11. General Requirements for a License.

All providers who provide dialysis services, regardless of affiliation or modality, shall be licensed. Patients receiving home dialysis services shall be under the purview of a licensed end stage renal disease (ESRD) facility.

(a) A facility shall obtain a license prior to admitting patients.

(b) A facility shall prominently and conspicuously display the license in a public area of the licensed premises that is readily visible to patients, employees, and visitors.

(c) A facility license shall not be altered.

(d) A facility license shall not be transferred or assigned. The facility shall comply with the provisions of §507.12(a) of this chapter (relating to Application and Issuance of Initial License) in the event of a change in the ownership.

(e) The following facilities are not required to be licensed under this chapter:

 (1) a home and community support services agency licensed under Texas Health and Safety Code, Chapter 142, with a home dialysis designation;

 (2) a hospital licensed under Texas Health and Safety Code, Chapter 241, that provides dialysis only to individuals receiving:

 (A) inpatient services from the hospital; or

 (B) outpatient services due to a disaster declared by the governor or a federal disaster declared by the president of the United States occurring in this state or another state during the term of the disaster declaration;

 (3) a hospital operated by, or on behalf of, the state as part of the managed health care provider network established under Texas Government Code Chapter 501 that provides dialysis only to individuals receiving:

 (A) inpatient services from the hospital; or

 (B) outpatient services while serving a term of confinement in a facility operated by, or under contract with, the Texas Department of Criminal Justice;

 (4) an end stage renal disease facility operated by, or on behalf of, the state as part of the managed health care provider network established under Texas Government Code Chapter 501 that provides dialysis only to individuals receiving those services while serving a term of confinement in a facility operated by, or under contract with, the Texas Department of Criminal Justice; or

 (5) the office of a physician, unless the office is used primarily as an end stage renal disease facility.

§507.12. Application and Issuance of Initial License.

(a) The applicant shall comply with the following before the projected opening date of the facility:

 (1) the applicant shall submit an accurate and complete application form;

 (2) the applicant shall submit the appropriate license fee, as required in §507.16 of this chapter (relating to Fees); and

 (3) the applicant for a new or existing facility that is increasing the number of in-center dialysis treatment stations shall have an isolation room, as specified in the current Centers for Medicare and Medicaid Services conditions of coverage or shall provide a waiver. The waiver shall demonstrate there is sufficient capacity in the geographic area for isolation rooms for hepatitis B positive patients. An applicant may submit a written request for a waiver through the Texas Health and Human Services Commission (HHSC) Health Facility Licensing Unit, for transmission to the Centers for Medicare and Medicaid Services (CMS).

(b) Prelicensure conference.

 (1) The applicant shall complete a prelicensure conference as requested by HHSC to review facility staff qualifications, inspection documents, and licensure rules, and to receive consultation prior to the on-site licensure inspection.

 (2) HHSC may waive the prelicensure conference requirement at their discretion.

 (3) The prelicensure conference shall be repeated if there is a change in the supervising nurse prior to opening of the facility.

 (4) HHSC shall make a recommendation regarding the issuance of the initial license.

(c) The applicant shall submit a copy of a fire safety inspection that meets the following criteria:

 (1) indicates approval by the local fire authority having jurisdiction where the facility is based, and

 (2) is dated no earlier than one year prior to the facility opening date.

(d) In addition to the document submission in subsection (a) of this section, the facility shall meet the requirements set forth in Subchapter H of this chapter (relating to Physical Plant and Construction Requirements) prior to the issuance of an ESRD facility license for a newly constructed ESRD facility or an ESRD facility converted from a non-ESRD building.

(e) The facility shall submit a complete chemical analysis of the product water and reports to verify that bacteriological and endotoxin levels of product water and dialysate are compliant with §507.32 of this chapter (relating to Water Treatment, Dialysate Concentrates, and Reuse). The reports shall be kept on file at the facility and made available to Commission staff during an on-site inspection or when requested by HHSC.

(f) When HHSC determines the facility has complied with subsections (a) - (d) of this section, HHSC shall issue the license to the applicant.

 (1) Effective date. The license shall be effective on the date the facility is determined to be compliant with subsections (a) - (d) of this section.

 (2) Expiration date. The license expires on the last day of the 24th month after issuance.

(g) If an applicant decides not to continue the application process for a license or renewal of a license, the application may be withdrawn.

(h) Denial of a license shall be governed by §507.88 of this chapter (relating to Disciplinary Action).

(i) During the initial licensing period, HHSC shall conduct an inspection of the facility to ascertain compliance with the provisions of Texas Health and Safety Code, Chapter 251, and this chapter.

 (1) After the facility admits and provides services to at least one patient, the facility shall request HHSC to conduct an on-site inspection, which will occur while patients are in the facility being dialyzed.

 (2) At the time of inspection, the facility shall provide services to at least one patient in each modality requested. HHSC may interview patients at the time of the inspection, either in the patient's home or at the facility. Peritoneal and home hemodialysis patients trained or retrained at the facility may be interviewed as part of the inspection.

§507.13. Application and Issuance of Renewal License.

(a) The Texas Health and Human Services Commission (HHSC) may send a renewal notice to a facility up to 90 calendar days prior to the expiration date of a license.

 (1) If the facility has not received the renewal notice from HHSC at least 45 calendar days before the expiration date, the facility shall notify HHSC and request a renewal application for a license.

 (2) If the facility fails to submit the application and fee at least 15 calendar days before the expiration date of the license, HHSC may send a letter to the facility advising that, unless the license is renewed, the facility shall cease operations upon the expiration date of the license.

(b) HHSC shall issue a license renewal to a facility that meets the minimum requirements for a license.

 (1) The facility shall submit the following to HHSC prior to the expiration date of the license:

 (A) a complete and accurate application form;

 (B) a copy of a current fire safety inspection that indicates approval by the local fire authority having jurisdiction where the facility is based. The facility fire safety inspection shall be conducted annually, and an approved facility fire safety inspection shall be submitted; and

 (C) the renewal license fee.

 (2) HHSC may conduct an inspection prior to issuing a renewal license in accordance with §507.81 of this chapter (relating to Inspections).

 (3) Renewal licenses shall be valid for 24 months.

(c) If a facility fails to submit the application, documents, and fee by the expiration date of the license, HHSC shall notify the facility that it shall cease operations and immediately return the license to HHSC.

 (1) If the facility wishes to provide services after the expiration date of the license, it shall apply for a license under §507.12 of this chapter (relating to Application and Issuance of Initial License). A facility shall not provide services until the license has been issued.

§507.14. Change in Status.

(a) A change of ownership occurs when there is a change in the person legally responsible for the operation of the facility, whether by lease or by ownership. If a corporate licensee amends its articles of incorporation to revise its name, this subsection does not apply, except that the corporation shall notify the Texas Health and Human Services Commission (HHSC) not later than the 10th calendar day after the effective date of the name change. The sale of stock of a corporate licensee does not cause this subsection to apply.

 (1) The new owner shall submit an application for an initial license to HHSC prior to the date of the change of ownership or not later than 10 calendar days following the date of the change of ownership. The application shall comply subsections (a) and (b) of this section. The applicant shall include the effective date of the change of ownership in the application. The new owner shall be responsible for previous regulatory violations and shall ensure compliance with all rules and regulations.

 (2) The inspection required by subsection (h) of this section may be waived by HHSC.

 (3) When the new owner has complied with the provisions of subsections (a) and (b) of this section, HHSC shall issue a license, which shall be effective the date of the change of ownership.

 (4) The expiration date of the license shall be in accordance with §507.12(f)(2).

 (5) The previous owner's license shall be void on the effective date of the new owner's license, and the voided license shall be returned to HHSC as outlined in (c) of this section.

(b) A facility planning to relocate shall notify HHSC at least 90 days before the planned relocation. Relocations shall be within the same geographical area, and the facility shall continue to provide services to the facility's existing patient population.

 (1) The facility shall submit an application for an initial license to HHSC prior to the date of the relocation. The application shall be in accordance with subsections (a) - (d) of this section.

 (2) The inspection required by subsection (h) of this section may be waived by HHSC.

 (3) The license shall be effective on the date the facility is determined to be compliant with subsections (a) - (d) of this section.

 (4) The expiration date of the license shall be in accordance with §507.12(f)(2).

 (5) The previous facility license shall be void once the relocation is effective and after all services have ceased at the previous location, and the voided license must be returned to HHSC as outlined in (c) of this section.

(c) Changes which affect the license.

 (1) A facility shall notify HHSC in writing at least 90 days before the occurrence of any of the following:

 (A) any construction; additions; alterations; renovations; remodeling; equipment and finish upgrades; removal of a function; conversion of a licensed or previously licensed facility to a different licensed designation; demolition; submission of an initial license application; relocation; change of services; or retrofitting a function, such as changing of end stage renal disease (ESRD) treatment and training station designations or change of an invasive procedural service.

 (2) A facility must notify HHSC in writing prior to, or not later than, 10 calendar days following the occurrence of any of the following:

 (A) a change in the facility name, mailing address, telephone number, or fax number;

 (B) a change of administrator; or

 (C) the facility ceasing operation.

 (3) A facility shall obtain written approval from HHSC prior to the using added, modified, or upgraded services or an increased number of stations. The written request shall be submitted to Health Facility Licensing 90 days prior to the planned change and shall comply with the provisions set forth in Subchapter H of this chapter (relating to Physical Plant and Construction Requirements).

 (A) For an additional service or increase in stations, HHSC may request the facility to provide evidence of appropriate staffing and policies and procedures which demonstrate the intent to comply with applicable requirements. HHSC may also request any other documentation it determines is necessary to evaluate the request.

 (B) For an increase in stations, the facility shall also be required to submit written evidence that the water treatment system is of sufficient size to accommodate the increase and maintain a safe water supply.

 (C) HHSC may conduct an on-site inspection prior to taking action on the requested changes.

 (D) The facility shall submit a complete chemical analysis of the product water and reports to verify that bacteriological and endotoxin levels of product water and dialysate are compliant with §507.32 of this chapter (relating to Water Treatment, Dialysate Concentrates, and Reuse). The reports shall be kept on file at the facility and made available to HHSC staff during the next on-site inspection, or at any time upon request.

 (E) HHSC shall send the facility written notice of HHSC’s approval or disapproval of the requested change.

 (F) All existing facilities increasing the number of in-center dialysis treatment stations shall have an isolation room, as specified in the current Centers for Medicare and Medicaid Services (CMS) conditions of coverage, or shall provide a waiver.

 (i) The waiver shall demonstrate there is sufficient capacity in the geographic area for isolation rooms for hepatitis B positive patients.

 (ii) An applicant may submit a written request for waiver through the HHSC Health Facility Licensure unit for transmission to CMS. See Subchapter H of this chapter (relating to Physical Plant and Construction Requirements) for additional guidance.

(d) The facility shall submit a complete chemical analysis of the product water and reports to verify that bacteriological and endotoxin levels of product water and dialysate are compliant with §507.32 of this chapter (relating to Water Treatment, Dialysate Concentrates, and Reuse). The reports shall be kept on file at the facility and made available to HHSC staff during an on-site inspection or when requested by HHSC.

(e) When HHSC determines the facility has complied with subsections (a) - (d) of this section, HHSC shall issue a revised license to the applicant, if applicable.

(f) If an applicant decides not to continue the application process for a license, the application may be withdrawn.

(g) Denial of a license shall be governed by §507.88 of this chapter (relating to Disciplinary Action).

(h) During the initial licensing period, HHSC may conduct an inspection of the facility to ascertain compliance with the provisions of Texas Health and Safety Code, Chapter 251, and this chapter.

 (1) After the facility admits and provides services to at least one patient, the facility shall request HHSC to conduct an on-site inspection, which will occur while patients are in the facility being dialyzed.

 (2) At the time of inspection, the facility shall provide services to at least one patient in each modality requested. HHSC may interview patients at the time of the inspection, either in the patient's home or at the facility. Peritoneal and home hemodialysis patients trained or retrained at the facility may be interviewed as part of the inspection.

§507.15. Inactive Status and Closure.

(a) A facility that does not provide services under its license for more than five calendar days shall inform HHSC, and HHSC will change the status of the facility license to inactive.

 (1) To be eligible for inactive status, a facility must be in good standing with no pending legal action or investigation.

 (2) The licensee shall be responsible for any license renewal requirements or fees, and for proper maintenance of patient records, while the license is inactive.

 (3) A license may not remain inactive for more than 60 calendar days.

 (4) To reactivate the license, the facility must inform HHSC no later than the 60th day after the facility stopped providing services under its license.

 (5) If the facility does not reactivate its license by the 60th day after the facility stopped providing services, HHSC will consider the license to be surrendered and the facility closed.

(b) The facility shall notify the HHSC Health Facility Licensing unit in writing prior to, or immediately upon, closure of an ESRD facility.

 (1) A license becomes invalid when a facility closes. The facility shall return the licensure certificate to the HHSC Health Facility Licensing Unit not later than the 30th day after the date the facility closes.

 (2) When a facility closes, the provider shall ensure that all clients are appropriately discharged or transferred before the facility closes and make appropriate arrangements for properly maintaining client records in compliance with Federal and State law as well as Commission rules.

§507.16. Fees.

(a) General.

 (1) All fees paid to HHSC are nonrefundable.

 (2) All fees shall be paid to HHSC.

(b) License fees.

 (1) The fees for both initial and renewal licenses are:

 (A) $3,500 for facilities licensed for 1 to 10 dialysis stations;

 (B) $4,300 for facilities licensed for 11 to 20 dialysis stations;

 (C) $5,100 for facilities licensed for 21 to 30 dialysis stations;

 (D) $5,900 for facilities licensed for 31 to 40 dialysis stations; and

 (E) $6,700 for facilities licensed for 41 dialysis stations or more.

 (2) All licenses are valid for 24 months.

(c) For all applications and renewal applications, HHSC is authorized to collect subscription and convenience fees, in amounts determined by the Texas Online Authority, to recover costs associated with application and renewal application processing through Texas Online, in accordance with Texas Government Code §2054.111.

§507.17. Time Periods for Processing and Issuing a License.

(a) General.

 (1) The date a license application is received is the date the application reaches the Texas Health and Human Services Commission (HHSC).

 (2) An application for an initial license is deemed complete when HHSC has received, reviewed, and found acceptable the information described in §507.12 of this chapter (relating to Application and Issuance of Initial License).

 (3) An application for a renewal license is deemed complete when HHSC has received, reviewed, and found acceptable the information described in §507.13 of this chapter (relating to Application and Issuance of Renewal License).

(b) An application from a facility for an initial license or a renewal license shall be processed in accordance with the following time periods.

 (1) The first-time period is 45 calendar days and begins on the date HHSC receives the application and ends on the date HHSC issues the license.

 (A) If the application is received incomplete, the first-time period ends on the date HHSC issues a written notice to the applicant that the application is incomplete.

 (B) The written notice shall describe the specific information required before HHSC will consider the application complete.

 (2) The second-time period is 45 calendar days and begins on the date HHSC receives the last item necessary to complete the application and ends on the date HHSC issues the license.

(c) Reimbursement of fees.

 (1) In the event HHSC does not process the application in the time periods stated in subsection (b) of this section, the applicant has the right to request HHSC to reimburse, in full, the fee paid in that application process. If HHSC does not agree that the established periods have been violated, or finds good cause existed for exceeding the established periods, HHSC shall deny the request for reimbursement.

 (2) HHSC shall consider good cause for exceeding the period established to exist if:

 (A) the number of applications for licenses to be processed exceeds by 15 percent, or more, the number processed in the same calendar quarter the preceding year;

 (B) another public or private entity used in the application process caused the delay; or

 (C) other conditions existed providing good cause for HHSC exceeding the established periods.

(d) If the request for reimbursement as authorized by subsection (c) of this section is denied, the applicant may then appeal to the commissioner for a resolution of the dispute. The applicant shall give written notice to the commissioner requesting reimbursement of the fee paid because the application was not processed within the established time period. HHSC shall submit a written report of the facts related to the processing of the application and good cause for exceeding the established time periods. The commissioner shall make the final decision and provide written notification of the decision to the applicant and HHSC.

§507.18. Exceptions to These Rules.

(a) All end stage renal disease (ESRD) facilities are required to maintain continuous compliance with the rules in this chapter. The rules do not prohibit the request for temporary exceptions. Temporary exceptions may be related to alternative concepts, methods, procedures, techniques, Food and Drug Administration (FDA) approved equipment, and the operation of a facility during an emergency disaster situation. Requests for temporary exceptions to these rules shall:

 (1) be submitted to HHSC in writing;

 (2) identify the specific rule for which an exception is requested;

 (3) describe in detail the specific circumstances which are believed by facility administration to justify the exception;

 (4) describe in detail what alternatives were considered, if any, and why the facility did not select any of the identified alternatives (including compliance with the rule);

 (5) demonstrate that the proposed exception is desirable to maintain or improve the health and safety of the patients, will not jeopardize patient health and safety, and will maintain patient access to care;

 (6) describe the proposed duration of the exception; and

 (7) during emergency disaster situations, shall be submitted to the HHSC Health Facility Compliance Unit. Requests for exceptions during emergency disaster situations shall meet the following criteria:

 (A) HHSC may only grant an exception in an emergency for a maximum of 120 days, with a single renewal period for an additional 120 days;

 (B) the facility shall develop an action plan to resolve any staffing crisis;

 (C) the facility shall submit the action plan to HHSC not later than the 60th calendar day after HHSC grants the exception;

 (D) during the period of exception to staffing requirements, the facility shall monitor outcome data related to quality of care and report these outcomes monthly to HHSC; and

 (E) the facility may request an exemption from clinical records for evacuees, except that the facility shall assess and document the hepatitis and tuberculosis status of the affected patients.

 (F) The following items shall be obtained at a minimum:

 (i) the patient's name, address, date of birth, and payor information, if available; and

 (ii) the name, address, and telephone number of the patient's usual dialysis facility.

(b) Requests for exceptions to the rules shall be submitted to the HHSC Health Facility Licensing Unit.

(c) HHSC may conduct an inspection and may consult with the medical review board prior to approving an exception.

(d) HHSC will respond to an exception request within 90 days. Upon finding that the facility has satisfied the conditions of this rule, HHSC may grant an exception and shall include the duration of the exception when notifying the facility of the granted exception.

(e) The facility may implement an exception only after written approval from HHSC.

(f) Granting of an exception is considered public information, is subject to disclosure, and may be posted on HHSC web site.

§507.19. License Renewal During the COVID-19 Pandemic.

(a) Based on Governor Greg Abbott’s March 13, 2020 declaration of a state of disaster in all Texas counties, the Texas Health and Human Services Commission adopts this section to establish continuing requirements and flexibilities to protect public health and safety during the COVID-19 pandemic. The requirements and flexibilities established in this section are applicable during an active declaration of a state of disaster in all Texas counties due to the COVID-19 pandemic, declared pursuant to Texas Government Code §418.014.

(b) Notwithstanding §507.13(b)(1)(B) of this subchapter (relating to Application and Issuance of Renewal License), an end stage renal disease facility applying for a renewal license need not submit with its application a current fire safety survey indicating approval by the local fire authority, if the local fire authority is not performing fire inspections.

§507.20. Use of Off-Site Facility During the COVID-19 Pandemic.

(a) Based on Governor Greg Abbott’s March 13, 2020, declaration of a state of disaster in all Texas counties, the Texas Health and Human Services Commission (HHSC) adopts this section to establish continuing requirements and flexibilities to protect public health and safety during the COVID-19 pandemic. The requirements and flexibilities established in this section are applicable during an active declaration of a state of disaster in all Texas counties due to the COVID-19 pandemic, declared pursuant to Texas Government Code §418.014.

(b) An end stage renal disease (ESRD) facility licensed under Texas Health and Safety Code, Chapter 251, that meets the requirements of this section may apply to temporarily use an off-site facility under its current license for added services or an increased number of stations to meet patient needs in response to COVID-19 for the duration of the pandemic.

(c) The off-site facility must be approved by HHSC and be:

 (1) An end stage renal disease (ESRD) facility no longer licensed under Texas Health and Safety Code, Chapter 251, that closed within the past 36 months, or a facility with a pending application for such a license that has passed its final architectural review inspection, which:

 (A) =can meet the current licensing requirements at §507507.32(a) - (e) of this chapter (relating to Water Treatment, Dialysate Concentrates, and Reuse); or

 (B) shall provide integrated hemodialysis machines, which incorporate water treatment and dialysis preparation and delivery into one system;

 (2) A mobile, transportable, or relocatable medical unit using integrated dialysis systems; defined as any trailer or self-propelled unit:

 (A) equipped with a chassis on wheels;

 (B) without a permanent foundation; and

 (C) intended for provision of medical services on a temporary basis.

 (3) A physician’s office built after January 1, 2015, that is currently in use, which may be used for home training of dialysis patients at HHSC’s discretion;

 (4) A physician’s office built after January 1, 2015, that has closed within the past 12 months, which may be used for home training of dialysis patients at HHSC’s discretion, and complies with the following:

 (A) The office shall be well maintained with all building systems in good working condition; and

 (B) Manual fire extinguishers shall be provided in accordance with the latest NFPA code and standard;

 (5) An ambulatory surgical center no longer licensed under Texas Health and Safety Code, Chapter 243, that closed within the past 36 months and will be used for either home training or providing in-center dialysis treatment where both of the following are met:

 (A) The ESRD facility shall only provide integrated hemodialysis machines; and

 (B) The building layout shall provide a direct view of all patient stations from a nurse’s station.

 (6) A freestanding emergency medical care facility no longer licensed under Texas Health and Safety Code, Chapter 254, that closed within the past 36 months and will be used for either for home training services or providing in-center dialysis treatment where both of the following are met:

 (A) The ESRD facility shall only provide integrated hemodialysis machines; and

 (B) The building layout shall provide a direct view of all patient stations from a nurse’s station.

 (7) A hospital or portion of a hospital currently licensed under Texas Health and Safety Code, Chapter 241; or

 (8) A building or structure of opportunity temporarily converted for health care use, including an alternate care site, that is created or maintained by the ESRD facility in partnership with or under the supervision of the health authority, local health department, public health district, or public health consortium that has jurisdiction over the site location.

(d) Before receiving approval to use an off-site facility under this section, the ESRD facility must submit the following to INFOHFLC@hhsc.state.tx.us on a form provided by HHSC:

 (1) an application to use an off-site facility for the addition of services or increased number of stations; and

 (2) water culture testing results that meet the requirements of §507.32(c)(4) of this chapter.

(e) HHSC has the discretion to approve or deny any application to use an off-site facility under this section. HHSC may require an inspection of the off-site facility or additional documentation before considering an application.

(f) In order to protect the health, safety, and welfare of patients and the public, HHSC may withdraw its approval for an ESRD facility to use the off-site facility under this section at any time. Any patients being treated in the off-site facility at the time approval is withdrawn shall be safely relocated as soon as practicable according to the ESRD facility’s policies and procedures.

TITLE 26 HEALTH AND HUMAN SERVICES

PART 1 HEALTH AND HUMAN SERVICES COMMISSION

CHAPTER 507 END STAGE RENAL DISEASE FACILITIES

SUBCHAPTER C OPERATIONAL REQUIREMENTS FOR EQUIPMENT, WATER TREATMENT AND REUSE, AND SANITARY AND HYGIENIC CONDITIONS

§507.32. Water Treatment, Dialysate Concentrates, and Reuse.

(a) A facility shall meet the requirements of this section and Subchapter H of this chapter (relating to Physical Plant and Construction Requirements). A facility may follow more stringent requirements than the minimum standards required by this section.

 (1) The facility owner and medical director shall each demonstrate responsibility for the water treatment and dialysate supply systems to protect hemodialysis patients from adverse effects arising from known chemical and microbial contaminates that may be found in water and improperly prepared dialysate, to ensure the dialysate is correctly formulated and meets the requirements of all applicable quality standards.

 (2) The facility owner and medical director shall each assure that policies and procedures related to water treatment, dialysate, and reuse are understandable and accessible to the operators, and that the training program includes quality testing, risks, and hazards of improperly prepared concentrate, and bacterial issues.

 (3) The facility owner and medical director shall be informed prior to any alteration of, or any device being added to, the water system.

(b) These requirements apply to water intended for use in the delivery of hemodialysis, including the preparation of concentrates from powder at a dialysis facility and dialysate, and for reprocessing dialyzers for multiple use.

 (1) The design for the water treatment system in a facility shall be based on considerations of the source water for the facility and designed by a water quality professional with education, training, or experience in dialysis system design.

 (2) When a public water system supply is not used by a facility, the source water shall be tested by the facility at monthly intervals in the same manner as a public water system, as required by the Texas Commission on Environmental Quality (TCEQ) under 30 TAC, Chapter 290, Subchapter F (relating to Drinking Water Standards Governing Drinking Water Quality and Reporting Requirements for Public Water Systems).

 (3) The physical space in which the water treatment system is located shall be adequate to allow for maintenance, testing, and repair of equipment. If mixing of concentrates is performed in the same area, the physical space shall also be adequate to house and allow for the maintenance, testing, and repair of the mixing equipment and for performing the mixing procedure. When a water distribution system is used by the facility, the system shall be configured as a continuous recirculation loop. To minimize biofilm formation, there shall always be flow in a piping system, except during the backwash cycle of the carbon tanks for direct feed systems.

 (A) For indirect feed systems, a minimum of three feet per second water flow shall be achieved in the distribution loop.

 (B) For direct feed systems, a minimum flow rate in the distribution shall be in agreement with standards as set forth by the Centers for Medicare and Medicaid Services (CMS) Conditions for Coverage.

 (C) This rule shall not apply to facilities providing only home training and support services utilizing single patient devices. Devices used in the facility for training and support services shall be compliant with the U.S. Food & Drug Administration (FDA) and Underwriters’ Laboratories (UL) requirements listed.

 (D) The water treatment and distribution system shall include appropriate pressure gauges, flow meters, sample ports, and other ancillary equipment necessary to allow monitoring of the performance of individual system components, and the system as a whole, as determined by the facility medical director.

 (4) The water treatment system components shall be arranged and maintained so that bacterial and chemical contaminant levels in the product water do not exceed the standards for hemodialysis water quality described by the most current edition of the American National Standards Institute (ANSI), Water Treatment Equipment for Hemodialysis Applications, published by Association for the Advancement of Medical Instrumentation (AAMI).

 (5) Written policies and procedures for the operation of the water treatment system shall be developed, approved by the medical director, implemented, and enforced by the facility. Parameters for the operation of each component of the water treatment system shall be developed in writing and known to the operator. Each major water system component shall be labeled in a manner that identifies the device, describing its function, how performance is verified, and actions to take in the event performance is not within an acceptable range. The facility's policies and procedures for the bypass valves for the carbon tanks and any other bypass valves considered to be critical by the medical director shall have a means to minimize the likelihood the device will be inadvertently bypassed during the normal operation of the system.

 (6) The materials of any components of water treatment systems (including piping, storage, filters, and distribution systems) that contact the product water shall not interact chemically or physically to affect the purity or quality of the product water adversely. Such components shall be fabricated from unreactive materials (e.g., plastics) or appropriate stainless steel. The use of materials that are known to cause toxicity in hemodialysis, such as copper, brass, galvanized material, or aluminum, is prohibited at any point beyond the water treatment component used to remove contaminating metal ions (e.g., reverse osmosis system or deionizer).

 (7) Chemicals infused into the water such as iodine, acid, flocculants, and complexing agents shall be shown to be nondialyzable or shall be adequately removed from product water. Systems shall be monitored in accordance with the manufacturer's direction for use, and specific test procedures to verify removal of additives shall be provided and documented. Chemical injection systems shall include a means of regulating the metering pump to control the addition of a chemical. This control system shall be designed to tightly control addition of the chemical. The control system shall ensure the chemical is added only when the water is flowing through the pre-treatment cascade and that it is added in fixed proportion to the water flow. If an automated control system is used to inject the chemical, there shall be an independent monitor of the controlling parameter.

 (8) Each water treatment system shall include reverse osmosis membranes or deionization tanks and a minimum of two carbon tanks in series. If the source water is from a private supply which does not use chlorine or chloramine, the water treatment system shall include reverse osmosis membranes or deionization tanks and a minimum of one carbon tank.

 (A) Reverse osmosis systems, if used, shall meet the standards set forth by the CMS Conditions for Coverage.

 (i) Single patient devices used in a dialysis facility shall meet the appropriate standards set forth in the CMS Conditions for Coverage to provide dialysis-quality water.

 (B) Deionization systems.

 (i) Deionization systems, if used, shall be monitored continuously to produce water of one megohm-centimeter (cm) or greater specific resistivity (or conductivity of one microsiemen/cm or less) at 25 degrees Celsius. An audible and visual alarm shall be activated in the facility to include the patient care area when the product water resistivity falls below this level, and the product water stream shall be prevented from reaching any point of use.

 (ii) Patients shall not be dialyzed on deionized water with a resistivity less than 1.0 megohm-cm measured at the output of the final deionizer.

 (iii) Deionization tanks, if used, shall be a minimum of two mixed beds in series and shall be used with resistivity monitors including audible and visual alarms placed pre and post the final deionization tank in the system and audible in the patient care area.

 (iv) Feed water for deionization systems shall be pretreated with activated carbon adsorption, or a comparable alternative, to prevent nitrosamine formation.

 (v) If a deionization system is the last process in a water treatment system, it shall be followed by an ultrafilter or other bacteria and endotoxin reducing device.

 (vi) Facilities shall ensure all devices that are regenerated or reconstituted off site, such as deionizers, shall be disinfected at the time of regeneration or reconstitution, so contaminated water is not reintroduced into the system after regeneration or reconstitution.

 (C) Carbon tanks.

 (i) The carbon tanks shall contain granular activated carbon, with a minimum iodine number of 900 or equivalent, as indicated by the manufacturer of the medical device. Previously used carbon shall not be used.

 (ii) A minimum of two carbon adsorption beds shall be installed in series with a sample port following the first bed. A sample port shall also be installed following the second bed for use in the event of free chlorine or cloramine breaking through the first bed.

 (iii) The total empty bed contact time (EBCT) shall be at least 10 minutes, with the final tank providing at least five minutes EBCT at the maximum flow rate through the bed. Carbon adsorption systems used to prepare water for home dialysis or for portable dialysis systems are exempt from the requirement for the second carbon and a ten-minute EBCT, if removal of chloramines to below 0.1 milligram (mg)/liter is verified before each treatment.

 (iv) Water from the sample ports following the first carbon bed shall be tested for chlorine or chloramine levels at the beginning of each treatment day prior to patients initiating treatment, prior to reprocessing of dialyzers, and again prior to the beginning of each patient shift. If there are no set patient shifts, testing should be performed every four hours until all activities that require use of dialysis-quality water are completed.

 (v) If used, an automated chlorine monitoring system will provide, at minimum, the equivalent frequencies of monitoring as defined above and used in accordance with the manufacturer’s direction for use. The automated chlorine monitoring system will be verified by independent manual testing each morning prior to the first patient treatment to verify that the device is functioning within manufacturers specifications to ensure water quality. If a breakdown in the system should occur at any time before or during the treatment day, the facility shall return to manually testing the system every four hours during the treatment day and maintain the appropriate records for manual monitoring.

 (vi) Carbon beds are sometimes arranged as series-connected pairs of beds so that they need not be overly large. The beds within each pair are of equal size and water flows through them are parallel. In this situation, each pair of beds should have a minimum empty bed contact time of five minutes at the maximum flow rate through the bed. When series connected pairs of beds are used, the piping should be designed to minimize differences in the resistance to flow from inlet and outlet between each parallel series of beds to ensure an equal volume of water flows through all beds.

 (vii) All samples for chlorine or chloramine testing shall be drawn when the water treatment system has been operating for at least 15 minutes.

 (viii) Tests for total chlorine, which include both free and combined forms of chlorine, may be used as a single analysis with the maximum allowable concentration of 0.1 mg/liter (L). Test results of greater than 0.5 parts per million (ppm) for chlorine or 0.1 ppm for chloramine from the port between the initial tanks and final tanks shall require testing to be performed at the final exit and replacement of the initial tanks. Testing equipment, supplies, and procedures shall be used in accordance with the manufacturer's directions for use.

 (ix) In a system without a holding tank, if test results at the exit of the final tanks are greater than the parameters for chlorine or chloramine described in this subparagraph, dialysis treatment shall be immediately terminated to protect patients from exposure to chlorine or chloramines, and the medical director shall be notified. In systems with holding tanks, if the holding tank tests less than 0.1 mg/L for total chlorine, the reverse osmosis (RO) may be turned off and the product water in the holding tank may be used to finish treatments in process. The medical director shall be notified.

 (x) If means other than granulated carbon is used to remove chlorine or chloramine, the facility's governing body shall approve such use, in writing, after review of the intended method’s safety for use in hemodialysis applications. If such methods include the use of additives, there shall be evidence the product water does not contain unsafe levels of these additives.

 (9) Water softeners, if used, shall be tested at the end of the treatment day to verify their capacity to treat a sufficient volume of water to supply the facility for the entire treatment day, and shall be fitted with a mechanism to prevent water containing the high concentrations of sodium chloride used during regeneration from entering the product water line during regeneration.

 (10) If used, the faces of timers used to control any component of the water treatment or dialysate delivery system shall be visible to the operator always. Written evidence that timers are checked for operation and accuracy each day of operation shall be maintained.

 (11) Filter housings, if used during disinfectant procedures, shall include a means to clear the lower portion of the housing of the disinfecting agents. Filter housings shall be opaque.

 (12) Ultrafilters, or other bacterial reducing filters, if used, shall be fitted with pressure gauges on the inlet and outlet water lines to monitor the pressure drop across the membrane. Ultrafilters shall be included in routine disinfection procedures.

 (13) If used, storage tanks shall have a conical or bowl-shaped base, and shall drain from the lowest point of the base. Storage tanks shall have a tight-fitting lid and be vented through a hydrophobic 0.2-micron air filter. A means shall be provided to effectively disinfect any storage tank installed in a water distribution system.

 (14) Ultraviolet (UV) lights, if used, shall be monitored at the frequency in accordance with the manufacturer's direction for use, and shall have an endotoxin-reducing filter located downstream of the device. Records shall be maintained for monitoring, as outlined by the manufacturer’s directions for use. Monitoring of all water system components shall be maintained on water system logs.

 (15) Water treatment system piping shall be labeled to indicate the contents of the pipe and direction of flow.

 (16) The water treatment system shall be continuously monitored during patient treatment and be guarded by audible and visual alarms, which can be seen and heard in the dialysis treatment area should water quality drop below specific parameters. Quality monitor sensing cells shall be located at the last component of the water treatment system and at the beginning of the distribution system. No water treatment components that could affect the quality of the product water as measured by this device shall be located after the sensing cell.

 (17) When deionization tanks do not follow a reverse osmosis system, parameters for the rejection rate of the membranes shall assure that the lowest rate accepted would provide product water in compliance with §4.1.1 (concerning Maximum level of chemical contaminants of water) of the American National Standards Institute, Dialysate for Hemodialysis, RD 52:2004 Edition published by the AAMI, and consistent with the CMS Conditions for Coverage and the Centers for Disease Control and Prevention (CDC).

 (18) A facility shall maintain records of the operation of the water treatment system for each treatment day. The log book shall include each component's operating parameter and the action taken when a component is not within the facility's set parameters.

 (19) Microbiological testing of product water shall be conducted.

 (A) Routine microbiological testing shall be conducted monthly. For a newly installed water distribution system, or when any repairs, modifications, or changes to the configuration have been made to an existing system, weekly testing shall be conducted for four weeks to verify that bacteria and endotoxin levels are consistently within the allowed limits. Changes to components that are designed to be replaced on a routine schedule such as filters, ultrafilters, and ultraviolet lamps do not require a period of more frequent testing.

 (B) At a minimum, sample sites chosen for the testing shall include the beginning of the distribution piping, the product water in the reuse room, at any site of concentrate mixing, and the end of the distribution piping.

 (C) Samples shall be collected prior to sanitization or disinfection of the water treatment system and the dialysis machines. Water testing results shall be routinely trended and reviewed by the medical director to determine if results seem questionable or if there is an opportunity for improvement. The medical director shall determine if there is a need for retesting. If internal testing is performed with repeated results of "no growth" for three consecutive months, the testing shall be validated via an outside laboratory. A calibrated loop may not be used in microbiological testing of water samples. Colonies shall be counted using a magnifying device.

 (D) Product water used to prepare dialysate, concentrates from powder, or to reprocess dialyzers for multiple use shall contain a total viable microbial count of less than 200 colony forming units (CFU)/millimeter (ml) and an endotoxin concentration of less than 2 endotoxin units (EU)/ml. The action level for the total viable microbial count in the product water shall be 50 CFU/ml and the action level for the endotoxin concentration shall be 1 EU/ml, consistent with the CMS Conditions for Coverage.

 (E) If the action levels described at subparagraph (D) of this paragraph are observed in the product water, the medical director shall be notified, and corrective measures shall be taken promptly to reduce the levels into an acceptable range.

 (F) All bacteria and endotoxin results shall be recorded to identify trends that may indicate the need for corrective action.

 (20) If ozone generators are used to disinfect any portion of the water or dialysate delivery system, the ozone generator shall be capable of delivering ozone at the concentration and for the exposure time specified and in accordance with the manufacturer's direction for use. Testing based on the manufacturer's direction shall be used to measure the ozone concentration each time disinfection is performed, to include testing for safe levels of residual ozone at the end of the disinfection cycle. Testing for ozone in the ambient air shall be conducted on a periodic basis as recommended by the manufacturer. The records of all testing shall be maintained in a log. The frequency of disinfection shall be performed at least monthly.

 (21) If used, hot water disinfection systems shall use Association for the Advancement of Medical Instrumentation (AAMI) quality water, be capable of delivering hot water at the temperature and for the exposure time specified and in accordance with the manufacturer's direction for use; and be monitored for temperature and time of exposure to hot water, as specified by the manufacturer. Temperature of the water shall be monitored at a point furthest from the water heater, where the lowest water temperature is likely to occur. The water temperature shall be measured each time a disinfection cycle is performed. A record that verifies successful completion of the heat disinfection shall be maintained. The frequency of disinfection shall be performed at least monthly.

 (22) After chemical disinfection, a mechanism shall be incorporated to ensure that the equipment and the system are restored to a safe condition prior to using the equipment and the product water being used for dialysis applications. The results of all absence testing shall be documented. The frequency of disinfection shall be performed at least monthly. A mechanism shall be incorporated in the distribution system to ensure disinfectant does not drain from pipes during the disinfection period.

 (23) Users shall establish and implement a procedure for regular disinfection of the line between the outlet from the water distribution system and the back of the dialysis machine.

 (24) Samples of product water used for dialysis shall be submitted for chemical analysis every six months, and after a change of the reverse osmosis membranes, and shall demonstrate that the quality of the product water used to prepare dialysate, concentrates from powder, or to reprocess dialyzers for multiple use meets §4.1.1 (concerning Maximum level of chemical contaminants in water) of the American National Standards Institute, Water Treatment Equipment for Hemodialysis Applications, RD52:2004 Edition, published by the AAMI.

 (A) Samples for chemical analysis shall be collected at the most distal point in each water distribution loop. All other outlets from the distribution loops shall be inspected to ensure that the outlets are fabricated from compatible materials. Appropriate containers and pH adjustments shall be used to ensure accurate determinations. New facilities, or facilities that add or change the configuration of the water distribution system, shall draw samples at the most distal point for each water distribution loop and then every six months thereafter.

 (B) Additional chemical analysis shall be submitted when any modification or change to the configuration of the existing system is made to the water treatment system, or if the percent rejection of a reverse osmosis system decreased 5.0 percent or more from the percent rejection measured at the time the water sample for the preceding chemical analysis was taken.

 (25) Facility records shall include all test results and provide evidence the medical director has reviewed the results of the water quality testing and directed corrective action when indicated.

 (26) Only persons qualified by the education or experience described in §507.46(f) of this chapter (relating to Qualifications of Staff) may operate, repair, or replace components of the water treatment system.

(c) Dialysate.

 (1) The facility shall develop, implement, maintain, and evaluate quality assessment and performance improvement (QAPI) procedures to ensure ongoing conformance to policies and procedures regarding dialysate quality.

 (2) Each facility shall set all hemodialysis machines to use only one family of concentrates. When new machines are put into service, the concentrate family changes, or the concentrate manufacturer changes, dialysate samples shall be taken from each machine and shall be sent to a laboratory for verification of the dialysate electrolyte values.

 (3) Prior to each patient treatment, staff shall verify the dialysate conductivity and pH of each machine with an independent device.

 (4) Bacteriological testing shall be conducted.

 (A) For newly installed bicarbonate concentrate mixing and delivery systems, weekly testing shall be conducted for four weeks to verify that bacteria and endotoxin levels are consistently within the allowed limits. Responsible facility staff shall develop a schedule to ensure each hemodialysis machine is tested quarterly for bacterial growth and the presence of endotoxins. Hemodialysis machines of home patients, conventional and integrated hemodialysis systems, shall be conducted for four weeks until results not exceeding 200 colony-forming units per milliliter are obtained for three consecutive months, and thereafter quarterly samples shall be cultured. This subparagraph does not apply to closed systems as defined in §507.2(11) of this chapter (relating to Definitions).

 (B) Dialysate shall contain less than 200 CFU/ml and an endotoxin concentration of less than 2 EU/ml. The action level for total viable microbial count shall be 50 CFU/ml, and the action level for endotoxin concentration shall be 1 EU/ml.

 (C) Disinfection and retesting shall be done when bacterial or endotoxin counts exceed the action levels. The medical director shall be notified. Additional samples shall be collected when there is a clinical indication of a pyrogenic reaction or septicemia.

 (5) Only a qualified, licensed nurse may use an additive to increase concentrations of specific electrolytes in the acid concentrate. Mixing procedures shall be followed, as specified by the additive manufacturer. When additives are prescribed for a specific patient, the container holding the prescribed acid concentrate shall be labeled with the name of the patient, the final concentration of the added electrolyte, the date the prescribed concentrate was made, and the name of the person who mixed the additive. Additives are to be used rarely and only when the following applies:

 (A) other interventions were not effective;

 (B) per physician order; and

 (C) the additive is reviewed by the governing body.

 (6) All components used in concentrate preparation systems (including mixing and storage tanks, pumps, valves, and piping) shall be fabricated from materials (e.g., plastics or appropriate stainless steel) that do not interact chemically or physically with the concentrate to affect its purity, or with the germicides used to disinfect the equipment. The use of materials that are known to cause toxicity in hemodialysis such as copper, brass, galvanized material, and aluminum is prohibited.

 (7) Facility policies shall address means to protect stored dialysate components (acid concentrates, bicarbonate concentrates, or bulk storage of dialysate components) from tampering or from degeneration due to exposure to extreme heat or cold.

 (8) Procedures shall be developed, implemented, and enforced:

 (A) to control the transfer of acid concentrates from the delivery container to the storage tank and prevent the inadvertent mixing of different concentrate formulations. The storage tanks shall be clearly labeled;

 (B) the tank and associated plumbing shall form an integral system to prevent contamination of the acid concentrate; and

 (C) the storage tank and inlet and outlet connections, if remote from the tank, shall be secured and clearly labeled.

 (9) Concentrate mixing systems shall include a purified water source, a suitable drain, and an acceptable electrical outlet, as specified by the manufacturer’s recommendations, directions, or instructions.

 (A) Operators of mixing systems shall use personal protective equipment as specified and in accordance with the manufacturer's direction for use during all mixing processes.

 (B) The manufacturer's directions for use of a concentrate mixing system shall be followed, including instructions for mixing the powder with the correct amount of water. The number of bags or weight of powder added shall be determined and recorded.

 (C) The mixing tank shall be clearly labeled to indicate the fill and final volumes required to correctly dilute the powder.

 (D) Systems for preparing either bicarbonate or acid concentrate from powder shall be monitored according to the manufacturer's directions for use, to ensure compliance with paragraph (11)(A) of this subsection.

 (E) Concentrates shall not be used or transferred to holding tanks or distribution systems until all tests are completed per the manufacturer's specifications and in accordance with the manufacturer's directions for use. The results of the tests shall be documented and contain the signature of the person who completed the tests.

 (F) Where a facility designs its own system for mixing concentrates, procedures shall be developed and validated using an independent laboratory to ensure proper mixing of the concentrate, including establishment of acceptable limits for tests of proper concentration.

 (10) Acid concentrate mixing tanks shall be designed to allow the inside of the tank to be rinsed when changing concentrate formulas.

 (A) Acid mixing systems shall be designed and maintained to prevent rust and corrosion.

 (B) Acid concentrate mixing tanks shall be emptied completely and rinsed with dialysis-quality water before mixing another batch of concentrate to prevent cross-contamination between different batches.

 (C) Acid concentrate mixing equipment shall be disinfected, as specified by the equipment manufacturer or, in the case where no specifications are given, as defined by facility policy.

 (D) Records of disinfection and rinsing of disinfectants to safe residual levels shall be maintained.

 (11) Bicarbonate concentrate mixing tanks shall have conical or bowl-shaped bottoms and shall drain from the lowest point of the base. The tank design shall allow all internal surfaces to be disinfected and rinsed.

 (A) Bicarbonate concentrate mixing tanks shall not be pre-filled the night before use, and mixed solution shall not remain in mixing or holding tanks overnight.

 (B) If disinfectant remains in the mixing tank overnight, this solution shall be completely drained, the tank rinsed and tested for residual disinfectant prior to preparing the first batch of that day of bicarbonate concentrate.

 (C) The container shall be emptied and rinsed with dialysis-quality water prior to mixing a new batch of bicarbonate solution, and unused portions of bicarbonate concentrate shall not be mixed with fresh concentrate.

 (D) At a minimum, bicarbonate distribution systems shall be disinfected weekly. More frequent disinfection shall be done if required in accordance with the manufacturer's direction for use, or if dialysate culture results are above the action level.

 (E) If jugs are reused to deliver bicarbonate concentrate to individual hemodialysis machines:

 (i) jugs shall be emptied of concentrate, rinsed with dialysis-quality water, and inverted to drain at the end of each treatment day;

 (ii) pick-up tubes shall be rinsed and allowed to air dry at the end of each treatment day;

 (iii) at a minimum, jugs and pick-up tubes shall be disinfected weekly, and more frequent disinfection shall be considered by the facility QAPI committee if dialysate culture results are above the action level; and

 (iv) following disinfection, jugs shall be drained, rinsed free of residual disinfectant using dialysis-quality water, and inverted to dry; pick-up tubes shall be rinsed free of residual disinfectant and allowed to air day; and testing for residual disinfectant shall be done and documented.

 (12) All mixing tanks, bulk storage tanks, dispensing tanks, and containers for single hemodialysis treatments shall be labeled to indicate the contents of the tank or container.

 (A) Prior to batch preparation, a label shall be affixed to the mixing tank that includes the date of preparation and the chemical composition or formulation of the concentrate being prepared. This labeling shall remain on the mixing tank until the tank has been emptied.

 (B) Bulk storage and dispensing tanks shall be permanently labeled to identify the chemical composition or formulation of their contents.

 (C) At a minimum, single-machine containers shall be labeled with sufficient information to differentiate the contents from other concentrate formulations used in the facility and permit positive identification by users of container contents.

 (13) Permanent records of batches produced shall be maintained to include the concentrate formula produced, the volume of the batch, the lot numbers of powdered concentrate packages, the manufacturer of the powdered concentrate, the date and time of mixing, the test results, the person performing mixing, and the expiration date (if applicable).

 (14) If acid and bicarbonate concentrates are prepared in the facility, preventive maintenance shall be completed in accordance with the manufacturer's direction for use. Records shall be maintained indicating the date, time, person performing the procedure, and results (if applicable).

(d) Reuse of hemodialyzers and related devices.

 (1) Reuse practice in a facility shall comply with the American National Standards Institute (ANSI), Reuse of Hemodialyzers, Third Edition, ANSI/AAMI RD47:2002 and RD47:2002/A1:2003, published by the Association for the Advancement of Medical Instrumentation (AAMI) and consistent with the Centers for Medicare and Medicare Services (CMS), Conditions for Coverage.

 (2) Dialyzer manufacturer's labeling shall be reviewed to determine if a specific dialyzer requires special considerations.

 (3) A transducer protector shall be replaced when wetted during a dialysis treatment and shall be used for one treatment only. Equipment with internal transducer protectors shall be inspected quarterly to ensure that it has not been contaminated.

 (4) Arterial lines may be reused only when the arterial lines are labeled to allow for reuse by the manufacturer, and the manufacturer-established protocols for the specific line have been approved by the United States Food and Drug Administration.

 (5) The water supply in the reuse room shall incorporate a check valve to prevent chemical agents used from inadvertently back flowing into the water distribution system.

 (6) Ventilation systems in the reuse room shall meet the requirements of Subchapter H of this chapter (relating to Physical Plant and Construction Requirements) and be connected to an exhaust system to the outside, which is separate from the building exhaust system; have an exhaust fan located at the discharge end of the system; and have an exhaust duct system of noncombustible corrosion-resistant material as needed to meet the planned usage of the system. Exhaust outlets shall be above the roof-level and arranged to minimize recirculation of exhaust air into the building.

 (7) A facility shall establish, implement, and enforce a policy for dialyzer reuse criteria (including any facility-set number of reuses allowed), which is included in patient education materials and posted in the waiting room and patient treatment areas. A dialyzer may be reused only if the dialyzer's original volume is measured and recorded prior to its first use, and the volume of that dialyzer is used as the basis for discard for that dialyzer.

 (8) A facility shall consider and address the health and safety of patients sensitive to disinfectant solution residuals.

 (9) A facility shall provide each patient with information regarding the reuse practices at the facility and the opportunity to have questions answered.

 (10) A facility shall restrict the reprocessing room to authorized personnel during the reprocessing of dialyzers.

 (11) A facility shall obtain written informed consent of the patient or legal representative.

(e) If a facility participates in centralized reprocessing at a different location, in which dialyzers from multiple facilities are reprocessed at one site, the facility shall:

 (1) ensure direct communication with the medical director at the centralized reprocessing center and the facility's medical director;

 (2) require the use of an automated reprocessing facility;

 (3) maintain responsibility and accountability for the entire reuse process;

 (4) adopt, implement, and enforce policies to ensure the transfer and transport of used and reprocessed dialyzers to and from the off-site location does not increase contamination of the dialyzers or the environment;

 (5) assure that each dialyzer is returned to the appropriate facility or patient home, and, in the case of home patients who participate in a dialyzer reprocessing program, a system shall be established to verify that the correct dialyzers are being returned to each patient's home; and

 (6) provide Commission staff access to the off-site reprocessing site as part of a facility inspection.

§507.33. Sanitary Conditions and Hygienic Practices.

(a) General infection control measures.

 (1) Universal precautions.

 (A) Universal precautions shall be followed in the facility for all patient care activities in accordance with 29 Code of Federal Regulations §1910.1030(d)(1) - (3) (concerning Bloodborne Pathogens) and the Health and Safety Code, Chapter 85, Subchapter I (concerning Prevention of Transmission of HIV and Hepatitis B Virus by Infected Health Care Workers).

 (B) The facility shall demonstrate that it follows standard infection control precautions by implementing the most current Recommended Infection Control Practices for Hemodialysis Units developed by the Centers for Disease Control and Prevention, to prevent and control cross-contamination and the spread of infectious agents.

 (C) Infection control precautions for all patients.

 (i) Disposable gloves shall be worn when caring for the patient or touching the patient's equipment or bloodlines at the dialysis station.

 (ii) Gloves shall be removed, and hands shall be cleaned between each patient contact, as well as after touching blood, body fluids, secretions, excretions, and contaminated items or station. A sufficient number of sinks, with hands-free operable controls, with warm water and soap shall be available to facilitate hand washing. Provisions for hand drying shall be included at each hand washing sink.

 (iii) If hands are not visibly soiled, use of a waterless antiseptic hand rub can be substituted for handwashing. Staff members may use a waterless antiseptic hand rub up for up to three consecutive uses, after which washing with soap and water is required.

 (iv) Staff members shall wear gowns, face shields, eye wear, and masks to protect themselves and prevent soiling of clothing when performing procedures during which spurting or spattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood). If visibly soiled, gowns shall be changed and discarded immediately.

 (v) Staff members shall not eat, drink, or smoke in the dialysis treatment area or in the laboratory.

 (vi) Items taken to the dialysis station shall either be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before being taken to a common clean area or used on another patient.

 (vii) Non-disposable items that cannot be cleaned and disinfected (e.g., adhesive tape, cloth covered blood pressure cuffs) shall be dedicated for use only on a single patient.

 (viii) Unused medications or supplies (syringes, alcohol swabs, etc.) taken to the patient's station shall be used only for that patient and shall not be returned to a common clean area or used on other patients.

 (ix) Clean areas shall be clearly designated for the preparation, handling, and storage of medications and unused supplies and equipment. Medications or clean supplies shall not be handled and stored in the same or an immediately adjacent area where used supplies, equipment, or blood samples are handled.

 (x) Contaminated areas where used supplies, equipment, or blood samples are handled shall be clearly designated.

 (xi) When multiple dose medication vials are used (including vials containing diluents), individual patient doses shall be prepared in a clean (centralized) area away from dialysis stations and delivered separately to each patient.

 (xii) Multiple dose medication vials shall not be carried from station to station.

 (xiii) Common medication carts shall not be used to deliver medications to patients. If trays are used to deliver medications to individual patients, they shall be cleaned and disinfected between each patient.

 (xiv) If a common supply cart is used to store clean supplies in the patient treatment area, this cart shall remain in a designated area at a sufficient distance from patient stations to avoid contamination with blood. Such carts shall not be moved between stations to distribute supplies.

 (xv) Medication vials, syringes, alcohol swabs, or supplies shall not be carried in pockets.

 (D) Location and arrangement of hand washing sinks shall permit ease of access and proper use.

 (E) Facility staff shall explain the potential risks associated with blood and blood products to patients and family members and provide the indicated personal protective equipment to a patient or family member, if the patient or family member assists in procedures which could result in contact with blood or body fluids. Patients shall be encouraged to cleanse their access sites prior to each treatment and to cleanse their hands following their treatment.

 (2) Documentation and coordination of infection control activities.

 (A) The facility shall designate a person to monitor and coordinate infection control activities.

 (B) A facility shall develop, maintain, and enforce a system to identify and track infections to allow identification of trends or patterns. This activity shall be reviewed as a part of the facility's quality assessment and performance improvement (QAPI) program described in §507.43 of this chapter (relating to Quality Assessment and Performance Improvement). The record shall include trends, corrective actions, and improvement actions taken.

(b) Environmental.

 (1) General procedures.

 (A) Facilities shall comply with the provisions set forth in Subchapter H of this chapter (relating to Physical Plant and Construction Requirements).

 (B) Blood spills shall be cleaned immediately, or as soon as is practical, as required by the Occupational Safety and Health Administration (OSHA)’s Bloodborne Pathogens Standards.

 (i) The surface shall be subjected to intermediate-level disinfection in accordance with the manufacturer's directions for use, if a commercial liquid chemical disinfectant is used.

 (ii) If a solution of chlorine bleach (sodium hypochlorite) is used, the solution shall be at least 1:100 sodium hypochlorite and mixed in accordance with the manufacturer's directions for use. The surface to be treated shall be compatible with this type of chemical treatment.

 (iii) The facility shall use dedicated cleaning supplies (such as a mop and bucket) for the cleaning of blood spills.

 (2) Specific procedures for equipment and dialysis machines.

 (A) Routine disinfection of active and backup dialysis machines shall be performed according to facility defined protocol, accomplishing at least intermediate-level disinfection, per Centers for Disease Control and Prevention (CDC) guidelines. The facility personnel responsible for the disinfection of the dialysis machines shall document the date and the time of the disinfection, verify the dialysis machines were rinsed, and verify the disinfectant was removed.

 (B) Between patient shifts, facility staff shall clean machine exteriors, treatment chairs, tourniquets, blood pressure cuffs, facility individual television sets at each treatment station, and hemostats. Blood pressure cuffs that become contaminated with blood shall be removed from service, disinfected, and allowed to dry prior to being returned to use, per CDC recommendations.

(c) Waste and waste disposal.

 (1) Special waste and liquid or sewage waste management.

 (A) The end stage renal disease (ESRD) facility shall comply with the requirements set forth by HHSC in §§1.131 - 1.137 of Title 25 (relating to Definition, Treatment, and Disposition of Special Waste from Health Care-Related Facilities); the Texas Commission on Environmental Quality (TCEQ) requirements in 30 TAC, Chapter 326 (relating to Medical Waste Management); and Subchapter H of this chapter (relating to Physical Plant and Construction Requirements).

 (B) All sewage and liquid wastes shall be disposed of in a municipal sewerage system or a septic tank system permitted by the TCEQ in accordance with 30 TAC, Chapter 285 (relating to On-Site Sewage Facilities).

 (2) Waste containers shall meet the provisions set forth in Subchapter H of this chapter (relating to Physical Plant and Construction Requirements).

(d) Hepatitis B prevention.

 (1) The facility shall offer hepatitis B vaccination to all previously unvaccinated, susceptible new staff members in accordance with 29 Code of Federal Regulations, §1910.1030(f)(1) - (2) (relating to Bloodborne Pathogens). Staff vaccination records shall be maintained in each staff member's health record.

 (2) Prevention requirements concerning patients.

 (A) Hepatitis B vaccination.

 (i) With an order from the patient's nephrologist, facility staff shall make the hepatitis B vaccine available to a patient who is susceptible to hepatitis B, provided that the patient has coverage or is willing to pay for the vaccination.

 (ii) The facility shall ensure the CDC’s most recent Hepatitis B Vaccine Information Statement (VIS) is available to patients.

 (B) Serologic screening of patients.

 (i) The Hepatitis B virus (HBV) serological status to include Hepatitis B surface antigen (HBsAg), total anti-Hepatitis B core antibody (anti-HBc), and antibody to Hepatitis B surface antigen (anti-HBs) of all patients should be known before admission to the hemodialysis unit. The anti-HBc results obtained previously or on admission shall be maintained in the clinical record and repeated only if clinically indicated.

 (ii) A patient returning to a facility after extended hospitalization or absence of 30 calendar days or longer shall have been screened for hepatitis B surface antigen (HBsAg) within one month before or at the time of admission to the facility or have a known hepatitis B surface antibody (anti-HBs) status of at least 10 milli-international units per milliliter no more than 12 months prior to admission. The facility shall document how this screening requirement is met.

 (iii) Repeated serologic screening shall be based on the antigen or antibody status of the patient.

 (I) Monthly screening for HBsAg is required for patients whose previous test results are negative for anti-HBs.

 (II) Screening of HBsAg-positive or anti-HBs-positive patients may be performed on a less frequent basis but shall be performed at least annually.

 (C) Isolation procedures for the HBsAg-positive patient.

 (i) An ESRD facility which was licensed prior to the effective date of these rules shall comply with §507.14(c)(3)(F) of this chapter (relating to Change in Status). An ESRD facility which is licensed after the effective date of these rules shall treat patients positive for HBsAg in a separate treatment room that complies with Subchapter H of this chapter (relating to Physical Plant and Construction Requirements).

 (ii) Separate dedicated supplies and equipment, including blood glucose monitors, shall be used to provide care to the Hepatitis B positive patients. All supplies used in the isolation area or room, such as clamps, blood pressure cuffs, testing reagents, etc., shall be labeled "isolation" and not routinely removed from the isolation area or room.

 (iii) Refillable concentrate containers shall be surface disinfected at the completion of each treatment. Refillable acid concentrate containers shall be kept in the isolation area or room and refilled at the door. Refillable bicarbonate concentrate containers shall be removed for cleaning and disinfection. In the disinfection area, containers labeled "isolation" containers and pick-up tubes shall be segregated in a dedicated, designated area away from all other containers and pick-up tubes.

 (iv) Separate gowns shall be used in the isolation area or room and removed before leaving the isolation area or room. Any one entering the isolation area or room during the patient's treatment shall wear a protective gown. Gowns used in the isolation area or room shall be discarded at the end of each treatment day. If visibly soiled, gowns shall be changed and discarded immediately.

 (v) Dedicated cleaning supplies (such as a mop and bucket) for cleaning the isolation area or room and blood spills shall be used and labeled "isolation."

 (vi) A patient who tests positive for HBsAg shall be dialyzed on equipment reserved and maintained for an HBsAg-positive patient's use only.

 (vii) When a direct patient care staff member is assigned to both HBsAg-negative and HBsAg-positive patients, the HBsAg-negative patients assigned to this grouping shall be Hepatitis B antibody positive. Hepatitis B antibody positive patients are to be seated at the treatment stations nearest the isolation station and assigned to the same staff member who is caring for the HBsAg-positive patient.

 (viii) If an HBsAg-positive patient is discharged, the equipment that had been reserved for that patient shall be given intermediate-level disinfection prior to use for a patient testing negative for HBsAg.

 (ix) In the case of patients new to dialysis or a patient returning to a facility after extended hospitalization or absence of 30 calendar days or longer, if these patients are admitted for treatment before results of HBsAg or anti-HBs testing are known, these patients shall undergo treatment as if the HBsAg test results were potentially positive, except that they shall not be treated in the HBsAg isolation room, area, or machine.

 (I) The facility shall treat potentially HBsAg-positive patients in a location in the treatment area which is outside of traffic patterns and may not reuse the dialyzer until the HBsAg test results are known.

 (II) The dialysis machine used by this patient shall be given intermediate-level disinfection prior to its use by another patient.

 (III) The facility shall obtain HBsAg status results of the patient no later than three days from admission.

(e) Tuberculosis prevention.

 (1) The facility's direct care staff shall be screened for tuberculosis upon employment prior to patient contact, or provide documentation of negative tuberculosis status, per current CDC recommendations.

 (2) Subsequent screening of facility staff shall be performed after any potential exposure to laryngeal or pulmonary tuberculosis, per current CDC recommendations.

 (3) Respiratory isolation procedures and precautions developed by the facility shall be employed by facility staff providing treatment to patients with pulmonary tuberculosis.

 (4) The facility shall screen patients for tuberculosis when indicated by the presence of risk factors for, or the signs and symptoms of tuberculosis. Screening shall be performed after potential exposure to active laryngeal or pulmonary tuberculosis, per current CDC recommendations.

(f) The facility shall adopt, implement, and enforce a policy for offering and providing pneumococcal and influenza vaccines. The policy shall:

 (1) include provisions that the influenza vaccine shall be offered according to the CDC annual recommendations, and the pneumococcal vaccine shall be offered throughout the year;

 (2) require the person administering the vaccine to ask the patient if they are currently vaccinated against influenza or pneumococcal disease, assess potential contraindications, and then, if appropriate, administer the vaccine under approved facility protocols;

 (3) address required documentation of the vaccination in the patient clinical record; and

 (4) include that HHSC may waive requirements related to the administration of the vaccines based on established shortages of the vaccines.

TITLE 26 HEALTH AND HUMAN SERVICES

PART 1 HEALTH AND HUMAN SERVICES COMMISSION

CHAPTER 507 END STAGE RENAL DISEASE FACILITIES

SUBCHAPTER D OPERATIONAL REQUIREMENTS FOR PATIENT CARE AND TREATMENT

§507.41. Governing Body.

(a) There shall be an identified governing body responsible for the organization, management, control, and operation of the facility, including the appointment of the facility's medical director as defined in §507.2(49) of this chapter (relating to Definitions).

 (1) A qualified medical director is a physician who:

 (A) is board certified in internal medicine, by the American Board of Internal Medicine, or pediatrics by the American Board of Pediatrics, has completed a board-approved training program in nephrology, and has at least 12 months of experience providing care to patients receiving dialysis; or

 (B) is board certified in nephrology or pediatric nephrology and has at least 12 months of experience providing care to patients receiving dialysis.

 (2) A facility may request a waiver to appoint or retain as medical director a physician who does not meet one or more of the qualifications in paragraph (1) of this subsection. The waiver shall explain why a physician meeting the board certification requirement is not available and include a resume of the physician the facility seeks to appoint or retain. A written request for waiver shall be made through the Texas Health and Human Services Commission Health Facility Licensing Unit, for transmission to the Centers for Medicare and Medicaid Services.

(b) The governing body shall develop, implement, and enforce policies and procedures for all services provided by the facility.

(c) The governing body shall adopt, implement, and enforce current laws, rules, and regulations pertaining to medical staff.

(d) The governing body shall implement and annually review current and effective administrative rules, regulations, and policies designed to protect the health and safety of patients.

(e) The governing body shall ensure there is a quality assessment and performance improvement (QAPI) program to evaluate the provision of patient care. The governing body shall review and monitor QAPI activities quarterly.

(f) The governing body shall ensure all facility staff are qualified (such as, advanced practice registered nurse, physician assistant, registered nurse, licensed vocational nurse, licensed master social worker, registered dietitian, patient care technician, and other technical staff) to serve the complex needs of dialysis patients and deliver dialysis services. The registered nurse, licensed vocational nurse, patient care technician and other technical staff shall demonstrate and sustain the skills and any professional licensures required to perform the specific duties of their positions.

(g) The governing body shall ensure adequate numbers of qualified personnel are present whenever patients are undergoing dialysis so that the patient to staff ratio is appropriate to the level of dialysis care given and meets the needs of patients.

(h) The governing body shall review, approve, and implement the facility's training program for staff, patients, and caregivers.

(i) The governing body shall develop, implement, and enforce policies and procedures relating to the facility's emergency preparedness plan, to meet the requirements of §507.45 this chapter (relating to Provision and Coordination of Treatment and Services). The plan shall address the continuity of essential building systems including emergency power and water, or a contract with another licensed end stage renal disease (ESRD) facility to provide emergency contingency care to patients to meet the requirements of Subchapter H of this chapter (relating to Physical Plant and Construction Requirements).

(j) The governing body shall ensure all equipment used by facility staff or patients is properly maintained in accordance with the manufacturer's direction for use.

(k) The governing body shall ensure the physical environment of the facility protects the health and safety of patients, personnel, and the public. The facility’s physical premises and areas of the facility's surrounding physical structure used by the patients (including stairwells, corridors, and passageways) shall meet the local building and fire safety codes and standards as they relate to design and space requirements for safe access and patient privacy.

(l) The governing body shall develop, implement, and enforce policies and procedures regarding disruptive patients or family members to ensure the health and safety of patients, personnel, and the public.

(m) The governing body shall ensure that all facility staff members have access to the most current version of all applicable laws, rules, and regulations.

§507.42. Patient Rights.

Each facility shall adopt, implement, and enforce policies and procedures appropriate to the patient population served, which ensure each patient is:

 (1) treated with respect, dignity, and full recognition of the patient's individuality and personal needs;

 (2) provided privacy and confidentiality, for the patient and the clinical record;

 (3) provided a safe, sanitary, and comfortable treatment environment;

 (4) provided information in a manner to facilitate understanding by the patient and the patient's legal representative, family member, or significant other, as applicable, including patient information materials available in the appropriate language; and staff shall document in the patient's clinical record how the consent forms for treatment were explained, whether staff obtained the patient's consent, and how staff explained to the patient the rights and responsibilities of the patient;

 (5) provided an interpreter, interpreter service, or visual and hearing assistance if written materials in the patient's primary language are not available or not appropriate for the patient’s needs;

 (6) informed by a physician of the patient's medical status;

 (7) informed of and receives education regarding all treatment modalities and settings, including self-care and transplant for the treatment of end stage renal disease upon initiating treatment and an annual basis thereafter;

 (8) informed about and provided the opportunity to participate in all aspects of care, including plan of care meetings, the right to refuse treatment, and the medical consequences of such refusal;

 (9) aware of all services available in the facility and all charges for services provided;

 (10) informed about the facility's reuse of dialysis supplies, including hemodialyzers; and if printed materials such as brochures are used to describe a facility and its services, the brochures shall contain a statement describing the methods and procedures used when such supplies are reused;

 (11) assured of a reasonable response by the facility to the patient's requests and needs for treatment or service, within the facility's capacity, the facility's stated mission, and applicable law and regulation;

 (12) provided hours of dialysis that are scheduled for patient convenience whenever feasible or possible, and consideration is given to a patient's work or school schedule;

 (13) transferred or discharged only for medical reasons, for the patient's welfare or that of other patients or staff members, or for nonpayment of fees; and is given 30 calendar days advanced notice in the event of a transfer or discharge, except in cases where the patient presents an immediate risk to others;

 (14) given an opportunity and assistance to improve problematic behavior prior to dismissal from the facility; and a facility shall establish, implement, and enforce a policy whereby a disruptive patient or family member or noncompliant patient is given an opportunity and assistance to improve the problematic behavior prior to dismissal from the facility, in accordance with the requirements of §507.45(a)(8) of this subchapter (relating to Provision and Coordination of Treatment and Services);

 (15) provided protection from abuse, neglect, or exploitation as those terms are defined in Texas Health and Safety Code, Chapter 161, Subchapter L, related to Abuse, Neglect, and Unprofessional or Unethical Conduct in Health Care Facilities;

 (16) provided information regarding advance directives and allowed to formulate such directives to the extent permitted by law, including documents executed under Texas Health and Safety Code, Chapter 166, Advance Directives Act;

 (16) fully informed on how to express complaint against the facility without fear of reprisal or denial of services, including a written statement provided at the time of admission informing patients of their rights to make a complaint directly to HHSC Complaint and Incident Intake; however correctional institutions shall not be required to provide a phone number for HHSC;

 (17) fully informed of the rights listed in this section, the responsibilities established by the facility, and all rules and regulations governing patient conduct and responsibilities, including a written copy of the patient's rights and responsibilities provided upon admission to each patient or the patient's legal representative, and a copy shall be posted with the facility license certificate; and

 (18) fully informed of the patient plan of care process, including the necessary services outlined in the patient plan of care.

§507.43. Quality Assessment and Performance Improvement.

(a) A facility shall develop, implement, maintain, and evaluate an effective, ongoing, facility-wide, data-driven, interdisciplinary quality assessment and performance improvement (QAPI) program. The program shall be individualized to the facility and meet the criteria and standards described in this section.

(b) The program shall reflect the complexity of the facility's organization and services involved. All facility services (including those services furnished under contract or arrangement), shall focus on indicators related to improved health outcomes and the prevention and reduction of medical errors.

(c) The program shall include 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.

(d) The facility shall demonstrate that facility staff evaluate the provision of dialysis care and patient services, set treatment goals, identify opportunities for improvement, develop and implement improvement plans, and evaluate the implementation until resolution is achieved. The dialysis facility shall measure, analyze, and track quality indicators or other aspects of performance the facility adopts or develops that reflect processes of care and facility operations. Evidence shall support that aggregate patient data, including identification and tracking of patient infections, is continuously reviewed for trends.

(e) Core staff members shall actively participate in the QAPI activities and monthly meetings.

(f) Core staff members shall actively participate in QAPI meetings more often as necessary to identify or correct problems. The QAPI meetings shall be conducted separately from a patient plan of care conference and the meetings shall be documented. The facility patient representatives shall be invited and encouraged to attend the QAPI meetings.

(g) The facility's QAPI program shall include:

 (1) an ongoing review of key elements of care using comparative and trend data to include aggregate patient data;

 (2) identification of areas where performance measures or outcomes indicate an opportunity for improvement, including review of the progress of ESRD Network and Centers for Medicare and Medicaid Services (CMS) assigned activities;

 (3) appointment of interdisciplinary improvement teams to:

 (A) identify, measure, analyze, and track indicators for variation from desired outcomes;

 (B) create and implement improvement plans;

 (C) evaluate the implementation of the improvement plans; and

 (D) continue monitoring and improvement activities until resolution of the improvement plan; and

 (4) establishment and monitoring of quality indicators related to improved health outcomes.

(h) For each quality assessment indicator, the facility shall establish and monitor a level of performance consistent with current professional knowledge. These performance components shall influence or relate to the desired outcomes themselves. At a minimum, the following indicators shall be measured, analyzed, and tracked monthly:

 (A) water quality (chemical, bacteriological analysis, and other indicators specific to the facility's water treatment system);

 (B) equipment preventive maintenance and repair;

 (C) reprocessing of hemodialyzers (dialyzer performance measures, labeling, and disinfection);

 (D) infection control (staff and patient screening; standard precautions; bacteriological monitoring of dialyzers, water, machines, and dialysate; pyrogen reactions; sepsis episodes; patient infections; and peritonitis rate);

 (E) adverse event;

 (F) vascular access;

 (G) reportable incidents as required to be reported under §507.48 of this chapter (relating to Incident Reports);

 (H) mortality (review of each death and monitoring modality specific mortality rates);

 (I) complaints and suggestions (from patients, family, or staff);

 (J) staffing to include orientation, training, delegation, licensing and certification, and non-adherence to policies and procedures by facility staff;

 (K) safety (fire and emergency preparedness, use of a HHSC-approved reporting system, and disposal of special waste);

 (L) clinical records review to include dialysis treatment errors, and medication errors;

 (M) clinical outcomes (laboratory indicators, hospitalizations, vascular access complications, intradialytic complications, fluid management, patient no-shows, patient non-adherence to the dialysis prescription, and transplantation);

 (N) patient's health-related quality of life surveys; and

 (O) involuntary transfer or discharge of a patient.

 (6) The dialysis facility shall continuously monitor the performance, take actions that result in performance improvement, and track performance to ensure that improvements are sustained over time. The facility shall immediately correct any identified problems that threaten the health and safety of patients.

(i) HHSC shall review a facility's QAPI activities to determine compliance with this section.

 (1) A HHSC inspector shall verify that the facility has a QAPI program that addresses concerns relating to quality of care provided to its patients and that the core staff members have knowledge of and the ability to access the facility's QAPI program.

 (2) HHSC shall require disclosure of QAPI program records when disclosure is necessary to determine compliance with this section.

§507.44. Indicators of Quality of Care.

The facility shall regularly review data to identify opportunities to improve care. Assistance in improving care from HHSC or HHSC's designee may include feedback of comparative data, a plan of correction, or an on-site inspection.

§507.45. Provision and Coordination of Treatment and Services.

(a) Patient assessment and plan of care.

 (1) A facility shall develop, implement, and enforce policies and procedures on the patient's plan of care process, which specifies the services necessary to address the patient's comorbid conditions and other needs based on the patient's interdisciplinary assessment. The patient services are coordinated using an interdisciplinary team approach, per CMS guidance. The interdisciplinary team shall consist of the patient, the patient's primary dialysis physician, registered nurse, social worker, and dietitian.

 (2) The interdisciplinary team shall engage in an interactive conference to develop a written, individualized, comprehensive patient plan of care that specifies the services necessary to address the patient's medical, psychological, social, and functional needs, and includes treatment goals.

 (3) The patient plan of care shall include measurable and expected outcomes and estimated timetables to achieve these outcomes. The patient plan of care shall include the patient's current dose of dialysis, dialysis adequacy, other medical comorbidity issues, nutritional status, mineral metabolism, anemia, vascular access, psychosocial status, modality, transplantation status, rehabilitation status, patient's goals, and patient education and training.

 (4) The patient plan of care shall include evidence of coordination with other service providers (e.g., hospitals, long term care facilities, home and community support services agencies, or transportation providers) as needed to assure the provision of continuity of safe care.

 (5) The patient plan of care shall include evidence of the patient's (or patient's legal representative's) input and participation, unless they refuse to participate. If the patient refuses to participate, the facility shall document the patient refusal in the patient’s record. At a minimum, the patient plan of care shall demonstrate a member of the interdisciplinary team discussed the content with the patient or the patient's legal representative.

 (6) The patient plan of care shall be developed and implemented within 30 calendar days, or 13 outpatient dialysis treatments, from the patient's admission to the facility. The patient plan of care shall be revised due to changes in the patient’s personal treatment goals, lack of progress towards the goals of the plan of care, marked deterioration in health status, significant changes in the patient's psychosocial needs, or changes in the patient's nutritional condition, as needed, but no less than annually after the date of the patient's last plan of care.

 (7) The facility shall monitor the patient plan of care at least monthly to recognize and address any deviations from the patient plan of care as follows:

 (A) implement changes in interventions due to the lack of progress toward the goals of the patient plan of care;

 (B) document the reasons why the patient was unable to achieve the goals; and

 (C) implement changes to address the revised patient plan of care.

 (8) An interdisciplinary team conference may be conducted via phone or telehealth conferencing, as allowed by current federal regulations. A phone or telehealth patient plan of care conference conducted with the interdisciplinary team and the patient (or their legal representative) shall be documented as a phone or telehealth conference.

 (9) In the case of disruptive patients or family members or patients who do not conform to the treatment plan, the facility shall develop, implement, and enforce a process for more intensive interdisciplinary team intervention with this patient to include assessment of needs and planned interventions to assist the patient in adjusting to the requirements for safe care. The ESRD Network shall be contacted for assistance with these patients prior to consideration for an involuntary discharge of the disruptive patient.

(b) Emergency preparedness.

 (1) A facility shall implement written procedures that describe staff and patient actions to manage potential medical and nonmedical emergencies, including fire, equipment failure, power outages, medical emergencies, and natural or other disasters that are likely to threaten the health, welfare, or safety of the facility patients or staff, or the public.

 (2) A facility shall have a functional plan to access the community emergency medical services.

 (3) A facility shall have personnel qualified to operate emergency equipment and to provide emergency care to patients on site and available during all treatment times. A charge nurse qualified to provide basic cardiopulmonary life support (BCLS) shall be on site and available to the treatment area whenever patients are present. All direct care staff members shall maintain current certification and competency in BCLS.

 (4) A facility shall have a transfer agreement with one or more hospitals that provide acute dialysis service for the provision of inpatient care and other hospital services to the facility's patients. The facility shall have documentation from the hospital to the effect that patients from the facility shall be accepted and treated in emergencies. There shall be reasonable assurances that:

 (A) the transfer or referral of patients will be affected between the hospital and the facility whenever such transfer or referral is determined as medically appropriate by the attending physician, with timely acceptance and admission;

 (B) the interchange of medical and other information necessary or useful in the care and treatment of the patient transferred shall occur within one business day; and

 (C) security and accountability shall be assured for the transferred patient's personal effects.

 (5) A written disaster preparedness plan for natural and other disasters specific to each facility shall be developed and in place. The plan shall be based on an assessment of the probability and type of disaster in each region and the local resources available to the facility.

 (A) The plan shall incorporate the use of HHSC approved reporting system and participation in the ESRD Network of Texas disaster preparedness activities. Contact shall be made annually with a local disaster management representative Emergency Operations Center (EOC) to assess the need to revise the plan and to ensure that local agencies are aware of the dialysis facility, its provision of life-saving treatment, and the patient population served.

 (B) The plan shall include procedures designed to minimize harm to patients and staff along with ensuring safe facility operations. The plan and in-service programs for patients and staff shall include provisions or procedures for responsibility of direction and control, communications, alerting and warning systems, evacuation, and closure. Each staff member employed by or under contract with the facility shall be able to demonstrate their role or responsibility to implement the facility's disaster preparedness plan. The facility shall designate a person to monitor and coordinate disaster preparedness activities. The facility shall maintain documentation of the monitoring and coordination of disaster preparedness activities.

 (C) The plan shall address the continuity of essential building systems including emergency power and water, or a contract with another licensed ESRD facility to provide emergency contingency care to patients to meet the requirements of §507.92(h) (relating to Fire Prevention, Protection, and Emergency Contingency Plan).

 (6) A facility shall post a telephone number listing specific to the facility equipment and locale to assist staff in contacting mechanical and technical support in the event of an emergency.

 (7) The facility shall maintain information on HHSC approved reporting system to be updated online monthly.

(c) Medication storage and administration.

 (1) Pharmaceutical and therapeutic items shall be provided in accordance with accepted professional principles and federal and state laws and regulations.

 (2) Medications shall be administered only when medication is ordered by the patient's physician, attending physician, or an advanced practice provider. Medication shall be administered as ordered.

 (3) The sponsoring physician shall document and authenticate or countersign all physician or advanced practice provider orders within 15 calendar days from the date the physician or advanced practice provider gave the order.

 (4) Medications maintained in the facility shall be properly stored and safeguarded in enclosures of sufficient size, which are not accessible to unauthorized persons. Refrigerators used for storage of medications shall be maintained with documentation of the appropriate temperatures for such storage.

 (5) A facility shall maintain emergency medications, as specified by the medical director, to treat the emergency needs of patients.

 (6) Medications shall not be prepared for administration in the patient's immediate treatment area. The medication preparation area shall include a work counter and a sink and shall be located in an area to prevent contamination of medicines being prepared for administration.

 (7) Medication vials shall not be taken to a patient station. Intravenous medication vials labeled for single-use shall not be punctured more than once.

 (8) Medications not given immediately shall be labeled with the patient's name, the name of the medication, the dosage prepared, and the initials of the person preparing the medication, and shall be protected to prevent contamination and casual access of the prepared medications to unauthorized persons. All medications shall be administered by the facility staff member who prepared the medication.

 (9) Saline shall not be drawn from the IV bag or tubing in use for the patient; and shall be drawn separately in a clean area separate from potentially contaminated items and surfaces.

 (10) All medications shall be administered by licensed nurses, physician assistants, or physicians except that intravenous normal saline, intravenous heparin, subcutaneous lidocaine, and oxygen may be administered as part of a routine hemodialysis treatment by dialysis technicians qualified according to §507.62 of this chapter (relating to Training Curricula and Instructors) and §507.63 of this chapter (relating to Competency Evaluation). Such administration by dialysis technicians shall be compliant with Chapter 157 of Texas Occupations Code concerning the delegation of medical acts by a licensed physician in the State of Texas.

(d) Nursing services.

 (1) Nursing services shall be provided to prevent or reduce complications, to maximize the patient's functional status, and to educate the end stage renal disease (ESRD) patient, the patient's family, patient's caregiver, or significant other.

 (2) A full-time supervising nurse shall be employed to supervise and manage the provision of safe patient care. A contract staff person shall not be considered an employee and shall not be considered for the full-time supervising nurse.

 (3) A registered nurse shall be in the facility when patients are present in the facility.

 (A) In inclement weather or due to safety concerns, when two or more basic cardiopulmonary life support CPR trained staff members are in the building, patients may enter the lobby of the facility.

 (B) The governing body of the facility shall develop policies and procedures for allowing patients in the building when a registered nurse is not present and inclement weather or safety concerns exist. The policy and procedure shall include a review of any incident when patients are allowed in the building when a registered nurse is not present. Based on the reasons above, a date of the incident, reasons, patients affected, and staff present shall be presented to Quality Assessment and Performance Improvement (QAPI) and governing body for review and development of appropriate plan.

 (C) A registered nurse shall conduct:

 (i) admission nursing assessments;

 (ii) assessments of a patient when indicated by a question relating to a change in the patient's status, extended or frequent hospitalizations, or at the patient's request;

 (iii) pre-dialysis evaluations on all patients, which shall be conducted within the first hour of treatment on all patients every time the patient receives treatment; and

 (iv) post-dialysis assessments, which shall be conducted immediately if an abnormal finding or change of condition is identified pre-dialysis or intradialytic.

 (D) A registered nurse shall participate in the interdisciplinary team review of a patient's progress and recommend changes in treatment based on the patient's current needs and shall facilitate communication between the patient, patient's family, and the patient’s significant other, as applicable, and other interdisciplinary members, to ensure needed care is delivered.

 (E) A registered nurse shall provide oversight and direction to dialysis technicians and licensed vocational nurses.

 (F) A registered nurse shall participate in the facility's QAPI activities.

 (4) A registered nurse functioning in the charge role shall be present during all dialysis treatments.

 (5) If pediatric dialysis is provided, a registered nurse with experience or training in pediatric dialysis shall be available to provide care for pediatric dialysis patients smaller than 35 kilograms in weight.

 (6) Sufficient direct care staff, as defined in §507.2(25) of this chapter (relating to Definitions), shall be on site to meet the needs of the patients, and at least one licensed nurse shall be available on site for every twelve patients or portion thereof. A registered nurse functioning in the charge role shall be present during all dialysis treatments.

 (A) During treatment of six or fewer patients, direct care staff shall consist of at least one registered nurse and one direct care staff, as demonstrated in Figure: 26 TAC §507.106.

 (B) During treatment of 7 to 12 patients, two licensed nurses shall be available, only one of which shall be a charge nurse with no direct patient care assignment, as demonstrated in Figure: 26 TAC §507.106.

 (C) For pediatric dialysis patients, one registered nurse shall be provided on site for each patient weighing less than 10 kilograms and one registered nurse provided on site for every two patients weighing from 10 to 20 kilograms.

 (7) A facility shall ensure patients are in view of staff during hemodialysis treatments, and shall visualize the patient, their access site, and their bloodline connections during the dialysis treatment.

 (8) The facility shall include documentation in the patient's record verifying the patient has been educated on the importance of leaving their access sites uncovered during treatment, upon admission and annually.

 (9) A licensed nurse or dialysis technician shall collect and document objective and subjective data for each patient before and after treatment, according to facility policy and the staff member's level of training. There shall be written policies and procedures specific to the facility to guide nursing staff actions in the event a patient's condition deteriorates during treatment to identify parameters which would require a patient be referred to a nurse for evaluation. A registered nurse shall conduct a patient assessment when indicated by a question relating to a change in the patient's status or at the patient's request.

 (10) A registered nurse shall conduct the initial patient assessment prior to the patient's initial dialysis treatment in the facility.

(e) This chapter does not preclude a licensed vocational nurse (LVN) from practicing in accordance with the rules adopted by the Texas Board of Nursing. If the LVN is acting in the capacity of a dialysis technician, the facility shall determine that the LVN has passed a training and competency evaluation curriculum that meets the requirements in §507.62 of this chapter (relating to Training Curricula and Instructors) and §507.63 of this chapter (relating to Competency Evaluation).

(f) A dialysis technician providing direct patient care shall demonstrate knowledge and competency for the responsibilities specified in §507.62 of this chapter and §507.63 of this chapter.

(g) Nutrition services.

 (1) Nutrition services shall be provided to a patient and the patient's caregivers to maximize the patient's nutritional status.

 (2) The dietitian shall be responsible for:

 (A) conducting a nutrition assessment of a patient;

 (B) participating in an interdisciplinary team review of a patient's progress;

 (C) recommending therapeutic diets in consideration of cultural preferences and changes in treatment based on the patient's nutritional needs in consultation with the patient's physician;

 (D) counseling a patient, a patient's family, and a patient's significant other on prescribed diets and monitoring adherence and response to diet therapy; however correctional institutions shall not be required to provide counseling to family members or significant others;

 (E) referring a patient for assistance with nutrition resources such as financial assistance, community resources, or in-home assistance;

 (F) participating in the facility's QAPI activities; and

 (G) providing ongoing monitoring of subjective and objective data to determine the need for timely intervention and follow-up, including but not limited to weight changes, blood chemistries, adequacy of dialysis, and medication changes that affect nutrition status and potentially cause adverse nutrient interactions.

 (3) The initial contact between the dietitian and the patient to assess nutritional status shall occur, and be documented, within two weeks or seven treatments from admission to the facility, whichever occurs later. A comprehensive nutrition assessment with an educational component shall be completed within 30 days or 13 treatments from the patient's admission to the facility, whichever occurs later.

 (4) A nutrition reassessment shall be conducted no less than annually or more often when indicated by a question relating to a change in the patient's status, extended or frequent hospitalizations, a change in the patient's modality, or at the patient's request.

 (5) Each facility shall employ or contract with a dietitian to provide clinical nutrition services for each patient. One full-time equivalent of dietitian time shall be available for up to 100 patients per facility, which is the maximum caseload for all modalities available in the facility. A second dietitian shall be employed or contracted for a patient caseload over 100.

 (6) Nutrition services shall be available at the facility during scheduled treatment times. Access to services may require an appointment.

 (7) There shall be written physician standing orders specific to the facility authorizing delegation of responsibilities for the facility dietitian as determined by the medical director and the facility. These standing orders shall be reviewed and approved by the medical director at least annually and be consistent with the statutes and rules of the Texas Medical Board, the Texas Board of Nursing, and the Texas Department of Licensing and Regulation.

 (8) When the facility uses a medication algorithm or protocol for managing renal bone disease, the nutritional care for each patient shall be individualized.

(h) Social services.

 (1) Social services shall be provided to patients and their families and shall be directed at supporting and maximizing the adjustment, social functioning, and rehabilitation of the patient.

 (2) The social worker shall be responsible for:

 (A) conducting psychosocial evaluations, which include health-related quality of life surveys;

 (B) participating in the interdisciplinary team review of a patient's progress;

 (C) providing an ongoing assessment and recommend changes in treatment based on the patient's current psychosocial needs;

 (D) providing social work interventions including counseling, case work, and group work services to patients and their families experiencing special problems associated with end stage renal disease;

 (E) except in the case of social workers providing service in correctional institutions, identifying community social agencies and other resources, and assisting patients and families to use them;

 (F) participating in the facility's QAPI activities; and

 (G) assisting patients to achieve optimum levels of productive activity and making rehabilitation referrals as appropriate.

 (3) Initial contact between the social worker and the patient shall occur, and be documented, within two weeks or seven treatments from the patient's admission, whichever occurs later. A comprehensive psychosocial assessment shall be completed within 30 days or 13 treatments from the patient's admission, whichever occurs later.

 (4) A governing body-approved psychosocial and quality of life reassessment shall be conducted 90 days after the initial assessment, and annually thereafter. These reassessments may be conducted earlier when there is a significant change to the patient’s psychosocial needs, extended or frequent hospitalizations, any event that would interfere with the patient's ability to follow aspects of the plan of care, a change in the patient's modality, or at the patient's request.

 (5) Each facility shall employ or contract with a social worker to meet the psychosocial needs of the patients. One full-time equivalent of qualified social worker time shall be available for up to 125 patients per facility, which is the maximum case load for all modalities available in the facility. A second social worker shall be employed or contracted for a patient caseload over 125.

 (A) The governing body shall ensure personnel are assigned to assist social workers with ancillary tasks, such as assistance with financial services, transportation, and administrative and clerical duties, when the patient load, including all modalities, exceeds 100 patients per facility. The maximum patient load per full-time equivalent qualified social worker with assigned personnel assistance, including all modalities is 125 patients.

 (6) Social services shall be available at the facility during the times of patient treatment. Access to social services may require an appointment.

(i) Medical services.

 (1) The medical director shall meet the requirements set forth in the CMS Conditions of Coverage and is responsible for:

 (A) developing facility treatment goals which are based on review of aggregate data assessed through QAPI activities;

 (B) assuring adequate training of licensed nurses and dialysis technicians;

 (C) adequate monitoring of patients and the dialysis process;

 (D) developing, implementing, and enforcing all policies required by this chapter;

 (E) ensuring attending physicians of the facility follow the policies and procedures of the facility, and that the physicians follow the established treatment and clinical standards of the facility, including quality, safety, and infection control standards; and

 (F) ensuring all facility care staff, including nurses, patient care technicians, social workers, dietitians, physicians, and other ancillary staff receive annual training in all modalities, including transplant.

 (2) Medical staff.

 (A) Each patient shall be under the care of a licensed and qualified nephrologist on the medical staff, or a physician who has demonstrated experience treating dialysis patients for at least 18 months and is on the medical staff.

 (B) The care of a pediatric dialysis patient shall be in accordance with this subparagraph. If a pediatric nephrologist is not available as the primary physician, an adult nephrologist may serve as the primary physician with direct patient evaluation by a pediatric nephrologist according to the following schedule:

 (i) for patients two years of age or younger--monthly (two of three evaluations may be by phone);

 (ii) for patients three to 12 years of age--quarterly; and

 (iii) for patients 13 to 18 years of age--semiannually.

 (C) At a minimum, each patient receiving dialysis in the facility shall be seen by a physician on the medical staff twice a month, with visits separated by at least 10 days. Telehealth can be used for visits as allowed by the current federal regulations with the exception of the monthly complete assessment, as defined by the CMS Conditions of Coverage.

 (D) Home dialysis patients shall be seen by a physician, advanced practice registered nurse, or physician's assistant no less than one time a month. If home dialysis patients are seen by an advanced practice registered nurse or a physician's assistant, the physician shall see the patient at least one time every three months. This visit may be conducted in the dialysis facility, at the physician's office, or in the patient's home. The record of these contacts shall include evidence of assessment for new and recurrent problems and review of dialysis adequacy each month.

 (E) A physician on the medical staff shall be on call and available 24 hours a day (in person or by telecommunication) to patients and staff.

 (F) All orders for treatment shall be verified and signed by the physician. Routine orders for treatment shall be updated at least annually. Any changes in patient treatment shall be per physician's order.

 (i) Orders for hemodialysis treatment shall include length of treatment, dialyzer, blood flow rate, dialysate composition, target weight, all medications administered during or needed for treatment, and, as needed, specific infection control measures.

 (ii) Orders for peritoneal dialysis treatment shall include fill volumes, number of exchanges, dialysate concentrations, catheter care, medications, and, as needed, specific infection control measures.

 (3) Physician Extenders. If advanced practice registered nurses or physician assistants are used:

 (A) there shall be documented evidence of communication with the treating physician whenever the advanced practice registered nurse or physician assistant changes treatment orders;

 (B) the advanced practice registered nurse or physician assistant may not replace the physician in participating in patient care planning or in QAPI activities;

 (C) the advanced practice registered nurse or physician assistant may not replace the physician for the completion of assessments, as defined by the CMS Conditions of Coverage or for the twice monthly evaluation of the in-center dialysis patient;

 (D) the advanced practice registered nurse or physician assistant shall notify the treating physician of patient medical emergencies;

 (E) if an advanced practice registered nurse or physician assistant is used, such individuals shall meet the requirements established by the Texas Board of Nursing (for an advanced practice registered nurse) or the Texas Medical Board (for a physician assistant);

 (F) if an advanced practice registered nurse or a physician assistant is used, such individuals shall use mechanisms which provide authority for that care, which shall include protocols or other written authorization which shall be

 (i) jointly developed by the advanced practice registered nurse or physician assistant and the appropriate physicians;

 (ii) signed by both the advanced practice registered nurse or physician assistant and the physician;

 (iii) reviewed and re-signed at least annually;

 (iv) maintained in the practice setting of the advanced practice registered nurse or physician assistant; and

 (v) made available as necessary to HHSC to verify authority to provide medical aspects of care; and

 (G) telehealth may be used to meet the requirements for dialysis visits in accordance with the federal regulations governing telehealth.

(j) Home dialysis service.

 (1) A facility that provides home dialysis training and support shall be approved to provide home dialysis services and ensure through its interdisciplinary team that home dialysis services are at least equivalent to those provided to in-facility patients and meet all applicable licensure rules.

 (2) A facility shall provide a separate room for home dialysis services.

 (A) The room shall include a hand washing sink with hands-free operable controls, warm water, and soap to facilitate hand washing. Provisions for hand drying shall be included at each hand washing sink.

 (B) Clean areas shall be clearly designated for the preparation, handling, and storage of medications and unused supplies and equipment. Medications or clean supplies shall not be handled and stored in the same or an immediately adjacent area where used supplies, equipment, or blood samples are handled.

 (C) There shall be a designated area in the facility with a separate sink for the disposal of blood or body fluids. Contaminated areas where used supplies, equipment, or blood samples are handled shall be clearly designated.

 (3) On completion of training, each individual home dialysis patient, regardless of modality, shall be assigned one machine for the patient's exclusive use in the home.

 (4) The staffing level for home dialysis patients, including all modalities, shall be one full-time equivalent registered nurse per 20 patients, or portion thereof.

 (5) The training curriculum for the facility that provides home dialysis training and support shall be developed and approved by the medical director of the facility and include:

 (A) training conducted by a registered nurse with at least 12 months clinical nursing experience and a minimum of six months experience, occurring within the last 24 months, in the specific modality with the responsibility for training the patient and the patient's caregiver;

 (B) training conducted for each home dialysis patient that addresses the specific needs of the patient in the nature and management of end stage renal disease;

 (C) training including 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;

 (D) training of the patient and caregiver, as applicable, regarding the effective and safe administration of erythropoiesis-stimulating agents (if prescribed) to achieve and maintain a target level hemoglobin, hematocrit, and blood pressure levels, or hematocrit, as written in the patient's plan of care;

 (E) training of the patient and caregiver, as applicable, on how to detect, report, and manage potential dialysis complications, including water treatment problems;

 (F) training of the patient, and caregiver, as applicable, regarding the availability of support resources and how to access and use resources;

 (G) training of the patient, and caregiver, as applicable, on how to self-monitor health status and record and report health status information;

 (H) training of the patient, and caregiver, as applicable, on how to handle medical and nonmedical emergencies;

 (I) training of the patient, and caregiver, as applicable, regarding infection control precautions;

 (J) training of the patient, and caregiver, as applicable, regarding proper waste storage and disposal procedures;

 (K) training of the patient, and caregiver, as applicable, on how to order supplies on an ongoing basis;

 (L) training of the patient, and caregiver, as applicable, that non-medical electrical equipment shall not be used within six feet of the home hemodialysis machine;

 (M) training of the patient, and caregiver, as applicable, shall include directions on notifying the facility of any change in machinery used in home dialysis; and

 (N) maintenance of the training documentation in the clinical record that the patient, the caregiver, or both, received and demonstrated adequate comprehension of the training.

 (6) The interdisciplinary team shall oversee training of the home dialysis patient and the designated caregiver before the initiation of home dialysis, and when the home dialysis caregiver or home dialysis modality changes.

 (7) The dialysis facility shall retrieve and review complete self-monitoring data and other information from the home dialysis self-care patient, or their designated caregiver, at least every two months and maintain this information in the patient's clinical record in the facility.

 (8) A home dialysis facility shall furnish home dialysis support services, regardless of whether dialysis supplies may be provided by the dialysis facility or a durable medical equipment company.

 (9) A home dialysis facility shall provide services as described in this section.

 (A) An initial monitoring visit of the patient's home adaptation, including visits to the patient's home by facility personnel (including the registered nurse responsible for training the patient in the chosen modality and technical staff as appropriate), shall be completed in accordance with the patient's plan of care, and no less than annually thereafter. The initial home visit shall be completed prior to the patient beginning training for the selected home modality.

 (B) The patient shall be seen by the prescribing physician, advanced practice registered nurse, or physician's assistant no less than one time a month. The prescribing physician shall see the patient at least one time every three months, if an advanced practice registered nurse, or physician's assistant sees the patient monthly. This visit may be conducted in the dialysis facility, at the physician's office, or in the patient's home.

 (C) An individualized and comprehensive plan of care shall be developed for the patient and periodically reviewed. The plan of care shall specify the services necessary to address the patient's needs and meet the measurable and expected outcomes, which meet a hemodialysis Kt/V of at least 1.2 (3 times a week), or standard Kt/V of 2.0 (4-6 times a week), or a peritoneal dialysis weekly Kt/V of at least 1.7, or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis.

 (D) The facility shall provide patient consultation with members of the interdisciplinary team as needed.

 (10) A home dialysis facility shall monitor the quality of water and dialysate used by a home hemodialysis patient, including an on-site evaluation and testing of the water and dialysate system initially, and any time repairs or exchanges of the water treatment equipment are made.

 (A) An Association for the Advancement of Medical Instrumentation (AAMI) analysis of the product water used for dialysate preparation shall be performed annually and be consistent with the Conditions for Coverage under the Center for Medicare and Medicaid Services (CMS).

 (B) The water and dialysate system shall be tested in accordance with the manufacturer's direction for use.

 (C) The water and dialysate system shall be tested in accordance with the system's Food and Drug Administration (FDA) approved labeling, for integrated hemodialysis system designed, tested, and validated to meet AAMI quality (which includes standards for chemical and chlorine or chloramines testing) water and dialysate. The facility shall meet testing and other requirements of AAMI RD 52:2004, when using an integrated water and dialysate system, which is designed and validated to meet AAMI quality and is consistent with the current Conditions for Coverage under the Center for Medicare and Medicaid Services (CMS).

 (D) The bacteriological and endotoxin testing of water used for dialysate preparation and dialysate shall be performed monthly until results do not exceed 200 CFU/ml and an endotoxin concentration less than 2 EU/ml are obtained for three consecutive months and quarterly thereafter, on a more frequent basis as needed, to ensure that the water and dialysate are within the AAMI limits and consistent with the Conditions for Coverage under CMS.

 (11) The dialysis facility shall 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:

 (A) an analysis of the water and dialysate quality indicates contamination; or

 (B) if the home hemodialysis patient demonstrates clinical symptoms associated with water and dialysate contamination.

 (12) The dialysis facility shall be responsible for the arrangement of the purchase, lease, or rent of medically necessary home dialysis supplies and equipment, and the delivery, installation, repair, and maintenance of these supplies and equipment (including supportive equipment), as prescribed by the attending physician. If the patient purchases, leases or rents dialysis equipment, the facility shall ensure that the equipment is installed, repaired, and maintained in accordance with the manufacturer’s directions for use.

 (13) The dialysis facility shall identify a plan and arrange for emergency backup dialysis services when needed.

 (14) The dialysis facility shall maintain a record keeping system that ensures continuity of care and patient privacy.

 (15) Hemodialysis machines of home patients shall be cultured and measured for colony forming units and endotoxins prior to disinfection. The facility shall follow the manufacturer’s recommendations regarding the proper procedure for disinfection. For integrated hemodialysis system devices, disinfection, culture, and measurement for colony forming units and endotoxins may not be required if consistent with the device’s FDA labeling and manufacturer’s recommendations.

 (16) As applicable, all dialysis machines and dialysis equipment shall have maintenance records maintained at the dialysis facility.

 (17) If required, the electrical connection for the home hemodialysis machines shall be connected to a ground-fault circuit interrupter (GFCI) receptacle in accordance with Subchapter H of this chapter (relating to Physical Plant and Construction Requirements).

 (18) The dialysis machine shall comply with the requirements of §507.32 of this chapter (relating to Water Treatment, Dialysate Concentrates, and Reuse). The facility shall ensure that the water pressure in the patient's home meets the minimum requirement specified by the manufacturer of the water treatment system.

 (A) Integrated hemodialysis system.

 (i) The facility shall perform an analysis of the source water used for dialysate, to ensure the water quality meets the manufacturer's guidelines for source water purity, annually or if there is a change in the source water.

 (ii) The chemical quality of the product water shall be obtained every six months prior to a replacement of the water purification disposable component, or when any modifications are made to the integrated hemodialysis system to ensure that the product water meets the current CMS guidelines.

 (iii) A means shall be provided to sample the product water to test for chlorine or chloramines levels immediately prior to using the dialysate. Chlorine or chloramines level shall be less than 0.1 mg/L, and the results shall be documented.

 (iv) The microbiological quality of the dialysate shall be obtained at the end of a prepared dialysate bag, with the requirements at §507.32 of this chapter.

 (B) A dialysis system that uses manufactured dialysate solution in its existing form, shall be used according to manufacturer's directions for use.

 (C) A peritoneal dialysis system, if using manufactured dialysis solution, shall be used according to manufacturer's directions for use.

 (D) If sorbent technology is used, prior to each treatment the sorbent regeneration dialysis system (machine) shall be tested through the manufacturer's self-test method, and the evidence of the self-test shall be documented. The facility shall perform an analysis of the source water used for dialysate to ensure the water quality meets the manufacturer's guidelines for source water purity annually or if there is a change in the source water.

(k) If a facility dialyzes a patient who is normally dialyzed in another facility, the facility shall meet the requirements in this subsection.

 (1) The facility shall continuously evaluate staffing levels and use this information in determining whether to accept a transient patient for treatment.

 (2) The facility shall obtain the information described in §507.47(e) of this chapter (relating to Clinical Records) prior to providing dialysis. However, if the transient patient arrives unannounced, the facility may provide dialysis with, at a minimum, the following information:

 (A) records;

 (B) orders for treatment;

 (C) hepatitis B status; and

 (D) medical justification by the physician ordering treatment that the patient's need for dialysis outweighs the need for the additional clinical information set out in §507.47(e) of this chapter.

 (3) In the event a transient patient's hepatitis status is unknown, the patient may undergo treatment as if the HBsAg test results were potentially positive, except that such a patient shall not be treated in the HBsAg isolation room, area, or machine.

(l) A facility that provides laboratory services shall comply with the requirements of Federal Public Law 100 - 578, Clinical Laboratory Improvement Amendments of 1988 (CLIA 1988). CLIA 1988 applies to all facilities that examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

(m) A facility shall not violate Texas Occupations Code, Chapter 102, concerning the prohibition on soliciting patients or patronage.

(n) Balance Billing.

 (1) A facility may not violate a law that prohibits the facility from billing a patient who is an insured, participant, or enrollee in a managed care plan an amount greater than an applicable copayment, coinsurance, and deductible under the insured's, participant's, or enrollee's managed care plan or that imposes a requirement related to that prohibition.

 (2) A facility shall comply with Senate Bill 1264, 86th Legislature, Regular Session (2019) and with related Texas Department of Insurance rules at 28 TAC Chapter 21, Subchapter OO, §§21.4901-21.4904 (relating to Disclosures by Out-of-network Providers) to the extent this subchapter applies to the facility.

(o) The facility shall comply with Texas Health and Safety Code, Chapter 166, concerning out-of-hospital do-not-resuscitate orders.

(p) If the facility has a contract or agreement with an accredited school of health care to use their facility for a portion of the students' clinical experience, those students may provide care under the following conditions.

 (1) Students may be used in facilities, provided the instructor gives class supervision and assumes responsibility for all student activities occurring within the facility.

 (2) A student may administer medications only if:

 (A) on assignment as a student of his or her school of health care; and

 (B) under the direct supervision of a qualified registered nurse on staff at the facility.

 (3) Students shall not be used to fulfill the requirement for administration of medications by licensed personnel.

 (4) Students shall not be considered when determining staffing levels required by the facility.

 (5) Students are prohibited from concentrate mixing and water quality testing.

 (6) Students shall not accept or transcribe physician orders.

 (7) Students are prohibited from conducting the assessments of new or unstable patients.

 (8) There shall be direct supervision of the students by the qualified registered nurse to ensure the protection of the students and the patients of the facility.

(q) A facility shall adopt, implement, and enforce procedures for the resolution of complaints relevant to quality of care or services rendered by licensed health care professionals and other members of the facility staff, including contract services or staff. The facility shall document the receipt and the disposition of the complaint. The investigation and documentation shall be completed within 30 calendar days after the facility receives the complaint, unless the facility has and documents reasonable cause for a delay.

§507.46. Qualifications of Staff.

(a) The dialysis facility's staff (whether employees or contractors) shall meet the personnel qualifications and demonstrated competencies necessary to serve collectively the comprehensive needs of the patients. The dialysis facility's staff shall have the ability to demonstrate and sustain the skills needed to perform the specific duties of their positions.

 (1) The facility shall have a written orientation program to familiarize all new employees (including office staff) with the facility, its policies, and job responsibilities. The orientation program shall be developed and implemented. The facility shall ensure that each new direct care staff member (whether employee or contractor) is provided sufficient time to become familiar with the facility, as outlined in the following subparagraphs:

 (A) The training program provided by the facility shall be a minimum time of two weeks for individuals with previous dialysis experience. For new direct care staff members with no previous dialysis experience, the training program shall be two weeks plus additional orientation time as determined by the facility.

 (B) The facility shall ensure that, in facilities with similar policies and equipment, experienced staff oriented to one facility may be shared with another facility after a shorter orientation period. Documentation of current competency of any shared staff and delegation by that facility's medical director to unlicensed technicians shall be on file in each facility where the shared employee works.

 (C) The facility shall ensure that registered nurses with no previous dialysis experience shall be provided a training program of a minimum of seven weeks. For these registered nurses, the seven-week training program shall contain at least the following subject content specific to the management of the end stage renal disease patient and appropriate to the population served by the facility:

 (i) fluid, electrolyte, and acid-base balance;

 (ii) kidney disease and treatment;

 (iii) dietary management of kidney disease;

 (iv) principles of dialysis;

 (v) dialysis technology;

 (vi) venipuncture technique;

 (vii) care of the dialysis patient;

 (viii) psychological, social, financial, and physical complications of long-term dialysis;

 (ix) prevention of hepatitis and other infectious diseases;

 (x) risks and benefits of reuse (if reuse is practiced); and

 (xi) all available treatment modalities, including the availability of kidney transplantation.

 (5) The facility shall ensure that each licensed nurse and dialysis technician demonstrate competency through written and skills testing after the completion of the training program and annually thereafter. Evidence of competency shall be documented in writing and maintained in personnel files. Current certification by a nationally recognized board may substitute for the annual written test. All dialysis technicians shall be certified under a national commercially available certification program, within 18 months of being hired as a dialysis technician.

(b) Medical staff.

 (1) Each physician on the medical staff shall have a current license to practice medicine in the State of Texas.

 (2) The members of the medical staff may include nephrologists and other physicians with training or demonstrated experience in the care of end stage renal disease patients.

 (3) If an advanced practice registered nurse is used, such professionals shall meet the requirements established by the Texas Board of Nursing in 22 TAC, Part 11, Chapter 221, Advanced Practice Registered Nurses.

 (4) If a physician assistant is used, such individuals shall meet the requirements established by the Texas Medical Board in 22 TAC, Part 9, Chapter 185, Physician Assistants.

(c) Nursing staff.

 (1) Each person licensed as a nurse shall have a current Texas license to practice nursing in accordance with the statutes and rules of the Texas Board of Nursing, or a current license from another state in the Nurse Licensure Compact (NLC).

 (2) Each registered nurse assigned charge nurse responsibilities shall have at least 12 months of clinical experience and have six months experience in hemodialysis after completion of the facility's training program concurrent with six months of dialysis experience. For a newly licensed registered nurse, the last six months of clinical experience may run concurrently with the six months of dialysis experience. The hemodialysis experience shall be within the last 24 months. A registered nurse who holds a current certification from a nationally recognized board in nephrology nursing or hemodialysis may substitute the certification for the six months experience in dialysis obtained within the last 24 months.

 (3) There shall be written physician standing orders specific to the facility to guide actions to be taken by the nursing staff in the event a patient's condition deteriorates during treatment. These standing orders shall be reviewed and approved by the medical director at least annually, consistent with the Texas Medical Board statutes and rules and the Texas Board of Nursing, Nursing Practice Act, rules, and policy statements for registered nurses and licensed vocational nurses.

 (4) If patient self-care in-center or home training is provided, a registered nurse, who has at least 12 months clinical experience and six months experience in the specific modality, shall be responsible for training the patient or family in that modality. When other personnel assist in the training, supervision by the qualified registered nurse shall be demonstrated.

 (5) When other personnel assist in the training of a patient and the patient's caregiver for self-care training, there shall be documentation in the personnel record that the employee is qualified, as approved by the medical director.

 (6) The facility shall establish a nursing peer review committee to conduct nursing peer review, as required by Texas Occupations Code, Chapter 303.

(d) Each dietitian shall have a current Texas license, be a registered dietitian, and have a minimum of one year of professional work experience in clinical dietetics after becoming a registered dietitian.

(e) Each social worker shall:

 (1) be licensed as a social worker under Texas Occupations Code, Chapter 505, and hold a master’s degree in social work from a graduate school of social work accredited by the Council on Social Work Education; or

 (2) have worked for at least two years as a social worker, one year of which was in a dialysis facility or transplantation program prior to September1, 1976, and have established a consultative relationship with a social worker who has a master’s degree in social work from a graduate school of social work accredited by the Council on Social Work Education.

(f) Biomedical technical staff.

(1) A facility shall have the technical staff as described in this subsection. The facility's technical staff may be one or more individuals (including nursing staff) employed by or under contract with the facility as long as the individual meets the minimum qualifications for each required level of responsibility as described in this subsection.

 (2) Only individuals qualified by training, education, or experience may operate, repair, or replace components of the systems used in providing dialysis treatment or reprocessing dialyzers.

 (A) Technical staff shall have the following minimum education, training, and experience and documentation of such education, training, and experience shall be maintained on file in the facility:

 (i) high school diploma or equivalent, except for technical staff employed by the facility for two or more years prior to April 11, 1999, who are exempt from this requirement; and

 (ii) training or experience in one or more of the following:

 (I) completion of a college based technical dialysis program;

 (II) completion of the didactic training and education requirement for patient care technicians set out in §507.62(a) and (b) of this chapter (relating to Training Curricula and Instructors);

 (III) current certification in technical aspects of dialysis by a nationally recognized testing organization; or

 (IV) 12 months experience in dialysis within the last two years.

 (B) Any staff member assigned responsibilities in the technical area shall pass a written competency examination, demonstrate skills related to the required level of responsibility, and be certified by the facility's medical director as competent to perform their assigned duties. Current certification by a national board in dialysis technology may substitute for the written test.

 (C) The technical staff shall demonstrate competency for the required level of responsibility through written and skills testing annually. Current certification by a national board in dialysis technology may substitute for the written test. Evidence of competency shall be documented in writing and maintained in the personnel file.

 (D) The technical staff shall complete a minimum of five hours of continuing education with a technical or end stage renal disease focus annually. Continuing education may be provided by facility staff. Documentation shall include the title, duration, and the author or instructor of the continuing education course.

 (3) The technical supervisor is responsible for supervision of technical services. The technical supervisor shall meet the education, training, and experience requirements described in this paragraph.

 (A) The technical supervisor shall meet the requirements in paragraph (1) of this subsection.

 (B) At a minimum, the technical supervisor shall ensure technical staff demonstrate competency in equipment maintenance and repair; mechanical service; water treatment systems; and reprocessing of hemodialyzers (if applicable).

 (i) Prior to initially assuming technical supervisory responsibility, a technical supervisor trainee shall successfully complete the facility's orientation and training courses as established for each technical area.

 (ii) The training courses shall be approved by the medical director and follow a written curriculum with stated objectives. The curriculum shall include all items noted in paragraphs (3)(B)(ii), (4)(B), and (5)(A) of this subsection.

 (4) Staff responsible for water treatment and dialysate systems.

 (A) Facility staff responsible for the water treatment and dialysate systems shall demonstrate understanding of the risks to patients of exposure to water which has not been treated to remove contaminants and impurities. Documentation of training to assure safe operation of the water treatment and dialysate systems shall be maintained for each individual who operates (regularly or intermittently) these systems.

 (B) The staff responsible for the water treatment and dialysate systems shall meet the education, training, and experience requirements described in paragraph (1) of this subsection and shall demonstrate competency by:

 (i) successful completion of the facility training course specific to water treatment, dialysate preparation, and related tasks. The training course shall be approved by the medical director and follow a written curriculum with stated objectives;

 (ii) completion of a training curriculum that includes the following minimum components:

 (I) introduction to end stage renal disease;

 (II) principles of hemodialysis;

 (III) principles of infection control and basic microbiology for water treatment systems, machines, and sampling techniques;

 (IV) rationale for water treatment for dialysis;

 (V) risks and hazards of the use of unsafe water for dialysis;

 (VI) current water standards;

 (VII) source water characteristics;

 (VIII) communication with source water agencies and water treatment vendors;

 (IX) selection of water treatment equipment;

 (X) water purification equipment, to include filtration, carbon adsorption, and reverse osmosis;

 (XI) ion exchange to include softeners and deionizers;

 (XII) water distribution system and other equipment specific to the facility;

 (XIII) monitoring system performance, to include on-line and off-line monitoring, aseptic sample collection, incubation of samples, and interpretation of results;

 (XIV) evaluation of water treatment component performance, to include filters, activated carbon adsorption beds, reverse osmosis, and ion exchange;

 (XV) evaluation of system performance, to include monitoring schedules and review of system failures;

 (XVI) purpose of each component of dialysate, to include electrolytes, glucose, acid, and buffer;

 (XVII) hazards of exposure of patients to a dialysate containing a different concentration of electrolytes than prescribed;

 (XVIII) testing methods in use to verify expected concentrations in any reconstituted components of the dialysate are achieved;

 (XIX) action to take in the event testing of a mixed batch of dialysate concentrate does not meet the expected parameters;

 (XX) labeling employed to positively identify each concentrate; and

 (XXI) procedures to ensure the proper transfer of concentrates from the manufacturer's drums to the holding tanks.

 (iii) confirmation of the ability to distinguish all primary colors; and

 (iv) successful completion of the facility's orientation and training course as established for the water treatment and dialysate preparation systems technician trainee prior to the trainee's initial assumption of responsibility.

 (5) The staff responsible for equipment maintenance and repair shall meet the education, training, and experience requirements described in paragraph (1) of this subsection and shall demonstrate competency by:

 (A) successful completion of the facility training course outlined in paragraph (3) of this subsection, relating to water treatment systems;

 (B) successful completion of a training curriculum, which includes:

 (i) prevention of transmission of hepatitis through dialysis equipment;

 (ii) safety requirements of dialysate delivery systems;

 (iii) repair and maintenance of dialysis and other equipment specific to the facility;

 (iv) electrical safety, including lockout or tagout;

 (v) emergency equipment maintenance;

 (vi) building maintenance;

 (vii) fire safety and prevention requirements; and

 (viii) emergency response procedures; and

 (C) successful completion of a written competency exam and demonstration of skills specific to the facility's mechanical and equipment service and water treatment and distribution systems.

 (6) The staff responsible for reprocessing hemodialyzers and other supplies shall meet the education, training, and experience requirements described in paragraph (1) of this subsection and shall demonstrate competency by:

 (A) successful completion of a training curriculum that includes the components in the American National Standards Institute (ANSI), Reuse of Hemodialyzers, Third Edition, ANSI/AAMI RD47:2002 and RD47:2002/A1:2003, §5.2.1 published by the Association for the Advancement of Medical Instrumentation (AAMI) or the most recently published equivalent; and

 (B) successful completion of a written competency exam that includes return demonstration of skills specific to reprocessing of hemodialyzers and other dialysis supplies.

§507.47. Clinical Records.

(a) A facility shall develop, implement, and enforce policies and procedures for a clinical record system to assure that the care provided to each patient is completely and accurately documented, readily available, and systematically organized to facilitate the compilation and retrieval of information.

 (1) All information shall be centralized in the patient's clinical record and be protected against loss or damage in accordance with state and federal regulations.

 (2) The facility shall provide an area for clinical records storage that is separate from all patient treatment areas and shall be secured from unauthorized access. The facility shall store the active clinical record of each patient currently treated by the facility on site.

 (3) The facility shall ensure that each patient's personal and clinical records are treated with confidentiality.

 (4) Signature stamps shall not be used to authenticate clinical record entries.

 (5) Clinical records may be preserved electronically. Electronic records shall meet all requirements of paper records, including protection from casual access and retention for the specified period. Systems shall assure that entries regarding the delivery of care may not be altered without evidence and explanation of such alteration.

 (6) Inactive clinical records may be preserved by electronic means and may be stored off site, as long as security is maintained, and the record is readily retrievable for review by HHSC or HHSC's designee.

 (7) Each patient's clinical record, whether hard copy, electronic, or a combination of both, shall include complete and pertinent information about the condition of the patient, assessments by the interdisciplinary team, updated plans of care, all interventions and treatments prescribed and delivered, and details of any events occurring with the patient during treatment. The record of care shall be readily accessible to every authorized member of the interdisciplinary team so that safe care can be coordinated to best meet the needs of the patient.

 (8) Each clinical record shall include:

 (A) identifying information;

 (B) consents and notifications;

 (C) physician orders;

 (D) progress notes;

 (E) problem list;

 (F) medical history and physical;

 (G) professional assessments by the registered nurse, social worker, and dietitian;

 (H) medication record to include medications given during treatment (which may be listed on the treatment record) and a listing of medications the patient takes at home;

 (I) transfusion record;

 (J) laboratory reports;

 (K) diagnostic studies;

 (L) hospitalization records;

 (M) consultations;

 (N) record of creation and revision of access for dialysis;

 (O) plans of care, including evidence of interdisciplinary team review and adjustment;

 (P) evidence of patient education;

 (Q) daily treatment records; and

 (R) discharge summary, if applicable.

(b) A comprehensive medical history and physical shall be completed within 30 days of a patient's admission to the facility and no less than annually thereafter. For a patient new to dialysis, the physician responsible for the dialysis care shall complete the history and physical. For an established dialysis patient, the history and physical may be completed by an advanced practice registered nurse or physician assistant. Prior to the first treatment in the facility, the physician shall inform the registered nurse functioning in the charge role of at least the patient's diagnoses, medications, hepatitis status, allergies, and dialysis prescription. The patient’s clinical record shall include this data.

(c) The patient’s clinical record shall provide an ongoing and accurate picture of the progress of the patient, reflecting changes in patient status, plans for and results of changes in treatment, diagnostic testing, consultations, and unusual events. Each of the interdisciplinary team members shall record the progress of the patient as indicated by any change in the patient's medical, nutritional, or psychosocial condition.

(d) The patient's condition and response to treatment shall be noted on the daily treatment record.

(e) Prior to providing dialysis treatment of a transient patient, a facility shall obtain and include, at a minimum:

 (1) orders for treatment in this facility;

 (2) list of medications and allergies;

 (3) laboratory reports, which shall indicate laboratory work was performed no later than one month prior to treatment at the facility and include screening for hepatitis B status;

 (4) the most current plan of care;

 (5) the most current treatment records from the home facility; and

 (6) records of care and treatment at this facility.

(f) Clinical records shall be completed within 30 days after discharge. The discharge summary shall clearly identify the disposition of the patient and include the diagnosis or cause of death, date of discharge or death, location of death, transplant, or relocation information when appropriate, and reason for discharge if not for transplantation or death.

(g) Clinical records are the property of the facility and shall be safeguarded against loss, destruction, or unauthorized use.

(h) Copies of pertinent portions of a patient's record shall be provided when the patient is transferred. The records provided shall include, at a minimum, the most current orders for dialysis treatment, the last three treatment records, the current hepatitis status, and the most current plan of care. If the patient is transferred to another outpatient facility, copies of the most recent history and physical and assessment of each member of the interdisciplinary team shall also be provided.

(i) Records shall be retained by a facility for a minimum of five years after the discharge of the patient and in accordance with state and federal regulations. The facility may not destroy clinical records that relate to any matter that is involved in litigation, if the facility knows the litigation has not been finally resolved.

(j) If a facility ceases operation, there shall be an arrangement for the preservation of records to insure compliance with this section. The facility shall send HHSC written notification of the location of the clinical records and the name and address of the clinical records custodian.

§507.48. Incident Reports.

(a) A facility shall report the following incidents to HHSC within 10 business days:

 (1) death of a dialysis patient which occurs in the facility;

 (2) death of a dialysis patient that occurs at home or in a hospital within 24 hours of the last dialysis treatment, unless the death is related to a traffic accident, pre-scheduled elective surgery, hospitalization greater than 14 days, a previously executed do-not-resuscitate (DNR) directive, a hospice patient, or a patient who withdraws from dialysis;

 (3) hospital transfers from the facility if CPR (cardiopulmonary resuscitation) was initiated or a change in the medical condition of the patient occurred during or immediately following dialysis treatment;

 (4) confirmed conversion of staff or a patient to hepatitis B surface antigen (HbsAg) positive;

 (5) involuntary transfer or discharge of a patient; unless the patient was a participant in the ESRD Network’s Second Chance program, in which case there is no incident report required if the patient is involuntarily discharged within the first 90 days of placement;

 (6) a fire in the facility; and

 (7) a generator out of operation.

(b) An incident listed in subsection (a) of this section shall be reported to Texas Health and Human Services Commission, Complaint and Incident Intake. The incident report shall be on a form provided by HHSC and include the information requested on the form in full. The incident reporting form is available on HHSC’s website.

§507.49. Nonconventional Dialysis.

(a) Self-care.

 (1) If a licensed dialysis facility offers in center self-care in addition to conventional hemodialysis, the facility shall develop, implement, and maintain policies and procedures related to self-care, including policies regarding staffing levels in the self-care milieu.

 (2) While nurse to patient ratios must remain the same, the number of patient care technicians may be reduced from a 4:1 ratio to a 6:1 ratio if:

 (A) The self-care area is separated from the conventional dialysis area, such as in a separate bay or room within the facility; and

 (B) Self-care patients are able to, at a minimum, demonstrate the ability to:

 (i) set up and tear down the machinery used in their treatment;

 (ii) hold their own sites at termination of treatment, with the exception of a catheter patient; and

 (iii) monitor and record their own vital signs prior to initiation and at termination of the day’s treatment.

 (3) A licensed facility that offers the option of in-center, self-care shall ensure that all assessments, evaluations, history and physicals, treatment plans, modality options education, and similar documents and activities are completed prior to the initiation or transition to self-care.

 (4) Prior to a patient moving from conventional dialysis to self-care in a licensed dialysis facility, the patient shall demonstrate verbal understanding of competencies in the self-care areas, as determined by the facility staff.

 (5) Written documentation of self-care competencies via checklists and competency testing shall be maintained in the patient's medical record.

 (6) Annual competency and skills verification retesting and documentation shall be maintained by the facility to verify the patient on self-care maintains the abilities to complete self-care. In addition, patients may take on additional aspects of self-care, and those additional aspects shall have documented competencies prior to independent completion of tasks and annual re-evaluation of those competencies.

(b) Transitional care services.

 (1) Transitional services provide short term in-center dialysis to transition a patient from a current modality to a self-care modality whether in-center or at home.

 (2) A facility offering transitional services shall develop, implement, and enforce policies and procedures specific to the operation of transitional services.

 (3) Licensed dialysis facilities that offer transitional care shall ensure that all assessments, evaluations, history and physicals, treatment plans and similar documents and activities are completed prior to the initiation of treatment.

 (4) A facility offering transitional services shall provide the patient with appropriate education regarding end-stage renal disease, its treatment, the availability and advisability of all modalities to include renal transplant, dietary concerns and needs, and social services.

 (5) A facility offering transitional services shall ensure that the patient retains all rights applicable to treatment in a licensed dialysis facility. A patient shall be assessed by the interdisciplinary treatment team for transitioning services no later than 30 days after entry into the program. In the event a patient is assessed as requiring continued services only available in a conventional dialysis setting, the patient shall be considered for transfer to a conventional setting for continuation of the benefits of dialysis. This transfer shall not be considered as an involuntary discharge from the transitional facility.

 (6) Transitional care staff shall receive equivalent training to both in-center and home hemodialysis staff, including training to the specifications of the manufacturer of the hemodialysis machine being used. Training and skills shall be documented, and competencies shall be approved by the medical director and available upon request.

(c) Integrated hemodialysis systems.

 (1) A licensed facility offering the use of self-contained or integrated hemodialysis systems shall develop, implement, and enforce policies and procedures related to these systems and staff shall have verification of competency for each type of machine they perform or monitor treatments on.

 (2) If the licensed dialysis facility uses self-contained or integrated hemodialysis systems along with conventional hemodialysis machines, the facility shall congregate the self-contained units or integrated hemodialysis systems separate from the conventional machines.

 (3) Licensed dialysis facilities that use self-contained or integrated hemodialysis systems shall ensure that all assessments, evaluations, history and physicals, treatment plans and similar documents and activities are completed prior to the initiation of treatment.

 (4) The patients shall receive education on the use and efficacy of the self-contained units.

 (5) For those licensed dialysis facilities that solely use self-contained or integrated hemodialysis systems, the facility shall follow the manufacturer's recommendations and instructions for the use of the machines.

 (6) A licensed facility offering the use of self-contained or integrated hemodialysis systems shall maintain a copy of the manufacturer's instructions on each type of unit used in the facility. The facility shall provide inspectors with a copy of the manufacturer's instructions and recommendations upon request.

 (7) A registered nurse shall be present in the integrated hemodialysis systems area, and staffing ratios shall remain the same as for conventional dialysis.

§507.50. Staffing and Reporting Requirements During the COVID-19 Pandemic.

(a) Based on Governor Greg Abbott’s March 13, 2020, declaration of a state of disaster in all Texas counties, the Texas Health and Human Services Commission (HHSC) adopts this section to establish continuing requirements and flexibilities to protect public health and safety during the COVID-19 pandemic. The requirements and flexibilities established in this rule are applicable during an active declaration of a state of disaster in all Texas counties due to the COVID-19 pandemic, declared pursuant to Texas Government Code §418.014.

(b) An end stage renal disease (ESRD) facility that is experiencing a documented, significant staffing shortage may temporarily adopt the accommodations under this section to meet patient needs for the duration of the COVID-19 pandemic.

(c) An ESRD facility may request a temporary exemption from the following staffing requirements, subject to HHSC’s approval:

 (1) for nursing services, §507.45(d)(6)(A)-(B) of this subchapter (relating to Provision and Coordination of Treatment and Services);

 (2) for nutrition services, §507.45(g)(5) of this subchapter;

 (3) for social services, §507.45(h)(5) of this subchapter; and

 (4) for staffing levels of direct care staff, §507.106 of this chapter (relating to Tables).

(d) Notwithstanding §507.43(e) of this subchapter (relating to Quality Assessment and Performance Improvement), core staff members shall actively participate in quality assessment and performance improvement (QAPI) activities and attend meetings every other month.

(e) Notwithstanding §507.45(c)(3) of this subchapter, all verbal or telephone physician orders shall be documented and authenticated or countersigned by the physician not more than 30 calendar days from the date the order was given.

(f) Notwithstanding §507.45(j)(4) of this subchapter, the staffing level for home dialysis patients, including all modalities, shall be one full-time equivalent registered nurse per 25 patients, or portion thereof.

(g) Notwithstanding §507.45(j)(5)(A) of this subchapter, the home dialysis training curriculum shall be conducted by a registered nurse with at least 12 months clinical experience and three months experience in the specific modality with the responsibility for training the patient and the patient's caregiver.

(h) Notwithstanding §507.46(c)(2) of this subchapter (relating to Qualifications of Staff), each registered nurse who is assigned charge nurse responsibilities shall have at least 12 months of clinical experience and have three months of experience in hemodialysis after completion of the facility’s training program. In addition:

 (1) the registered nurse must be able to demonstrate competency for the required level of responsibility and the facility shall maintain documentation of that competency;

 (2) the registered nurse must be certified by the facility’s medical director and governing body;

 (3) the hemodialysis experience shall be within the last 24 months; and

 (4) a registered nurse who holds a current certification from a nationally recognized board in nephrology nursing or hemodialysis may substitute the certification for the three months experience in dialysis obtained within the last 24 months.

(i) Notwithstanding §507.46(c)(4) of this subchapter, if patient self-care training is provided, a registered nurse who has at least 12 months clinical experience and three months experience in the specific modality shall be responsible for training the patient or family in that modality. When other personnel assist in the training, supervision by the qualified registered nurse shall be demonstrated.

(j) Notwithstanding the deadline provision of §507.48(a) of this subchapter (relating to Incident Reports), a facility shall report an incident listed in §507.48(a)(1)-(5) of this subchapter to HHSC within 20 working days of the incident.

(k) Notwithstanding §507.62(i) of this chapter (relating to Training Curricula and Instructors), for persons with no previous experience in direct patient care, a minimum of 80 clock hours of classroom education and 200 clock hours of supervised clinical training shall be required for dialysis technicians. Training programs for dialysis technician trainees who have confirmed previous direct patient care experience may be shortened to a total of 40 clock hours of combined classroom education and clinical training if they demonstrate competency with the required knowledge and skills and there has not been more than a year of time elapsed since they provided patient care in a licensed ESRD facility setting.

§507.51. Medical Services and Home Dialysis During The COVID-19 Pandemic.

(a) Based on Governor Greg Abbott’s March 13, 2020, declaration of a state of disaster in all Texas counties, the Texas Health and Human Services Commission adopts this section to establish continuing requirements and flexibilities to protect public health and safety during the COVID-19 pandemic. The requirements and flexibilities established in this section are applicable during an active declaration of a state of disaster in all Texas counties due to the COVID-19 pandemic, declared pursuant to Texas Government Code §418.014.

(b) An end stage renal disease (ESRD) facility may temporarily adopt the accommodations under this section to meet patient needs, support infection control procedures, and maintain necessary social distancing in response to the COVID-19 pandemic.

(c) Notwithstanding §507.45(i)(2)(C) of this subchapter (relating to Provision and Coordination of Treatment and Services), at a minimum, each patient receiving dialysis in the facility shall be seen by a physician on the medical staff once per month during the patient's treatment time.

 (1) Home dialysis patients shall be seen by a physician, advanced practice registered nurse, or physician's assistant no less than one time a month.

 (2) If home dialysis patients are seen by an advanced practice registered nurse or a physician's assistant, the physician shall see the patient at least one time every three months. This visit may be conducted using telemedicine medical services.

 (3) The record of these contacts shall include evidence of assessment for new and recurrent problems and review of dialysis adequacy each month.

(d) Notwithstanding §507.45(j)(9)(A) of this subchapter, an initial monitoring visit of a patient’s home adaptation before the patient beginning training for the selected home modality may be conducted from outside the patient’s home if the visit is performed using a synchronous audiovisual interaction between the registered nurse and the patient while the patient is at home.

 (1) The visit must be conducted to the same review standards as a normal face-to-face visit.

 (2) If the visit is incapable of being performed using a synchronous audiovisual interaction between the registered nurse and the patient, the visit must be conducted in the patient’s home.

(e) A home patient visit required by §507.45(j)(9)(B) of this subchapter may be conducted using telemedicine medical services.

TITLE 26 HEALTH AND HUMAN SERVICES

PART 1 HEALTH AND HUMAN SERVICES COMMISSION

CHAPTER 507 END STAGE RENAL DISEASE FACILITIES

SUBCHAPTER E REQUIREMENTS FOR DIALYSIS TECHNICIANS

§507.61. General Requirements.

(a) An individual may not act as a dialysis technician unless that individual is trained and competent under this subchapter.

(b) Trainees shall be identified as such during any time spent in the patient treatment area.

(c) Until the successful completion of the competency evaluation, the trainee may provide patient care only as part of a training program and under the immediate supervision of a registered nurse or an assigned preceptor. A preceptor shall be a licensed nurse or dialysis technician who has one year of experience in hemodialysis obtained within the last 24 months, a recommendation by the supervising nurse to be a preceptor, and a current competency skills checklist on file in the facility.

§507.62. Training Curricula and Instructors.

(a) Each training program for dialysis technicians shall develop a written curriculum with objectives specified for each section.

(b) The training curricula for dialysis technicians shall include the following minimum components:

 (1) introduction to dialytic therapies to include history and major issues:

 (A) history of dialysis;

 (B) definitions and terminology;

 (C) communication skills;

 (D) ethics and confidentiality;

 (E) multidisciplinary process;

 (F) roles of other team members; and

 (G) information about renal organizations and resources;

 (2) principles of hemodialysis to include:

 (A) principles of dialysis;

 (B) access to the circulatory system; and

 (C) anticoagulation, local anesthetics, and normal saline;

 (3) understanding the individual with kidney failure to include:

 (A) basic renal anatomy, physiology, and pathophysiology;

 (B) the effect of renal failure on other body systems;

 (C) symptoms and findings related to the uremic state;

 (D) modes of renal replacement therapy, including transplantation;

 (E) basic renal nutrition;

 (F) basic psychosocial aspects of end stage renal disease (ESRD);

 (G) medications commonly administered to patients with ESRD;

 (H) confidentiality of patient personal and clinical records;

 (I) professional conduct;

 (J) patient rights and responsibilities; and

 (K) rehabilitation;

 (4) dialysis procedures to include:

 (A) using aseptic technique;

 (B) technical aspects of dialysis, operation and monitoring of equipment, initiation and termination of dialysis;

 (C) delivering an adequate dialysis treatment and factors that may result in inadequate treatment;

 (D) observing and reporting patient reactions to treatment;

 (E) glucose monitoring and hemoglobin and hematocrit monitoring;

 (F) emergency procedures and responses such as cardiopulmonary resuscitation, air embolism management, and response to line separation and hemolysis;

 (G) external and internal disasters, fire, natural disasters, and emergency preparedness; and

 (H) safety, quality assurance and performance improvement (QAPI);

 (5) hemodialysis devices to include:

 (A) theory and practice of conventional, high efficiency, and high flux dialysis;

 (B) dialysate composition, options, indications, complications, and safety;

 (C) monitoring and safety; and

 (D) disinfection of equipment;

 (6) water treatment to include:

 (A) standards for water treatment used for dialysis as described in the American National Standards Institute (ANSI), Dialysate for Hemodialysis RD 52:2004 Edition, published by the Association for the Advancement of Medical Instrumentation (AAMI), or most current edition;

 (B) systems and devices;

 (C) monitoring; and

 (D) risks to patients of unsafe water;

 (7) reprocessing, if the facility practices reuse, to include:

 (A) principles of reuse;

 (B) safety, QAPI, universal precautions, and water treatment; and

 (C) standards for reuse as described in the American National Standards Institute (ANSI), Reuse of Hemodialyzers, Third Edition, ANSI/AAMI RD47:2002 and RD47:2002/A1:2003, published by the AAMI, or most current edition;

 (8) patient teaching to include:

 (A) the role of the technician in supporting patient education goals; and

 (B) adult education principles;

 (9) infection control and safety to include:

 (A) risks to patients of nosocomial infections, accidents, and errors in treatment;

 (B) universal precautions, aseptic technique, sterile technique, and specimen handling;

 (C) basic bacteriology and epidemiology;

 (D) risks to employees of blood and chemical exposure; and

 (E) electrical, fire, disaster, environmental safety, and hazardous substances; and

 (10) QAPI to include:

 (A) role of the technician in QAPI activities;

 (B) principles of QAPI; and

 (C) the importance of ongoing QAPI activities in assuring safe dialysis treatments are provided to patients.

(c) Additional responsibilities.

 (1) If a dialysis technician is to assist with training or treatment of peritoneal dialysis patients, the following content shall also be included:

 (A) principles of peritoneal dialysis;

 (B) sterile technique;

 (C) peritoneal dialysis delivery systems;

 (D) symptoms of peritonitis; and

 (E) other complications of peritoneal dialysis.

 (2) If a dialysis technician, other than a licensed vocational nurse (LVN), is to cannulate access or administer normal saline, heparin, or lidocaine, the following content shall be included:

 (A) access to the circulation to include:

 (i) fistula: creation, development, needle placement, and prevention of complications;

 (ii) grafts: materials used, creation, needle placement, and prevention of complications; and

 (iii) symptoms to report;

 (B) safe administration of medications to include:

 (i) identifying the right patient;

 (ii) assuring the right medication;

 (iii) measuring the right dose;

 (iv) ascertaining the right route; and

 (v) checking the right time for administration;

 (C) administration of normal saline to include:

 (i) reasons for administration;

 (ii) potential risks and complications;

 (iii) administration limits; and

 (iv) information to report and record;

 (D) administration of heparin to include:

 (i) reasons for administration;

 (ii) methods of administration;

 (iii) preparation of ordered dose;

 (iv) potential risks and complications; and

 (v) information to report and record.

 (E) administration of lidocaine to include:

 (i) reasons for administration;

 (ii) method of administration;

 (iii) preparation of ordered dose;

 (iv) potential complications and risks; and

 (v) information to report and record.

 (F) administration of oxygen to include:

 (i) reasons for administration;

 (ii) method of administration;

 (iii) delivery of the ordered flow rate;

 (iv) potential complications and risks; and

 (v) information to report and record.

(d) A roster of attendance for each training class shall be maintained by the instructor.

(e) Each trainee shall be evaluated on a weekly basis during the training program to ascertain the trainee's progress.

(f) The dialysis technician trainee shall complete a written examination. The examination shall encompass the content required in subsection (b) of this section. When the dialysis technician trainee cannulates access and administers medications, the examination shall encompass the content described in subsection (c) of this section. A score of 80 percent is required on the written examination covering the required content prior to the dialysis technician trainee's release from orientation. Other than the first examination for a specific responsibility in a facility, current certification as a dialysis technician by a nationally recognized testing organization may be substituted for the written examination.

(g) An instructor for the course to train an individual as a dialysis technician shall be:

 (1) a physician who qualifies as a medical director;

 (2) a registered nurse with at least 12 months of experience in hemodialysis obtained within the last 24 months and a current competency skills checklist on file in the facility, or a registered nurse instructor of a dialysis technician training course of an accredited college or university;

 (3) a qualified dietitian or social worker providing training only within the person's area of expertise; or

 (4) a technician with at least 12 months experience, qualified by training and experience in water treatment, dialysate preparation, reprocessing, or other technical aspects of dialysis providing training within their area of expertise.

(h) Licensed nurses and patient care technicians who have at least one year of experience in hemodialysis and a current competency skills checklist on file in the facility may assist in didactic sessions and serve as preceptors.

(i) For persons with no previous experience in direct patient care, a minimum of 80 clock hours of classroom education and 200 clock hours of supervised clinical training shall be required. Training programs for dialysis technician trainees who have previous direct patient care experience may be shortened, if competency with the required knowledge and skills is demonstrated, but may not be less than a total of 80 clock hours of combined classroom education and clinical training.

§507.63. Competency Evaluation.

(a) The governing body shall ensure that the core staff members of the facility review the training records of each trainee, including tests and skills checklists, hear comments from the training instructors and preceptors, and validate that the trainee has successfully completed the training program and is competent to perform their job duties and tasks.

(b) An individual who completed the facility's orientation program and was determined by the facility to be qualified to deliver dialysis patient care may qualify as a dialysis technician by passing the written examination described in §507.62(f) of this chapter (relating to Training Curricula and Instructors) and demonstrating competency by completion of the skills checklist described in subsection (c) of this section.

(c) The supervising nurse or a registered nurse who qualifies as an instructor under §507.62(g)(2) of this chapter shall complete a competency skills checklist to document each dialysis technician trainee's knowledge and skills for the following allowed acts:

 (1) assembling necessary supplies;

 (2) preparing dialysate according to procedure and dialysis prescription;

 (3) assembling and preparing the dialysis extracorporeal circuit correctly;

 (4) securing the correct dialyzer for the specific patient;

 (5) installing and rinsing dialyzer and all necessary tubing;

 (6) testing monitors and alarms, conductivity, and (if applicable) presence and absence of residual sterilants;

 (7) setting monitors and alarms according to facility and manufacturer protocols;

 (8) obtaining pre-dialysis evaluation to include vital signs, weight, and temperature according to facility protocol and informing the registered nurse of unusual findings;

 (9) inspecting access for patency and, after cannulation is performed and heparin administered, initiating dialysis according to the patient's prescription, observing universal precautions, and reporting unusual findings to the registered nurse;

 (10) adjusting blood flow rates according to established protocols and the patient's prescription;

 (11) calculating and setting the dialysis machine to allow fluid removal rates according to established protocols and the patient's prescription;

 (12) monitoring the patient and equipment during treatment, responding appropriately to patient needs and machine alarms, and reporting unusual occurrences to the registered nurse;

 (13) changing fluid removal rate, placing patient in Trendelenburg position, and administering replacement normal saline as directed by the registered nurse, physician order, or facility protocol;

 (14) documenting findings and actions per facility protocol;

 (15) describing appropriate response to dialysis-related emergencies such as cardiac or respiratory arrest, needle displacement or infiltration, clotting, blood leaks, or air emboli and to nonmedical emergencies such as power outages or equipment failure;

 (16) discontinuing dialysis and establishing hemostasis:

 (A) inspecting, cleaning, and dressing access according to facility protocol; and

 (B) reporting unusual findings and occurrences to the registered nurse;

 (17) obtaining and recording post-dialysis vital signs, temperature, and weight and reporting unusual findings to the registered nurse;

 (18) discarding supplies and sanitizing equipment and treatment chair according to facility protocol;

 (19) communicating the patient's emotional, medical, psychological, and nutritional concerns to the registered nurse;

 (20) maintaining current certification in cardiopulmonary resuscitation; and

 (21) maintaining professional conduct, good communication skills, and confidentiality in the care of patients.

(d) For dialysis technician trainees who will be assisting with training or treatment of peritoneal dialysis patients, the following checklist shall be completed satisfactorily:

 (1) assisting patients in ordering supplies;

 (2) making a dialysate exchange (draining and refilling the peritoneal space with dialysate) to include continuous ambulatory peritoneal dialysis exchange procedures, and initiation or discontinuation of continuous cycling peritoneal dialysis;

 (3) observing peritoneal effluent;

 (4) knowing what observations to report;

 (5) collecting dialysate specimen; and

 (6) setting up and operating continuous cycling peritoneal dialysis equipment.

(e) For dialysis technician trainees who will be cannulating dialysis access, administering heparin, normal saline, lidocaine, or oxygen the following checklist shall also be completed satisfactorily:

 (1) cannulation to include:

 (A) inspecting the access for patency;

 (B) preparing the skin;

 (C) using aseptic technique;

 (D) placing needles correctly;

 (E) establishing blood access;

 (F) replacing needles;

 (G) knowing when to call for assistance;

 (H) securing needles; and

 (I) removing needles.

 (2) administration of heparin or other prescribed anticoagulants, to include:

 (A) checking the patient's individual prescription;

 (B) preparing the dose;

 (C) labeling the prepared syringe;

 (D) administering the dose; and

 (E) observing for complications;

 (3) administration of normal saline to include:

 (A) understanding unit protocol;

 (B) checking the patient's prescription;

 (C) recognizing signs of hypotension;

 (D) notifying the registered nurse;

 (E) administering normal saline; and

 (F) rechecking vital signs;

 (4) administration of lidocaine and other anesthetics to include:

 (A) checking the patient's prescription;

 (B) identifying the correct medication;

 (C) preparing the dose;

 (D) administering the dose; and

 (E) observing for complications; and

 (5) administration of oxygen to include:

 (A) verifying the ordered flow rate from the nurse functioning in the charge role;

 (B) setting up the equipment; and

 (C) connecting the tubing for the patient.

(f) If a dialysis technician is to cannulate a dialysis access, administer normal saline, heparin, lidocaine or other anesthetics, or oxygen, the medical director shall verify and document competency of the dialysis technician to perform these tasks and delegate authority to the technician in accordance with Texas Occupations Code, Chapter 157.

§507.64. Documentation of Competency.

(a) A training program is required to provide a certification or verification document to the trainee, documenting their successful completion of the training program and competency evaluation. This document shall indicate that the program completed met the requirements of this subchapter.

(b) The document described in subsection (a) of this section may be accepted by another facility that may later employ the dialysis technician. Each employing facility shall have newly hired experienced dialysis technicians complete a written test and a competency checklist in accordance with §507.63(c) - (e) of this chapter (relating to Competency Evaluation) within two weeks of hire.

§507.65. Prohibited Acts.

Performance of the following acts by any dialysis technician is prohibited:

 (1) initiation of patient education;

 (2) alteration of ordered treatment, including shortening the treatment time;

 (3) initiation or discontinuation of dialysis via a central catheter, manipulation of a central catheter, or dressing changes for a central catheter;

 (4) administration of any medications other than normal saline, heparin or other prescribed anticoagulants, lidocaine or other anesthetics, or oxygen, which may only be administered during a routine dialysis treatment;

 (5) administration of blood or blood products;

 (6) performance of nonaccess site arterial puncture;

 (7) acceptance of physician orders;

 (8) provision of hemodialysis treatment to pediatric patients under the age of 18 who weigh less than 35 kilograms;

 (9) alteration of the level of electrolytes in dialysate through use of additives ("spiking"); and

 (10) initiation or discontinuation of dialysis via a central venous catheter.

TITLE 26 HEALTH AND HUMAN SERVICES

PART 1 HEALTH AND HUMAN SERVICES COMMISSION

CHAPTER 507 END STAGE RENAL DISEASE FACILITIES

SUBCHAPTER F INSPECTIONS, INVESTIGATIONS, AND ENFORCEMENT

§507.81 Inspections.

(a) The Health and Human Services Commission (HHSC) may conduct an unannounced, on-site inspection of a facility at any reasonable time, including when treatment services are provided, to inspect, investigate, or evaluate:

 (1) compliance with any applicable statute or rule;

 (2) a facility’s plan of correction;

 (3) an order of the commissioner or the commissioner’s designee;

 (4) a court order granting injunctive relief; or

 (5) for other purposes relating to regulation of the facility.

(b) An applicant or licensee, by applying for or holding a license, consents to entry and inspection of any of its facilities by HHSC.

(c) HHSC inspections to evaluate a facility’s compliance may include:

 (1) initial, change of ownership, or relocation inspections for the issuance of a new license;

 (2) inspections related to changes in status, such as new construction or changes in services, designs, or bed numbers;

 (3) routine inspections, which may be conducted without notice and at HHSC’s discretion, or prior to renewal;

 (4) follow-up on-site inspections, conducted to evaluate implementation of a plan of correction for previously cited deficiencies;

 (5) inspections to determine if an unlicensed facility is offering or providing, or purporting to offer or provide, treatment; and

 (6) entry in conjunction with any other federal, state, or local agency’s entry.

(d) A facility shall cooperate with any HHSC inspection and shall permit HHSC to examine the facility’s grounds, buildings, books, records, and other documents and information maintained by or on behalf of the facility.

(e) A facility shall permit HHSC access to interview members of the governing body, personnel, and patients. Members of the governing body and personnel shall provide a written statement upon request from HHSC.

(f) A facility shall permit HHSC to inspect and copy any requested information. If it is necessary for HHSC to remove documents or other records from the facility, HHSC will provide a written description of the information being removed and when it is expected to be returned. HHSC will make a reasonable effort, consistent with the circumstances, to return any records removed in a timely manner.

(g) Upon entry, HHSC will hold an entrance conference with the facility’s designated representative to explain the nature, scope, and estimated duration of the inspection.

(h) During the inspection, the HHSC representative will give the facility an opportunity to submit information and evidence relevant to matters of compliance being evaluated.

(i) When an inspection is complete, HHSC will hold an exit conference with the facility representative to inform the facility representative of any preliminary findings of the inspection. The facility may provide any final documentation regarding compliance during the exit conference.

§507.82 Complaint Investigations.

(a) A facility shall provide each client and applicable consenter at the time of admission with a written statement identifying HHSC as the agency responsible for investigating complaints against the facility.

 (1) The statement shall inform persons that they may direct a complaint to HHSC Complaint and Incident Intake (CII) and include current CII contact information, as specified by HHSC.

 (2) The facility shall prominently and conspicuously post this information in patient common areas and in visitor’s areas and waiting rooms so that it is readily visible to patients, employees, and visitors. The information shall be in English and in a second language appropriate to the demographic makeup of the community served.

(b) HHSC will evaluate all complaints. A complaint must be submitted using HHSC’s current CII contact information for that purpose, as described in subsection (a) of this section.

(c) HHSC will document, evaluate, and prioritize complaints based on the seriousness of the alleged violation and the level of risk to patients, personnel, and the public.

 (1) Allegations determined to be within HHSC’s regulatory jurisdiction relating to health care facilities may be investigated under this chapter.

 (2) Complaints outside HHSC’s jurisdiction may be referred to an appropriate agency, as applicable.

(d) Investigations to evaluate a facility’s compliance shall be conducted following a complaint of abuse, neglect, or exploitation; or a complaint related to the health and safety of patients.

(e) HHSC may conduct an unannounced, on-site investigation of a facility at any reasonable time, including when treatment services are provided, to inspect, investigate, or evaluate:

 (1) a facility’s compliance with any applicable statute or rule;

 (2) a facility’s plan of correction;

 (3) a facility’s compliance with an order of the commissioner or the commissioner’s designee;

 (4) a facility’s compliance with a court order granting injunctive relief; or

 (5) for other purposes relating to regulation of the facility.

(f) An applicant or licensee, by applying for or holding a license, consents to entry and investigation of any of its facilities by HHSC.

(g) A facility shall cooperate with any HHSC investigation and shall permit HHSC to examine the facility’s grounds, buildings, books, records, and other documents and information maintained by, or on behalf of, the facility.

(h) A facility shall permit HHSC access to interview members of the governing body, personnel, and patients. Members of the governing body and personnel shall provide a written statement upon request from HHSC.

(i) A facility shall permit HHSC to inspect and copy any requested information. If it is necessary for HHSC to remove documents or other records from the facility, HHSC will provide a written description of the information being removed and when it is expected to be returned. HHSC will make a reasonable effort, consistent with the circumstances, to return any records removed in a timely manner.

(j) Upon entry, HHSC will hold an entrance conference with the facility’s designated representative to explain the nature, scope, and estimated duration of the investigation.

(k) Once an investigation is complete, HHSC will review the evidence from the investigation to evaluate whether there is a preponderance of evidence supporting the allegations contained in the complaint.

 (1) If the findings result in a referral described in §507.85(a) of this title (relating to Corrective Action Plan), the surveyor may submit a written summary of the findings to the medical review board (MRB) for its review and recommendation for appropriate action by HHSC.

§507.83 Notice.

(a) A facility is deemed to have received any HHSC correspondence on the date of receipt, or three business days after mailing, whichever is earlier.

(b) When deficiencies are found:

 (1) HHSC will provide the facility with a written Statement of Deficiencies (SOD) within 10 business days of the exit conference via U.S. mail or email.

 (2) Within 10 calendar days of the facility’s receipt of the SOD, the facility shall return a written Plan of Correction (POC) to HHSC that addresses each cited deficiency, including timeframes for corrections, together with any additional evidence of compliance.

 (A) HHSC will determine if a POC and proposed timeframes are acceptable, and, if accepted, notify the facility in writing.

 (B) If the POC is not accepted by HHSC, HHSC will notify the facility in writing no later than 10 business days after notification and request a modified POC and any additional evidence.

 (C) The facility shall correct the identified deficiencies and submit evidence to HHSC verifying implementation of corrective action within the timeframes set forth in the POC, or as otherwise specified by HHSC.

 (3) Regardless of the facility’s compliance with this subsection or HHSC’s acceptance of a facility’s POC, HHSC may, at any time, propose to take enforcement action as appropriate under this chapter.

§507.84 Professional Conduct.

In addition to any enforcement action under this chapter, HHSC will report in writing to the appropriate licensing board any issue or complaint relating to the conduct of a licensed professional, intern, or applicant for professional licensure.

§507.85 Corrective Action Plan.

(a) The medical review board (MRB) may assist HHSC in determining the corrective action required when the results of an inspection or an annual report indicate that significant problems potentially impacting patient outcomes exist. At the conclusion of an on-site inspection, HHSC may refer a facility to the MRB if the results of the inspection present concerns related to patient outcomes. These facilities may be requested to provide additional information, or may be subject to an on-site inspection, corrective action plan, or enforcement action.

(b) A corrective action plan may be used in accordance with Texas Health and Safety Code §251.061. This subsection is consistent with Texas Health and Safety Code §251.061.

 (1) HHSC may use a corrective action plan as an alternative to enforcement action under the statute.

 (2) Before taking enforcement action, HHSC shall consider whether the use of a corrective action plan is appropriate. In determining whether to use a corrective action plan, the department shall consider whether:

 (A) the facility has violated the statute or this chapter and the violation has resulted in an adverse patient result;

 (B) the facility has a previous history of lack of compliance with the statute, this chapter, or a previously executed corrective action plan; or

 (C) the facility fails to agree to a corrective action plan.

(c) HHSC may use a level one, level two, or level three corrective action plan, as determined by HHSC in accordance with this subsection, after inspection of the facility.

 (1) A level one corrective action plan is appropriate if HHSC finds that the facility is not in compliance with the statute or this chapter, but the circumstances are not serious or life-threatening. HHSC or a monitor may supervise the implementation of the plan.

(2) A level two corrective action plan is appropriate if HHSC finds that the facility is not in compliance with the statute or this chapter and the circumstances are potentially serious or life-threatening, or if HHSC finds that the facility failed to implement or comply with a level one corrective action plan. HHSC or a monitor shall supervise the implementation of the plan. Supervision of the implementation of the plan may include on-site supervision, observation, and direction. The facility is expected to comply with all HHSC requests, including supervision, observation, and direction, when requested by HHSC.

 (3) A level three corrective action plan is appropriate if HHSC finds that the facility is not in compliance with the statute or this chapter and the circumstances are serious or life-threatening, or if HHSC finds that the facility failed to comply with a level two corrective action plan or to cooperate with HHSC in connection with that plan. HHSC may require the appointment of a monitor to supervise the implementation of the plan, the appointment of a temporary manager, or the appointment of a monitor and temporary manager. Appointment of a temporary manager by agreement shall be in accordance with §507.86 of this chapter (relating to Voluntary Appointment of a Temporary Manager). Involuntary appointment of a temporary manager shall be in accordance with §507.87 of this chapter (relating to Involuntary Appointment of a Temporary Manager).

 (4) A corrective action plan is not confidential. Information contained in the plan may be exempted from required disclosure under Texas Government Code, Chapter 552 or other applicable law.

 (5) HHSC shall approve the monitor for a corrective action plan. The monitor shall be an individual or team of individuals and may include a professional with end stage renal disease experience or a member of the medical review board.

 (A) The monitor may be a current or former employee of the dialysis organization but may not be a current or former employee of the subject facility within the last 24 months.

 (B) The purpose of the monitor is to observe, supervise, consult, and educate the facility and the employees of the facility under a corrective action plan; to bring the facility into substantial compliance with the regulations of this chapter and all other state and federal laws and regulations in as short a time as practicable.

 (C) Monitors shall report their findings no less than once per month to facility management, administrators, and HHSC to report goals and accomplishments, and to set forth further improvements needed in the facility. Monitors shall reduce their time spent in the facility to allow for staff to practice what they have learned, to the point that continued monitoring is no longer necessary nor desired.

 (D) HHSC may conduct an on-site inspection to determine the progress being made by the facility under the direction of the monitor. Monitored facilities shall be inspected by the staff of HHSC within six months from the imposition of the monitor to ascertain the necessity to maintain the corrective action plan under which the monitor was placed.

 (E) The facility shall pay the cost of the monitor.

 (F) A facility shall not use a monitor who is currently acting as a full-time monitor for another facility under a corrective action plan.

 (G) A facility shall select a monitor and submit the resume for HHSC approval of the monitor. Once a monitor has been selected and approved, the facility shall ensure that only that the approved monitor is used. The facility shall not allow a subcontractor to take the place of the approved monitor.

§507.86. Voluntary Appointment of a Temporary Manager.

(a) A person holding a controlling interest in a facility may, at any time, request HHSC to assume the management of the facility through the appointment of a temporary manager in accordance with Texas Health and Safety Code §251.091.

(b) After receiving the request, HHSC may enter into an agreement providing for the appointment of a temporary manager to manage the facility under conditions considered appropriate by both parties, if HHSC considers the appointment desirable.

(c) An agreement under this section shall:

 (1) specify all terms and conditions of the temporary manager's appointment and authority; and

 (2) preserve all rights of individuals served by the facility granted by law.

(d) The primary duty of the temporary manager is to ensure that adequate and safe services are provided to patients until temporary management ceases.

(e) The appointment terminates at the time specified by the agreement.

§507.87. Involuntary Appointment of a Temporary Manager.

(a) Under Texas Health and Safety Code §251.092, HHSC may request the attorney general to bring an action in the name and on behalf of the state for the appointment of a temporary manager to manage a facility if:

 (1) the facility is operating without a license;

 (2) HHSC has denied, suspended, or revoked the facility's license but the facility continues to operate;

 (3) the license denial, suspension, or revocation proceedings against the facility are pending, and HHSC determines that an imminent or reasonably foreseeable threat to the health and safety of a patient of the facility exists;

 (4) HHSC determines that an emergency exists that presents an immediate threat to the health and safety of a patient of the facility;

 (5) the facility is closing and arrangements for the care of patients by other licensed facilities have not been made before closure; or

 (6) HHSC determines a level three corrective action plan under §507.85(b)(6) of this subchapter (relating to Corrective Action Plan) that includes appointment of an involuntary temporary manager is necessary to address serious or life-threatening conditions at the facility.

(b) After a hearing, a court shall appoint a temporary manager to manage a facility, if the court finds that the appointment of the manager is necessary.

 (1) The court order shall address the duties and authority of the temporary manager, which may include management of the facility and the provision of dialysis services to facility patients until specified circumstances occur, such as new ownership of the facility, compliance with the statute or this chapter, or closure of the facility.

 (2) If possible, the court shall appoint as temporary manager an individual whose background includes administration of end stage renal disease (ESRD) facilities or similar facilities.

 (3) The venue for an action under this section is in Travis County.

(c) A temporary manager appointed under this section is entitled to a reasonable fee as determined by the court in accordance with Texas Health and Safety Code §251.093.

 (1) The fee shall be paid by the facility.

 (2) The temporary manager may petition the court to order the release to the manager of any payment owed the manager for care and services provided to patients of the facility, if the payment has been withheld.

 (3) Withheld payments that may be released may include payments withheld by a governmental agency or other entity before or during the appointment of the temporary manager, including:

 (A) Medicaid, Medicare, or insurance payment; or

 (B) payments from another third party.

§507.88. Enforcement.

(a) Denial, suspension or revocation of a license. HHSC has jurisdiction to enforce violations of the statute or the rules adopted under this chapter. HHSC may deny, suspend, or revoke a license or impose an administrative penalty for the following reasons:

 (1) failure to comply with any provision of Texas Health and Safety Code, Chapter 251;

 (2) failure to comply with any provision of this chapter (22 TAC, Chapter 507) or any other applicable laws;

 (3) the facility, or any of its employees, commits an act that causes actual harm or risk of harm to the health or safety of a patient;

 (4) the facility, or any of its employees, materially alters any license issued by HHSC;

 (5) failure to comply with minimum standards for licensure;

 (6) failure to provide an adequate licensure application or renewal information;

 (7) failure to comply with an order of the commissioner or another enforcement procedure under Texas Health and Safety Code, Chapter 251;

 (8) a history of failure to comply with the applicable rules relating to patient environment, health, safety, and rights;

 (9) the facility, or any of its employees, has aided, committed, abetted, or permitted the commission of an illegal act;

 (10) the facility, or any of its employees, commits fraud, misrepresentation, or concealment of a material fact on any documents required to be submitted to HHSC or required to be maintained by the facility pursuant to Texas Health and Safety Code, Chapter 251, and the provisions of this chapter;

 (11) failure to timely pay an assessed administrative penalty as required by HHSC;

 (12) failure to submit an acceptable plan of correction for cited deficiencies within the timeframe required by HHSC;

 (13) failure to timely implement plans of corrections to deficiencies cited by HHSC within the dates designated in the plan of correction;

 (14) failure to comply with applicable requirements within a designated probation period; or

 (15) if the facility is participating under Title XVIII, and the Centers for Medicare and Medicaid Services terminates the ESRD’s Medicare provider agreement.

(b) HHSC may deny a license if the applicant or licensee fails to provide the required license fee, application, or renewal information.

(c) HHSC may suspend or revoke an existing valid license or disqualify a person from receiving a license because of a person's conviction of a felony or misdemeanor, if the crime directly relates to the duties and responsibilities of a licensed facility.

 (1) In determining whether a criminal conviction directly relates, HHSC shall consider the provisions of Texas Occupations Code §53.022 and §53.023.

 (2) The following felonies and misdemeanors directly relate because these criminal offenses indicate an inability or a tendency for the person to be unable to own or operate a facility:

 (A) a misdemeanor violation of the statute;

 (B) a conviction relating to deceptive business practices;

 (C) a misdemeanor or felony involving moral turpitude;

 (D) a misdemeanor of practicing any health-related profession without a required license;

 (E) a conviction under any federal or state law relating to drugs, dangerous drugs, or controlled substances;

 (F) an offense under the Penal Code, Title 5, involving a patient or a patient of any health care facility, a home and community support services agency, or a health care professional; or

 (G) other misdemeanors and felonies which indicate an inability or tendency for the person to be unable to own or operate a facility, if action by HHSC will promote the intent of the statute, this chapter, or Texas Occupations Code §53.022 and §53.023.

 (3) Upon a licensee's felony conviction, felony probation revocation, revocation of parole, or revocation of mandatory supervision, the license shall be revoked.

(d) If HHSC proposes to deny, suspend, or revoke a license, HHSC shall notify the facility by certified mail, return receipt requested, or personal delivery, of the reasons for the proposed action, and offer the facility an opportunity for a hearing.

 (1) The facility shall request a hearing within 30 calendar days of receipt of the notice. Receipt of the notice is presumed to occur on the 10th calendar day after the notice is mailed to the last address known to HHSC, unless another date is reflected on a United States Postal Service return receipt.

 (2) The request for a hearing shall be in writing and submitted to the Enforcement Unit, Regulatory Services Division, Texas Health and Human Services Commission.

 (3) A hearing shall be conducted pursuant to the Administrative Procedure Act, Texas Government Code, Chapter 2001.

 (4) If the facility does not request a hearing in writing within 30 calendar days of receipt of the notice, the facility is deemed to have waived the opportunity for hearing, and the proposed action shall be taken.

 (5) If the facility fails to appear or be represented at the scheduled hearing, the facility has waived the right to a hearing, and the proposed action shall be taken.

(e) If HHSC suspends a license, the suspension shall remain in effect until HHSC determines that the reason for suspension no longer exists. An authorized representative of HHSC shall investigate prior to making a determination.

 (1) During the time of suspension, the suspended license holder shall return the license to HHSC.

 (2) If a suspension overlaps a renewal date, the suspended license holder shall comply with the renewal procedures in this chapter; however, HHSC may not renew the license until HHSC determines that the reason for suspension no longer exists.

(f) If HHSC revokes or does not renew a license, a person may reapply for a license by complying with the requirements and procedures in this chapter at the time of reapplication. HHSC may refuse to issue a license, if the reason for revocation or nonrenewal continues to exist.

(g) Upon revocation or nonrenewal, a license holder shall return the license to HHSC within 30 days of HHSC’s notification.

(h) HHSC may issue an emergency order to suspend a license issued under this chapter, if HHSC has reasonable cause to believe that the conduct of a license holder creates an immediate danger to the public health and safety.

 (1) An emergency suspension is effective immediately without a hearing or notice to the license holder.

 (2) On written request of the license holder, HHSC shall conduct a hearing not earlier than the 10th day or later than the 30th day after the date the hearing request is received to determine if the emergency suspension is to be continued, modified, or rescinded. The hearing and any appeal are governed by HHSC's rules for a contested case hearing and Texas Government Code, Chapter 2001.

(i) In lieu of denying, suspending, or revoking the license, HHSC may place the facility on probation for a period of not less than 30 days, if the facility is found in repeated noncompliance, and the facility's noncompliance does not endanger the health and safety of the public.

§507.89. Administrative Penalties.

(a) Under Texas Health and Safety Code §§251.066 - 251.070, HHSC may assess an administrative penalty against a person who violates the statute or this chapter.

(b) The penalty may not exceed $1,000 for each violation. Each day of a continuing violation constitutes a separate violation.

(c) In determining the amount of an administrative penalty assessed under this section, HHSC shall consider:

 (1) the seriousness of the violation;

 (2) the history of previous violations;

 (3) the amount necessary to deter future violations;

 (4) efforts made to correct the violation; and

 (5) any other matters that justice may require.

(d) All proceedings for the assessment of an administrative penalty are subject to the Administrative Procedure Act, Texas Government Code, Chapter 2001.

(e) If after investigation of a possible violation and the facts surrounding that possible violation, HHSC determines that a violation has occurred, HHSC shall give written notice of the violation to the person alleged to have committed the violation. The notice shall include:

 (1) a summary of the alleged violation;

 (2) a statement of the amount of the proposed penalty, based on the factors listed in subsection (c) of this section; and

 (3) a statement of the person's right to a hearing on the occurrence of the violation, the amount of the penalty, or both the occurrence of the violation and the amount of the penalty.

(f) Not later than the 20th calendar day after the date the notice is received, the person notified may accept the determination of HHSC made under this section, including the recommended penalty, or make a written request for a hearing on that determination.

(g) If the person notified of the violation accepts the determination of HHSC, the commissioner shall issue an order approving the determination and ordering that the person pay the recommended penalty.

(h) If the person notified fails to respond in a timely manner to the notice or if the person requests a hearing, the commissioner's designee shall:

 (1) set a hearing;

 (2) give written notice of the hearing to the person; and

 (3) designate a hearings examiner to conduct the hearing, who shall make findings of fact and conclusions of law and shall promptly issue to the commissioner a proposal for decision as to the occurrence of the violation and a recommendation as to the amount of the proposed penalty, if a penalty is determined to be warranted.

(i) Based upon the findings of fact and conclusions of law and the recommendation of the hearings examiner, the commissioner by order may find that a violation has occurred and may assess a penalty or may find that no violation has occurred. The commissioner or the commissioner's designee shall give notice of the Commissioner's order to the person notified. The notice shall include:

 (1) separate statements of the findings of fact and conclusions of law;

 (2) the amount of any penalty assessed; and

 (3) a statement of the right of the person to judicial review of the commissioner's order.

(j) Not later than the 30th calendar day after the date the decision is final, the person shall:

 (1) pay the penalty in full;

 (2) pay the amount of the penalty and file a petition for judicial review contesting the occurrence of the violation, the amount of the penalty, or both the occurrence of the violation and the amount of the penalty; or

 (3) without paying the amount of the penalty, file a petition for judicial review contesting the occurrence of the violation, the amount of the penalty, or both the occurrence of the violation and the amount of the penalty. Within the 30-day period, a person who acts under this paragraph may:

 (A) stay enforcement of the penalty by:

 (i) paying the amount of the penalty to the court for placement in an escrow account; or

 (ii) giving to the court a supersedeas bond that is approved by the court for the amount of the penalty and that is effective until all judicial review of the commissioner's order is final; or

 (B) request the court to stay enforcement of the penalty by:

 (i) filing with the court an affidavit of the person stating that the person is financially unable to pay the amount of the penalty and is financially unable to give the supersedeas bond; and

 (ii) giving a copy of the affidavit to HHSC by certified mail.

(k) If HHSC receives a copy of an affidavit under subsection (j)(3)(B) of this section, HHSC may file with the court, within five calendar days after the date the copy is received, a contest to the affidavit.

§507.90. Recovery of Costs.

(a) HHSC may assess reasonable expenses and costs against a person in an administrative hearing if, as a result of the hearing, the person's license is denied, suspended, or revoked, or if administrative penalties are assessed against the person.

(b) The person shall pay expenses and costs assessed under this section not later than the 30th calendar day after the date of an order requiring the payment of expenses and costs is final.

(c) HHSC may refer the matter to the attorney general for collection of the expenses and costs.

(d) If the attorney general brings an action against a person under Health and Safety Code §251.063 or §251.065, or to enforce an administrative penalty assessed, and an injunction is granted against the person or the person is found liable for a civil or administrative penalty, the attorney general may recover, on behalf of the attorney general and HHSC, reasonable expenses and costs.

(e) For purposes of this section, "reasonable expenses and costs" include expenses incurred by HHSC and the attorney general in the investigation, initiation, or prosecution of any actions, including reasonable investigative costs, court costs, attorney's fees, witness fees, and deposition expenses.

§507.91 Complaint Against an HHSC Representative.

(a) A facility may register a complaint against an HHSC representative who conducts an inspection or investigation in accordance with Subchapter F of this chapter (relating to Inspections, Investigations, and Enforcement).

(b) A complaint against an HHSC representative shall be registered with the HHSC Health Facility Compliance Manager.

TITLE 25 HEALTH SERVICES

PART 1 DEPARTMENT OF STATE HEALTH SERVICES

CHAPTER 507 END STAGE RENAL DISEASE FACILITIES

SUBCHAPTER G FIRE PREVENTION AND SAFETY REQUIREMENTS

§507.92. Fire Prevention, Protection, and Emergency Contingency Plan.

(a) An end stage renal disease (ESRD) facility shall comply with the provisions of this section with respect to fire prevention and protection.

 (1) An ESRD facility shall comply with local fire codes.

 (2) All incidents of fire shall be reported to the local fire authority and shall be reported in writing to HHSC Complaint and Incident Intake as soon as possible, but not later than 10 calendar days following the incident. Any fire incident causing injury to a person shall be reported no later than the next business day.

 (3) An ESRD facility shall adopt, implement, and enforce a written smoking policy.

(b) An ESRD facility shall adopt, implement, and enforce a written policy for periodic inspection, testing, and maintenance of firefighting equipment, portable fire extinguishers, and when installed sprinkler systems. If installed, fire sprinkler systems shall comply with National Fire Protection Association 13, Standard for the Installation of Sprinkler Systems, 2002 Edition (NFPA 13).

 (1) All fire sprinkler systems, fire pumps, fire standpipe and hose systems, water storage tanks, and valves and fire department connections shall be inspected, tested, and maintained in accordance with National Fire Protection Association 25, Standard for the Inspection, Testing and Maintenance of Water-Based Fire Protection Systems, 2002 Edition.

 (2) Every portable fire extinguisher located in an ESRD facility or upon ESRD facility property shall be installed, tagged, and maintained in accordance with National Fire Protection Association 10, Standard for Portable Fire Extinguishers, 2002 Edition.

(c) A plan for the protection of patients in the event of fire and their evacuation from the building when necessary shall be formulated according to NFPA 101, §21.7.1.1. Copies of the plan shall be available to all staff.

 (1) An evacuation floor plan shall be prominently and conspicuously posted for display throughout the ESRD facility in public areas that are readily visible to patients, employees, and visitors.

 (2) Each ESRD facility shall conduct an annual training program for instruction of all personnel in the location and use of firefighting equipment. All employees shall be instructed regarding their duties under the fire protection and evacuation plan.

 (3) The ESRD facility shall conduct one fire drill per shift per quarter, which shall include the transmission of the fire alarm signal and simulation of the emergency fire condition, simulation of evacuation of patients and other occupants, and use of fire-fighting equipment. Written reports shall be maintained to include evidence of patient and staff participation. Fire exit drills shall incorporate the minimum requirements of NFPA 101, §§21.7.1.2 - 21.7.2.3.

 (4) All staff shall be familiar with the locations of firefighting equipment. Firefighting equipment shall be located so that a person shall not have to travel more than 75 feet from any point to reach the equipment.

(d) A fire alarm system shall be installed, maintained, and tested, in accordance with National Fire Protection Association 72, National Fire Alarm Code, 2002 Edition (NFPA 72) and NFPA 101, §21.3.4.

(e) A reliable communication system shall be provided as a means of reporting a fire to the fire department. This is in addition to the automatic alarm transmission to the fire department required by NFPA 101, §21.3.4.4.

(f) As an aid to fire department services, every ESRD facility shall:

 (1) maintain driveways, free from all obstructions, to main buildings for fire department apparatus use;

 (2) upon request, submit a copy of the floor plans of the building to the local fire department officials; and

 (3) place proper identification on the outside of the main building showing the locations of Siamese connections and standpipes as required by the local fire department services.

(g) When an ESRD facility is located outside of the service area or range of the public fire protection, arrangements shall be made to have the nearest fire department respond in case of a fire.

(h) The ESRD facility shall provide an emergency contingency plan for the continuity of emergency essential building systems. The emergency contingency plan shall consist of one of the three options as described as follows.

 (1) An onsite emergency generator shall be provided with a Type II essential electrical distribution system in accordance with requirements of NFPA 99, §4.5, and National Fire Protection Association 110, Standard for Emergency and Standby Power Systems, 2002 Edition.

 (A) An emergency generator standby power system shall require an onsite fuel source and enough fuel capacity in the tank for a period of twenty-four hours or more. When a vapor liquefied petroleum gas (LPG) (natural gas) system is used, the twenty-four-hour fuel capacity on site is not required. The vapor withdrawal LPG system shall require a dedicated fuel supply. The fuel tank capacity shall be sized by the electrical load demand on the emergency generator for a period of twenty-four hours.

 (B) The emergency generator shall be installed, tested and maintained in accordance with the National Fire Protection Association 99, §4.5.4, and National Fire Protection Association 110, Standard for Emergency and Standby Power Systems, 2002 Edition.

 (C) When the emergency generator and electrical transformer are located within the same area, they shall be located at least 10 feet apart.

 (D) Sufficient quantity of potable water supply shall be on site for the operation of the water treatment system for at least twenty-four hours. A water valve connection shall be provided to allow hook-up for potable water from an outside vendor to supply the water treatment system.

 (2) An executed contract with an outside supplier or vendor that will provide a portable emergency generator and potable water on demand.

 (A) An electrical transfer switch with plug-in device sized to provide emergency power for the patient care areas and the provisions in NFPA 99, §4.5.2.2.2.

 (B) A water valve connection to allow hook-up for potable water from an outside vendor to supply the water treatment system.

 (C) An alternate source of power (battery power lighting) shall be provided separate and independent from the normal electrical power source that will be effective for a minimum of one-and-a-half hours after loss of the electrical power. The emergency lighting system shall be capable of providing sufficient illumination to allow safe evacuation from the building. The battery pack systems shall be maintained and tested quarterly.

 (D) The facility shall implement the emergency contingency plan upon the loss of electrical power following a natural weather or man-made event when the electrical power may not be restored within 24 hours. The facility shall exercise the contract with the supplier or vendor to have portable emergency generators and potable water available within 36 hours after the loss of electrical power.

 (3) An executed contract with another licensed ESRD facility within a 100-mile radius to provide emergency contingency care for the patients.

 (A) The accepting licensed ESRD facility shall meet the requirements of paragraph (1) of this subsection.

 (B) An alternate source of power shall be provided separate and independent from the normal electrical power source that will be effective for a minimum of 2one-and-a-half hours after loss of the electrical power. The emergency lighting system shall be capable of providing sufficient illumination to allow safe evacuation from the building. The battery pack systems shall be maintained and tested quarterly.

§507.93. General Safety.

(a) An end stage renal disease (ESRD) facility shall provide a physical environment that protects the health, safety, and welfare of patients, personnel, and the public. The physical premises and the physical environment of the facility and those areas of the facility's surrounding physical structure that are used by the patients (including all stairwells, corridors, and passageways) shall meet the local building and fire safety codes as they relate to safe access and patient privacy.

(b) An emergency communication system, such as radio-frequency communication devices, battery operated emergency phone, or facility cellular telephones, shall be provided in each facility. The system shall be self-sufficient and capable of operating without reliance on the building's service or emergency power supply. Such system shall have the capability of communicating with the available community or state emergency networks, including police and fire departments.

(c) No portable or ceiling fans shall be used in patient treatment areas, or in the reprocessing room.

(d) Electrical extension cords and cables shall not be used for permanent wiring. When temporary electrical cords or cables are used, they shall be secured and protected to prevent tripping.

(e) A nurse’s emergency calling system shall be installed in the patient waiting areas, all individual treatment rooms, exam rooms, isolation hepatitis B rooms, and toilet rooms used by patients to summon nursing staff in an emergency. Activation of the system shall sound a repeating (every 5 seconds or less) distinct audible signal at the nurse station, indicate type and location of call on the system monitor, and activate a distinct visible signal in all areas. The visible and audible signals shall be cancelable only at the patient calling station. A nurse’s emergency call system shall be accessible to a collapsed patient lying on the floor. Inclusion of a pull cord extending to within six inches of the floor will satisfy this requirement.

(f) Doors to an isolation or home dialysis training room shall not be lockable from inside the room.

(g) When construction takes place during dialysis treatments, adequate provision shall be made for the safety and comfort of patients. Temporary sound barriers shall be provided where intense prolonged construction noises will disturb patients or staff in the occupied portions of the building during patient treatment times.

(h) When construction is done after hours or on weekends, the facility shall assure that all areas of construction are cleaned thoroughly, and a clean safe environment is provided before patients are treated.

§507.94. Handling and Storage of Gases and Flammable Liquids.

(a) An end stage renal disease (ESRD) facility shall comply with the requirements of this section for handling and storage of gas and flammable liquids. The ESRD facility premises shall be kept free from accumulations of combustible materials not necessary for immediate operation of the facility.

 (1) Flammability of liquids and gases shall be determined by National Fire Protection Association 329, Handling Releases of Flammable and Combustible Liquids and Gases, 2002 Edition. All documents published by National Fire Protection Association (NFPA) as referenced in this section may be obtained by writing or calling the NFPA at the following address or telephone number: National Fire Protection Association, 1 Batterymarch Park, Quincy, Massachusetts 02269-9101 or (800) 344-3555.

 (2) Nonflammable gases shall be stored and distributed in accordance with Chapter 5 of the National Fire Protection Association 99, Standard for Health Care Facilities, 2002 edition (NFPA 99).

 (3) Oxygen shall be administered in accordance with NFPA 99, §9.6.

(b) Alcohol-based hand rubs (ABHRs) are considered flammable. When used, the ABHRs shall meet the following requirements:

 (1) The dispensers may be installed in a corridor so long as the corridor width is six feet or greater. The dispensers shall be installed at least four feet apart.

 (2) The maximum individual dispenser fluid capacity is 1.2 liters for dispensers in rooms, corridors, and areas open to corridors, and 2.0 liters for dispensers in suites of rooms.

 (3) The dispensers shall not be installed over or directly adjacent to electrical outlets and switches.

 (4) Dispensers installed directly over carpeted surfaces shall be permitted only in sprinklered smoke compartments.

 (5) Each smoke compartment may contain a maximum aggregate of 10 gallons of ABHR solution in dispensers and a maximum of five gallons in storage.

(c) No motor vehicles including gasoline powered standby generators or any amount of gasoline shall be located within the ESRD facility building. Other devices which may cause or communicate fire, and which are not necessary for patient treatment or care, shall not be stored within the ESRD facility building. All such devices and materials when necessary shall be used within the building only with precautions ensuring a reasonable degree of safety from fire.

(d) The installation, use, and maintenance of gas fired appliances and gas piping installations shall comply with the National Fire Protection Association 54, National Fuel Gas Code, 2002 Edition. The use of portable gas heaters and unvented open flame heaters is specifically prohibited.

TITLE 25 HEALTH SERVICES

PART 1 DEPARTMENT OF STATE HEALTH SERVICES

CHAPTER 507 END STAGE RENAL DISEASE FACILITIES

SUBCHAPTER H PHYSICAL PLANT AND CONSTRUCTION REQUIREMENTS

§507.101. Construction Requirements for an Existing End Stage Renal Disease Facility.

(a) All buildings in which existing end stage renal disease (ESRD) facilities licensed by HHSC are located shall comply with this subsection.

 (1) A licensed ESRD facility which is licensed prior to the effective date of these rules is considered to be an existing licensed ESRD facility and shall continue, at a minimum, to meet the licensing requirements under which it was originally licensed.

 (2) Existing licensed ESRD facilities shall meet the requirements for Existing Ambulatory Health Care Occupancies contained in Chapter 21 of the 2000 edition of the National Fire Protection Association 101, Life Safety Code, (NFPA 101), the ESRD Standards/Rules (1996, 1999, or 2006 editions, as amended), and the ESRD rules under which the buildings or sections of buildings were constructed. All documents published by NFPA as referenced in this section may be obtained by writing or calling the NFPA at the following address or telephone number: National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9101 or (800) 344-3555.

 (3) In lieu of meeting the requirements in paragraph (1) of this subsection, an existing licensed ESRD facility may, instead, comply with National Fire Protection Association (NFPA) 101, Life Safety Code 2003 Edition (NFPA 101) Chapter 21, Existing Ambulatory Health Care Occupancies.

(b) All major remodeling, renovations, additions, and alterations to an existing ESRD facility shall be done in accordance with the requirements for new construction in §507.102 of this chapter (relating to Construction Requirements for a New End Stage Renal Disease Facility). All areas of an existing ESRD facility that are not part of a major remodel, renovation, addition or alteration to the ESRD facility, are not required to meet these new construction requirements as long as the existing portion of the facility met the rules and codes that were in effect when it was originally constructed and licensed. When existing conditions make such changes impractical, HHSC may grant a conditional approval of minor deviations from the requirements of §507.102 of this chapter, if the intent of the requirements is met and if the care, safety and welfare of patients will not be jeopardized. The operation of the ESRD facility, accessibility of individuals with disabilities, and safety of the patients shall not be jeopardized by a condition which is not in compliance with §507.102 of this chapter and this section.

 (1) Any alteration, modification, replacement, or any installation of new building equipment, such as mechanical, electrical, emergency power equipment, energy or utility management, conveying systems, plumbing, fire protection, or other equipment with a primary function of building service that affects life safety, infection control, changes the functional operation, or the health, safety and welfare of patients or staff shall comply with the requirements for new construction and shall not be replaced, materially altered, or extended in an existing ESRD facility until complete plans and specifications have been submitted to HHSC, and HHSC has reviewed and approved the plans and specifications in accordance with §507.104 of this chapter (relating to Preparation, Submittal, Review and Approval of Plans, and Retention of Records).

 (2) Minor remodeling or alterations within an existing ESRD facility which do not involve alterations to load bearing members and partitions, change functional operation, affect fire safety, or involve any of the major changes listed in paragraph (1) of this subsection are considered to be minor projects and require evaluation and approval by HHSC. An ESRD facility shall submit a written request and floor plan for evaluation, a brief description of the proposed changes, and sketches of the area being remodeled. Based on such submittal, HHSC shall evaluate and determine whether any additional submittals or inspections are required. HHSC shall notify the ESRD facility of its decision. The patching, restoration, or painting of materials, elements, equipment, or fixtures for the purpose of maintaining such materials, elements, equipment, or fixtures in good or sound condition would not require submission to HHSC for approval.

 (3) All remodeling or alterations which involve alterations to load bearing members or partitions, change functional operation, add treatment stations, or affect fire safety are considered major projects. An ESRD facility shall comply with this section prior to beginning construction of major projects.

 (A) Plans shall be submitted in accordance with §507.104 of this chapter for all major remodeling or alterations.

 (B) As of February 9, 2009, all new facilities or increasing the number of in-center dialysis treatment stations in existing facilities shall have an isolation room or be granted a waiver by Center for Medicare and Medicaid Services (CMS). The waiver shall demonstrate that there is sufficient capacity in the geographic area for isolation rooms for hepatitis B positive patients. A written request for waiver shall be made through the HHSC Health Facility Compliance unit for transmission to CMS.

 (C) Phasing of construction in existing facilities.

 (i) Projects involving alterations of or additions to existing buildings shall be programmed and phased so that on-site construction shall minimize disruptions of existing functions.

 (ii) Access, exit access, and fire protection shall be maintained so that the safety of the occupants shall not be jeopardized during construction.

 (iii) A noncombustible or limited combustible dust and vapor barrier shall be provided to separate areas undergoing demolition and construction from occupied areas. When a fire-retardant plastic material is used for temporary daily usage, it shall be removed at the end of each day.

 (iv) The air inside the construction area shall be protected by mechanical filtration that recirculates inside the space or is exhausted directly to the exterior.

 (v) The area shall be properly ventilated and maintained. The area under construction shall have a negative air pressure differential to the adjoining areas and shall continue to operate as long as construction dust and odors are present.

 (vi) Temporary sound barriers shall be provided where intense prolonged construction noises will disturb patients or staff in the occupied portions of the building during patient treatment times.

 (vii) When construction is done after hours or on weekends, the facility shall assure that all areas of construction are cleaned thoroughly, and a clean safe environment is provided before patients are treated. All fire safety protection and building systems are in place and working properly.

(c) A previously licensed ESRD facility which has been vacated or used for other purposes shall comply with all the requirements for new construction contained in §507.102 of this chapter to be licensed.

§507.102. Construction Requirements for a New End Stage Renal Disease Facility.

(a) Any proposed new end stage renal disease (ESRD) facility shall be easily accessible to the community and to service vehicles such as delivery trucks, ambulances, and fire protection apparatus. No building may be converted for use as an ESRD facility which, because of its location, physical condition, state of repair, or arrangement of facilities, would be hazardous to the health and safety of the patients.

 (1) An ESRD facility shall have at least two exits remotely located in accordance with National Fire Protection Association (NFPA) 101, Life Safety Code, 2003 Edition (NFPA 101), §20.2.4.1. When a required means of egress from the ESRD facility is through another portion of the building, that means of egress shall comply with the requirements of NFPA 101 that are applicable to the occupancy of that other building. Such means of egress shall be open, available, unlocked, unrestricted, and lighted at all times during the ESRD facility hours of operation. All documents published by National Fire Protection Association (NFPA), as referenced in this section, may be obtained by writing or calling the NFPA at the following address or telephone number: National Fire Protection Association, 1 Batterymarch Park, Quincy, Massachusetts 02269-9101 or (800) 344-3555.

 (2) Hazardous locations.

 (A) A new ESRD facility or an addition to an existing ESRD facility shall not be constructed within 150 feet of easement boundaries or setbacks of hazardous underground locations including liquid butane or propane, liquid petroleum or natural gas transmission lines, high pressure lines, and not within the easement of high voltage electrical lines. Municipality's main natural gas lines in rights-of-way serving dwellings and gas lines on property servicing gas meters under this provision are not consider natural high-pressure lines.

 (B) A new ESRD facility and an addition to an existing ESRD facility shall not be built within 300 feet of above ground or underground storage tanks containing liquid petroleum or other flammable liquids used in connection with a bulk plant, marine terminal, aircraft refueling, bottling plant of a liquefied petroleum gas installation, or near other hazardous or hazard producing plants.

 (3) Undesirable locations.

 (A) In lieu of local codes, a new ESRD facility shall not be located closer than 1500 feet to nuisance producing industrial sites, feed lots, sanitary landfills, or manufacturing plants producing excessive noise or air pollution.

 (B) Flood plains.

 (i) When a new ESRD facility is constructed in a designated 100-year flood plain, the building finished floor elevation shall be one foot above the set base flood plain elevation. The building shall meet all local flood code ordinances and local flood control requirements.

 (ii) To obtain a license as an ESRD facility, a previously licensed ESRD facility and an existing building or a portion of an existing building located in a designated 100-year flood plain shall meet the requirement of clause (i) of this subparagraph.

 (iii) ESRD facility required functional components shall be constructed above the designated flood plain in a new addition to an existing ESRD facility located in a designated 100-year flood plain. The new addition shall meet the requirement of clause (i) of this subparagraph.

 (iv) Currently licensed ESRD facilities located within a designated 100-year flood plain are exempt from these requirements for renovations and repairs.

(b) The ESRD facility site shall include paved roads, walkways, and parking in accordance with the requirements set out in this subsection.

 (1) Paved roads and walkways.

 (A) Paved roads shall be provided within lot lines for access from public roads to the main entrance and to service entrances.

 (B) Finished surface walkways shall be provided for pedestrians. When public transportation or walkways serve the site, finished surface walkways or paved roads shall extend from the public conveyance to the building entrance.

 (2) Parking and disability requirements.

 (A) Off-street parking shall be available for visitors, employees, and staff. Parking structures directly accessible from an ESRD facility shall be separated with two-hour fire rated noncombustible construction. When used as required means of egress for ESRD facility occupants, parking structures shall comply with National Fire Protection Association 88A, Standard for Parking Structures, 2002 edition. This requirement does not apply to freestanding parking structures. All documents published by National Fire Protection Association (NFPA) as referenced in this section may be obtained by writing or calling the NFPA at the following address or telephone number: National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9101 or (800) 344-3555.

 (B) In the absence of local code, one parking space shall be provided for each staff member on duty, plus one space for each four treatment stations, and one visitor's space for every five treatment stations. This ratio may be reduced in an area convenient to a public transportation system or to public parking facilities. Parking facilities shall be increased accordingly when the size of existing facilities is increased.

 (C) When on-street parking is available and acceptable to the local authorities having jurisdiction, the numbers of parking spaces may be reduced accordingly and shall meet the requirement of subparagraph (B) of this paragraph.

 (D) Special considerations benefiting disabled staff, visitors, and patients shall be provided. Each ESRD facility shall comply with the Americans with Disabilities Act (ADA) of 1990, Public Law 101 - 336, 42 United States Code, Chapter 126, and Title 36 Code of Federal Regulations, Part 1191, Appendix A, Accessibility Guidelines for Buildings and Facilities or 16 TAC, Part 4, Chapter 68 §68.20 (relating to Buildings and Facilities Subject to Compliance with the Texas Accessibility Standards), Texas Accessibility Standards (TAS), April 1, 1994 edition, issued by the Texas Department of Licensing and Regulation, under the Texas Architectural Barriers Act, Texas Government Code, Chapter 469.

(c) Every building and every portion thereof shall be designed and constructed to sustain all dead and live loads in accordance with accepted engineering practices and standards and the local governing building codes. Where there is no local governing building code, the ESRD facility shall be constructed in accordance with the International Building Code, 2003 edition, published by the International Code Council, 500 New Jersey Avenue, Northwest, 6th Floor, Washington, District of Columbia 20001-2070, (800) 344-3555.

 (1) All new construction, including conversion of an existing building to an ESRD facility or establishing a separately licensed ESRD facility within another existing building, shall comply with NFPA 101, Chapter 20, New Ambulatory Health Care Occupancies, of the National Fire Protection Association 101, Life Safety Code, 2003 edition (NFPA 101), and subchapters G and H of this chapter (relating to Fire Prevention and Safety Requirements, and Physical Plant and Construction Requirements, respectively). Construction documents shall be submitted to HHSC in accordance with §507.104 of this chapter (relating to Preparation, Submittal, Review and Approval of Plans, and Retention of Records).

 (A) Construction types for multiple building occupancy.

 (i) When an ESRD facility is part of a larger building which complies with NFPA 101, §20.1.6, Minimum Construction Requirements for (fire resistance) construction type, the designated ESRD facility shall be separated from the remainder of the building with a minimum of one-hour fire rated construction.

 (ii) When an ESRD facility is located in a multistory building of two or more stories, the entire building shall meet the construction requirements of NFPA 101, §20.1.6.3. An ESRD facility shall not be located in a multistory building which does not comply with the minimum construction requirements of NFPA 101, §20.1.6.3.

 (iii) When an ESRD facility is part of a one-story building that does not comply with the construction requirements of NFPA 101, §20.1.6.2, the ESRD facility shall be separated from the remainder of the building with a 2-hour fire rated construction. The designated ESRD facility portion shall have the construction type upgraded to comply with NFPA 101, §20.1.6.2.

 (B) Special provisions shall be made in the design of a facility if located in a region where local experience shows loss of life or extensive damage to buildings resulting from hurricanes, tornadoes, or floods.

 (2) A physical environment that protects the health and safety of patients, personnel, and the public shall be provided in each facility. The physical premises of the facility and those areas of the facility's physical structure that are used by the patients (including all stairwells, corridors, and passageways) shall meet the local building and fire safety codes and the requirements of this chapter.

 (3) The more stringent standard, code or requirement shall apply when a difference in requirements for construction exists.

 (4) Nothing in this subchapter shall be construed to prohibit a better type of building construction, more exits, or otherwise safer conditions than the minimum requirements specified in this subchapter.

 (5) Nothing in this subchapter is intended to prevent the use of systems, methods, or devices of equivalent or superior quality, strength, fire resistance, effectiveness, durability, safety to health and welfare of individuals, and safety to those prescribed by this subchapter, provided technical documentation which demonstrates equivalency is submitted to HHSC for approval.

 (6) Separate freestanding buildings for nonpatient use such as the heating plant, boiler plant, laundry, repair workshops, or general storage may be of unprotected noncombustible construction, protected noncombustible construction, or fire-resistive construction and be designed and constructed in accordance with other occupancy classifications requirements listed in NFPA 101.

(d) Spatial requirements.

 (1) Administration and public areas.

 (A) Patient entrances shall be located at grade level, be accessible to individuals with disabilities, and provide exterior covered protection against inclement weather. The minimum exterior protection covering shall be no smaller than 4 feet by 6 feet wide. A covered area for patients in wheelchairs shall be provided next to the opening area of the door swing and door swing shall not interfere within this area. When an ESRD is located on a floor above grade level, elevators shall be accessible and shall meet the requirements of §507.103 of this chapter (relating to Elevators, Escalators, and Conveyors).

 (B) A waiting area or lobby shall be provided within the ESRD facility and include having the following rooms and items:

 (i) public toilet facilities; and

 (ii) telephones for public use.

 (C) A designated reception area with desk or counter shall be provided.

 (D) Space shall be provided for private interviews for family members relating to social services, credit, or admission.

 (E) An office shall be provided for business transactions, records, and administrative and professional staff.

 (F) The facility shall provide an area for storage of clinical records that is separate from all patient treatment areas and shall be secured from unauthorized access. The facility shall store the active clinical record of each patient currently treated by the facility on site.

 (G) A general storage room with a minimum of two square feet per treatment station shall be provided. General storage may be located in one or more rooms or closets and shall be located outside of the patient treatment areas.

 (H) Storage space for wheelchairs shall be provided and shall be out of the direct line of traffic.

 (2) Equipment rooms with adequate space shall be provided for mechanical and electrical equipment. These areas shall be separate from public, patient, and staff areas.

 (3) An exam room shall be provided for medical examinations. The room shall have a minimum clear floor space of 80 square feet area exclusive of fixed cabinets and shelves and contain a counter for writing and a hand washing sink with hands-free operable controls.

 (4) When a patient is hepatitis B positive, the treatment shall be in a separated dedicated isolation room. All treatment in the isolation room shall be for hepatitis B patients only.

 (A) A single hepatitis B patient isolation room shall be a minimum of 120 square feet clear area exclusive of fixed and movable cabinets and shelves.

 (B) When multiple-treatment stations for hepatitis B patients are treated in a single isolation room, each individual patient treatment area shall be 80 square feet with a minimum of 8 feet clear dimension exclusive of fixed or wall mounted cabinets and built-in shelves. The clearance between the side of a station or chair and a wall or partition shall be a minimum of three feet. The clearance between sides of stations or chairs shall be a minimum of four feet.

 (C) The isolation treatment room shall include a work counter and a hand washing sink with hands-free operable controls, and space for patient care supplies and equipment. The fixed and moveable cabinets and shelves shall not encroach upon the patient treatment station or chair clear floor space or area.

 (D) The isolation treatment room shall have viewing panels in doors or walls for continuous direct visual monitoring of the patient in the room.

 (E) The dialysis equipment shall be designated, reserved, and used for hepatitis B positive patients only.

 (F) Disinfection of dialysis equipment shall occur in the hepatitis B treatment isolation room and shall meet the requirements of §507.33(d)(2)(C) of this chapter (relating to Sanitary Conditions and Hygienic Practices).

 (G) As of February 9, 2009, all new facilities or increasing the number of in-center dialysis treatment stations in existing facilities shall have an isolation room or be granted a waiver by the Centers for Medicare and Medicaid Services (CMS). The waiver shall demonstrate that there is sufficient capacity in the geographic area for isolation rooms for hepatitis B positive patients. A written request for waiver shall be made through the HHSC Health Facility Compliance Group for transmission to CMS.

 (5) When home training is provided in the facility, a private treatment area of at least 120 square feet exclusive of fixed and movable cabinets and shelves shall be provided. This room shall contain a work counter, a hand washing sink with hands-free operable controls, and a separate drain for fluid disposal.

 (6) A sufficient number of janitor's closets shall be provided throughout the facility to maintain a clean and sanitary environment. The closet shall contain a floor receptor or service sink and storage space for housekeeping supplies and equipment.

 (7) When laboratory services are provided on site the following shall be provided and meet the requirements of §507.45(l) of this chapter (relating to Provision and Coordination of Treatment and Services).

 (A) The laboratory workroom or area shall include a counter and a sink with hands-free operable controls. Laboratory services and medication preparation and dispensing shall not be done within the same designated space.

 (B) Cabinets or closets shall be provided for supplies and equipment used in obtaining samples for testing.

 (C) Refrigerated specimen storage shall be provided for specimens waiting for transfer to off-site testing. The refrigerators shall be maintained with documentation of the appropriate temperature for such storage.

 (8) When laundry and linen is provided, processing may be done within the center or off site at a commercial laundry.

 (A) When on-site linen processing is provided, soiled and clean processing operations shall be separated and arranged to provide a one-way traffic pattern from soiled to clean areas. The following rooms and items shall be provided:

 (i) a soiled linen processing room which includes areas for receiving, holding, sorting, and washing;

 (ii) a clean linen processing room, which includes areas for drying, sorting, folding, and holding prior to distribution;

 (iii) supply storage cabinets in the soiled and clean linen processing rooms;

 (iv) hand washing sink within the soiled linen processing room; and

 (v) a storage room for clean linen, which may be combined with the clean work room.

 (B) When linen is processed off site, the following areas shall be provided:

 (i) clean linen shall be stored within the clean supply area; and

 (ii) soiled linen shall be stored in a designated space in the facility.

 (9) Space shall be provided for the safe storage and disposal of waste as appropriate for the material being handled and in compliance with all applicable rules and regulations.

 (10) At a minimum, the medication area shall include a counter, a refrigerator, and a hand washing sink with hands-free operable controls. Storage and preparation of medication shall be done from a medication area and shall be under visual control of nursing staff. Medication preparation, dispensing and laboratory services shall not be done within the same designated areas. The refrigerators used for storage of medications shall be maintained with documentation of the appropriate temperatures for such storage.

 (11) When peritoneal dialysis (PD) training is provided within the ESRD facility, a patient treatment training room shall have a minimum of 120 square feet of clear floor area exclusive of fixed and movable cabinets and shelves.

 (A) The PD treatment room shall contain cabinets, a work counter, and a hand washing sink with hands-free operable controls.

 (B) An additional clinical sink or equivalent flushing rim sink with hands-free operable controls shall be provided. The clinical sink or equivalent flushing rim sink and the hand washing sink shall have a minimum separation of six feet.

 (C) A physical partition between the clinical sink or equivalent flushing rim sink and the hand washing sink may be constructed in-lieu-of the six-foot separation. The partition shall be a minimum of five feet in height from the finished floor and two feet in width from the wall or from the wall to the front edge of the countertop whichever is greater.

 (12) When a reuse room is provided, the room shall be sufficiently sized to house dialyzers reprocessing area, breakdown area, a storage area or room and work area. All fixed and moveable equipment shall require a minimum of three feet of clear and unobstructed working space on all sides of fixed or moveable equipment that require access for staff. The reuse room shall include a work counter, deep utility service sink and separate hand washing sink with hands-free operable controls, refrigerator and storage space and shall meet the requirements of §507.32(d) of this chapter (relating to Water Treatment, Dialysate Concentrates, and Reuse).

 (A) Dialyzers reprocessing area shall be arranged for the one-way movement from soiled dialyzers and materials to cleaning and storage.

 (B) Breakdown of dialyzers shall be processed in the soiled processing area of the reprocessing area. The deep utility service sink with hands-free operable controls shall be located within the soiled processing area. There shall be adequate storage space to store the soiled or used dialyzers before processing occurs. The minimum depth of the utility sink shall not be less than 14 inches.

 (C) The reuse room shall provide either a separate storage room or within the reuse room storage space to store all reprocessed cleaned dialyzers. There shall be a definitive separation between storing used and reprocessed dialyzers, and the temperature in the storage areas shall be maintained in accordance with the manufacturer's direction for use.

 (13) The treatment areas or rooms shall be separate from the administrative areas.

 (A) When individual hemodialysis patient treatment rooms are provided, the room shall have a minimum of 120 square feet of clear floor area exclusive of fixed and movable cabinets and shelves. The patient treatment room shall contain cabinets, work counter, and a hand washing sink with hands-free operable controls.

 (B) In multiple-treatment stations, each individual patient treatment area shall be 80 square feet exclusive of fixed or wall mounted cabinets and built-in shelves. A minimum of eight feet width shall be provided for the head wall for each station. The clearance between the side of a chair and a wall shall be a minimum of three feet, and the back of the extended chair and a wall shall be a minimum of one foot. A clear unobstructed width of three feet eight inches shall be available at the foot of each treatment area outside of the 80 square feet treatment area for passage of equipment, gurneys, and personnel.

 (C) The multiple-treatment station area shall contain cabinets, work counters, and hand washing sinks with hands-free operable controls. The fixed and moveable cabinets and shelves shall not encroach upon the patient treatment station.

 (D) A nurse station shall be located within the dialysis treatment area and designed to provide visual observation of all patient stations. The nurse station shall have counters for storage and access to a hand washing sink with hands-free operable controls.

 (E) One hand washing sink with hands-free operable controls shall be provided for every six stations. Sinks shall be uniformly distributed.

 (F) When required or requested, privacy shall be provided for each patient in the open treatment area with portable moveable screens.

(e) Service areas.

 (1) A clean storage room or closet shall be provided for patient care items and clean and sterile supplies.

 (2) Emergency eyewash shall be provided conveniently for staff use and to comply with ANSI Z358.1.

 (3) Dialysis solutions may be processed from a central batch delivery system or prepared in an on-site mixing room. When provided, a mixing room shall include a sink, storage space, and holding tanks.

 (4) Patient toilet rooms shall be located within the treatment area and include hand washing sinks with hands-free operable controls. Patient toilet room shall be at a ratio of one toilet room for every 40 treatment stations or fraction thereof.

 (5) Staff toilet rooms shall be provided and include hand washing sinks with hands-free operable controls. The toilet room shall be outside the treatment area but convenient for staff use only.

 (6) The water treatment and equipment for the dialysis shall be located in a room not accessible to unauthorized persons. The water room shall be designed and house the water treatment system and meet the requirements of §507.32(b) of this chapter.

(f) Details and finishes in new construction projects, including additions and alterations, shall comply with this subsection, with NFPA 101, Chapter 20, and with local building codes.

 (1) General detail requirements.

 (A) Fire safety features, including compartmentation, means of egress, automatic extinguishing systems, inspections, smoking regulations, and other details relating to fire prevention and fire protection shall comply with §507.101 of this chapter (relating to Construction Requirements for an Existing End Stage Renal Disease Facility), and NFPA 101, Chapter 20. The Fire Safety Evaluation System for Health Care Occupancies contained in the National Fire Protection Association 101A, Alternative Approaches to Life Safety, 2001 Edition, Chapter 4, shall not be used in new building construction, renovations or additions to existing ESRD facilities.

 (B) Exits, corridors and doors.

 (i) A facility shall provide two exits remote from each other in accordance with NFPA 101, §20.2.4.1. At least one exit door shall be accessible by an ambulance from the outside. This door may also serve as an entry for loading or receiving goods.

 (ii) Corridors providing access to all patient treatment areas and exits shall be at least three feet eight inches in clear and unobstructed width, not less than seven feet six inches in height, and constructed in accordance with requirements listed in NFPA 101, §20.2.1.

 (iii) Items such as drinking fountains and vending machines shall be so located as to not project into and restrict exit corridor traffic or reduce the exit corridor width below the required minimum. Portable equipment shall not be stored so as to project into and restrict exit corridor traffic or reduce the exit corridor width below the required minimum.

 (iv) Doors at all openings between corridors and rooms or spaces subject to occupancy shall be swing type. Elevator doors are excluded from this requirement.

 (v) Doors, except doors to spaces such as small closets which are not subject to occupancy, shall not swing into corridors in a manner that might obstruct traffic flow or reduce the required corridor width. Large walk-in type closets are considered as occupiable spaces.

 (vi) All doors in the means of egress shall be not less than 36 inches in clear width.

 (vii) The minimum width of doors for patient access to treatment, examination, and consultation areas or rooms shall be 36 inches in clear width.

 (viii) Rooms containing a toilet, intended for patient use, shall be provided with at least one door having hardware that will permit access from the outside in any emergency.

 (ix) Horizontal sliding doors serving an occupant load of fewer than 10 shall be permitted. The area served by the door shall have no high hazard contents. The door shall be readily operable from either side without special knowledge or effort. The force required to operate the door in the direction of door travel shall be not more than 30 pounds per foot to set the door in motion and shall be not more than 15 pounds per foot to close the door or open in the minimum required width. The door assembly shall comply with any required fire protection rating, and, where rated, shall be self-closing or automatic closing. The sliding doors opening to the egress corridor doors shall have a latch or other mechanism that ensures that the doors will not rebound into a partially open position if forcefully closed. The sliding doors may have breakaway provisions and shall be installed to resist passage of smoke. The latching sliding panel shall have a minimum clear opening of 36 inches in the fully open position. The fixed panels may have recessed tracks.

 (x) Doors shall not open immediately onto a stair without a landing. The landing shall be 44 inches deep or have a depth at least equal to the door width, whichever is greater.

 (xi) All fire doors shall be listed by an independent testing laboratory and shall meet the construction requirements for fire doors in National Fire Protection Association 80, Standard for Fire Doors and Fire Windows, 1999 Edition. Reference to a labeled door shall be construed to include labeled frame and hardware.

 (C) Glass doors, lights, sidelights, borrowed lights, and windows located within 12 inches of a door jamb or with a bottom-frame height of less than 18 inches and a top-frame height of more than 36 inches above the finished floor which may be broken accidentally by pedestrian traffic shall be glazed with safety glass or plastic glazing material that will resist breaking and will not create dangerous cutting edges when broken. Similar materials shall be used for wall openings in activity areas such as recreation and exercise rooms, unless otherwise required for fire safety. Safety glass, tempered or plastic glazing materials shall be used for shower doors and bath enclosures, interior windows and doors. Plastic and similar materials used for glazing shall comply with the flame spread ratings of NFPA 101, §18.3.3.

 (D) Grab bars shall be provided at patient toilets and at the weight scales. The bars shall be one and one-half inches in diameter, have either one and one-fourth or one and one-half inches clearance to walls, and have sufficient strength and anchorage to sustain a concentrated vertical or horizontal load of 250 pounds. Grab bars intended for use by the disabled shall also comply with ADA requirements.

 (E) Location and arrangement of fittings for hand washing sinks shall permit their proper use and operation. Hand washing sinks with hands-free operable controls shall be provided within each workroom, examination, treatment room, and toilet room. Hands-free includes blade-type handles, and foot, knee, or sensor operated controls. Care shall be given to the clearances required for blade-type operating handles. Lavatories and hand washing sinks shall be securely anchored to withstand an applied vertical load of not less than 250 pounds on the front of the sink. In addition to the specific areas noted, hand washing sinks shall be provided and conveniently located for staff use throughout the ESRD facility where patient care contact occurs, and services are provided.

 (F) A liquid or foam soap dispenser shall be located at each hand washing sink.

 (G) Provisions for hand drying shall be included at all hand washing sinks. There shall be hot air dryers or individual paper towel dispensers enclosed in such a way as to provide protection against dust or soil and ensure single-unit dispensing.

 (H) The minimum ceiling height shall be eight feet with the following exceptions.

 (i) Boiler rooms shall have ceiling clearances not less than two feet six inches above the main boiler header and connecting piping.

 (ii) Rooms containing ceiling-mounted equipment shall have the ceiling height clearance increased to accommodate the equipment or fixtures.

 (iii) Suspended tracks, rails, pipes, signs, lights, door closers, exit signs, and other fixtures that protrude into the path of normal traffic shall not be less than six feet eight inches above the finished floor.

 (I) The dialysis facility shall not be located directly under recreation rooms, exercise rooms, and similar spaces where impact noises may be generated unless special provisions are made to minimize noise.

 (J) Rooms containing heat-producing equipment such as heater rooms, laundries, etc. shall be insulated and ventilated to prevent any occupied floor surface above from exceeding a temperature differential of 10 degrees Fahrenheit above the ambient room temperature.

 (K) Thresholds and expansion joint covers shall be flush or not more than one-half inch above the floor surface to facilitate the use of wheelchairs and carts. Expansion and seismic joints shall be constructed to restrict the passage of smoke and fire and shall be listed by a nationally recognized testing laboratory.

 (2) General finish requirements.

 (A) Portable privacy screens shall be provided to assure patient privacy when required or requested by a patient. When not in use the screens shall be stored conveniently within the treatment area for immediate use.

 (B) Flame spread, and smoke developed limitations of interior finishes shall comply with NFPA 101, §10.2. The use of materials known to produce large or concentrated amounts of noxious or toxic gases shall not be used in exit accesses or in-patient areas. Copies of laboratory test reports for installed materials tested in accordance with National Fire Protection Association 255, Standard Method of Test of Surface Burning Characteristics of Building Materials, 2000 Edition, and National Fire Protection Association 258, Standard Research Test Method for Determining Smoke Generation of Solid Materials, 2001 Edition, shall be provided.

 (C) Flooring shall be easy to clean and have wear resistance appropriate for the location involved. Floors that are subject to traffic while wet shall have a nonslip surface. In all areas frequently subject to wet cleaning methods, floor materials shall not be physically affected by germicidal and cleaning solutions. The following are acceptable floor finishes:

 (i) painted concrete for water treatment areas, mechanical, electrical, janitor's closets and general storage;

 (ii) exposed concrete shall be sealed for water treatment areas, mechanical, electrical, janitor's closets and general storage;

 (iii) vinyl sheets and vinyl composition tiles for offices, lobbies, administrative areas, storage, toilet rooms, treatment areas or rooms, isolation treatment room, exam rooms, training room, reprocessing rooms, support spaces and nontreatment areas;

 (iv) when monolithic or seamless flooring is installed it shall be impervious to water, coved and installed integral with the base, tightly sealed to the wall, and without voids that can harbor insects or retain dirt particles, the base of which shall not be less than six inches in height; welded joint flooring is acceptable;

 (v) marble, ceramic and quarry tile for offices, lobbies, waiting, toilet rooms, administrative areas, wet areas, and similar spaces;

 (vi) carpet flooring for offices, administrative areas, and similar spaces; and

 (vii) terrazzo for offices, lobbies, administrative areas, and similar spaces.

 (D) Wall finishes shall be smooth, washable, moisture resistant, and cleanable.

 (i) Wall finishes shall be water-resistant in the immediate area of plumbing fixtures.

 (ii) Wall finishes subject to frequent wet cleaning methods shall be impervious to water, tightly sealed and without voids.

 (E) Ceilings which are a part of a rated roof to ceiling assembly or a floor to ceiling assembly shall be constructed of listed components and installed in accordance with the listing. Three types of ceilings that are required in various areas of the ESRD facility are:

 (i) ordinary ceilings in all areas or rooms in the ESRD facility unless a requirement requires a specific type of ceiling for such space, which includes ceilings such as acoustical tiles installed in a metal grid which are dry cleanable with equipment used in daily housekeeping activities such as dusters and vacuum cleaners;

 (ii) washable ceilings are ceilings that are made of washable, smooth, moisture impervious materials such as painted lay-in gypsum wallboard or vinyl faced acoustic tile in a metal grid when installed in the water treatment room and reuse room;

 (iii) monolithic ceilings, which are monolithic from wall to wall (painted solid gypsum wallboard), smooth and without fissures, open joints, or crevices and with a washable and moisture impervious finish shall be provided for the isolation room and reuse room; and

 (iv) no finished ceilings in mechanical, electrical, general storage, and water treatment rooms.

 (F) Floor, wall and ceiling penetrations by pipes, ducts, and conduits, or any direct openings shall be tightly sealed to minimize entry of dirt particles, rodents and insects. Joints of structural elements shall be similarly sealed.

 (G) Materials known to produce noxious gases when burned shall not be used for mattresses, upholstery, and wall finishes.

 (H) A sign shall be posted at the entrance to each toilet and restroom to identify the facility for public, staff, or patient use.

 (I) When vinyl sheets and vinyl composition tiles are used for toilet rooms, treatment areas or rooms, isolation treatment rooms, exam rooms, training rooms, and reprocessing rooms the joints shall be sealed to prevent moisture and blood from seeping into the joints and under the tile.

(g) This subsection contains common requirements for mechanical systems; steam and hot and cold water systems; air conditioning, heating and ventilating systems; and thermal and acoustical insulation.

 (1) When mechanical equipment is exposed to weather, it shall be protected by weatherproof construction or weather protected.

 (2) Mechanical equipment shall be mounted on vibration isolators as required to prevent unacceptable structure-borne vibration. Ducts, pipes, etc. connected to mechanical equipment which is a source of vibration shall be isolated from the equipment with vibration isolators.

 (3) Prior to completion and acceptance of the facility, all mechanical systems shall be tested, balanced, and operated to demonstrate to the design engineer or his representative that the installation and performance of these systems conform to the requirements of the plans and specifications.

 (A) Upon acceptance of the mechanical system, the owner shall be provided with parts lists and procurement information with numbers and description for each piece of equipment.

 (B) Upon acceptance of the mechanical system, the owner shall be provided with instructions in the operational use of systems and equipment as required.

 (4) All heating, ventilating, and air conditioning (HVAC) systems shall comply with and shall be installed in accordance with the requirements of National Fire Protection Association 90A, Standard for the Installation of Air Conditioning and Ventilating Systems, 2002 edition (NFPA 90A), NFPA 99, Chapter 6 and the requirements contained in this subsection.

 (5) All rooms and areas in the ESRD facility shall have provision for positive ventilation. Fans serving exhaust systems shall be located at the discharge end and shall be conveniently accessible for service. Exhaust systems may be combined, unless otherwise noted, for efficient use of recovery devices required for energy conservation. Supply air to the building and exhaust air from the building shall be regulated to provide a positive pressure within the building with respect to the exterior.

 (A) The systems serving all treatment areas or rooms, exam rooms, and isolation rooms, shall be capable of maintaining a temperature range between 68 and 78 degrees Fahrenheit and a relative humidity range between 45 percent and 60 percent.

 (B) The indoor design temperature in all other areas shall be between 68 and 75 degrees Fahrenheit with relative humidity of not less than 30 percent.

 (6) Ventilation systems for the reuse room and airborne isolation room shall be connected to an air exhaust system to the outdoors which is separate from the building exhaust system, have an exhaust fan located at the discharge end of the system, and have an exhaust duct system of noncombustible corrosion-resistant material as needed to meet the planned usage of the system.

 (A) The bottoms of wall-mounted return and exhaust air openings shall be at least six inches above the floor. All exhaust air openings and return air openings located higher than six inches but less than seven feet above the floor shall be protected with grilles or screens having openings through which a one-half inch sphere will not pass.

 (B) Exhaust outlets shall be above the roof level and arranged to minimize recirculation of exhaust air into the building. Exhaust outlets shall be located at least 25 feet from any fresh air intake of ventilating systems. (Prevailing winds and proximity to other structures may require more stringent requirements.) Plumbing and vacuum vents that terminate five feet above the level of the top of the air intake may be located as close as 10 feet.

 (C) If applicable, the reuse room and the airborne isolation room exhaust systems shall be connected to the emergency electrical system and shall meet the requirements of paragraph (10) of this subsection.

 (7) All toilet exhaust ventilation shall be exhausted to the outdoors. Exhaust systems may be combined, unless otherwise noted, for efficient use of recovery devices required for energy conservation.

 (8) To reduce utility costs, facility design may use energy conserving procedures including recovery devices, variable air volume, load shedding, systems shutdown, or reduction of ventilation rates (when specifically permitted) in certain areas when unoccupied. In no case shall patient care be jeopardized.

 (9) Mechanical systems shall be arranged to take advantage of outside air conditions by using an economizer cycle when appropriate to reduce heating and cooling systems loads. Innovative design that provides for additional energy conservation while meeting the intent of this subsection for acceptable patient care may be presented to HHSC for consideration.

 (10) Outside air intakes shall be located at least 25 feet from exhaust outlets of ventilating systems, combustion equipment stacks, plumbing vents, or areas which may collect vehicular exhaust or other noxious fumes. (Prevailing winds and proximity to other structures may require more stringent requirements). Plumbing vents that terminate five feet above the level of the top of the air intake may be located as close as 10 feet.

 (11) Fully ducted supply, return and exhaust air for HVAC systems shall be provided for all patient treatment care areas, storage rooms, and where required for fire safety purposes. Combination systems, utilizing both ducts and plenums for movement of air in these areas, shall not be permitted.

 (12) Air handling systems shall not be started or operated without 30 percent or equal minimum efficient rating value (merv) of eight and the filters installed in place. Ducts shall be cleaned thoroughly and throughout by a certified air duct cleaning contractor when the air handling systems have been operating without the required filters in place. When ducts are determined to be dirty or dusty, HHSC shall require a written report assuring cleanliness of duct and clean air quality.

 (13) Ductwork with duct-mounted humidifiers shall be provided with a means of removing water accumulation. An adjustable high-limit humidistat shall be located downstream of the humidifier to reduce the potential of condensation inside the duct. All duct take-offs shall be sufficiently downstream of the humidifier to ensure complete moisture absorption. Reservoir-type water spray or evaporative pan humidifiers shall not be used.

 (14) All central air handling systems shall be equipped with filters having efficiencies 30 percent or equal to eight merv. Filter efficiencies shall be average efficiencies tested in accordance with American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE), Inc., Standard 52.2, 1999 edition, Method of Testing General Ventilation Air-Cleaning Devices for Removal Efficiency by Particle Size. All joints between filter segments, and between filter segments and the enclosing ductwork, shall have gaskets and seals to provide a positive seal against air leakage. Air handlers serving more than one room shall be considered as central air handlers. All documents published by ASHRAE as referenced in this section may be obtained by writing or calling the ASHRAE, Inc. at the following address or telephone number: ASHRAE, Inc., 1791 Tullie Circle, Northeast, Atlanta, Georgia 30329; telephone (404) 636-8400.

 (A) Filtration requirements for air handling units serving single rooms. Dedicated air handlers serving single rooms shall be equipped with nominal filters installed at the return air system.

 (B) A filter bed shall be located upstream of the supply fan. Filter frames shall be durable and constructed to provide an airtight fit with the enclosing ductwork.

 (15) Thermal and acoustical insulation for air handling systems. Asbestos insulation shall not be used.

 (A) Air ducts and casings with outside surface temperature below ambient dew point or temperature above 80 degrees Fahrenheit shall be provided with thermal insulation.

 (B) Linings in air ducts and equipment shall meet the Erosion Test Method described in Underwriters Laboratories (UL), Inc., Standard Number 181 (relating to Factory-Made Duct Materials and Air Duct Connectors), April 4, 1996 edition. This document may be obtained from the Underwriters Laboratories, Inc., 333 Pfingsten Road, Northbrook, Illinois 60062-2096.

 (C) Interior and exterior insulation, including finishes and adhesives on the exterior surfaces of ducts and equipment, shall have a flame spread rating of 25 or less and a smoke developed rating of 50 or less as required by NFPA 90A, Chapters 4 and 5.

 (D) Insulation of soft and spray-on types shall not be used where it is subject to air currents or mechanical erosion or where loose particles may create a maintenance problem.

 (16) Fire dampers shall be located and installed in all ducts at the point of penetration of a required two-hour or higher fire rated wall or floor in accordance with the requirements of NFPA 101, §20.1.

 (17) Smoke dampers shall be located and installed in accordance with the requirements of NFPA 101, and NFPA 90A, Chapter 5.

 (A) Smoke dampers shall close on activation of the fire alarm system by smoke detectors installed and located as required by National Fire Protection Association 72, National Fire Alarm Code, 2002 Edition (NFPA 72), Chapter 8; NFPA 90A, Chapter 6; and NFPA 101, §18.3.7; the fire sprinkler system; and upon loss of power. Smoke dampers shall not close by fan shutdown alone unless it is a part of an engineered smoke removal system.

 (B) Air handling fans and smoke damper controls may be interconnected so that closing of smoke dampers will not damage the ducts.

 (C) Use of frangible devices for shutting smoke dampers is not permitted.

 (18) Only fire damper and smoke damper assemblies integral with sleeves and listed for the intended purpose shall be acceptable.

 (19) Unobstructed access to duct openings in accordance with NFPA 90A, §4.3.4, shall be provided in ducts within reach and sight of every fire damper, smoke damper, and smoke detector. Each opening shall be protected by an internally insulated door, which shall be labeled externally to indicate the fire protection device located within.

 (20) Controls for restarting fans may be installed for convenient fire department use to assist in evacuation of smoke after a fire is controlled, if provisions are made to avoid possible damage to the system because of closed dampers. To accomplish this, smoke dampers shall be equipped with remote control devices.

(h) All piping systems and plumbing fixtures shall be designed and installed in accordance with the requirements of the National Standard Plumbing Code Illustrated published by the National Association of Plumbing-Heating-Cooling Contractors (PHCC), 2003 edition, and this paragraph. The National Standard Plumbing Code may be obtained by writing or calling the PHCC at the following address or telephone number: Plumbing-Heating-Cooling Contractors, Post Office Box 6808, Falls Church, Virginia 22046; telephone (800) 533-7694.

 (1) Piping systems.

 (A) Water service pipe to point of entrance to the building shall be brass pipe, copper tube (not less than type M when buried directly), copper pipe, cast iron water pipe, galvanized steel pipe, or approved plastic pipe. Domestic water distribution system piping within buildings shall be brass pipe, copper pipe, copper tube, or galvanized steel pipe. Piping systems shall be designed to supply water at sufficient pressure to operate all fixtures and equipment during maximum demand.

 (i) Each water service main, branch main, riser, and branch to a group of fixtures shall be equipped with accessible and readily identifiable shutoff valves. Stop valves shall be provided at each fixture.

 (ii) Backflow preventers (vacuum breakers) shall be installed on hose bibbs, laboratory sinks, janitor sinks, and on all other fixtures to which hoses or tubing can be attached. Backflow preventers are not required for hoses that are directly connected to the dialysis machines.

 (iii) Flush valves installed on plumbing fixtures shall be of a quiet operating type, equipped with silencers.

 (iv) Hot water distribution systems for patient care areas shall be under constant recirculation to provide continuous hot water at each hot water outlet. Non-recirculated fixtures branch piping shall not exceed 25 feet in length. Tankless water system may be used at point of use.

 (v) Water heating equipment shall have sufficient capacity to supply water for clinical, use.

 (vi) Water temperatures shall be measured at hot water point of use and shall be between 105 - 120 degrees Fahrenheit.

 (vii) The domestic hot water system shall make provisions to limit the amount of Legionella bacteria and opportunistic waterborne pathogens.

 (viii) Domestic water storage tanks shall be fabricated of corrosion-resistant metal or lined with noncorrosive material. When potable water storage tanks (hot and cold) are used, the water shall be used and replenished. Water shall not be stored in tanks for future use unless the water is tested weekly for contaminates or bacteria.

 (ix) Purified water distribution system piping shall be task specific and include, but not necessarily be limited to, polypropylene (PP), polyvinylidene fluoride (PVDF) or polyvinyl chloride (PVC) pipe. Final installed purified water system piping assemblies shall be UL approved and fully comply with applicable American Society for Testing and Materials (ASTM) Fire Resistant/Smoke Density requirements. The applicable documents are available from ASTM International, 100 Barr Harbor Drive, Post Office Box C700, West Conshohocken, Pennsylvania 19428-2959.

 (B) When fire sprinkler systems are required and provided in an ESRD facility, the fire sprinkler systems shall be designed, installed, and maintained in accordance with the requirements of NFPA 13, and shall be certified as required by §507.105(c)(1)(C) of this title (relating to Construction, Inspections, and Approval of Project).

 (C) Main storage of medical gases may be outside or inside the ESRD facility in accordance with NFPA 99, §5.1.

 (D) Steam and hot water systems.

 (i) When boilers are used the boilers shall have the capacity, based upon the net ratings as published in The I-B-R Ratings Book for Boilers, Baseboard Radiation and Finned Tube (commercial) by the Hydronics Institute Division of GAMA, to supply the normal requirements of all systems and equipment. The document published by the Hydronics Institute Division of GAMA as referenced in this rule may be obtained by writing or calling the Hydronics Institute Division of GAMA at 35 Russo Place, P.O. Box 218, Berkeley Heights, New Jersey 07922, telephone (908) 464-8200.

 (ii) Boiler feed pumps, heating circulating pumps, condensate return pumps, and fuel oil pumps shall be connected and installed to provide normal and standby service.

 (iii) Supply and return mains and risers of cooling, heating, and process steam systems shall be valved to isolate the various sections of each system. Each piece of equipment shall be valved at the supply and return ends except that vacuum condensate returns need not be valved at each piece of equipment.

 (E) Drainage systems.

 (i) All underground building drains shall be: cast iron soil pipe, hard temper copper tube (drain-waste-vent (DWV) or heavier), acrylonitrile-butodiene-styrene (ABS) plastic pipe (DWV Schedule 40 or heavier), polyvinyl chloride (PVC) plastic pipe (DWV Schedule 40 or heavier), or extra strength vitrified clay pipe (VCP) with compression joints or couplings with at least 12 inches of earth cover.

 (ii) Soil stacks, drains, vents, waste lines, and leaders installed above ground within buildings shall be DWV weight or heavier and shall be: copper pipe, copper tube, plastic pipe (DWV scheduled 40 or heavier) cast iron pipe, or galvanized iron pipe.

 (iii) Drainage systems for chemical wastes (acids and other corrosive materials) shall be provided. Materials acceptable for chemical waste drainage systems shall include chemically resistant glass pipe, high silicone content cast iron pipe, VCP, CPVC plastic pipe, or plastic lined pipe.

 (iv) Thermal insulation for piping systems and equipment shall be provided for:

 (I) boilers, smoke breeching, and stacks;

 (II) steam supply and condensate return piping;

 (III) hot water piping and all hot water heaters, generators, converters, and storage tanks;

 (IV) chilled water, refrigerant, other process piping, equipment operating with fluid temperatures below ambient dew point, and water supply and drainage piping on which condensation may occur;

 (V) an exterior vapor barrier for insulation on cold surfaces; and

 (VI) other piping, ducts, and equipment as necessary to maintain the efficiency of the system.

 (v) Flame spread shall not exceed 25 and smoke development rating shall not exceed 50 for pipe insulation as determined by an independent testing laboratory in accordance with National Fire Protection Association 255, Standard Method of Test of Surface Burning Characteristics of Building Materials, 2000 Edition. Smoke development rating for pipe insulation located in environmental air areas shall not exceed 50.

 (vi) Asbestos insulation shall not be used.

 (2) Plumbing fixtures shall be made of non-absorptive acid-resistant materials and shall comply with the recommendations of the National Standard Plumbing Code and this paragraph.

 (A) All sinks used by medical and nursing staff and all lavatories used by patients shall be trimmed with valves that can be operated without the use of hands. Blade handles used for this purpose shall not be less than four inches in length. Single lever or wrist blade devices may be used.

 (B) Clinical sinks shall have an integral trap in which the upper portion of a visible trap seal provides a water surface.

 (C) All plumbing fixtures and equipment shall be designed and installed to prevent the back-flow or back-siphonage of any material into the water supply. The over-the-rim type water inlet shall be used wherever possible. Vacuum-breaking devices shall be properly installed when an over-the-rim type water inlet cannot be used.

 (D) Each drinking fountain shall be designed so that the water issues at an angle from the vertical, the end of the water orifice is above the rim of the bowl, and a guard is located over the orifice to protect it from lip contamination.

 (E) All sterilizing equipment shall be designed and installed to prevent not only the contamination of the water supply but also the entrance of contaminating materials into the sterilizing units. Sterilizers shall be designed and installed so that both hot and cold water inlets shall be protected against back-siphonage at maximum water level.

 (F) No hose shall be affixed to any faucet if the end of the hose can become submerged in contaminated liquid unless the faucet is equipped with an approved, properly installed vacuum breaker.

 (G) The water supply spout for lavatories and sinks required in patient care areas shall be mounted so that its discharge point is a minimum of five inches above the rim of the sink.

 (H) Where floor drains or floor sinks are installed, they shall be of a type that can be easily cleaned by removal of the cover. Removable stainless steel mesh shall be provided in addition to grilled drain cover to prevent entry of large particles of waste which might cause stoppages.

 (I) Under counter piping and above floor drains shall be raised so as not to interfere with cleaning of floor below the equipment.

 (J) All ice-making machines used for human consumption shall be of the self-dispensing type. Copper tubing shall be provided for supply connections to ice machines.

(i) Common electrical requirements. The ESRD facility shall comply with the requirements of this subsection.

 (1) All new electrical material and equipment, including conductors, controls, and signaling devices, shall be installed in compliance with applicable sections of the National Fire Protection Association 70, National Electrical Code, 2002 Edition (NFPA 70), and NFPA 99 and as necessary to provide a complete electrical system. Electrical systems and components shall be listed by nationally recognized listing agencies as complying with available standards and shall be installed in accordance with the listings and with the manufacturer's direction for use.

 (A) All fixtures, switches, sockets, and other pieces of apparatus shall be maintained in a safe and working condition.

 (B) All electrical heating devices shall be equipped with a pilot light to indicate when the device is in service, unless equipped with a temperature limiting device integral with the heater.

 (C) All equipment, fixtures, and appliances shall be properly grounded in accordance with NFPA 70 and NFPA 99, §4.3.2.2.2.

 (D) Under counter receptacles and conduits shall be raised to not interfere with cleaning of floor below the equipment.

 (2) Installation testing and certification.

 (A) The electrical installations, including alarm, nurses calling system and communication systems, shall be tested to demonstrate that equipment installation and operation is appropriate and functional.

 (B) The grounding system shall be tested as described in NFPA 99, 4.3.3, for patient care areas in new or renovated work. The testing shall be performed by a qualified electrician or their qualified electrical testing agent. The electrical contractor shall provide a letter stating that the grounding system has been tested in accordance with NFPA 99, the testing device use complies with NFPA 99, and whether the grounding system passed the test. The letter shall be signed by the qualified electrical contractor, or their designated qualified electrical testing agent, certifying that the system has been tested and the results of the test are indicated.

 (3) Shielded isolation transformers, voltage regulators, filters, surge suppressors, and other safeguards shall be provided as required where power line disturbances are likely to affect fire alarm components, data processing, equipment used for treatment, and automated laboratory diagnostic equipment.

 (4) Electrical service and switchboards serving the required ESRD facility components shall be installed above the designated 100-year flood plain. Main switchboards shall be located in a permanently dry location and the electrical switchgear and distribution panels and shall be accessible to authorized persons only. These rooms or spaces shall be ventilated to provide an environment free of corrosive or explosive fumes and gases, or any flammable and combustible materials. When switchboards are installed in a damp or wet location the enclosure shall be installed in a waterproof cabinet. Switchboards shall be located convenient for use and readily accessible for maintenance as required by NFPA 70, Article 408. Overload protective devices shall operate properly in ambient temperatures.

 (5) Panelboards serving normal lighting and appliance circuits shall be located on the same floor as the circuits they serve. Panelboards serving critical branch emergency circuits shall be located on each floor that has major users and may also serve the floor above and the floor below. Panelboards serving life safety branch circuits may serve three floors, the floor where the panelboard is located, and the floors above and below.

 (6) All conductors for controls, equipment, lighting and power operating at 100 volts or higher shall be installed in accordance with the requirements of NFPA 70, Article 517. All surface mounted wiring operating at less than 100 volts shall be protected from mechanical injury with metal raceways to a height of seven feet above the floor. Conduits and cables shall be supported in accordance with NFPA 70, Article 300.

 (7) The wiring of the emergency system shall be mechanically protected by installation in nonflexible metal raceways in accordance with NFPA 70, §517.30(C)(3).

 (8) Lighting and receptacles.

 (A) Lighting intensity for staff and patient needs shall comply with guidelines for health care facilities set forth in the Illuminating Engineering Society of North America (IESNA) Handbook, 2000 edition, published by the IESNA, 120 Wall Street, Floor 17, New York, New York 10005.

 (i) Consideration shall be given to controlling intensity and wavelength to prevent harm to the patient's eyes (such as retina damage to cataracts due to ultraviolet light).

 (ii) Approaches to buildings and parking lots shall be illuminated. All rooms including storerooms, electrical and mechanical equipment rooms, and all attics shall have sufficient artificial lighting so that all parts of these spaces shall be clearly visible.

 (iii) Consideration shall be given to the special needs of the elderly. Excessive contrast in lighting levels that makes effective sight adaptation difficult shall be minimized.

 (B) Means of egress and exit sign lighting intensity shall comply with NFPA 101, §§7.8 - 7.10.

 (C) Electric lamps, which may be subject to breakage or which are installed in fixtures in confined locations when near woodwork, paper, clothing, or other combustible materials, shall be protected by wire guards, or plastic shields.

 (D) Only listed hospital grade single-grounding or duplex-grounding receptacles shall be used in all patient care areas. This does not apply to special purpose receptacles.

 (i) Installations of multiple-ganged receptacles shall not be permitted in patient care areas.

 (ii) Electrical outlets powered from the emergency system shall be provided in all patient care, procedure, and treatment locations in accordance with NFPA 99, §4.4.2.2.2.3. At least one receptacle at each patient treatment station or room, exam room, or procedure location shall be powered from the emergency electrical system power panel. At least one receptacle at each patient treatment station or room, exam room, or procedure location shall be powered from the normal power panel.

 (iii) Replacement of malfunctioning receptacles and installation of new receptacles powered from the emergency system in existing facilities shall be accomplished with receptacles of the same distinct color as the existing receptacles.

 (iv) In locations where other equipment requiring special electrical configuration is used, the additional receptacles shall be distinctively marked for the special use.

 (v) Each receptacle shall be grounded to the reference grounding point by means of a green insulated copper equipment grounding conductor.

 (vi) All emergency system receptacles shall be identified. The face plate for the receptacles shall have a nonremovable label or be engraved indicating the panel and circuit number.

 (E) Equipment.

 (i) Equipment required for safe operation of the ESRD facility shall be powered from the critical system in accordance with the requirements contained in NFPA 99, §4.5.2.2.3.

 (ii) Boiler accessories including feed pumps, heat-circulating pumps, condensate return pumps, fuel oil pumps, and waste heat boilers shall be connected and installed to provide both normal and standby service.

 (F) Ground fault circuit interrupters (GFCI) receptacles shall be provided for all general use receptacles located within three feet of a wash basin or sink. When GFCI receptacles are used, they shall be connected to not affect other devices connected to the circuit in the event of a trip. Receptacles connected to the critical branch that may be used for equipment that should not be interrupted do not have to be GFCI protected. Receptacles in wet locations, as defined by NFPA 70, §517.20 and §517.21, shall be GFCI protected regardless of the branch of the electrical system serving the receptacle.

 (9) A nurse’s emergency calling system shall be installed in the patient waiting area, all individual treatment rooms, exam rooms, isolation rooms, hepatitis B rooms, and toilet rooms used by patients to summon nursing staff in an emergency. Activation of the system shall sound a repeating (every five seconds or less) distinct audible signal at the nurse station, indicate type and location of call on the system monitor, and activate a distinct visible signal in all areas. The visible and audible signals shall be cancelable only at the patient calling station. A nurse’s emergency call system shall be accessible to a collapsed patient lying on the floor. Inclusion of a pull cord extending to within six inches of the floor will satisfy this requirement.

 (10) The ESRD facility shall provide, at submission of construction documents or plans a letter on facility letterhead indicating the method the ESRD facility has chosen for implementation of the emergency contingency plan for the continuity of emergency essential building systems (emergency generator). The contingency plan shall consist of one of the three options as described as follows.

 (A) An onsite emergency generator shall be provided with a Type II essential electrical distribution system in accordance with requirements of NFPA 99, §4.5, and National Fire Protection Association 110, Standard for Emergency and Standby Power Systems, 2002 Edition.

 (i) An emergency generator standby power system shall require an onsite fuel source and enough fuel capacity in the tank for a period of twenty-four hours or more. When a vapor liquefied petroleum gas (LPG) (natural gas) system is used, the twenty-four-hour fuel capacity on site is not required. The vapor withdrawal LPG system shall require a dedicated fuel supply.

 (ii) The emergency generator shall be installed, tested and maintained in accordance with the National Fire Protection Association 99, §4.5.4, and National Fire Protection Association 110, Standard for Emergency and Standby Power Systems, 2002 Edition.

 (iii) When the emergency generator and electrical transformer are located within the same area, they shall be located at least 10 feet apart.

 (iv) Sufficient quantity of potable water supply shall be on site for the operation of the water treatment system for at least 24 hours. A water valve connection shall be provided to allow hook-up for potable water from an outside vendor to supply the water treatment system.

 (B) A executed contract with an outside supplier or vendor that will provide a portable emergency generator and potable water on demand.

 (i) An electrical transfer switch with plug-in device sized to provide emergency power for the patient care areas and the provisions in NFPA 99, §4.5.2.2.2.

 (ii) A water valve connection to allow hook-up for potable water from an outside vendor to supply the water treatment system.

 (iii) An alternate source of power (battery power lighting) shall be provided separate and independent from the normal electrical power source that will be effective for a minimum of one and a half hours after loss of the electrical power. The emergency lighting system shall provide sufficient illumination to allow safe evacuation from the building. The battery pack systems shall be maintained and tested quarterly.

 (iv) The facility shall implement the emergency contingency plan upon the loss of electrical power following a natural weather or man-made event when the electrical power may not be restored within 24 hours. The facility shall exercise the contract with the supplier or vendor in order to have portable emergency generators and potable water available within 36 hours after the loss of electrical power.

 (C) An executed contract with another licensed ESRD facility within a 100-mile radius to provide emergency contingency care for the patients.

 (i) The accepting licensed ESRD facility shall meet the requirements of paragraph (1) of this subsection.

 (ii) An alternate source of power shall be provided separate and independent from the normal electrical power source that will be effective for a minimum of one and a half hours after loss of the electrical power. The emergency lighting system shall provide sufficient illumination to allow safe evacuation from the building. The battery pack systems shall be maintained and tested quarterly.

 (11) A fire alarm system, which complies with NFPA 101, §18.3.4, and with NFPA 72, Chapter 6 requirements, shall be provided in each facility. The required fire alarm system components are:

 (A) a fire alarm control panel (FACP) installed at a visible central location;

 (B) manual fire alarm pull stations installed in accordance with NFPA 101, §18.3.4;

 (C) smoke detectors for door release service installed on the ceiling at each door opening in the smoke partition in accordance with NFPA 72, §6.15.6, where the doors are held open with electromagnetic devices conforming with NFPA 101, §18.2.2.6;

 (D) smoke detectors installed in air ducts in accordance with NFPA 72, §5.14.4.2 and §5.14.5 and NFPA 90A, §6.4.2;

 (E) smoke detectors installed in return air ducts in accordance with requirements of NFPA 72 §5.14.4.2.2 and §5.14.5 and NFPA 90A, §6.4.2.2;

 (F) fire sprinkler system water flow switches installed in accordance with requirements of NFPA 101, §9.6.2; NFPA 13, §6.9; and NFPA 72, §8.5.3.3.3.4;

 (G) sprinkler system valve supervisory switches installed in accordance with the requirements of NFPA 72, §6.8.5.5;

 (H) audible alarm indicating devices installed in accordance with the requirements of NFPA 101, §18.3.4, and NFPA 72, §7.4;

 (I) visual fire alarm indicating devices, which comply with the requirements of NFPA 72, §7.5;

 (J) devices for transmitting alarm for alerting the local fire brigade or municipal fire department of fire or other emergency, listed for the fire alarm service by a nationally recognized laboratory, and installed in accordance with such listing and the requirements of NFPA 72;

 (K) a fire alarm signal notification, which complies with NFPA 101, §9.6.3, provided to alert occupants of fire or other emergency;

 (L) wiring for fire alarm detection circuits and fire alarm notification circuits that complies with requirements of NFPA 70, Article 760;

 (M) smoke detectors for shutdown of air handling units, which are installed in accordance with NFPA 90A, §6.4.3;

 (N) telecommunications and information systems central equipment installed in a separate location designed for the intended purpose and special air conditioning and voltage regulation provided as recommended by the manufacturer; and

 (O) when installed, lightning protection systems that comply with National Fire Protection Association 780, Standard for the Installation of Lightning Protection Systems, 2000 Edition.

§507.103. Elevators, Escalators, and Conveyors.

(a) All buildings that have patient services located on other than the main entrance floor shall have electric or electrohydraulic elevators. The elevators shall be installed in sufficient quantity, capacity, and speed to ensure that the average interval of dispatch time will not exceed one minute, and average peak loading can be accommodated. Elevators shall also give access to all building levels normally used by the public. Escalators and conveyors are not required but, when provided, shall comply with these requirements and the requirement of §20.3 of the National Fire Protection Association 101, Life Safety Code, 2003 Edition (NFPA 101), published by the National Fire Protection Association. All documents published by the NFPA, as referenced in this section, may be obtained by writing or calling the NFPA at the following address and telephone number: Post Office Box 9101, 1 Batterymarch Park, Quincy, Massachusetts 02269-9101, (800) 344-3555.

(b) New elevators, escalators and conveyors shall be installed in accordance with the requirements of Health and Safety Code, Chapter 754, Elevators, Escalators, and Related Equipment, and A17.1 Safety Code for Elevators and Escalators, 2000 edition, published by the American Society of Mechanical Engineers (ASME) and the American National Standards Institute (ANSI). All documents published by the ASME/ANSI as referenced in this section may be obtained by writing the ANSI, United Engineering Center, 345 East 47th Street, New York, New York 10017.

 (1) Elevators shall not open to an exit or exit passageway.

 (2) A facility located above the ground floor shall have an elevator of sufficient size to accommodate a gurney available at all times. Minimum elevator car size shall be five feet wide and seven feet deep.

 (3) The smallest elevator car door opening shall be at least three feet wide and seven feet high.

 (4) When light beams are used for operating door opening devices, the beams shall be used in combination with door edge devices and shall be interconnected with a system of smoke detectors. The light control feature shall be disengaged when smoke is detected in any elevator lobby.

 (5) Elevator call buttons, controls, and door safety stops shall be of a type that will not be activated by heat or smoke.

 (6) All elevators shall be equipped with an automatic leveling device of the two-way automatic maintaining type with an accuracy of one-half inch.

 (7) All elevators, except freight elevators, shall be equipped with a two-way key operated service switch permitting cars to bypass all landing button calls and be dispatched directly to any floor.

 (8) Elevator controls, alarm buttons, and telephones shall be accessible to wheelchair occupants in accordance with the Americans with Disabilities Act.

 (9) A smoke detection system for elevator recall shall be located in elevator lobbies, elevator machine rooms and at the top of elevator hoist ways as required by NFPA 72, §6.15.3.10.

 (A) The elevator recall smoke detection system in new construction shall comply with requirements of American Society of Mechanical Engineers/American National Standards Institute (ASME/ANSI) A17.1, Safety Code for Elevators and Escalators, 2000 edition. The publications of the ASME/ANSI referenced in this section may be obtained by writing ASME/ANSI, United Engineering Center, 345 East 47th Street, New York, New York 10017.

 (B) The elevator recall smoke detection system in existing ESRD facilities shall comply with requirements of ASME/ANSI A17.3, Safety Code for Existing Elevators and Escalators, 2002 edition.

 (10) Elevator machine rooms that contain solid-state equipment for elevators having a travel distance of more than 50 feet above the level of exit discharge or more than 30 feet below the level of exit discharge shall be provided with independent ventilation or air conditioning systems with the capability to maintain an operating temperature during fire fighter service operations. The operating temperature shall be established by the elevator equipment manufacturer's specifications and shall be posted in each such elevator machine room. When standby power is connected to the elevator, the machine room ventilation or air conditioning shall be connected to standby power. These requirements are not applicable to existing elevators.

 (11) An ESRD facility shall have all elevators and escalators routinely and periodically inspected and tested as specified in ASME/ANSI A17.1, Safety Code for Elevators and Escalators, 2000 edition. All elevators equipped with fire fighter service shall be subject to a monthly operation with a written record of the findings made and kept on the premises as required by NFPA 101, §9.4.6.

 (12) An ESRD facility shall obtain a certificate of inspection evidencing that the elevators, escalators, and conveyors and related equipment were inspected in accordance with the requirements in Health and Safety Code (HSC), Chapter 754, Subchapter B, and determined to comply with the safety standards adopted under HSC, §754.014, administered by the Texas Department of Licensing and Regulation. The certificate of inspection shall be on record in each center.

(c) Existing elevators and escalators shall comply with the ASME/ANSI A17.3, Safety Code for Elevators and Escalators, 1996 edition. All existing elevators having a travel distance of 25 feet or more above or below the level that best serves the needs of emergency personnel for firefighting or rescue purposes shall conform to Fire Fighters' Service Requirements of ASME/ANSI A17.3 as required by NFPA 101, §9.4.3.

§507.104. Preparation, Submittal, Review and Approval of Plans, and Retention of Records.

(a) General.

 (1) End stage renal disease (ESRD) facility owners or operators shall not begin construction of a new building, additions to, or renovations, or conversions of existing buildings until HHSC approves final construction documents.

 (2) Plans and specifications describing the construction of new buildings, and additions to, or renovations, and conversions of existing buildings shall be prepared by registered architects or licensed professional engineers and meet the requirements of this subchapter.

 (3) The names of spaces used in the functional program narrative, preliminary documents, final construction documents, and specifications shall be consistent with the names of the spaces used in this chapter.

 (4) HHSC shall notify the ESRD facility owner or operator of the result of its review of each type of submission discussed in this section.

 (5) The ESRD facility owner or operator shall respond to all department requests for additional information, including providing a plan of correction for deficiencies cited by HHSC.

 (6) Once final construction documents are approved, the ESRD facility owner or operator shall request inspections in accordance with §507.105 of this chapter (relating to Construction, Inspections, and Approval of Project).

 (7) When construction is delayed or put on hold for longer than one year from the plan approval or self-certification approval date, construction documents shall be resubmitted to HHSC for review and approval. The plans shall be accompanied by a new application for plan review and functional program narrative.

 (8) The ESRD facility owner or operator shall provide written notification to HHSC when a project has been placed on hold, canceled, or abandoned.

 (9) HHSC may close a project file after one year of assigning an application number to a project if the project has been placed on hold.

(b) Submission of projects and assignment of application number.

 (1) The ESRD facility owner, operator, or representative shall submit the following items to HHSC in care of the mailing or overnight delivery address that appears on the application for plan review:

 (A) a completed and signed application for plan review, which may be obtained by calling HHSC or by visiting the HHSC website;

 (B) a functional program narrative in accordance with subsection (d) of this section;

 (C) final construction documents in accordance with subsection (f) of this section; and

 (D) a letter on facility letterhead indicating the determination of the emergency contingency plan for the continuity of emergency essential building systems as noted in §507.102(i)(10) of this chapter (relating to Construction Requirements for a New End Stage Renal Disease Facility).

 (2) The cost of submitting documents/plans and specifications shall be borne by the sender.

 (3) Once HHSC has determined that the submission required in paragraph (1) of this subsection is complete, HHSC shall assign an application number to the project that shall be referenced on all documents and correspondence related to the project. Final construction documents shall be reviewed in the chronological order received.

 (4) All deficiencies noted in the final plan review shall be satisfactorily resolved before approval of project for construction will be granted.

 (5) Construction shall not begin until the ESRD facility owner or operator of the facility receives written notification from HHSC that the final construction documents have been approved.

(c) An ESRD facility owner, operator, or representative may request a feasibility conference. A feasibility conference is an informal meeting between a member of HHSC's architectural review group staff and the ESRD facility owner, operator, or representative to determine the feasibility of a project, for consultation and informational purposes, and to facilitate and establish understanding of compliance with the rules and codes.

 (1) A feasibility conference is not a substitute for plan review.

 (2) An ESRD facility owner, operator, or representative may schedule a feasibility conference by calling HHSC.

 (3) The ESRD facility owner, operator, or representative shall provide at the feasibility conference the items in subsection (b)(1)(A) - (C) of this section and a set of preliminary plans or final construction documents.

 (4) The ESRD facility owner, operator, or representative is responsible for recording conference notes and shall submit the notes to HHSC.

(d) The ESRD facility owner or operator shall submit a functional program narrative to HHSC with each new project in accordance with subsection (b)(1)(B) of this section. The functional program narrative shall be presented on facility letterhead, signed by ESRD facility administration, include the functional description of each space, and the following:

 (1) departmental relationships, number of patient stations, and other basic information relating to the fulfillment of the facility's objectives;

 (2) a description of each function to be performed, approximate space needed for these functions, occupants of the various spaces, projected occupant load, types of equipment required, interrelationship of various functions and spaces, and any special design features;

 (3) energy conservation measures, included in building, mechanical, and electrical designs;

 (4) a description of the type of asepsis control in diagnostic and treatment areas; and

 (5) the type of construction (existing or proposed) as stated in §20.1.6 of National Fire Protection Association 101, Life Safety Code, 2003 Edition (NFPA 101), published by the National Fire Protection Association. All documents published by the NFPA as referenced in this section may be obtained by writing or calling the NFPA at the following address and telephone number: 1 Batterymarch Park, Quincy, Massachusetts 02169-7471, (800) 344-3555.

(e) HHSC may request preliminary documents. If requested by HHSC, the submission shall consist of the items in subsection (b)(1)(A) - (C) of this section, preliminary plans, and outline specifications. The documents shall contain sufficient information to establish the project scope, description of functions to be performed, project location, required fire safety and exiting requirements, building construction type, compartmentation showing fire and smoke barriers, and the use of all spaces, areas, and rooms on every floor level.

(f) Final construction documents and specifications shall be submitted to HHSC for review and approval prior to start of construction. All final documents and specifications shall be appropriately sealed and signed by the project registered architect and professional engineers licensed by the State of Texas.

 (1) The ESRD facility owner or operator shall submit to HHSC for review and approval the items in subsection (b)(1)(A) - (C) of this section (if not previously submitted with preliminary documents) and one set of final construction documents and specifications covering the construction of new buildings or alterations, additions, conversions, modernizations, or renovations to existing buildings.

 (2) Construction documents shall be well-prepared so that clear and distinct prints may be obtained, shall be accurately and adequately dimensioned, shall include all necessary explanatory notes, schedules, and legends, and shall be adequate for contract purposes. Compliance with model building codes and this chapter shall be indicated. The type of construction, as classified by National Fire Protection Association 220, Standard on Types of Building Construction, 1999 Edition, shall be provided for existing and new facilities. Final plans shall be drawn to a sufficiently large-scale to clearly illustrate the proposed design but not less than one-eighth inch equals one foot. All spaces shall be identified by usage (using the names of spaces used in this chapter) on all plans (architectural, fire safety, mechanical, electrical, etc.) submitted. Separate drawings shall be prepared for each of the following branches of work.

 (A) Architectural drawings shall include:

 (i) a map of the area within a 500-foot radius of the facility site and any hazardous and undesirable location noted in §507.102(a) of this chapter identified;

 (ii) a site plan showing all new topography, newly established levels and grades, existing structures on the site (if any), new buildings and structures, roadways, parking, walks, easement, overhead or underground utilities or service lines, the extent of the areas to be landscaped, and a general description of the immediate area surrounding the site;

 (iii) all structures to be removed under the construction contract and improvements;

 (iii) a plan of each floor and roof to include fire and smoke separation, means of egress, and identification of all spaces;

 (iv) schedules of doors, windows, and finishes;

 (v) elevations of each facade;

 (vi) sections through building; and

 (vii) scaled details as necessary.

 (B) Fire safety plan drawings shall be provided for all newly constructed buildings, conversions of existing buildings for facilities, additions to existing licensed facilities, and remodeled portions of existing buildings containing licensed facilities. Fire safety plan drawings shall be of a sufficiently large-scale to clearly illustrate the proposed design but not less than one-sixteenth inch equals one foot and shall include:

 (i) separate fire safety plans (preferably one floor plan per sheet) indicating location of fire protection rated walls and partitions, location and fire-resistance rating of each fire damper, and the required means of egress (corridors, stairs, exits, exit passageways);

 (I) when a new building is to contain a proposed facility, when an existing building is converted to a facility, or when an addition is made to an existing facility building, plans of each floor and roof shall be provided; and

 (II) when a portion of a building is remodeled or when a new service is added, only the plan of the floor where the remodeling will take place or new service will be introduced, and the plan of the floor of discharge shall be provided;

 (ii) designated smoke compartments with floor areas of each compartment, location and fire-resistance rating (one or two-hour) of each smoke partition, location, type and fire-resistance rating of each smoke damper;

 (iii) location of all required fire alarm devices, including all fire alarm control panels, manual pull stations, audible and visual fire alarm signaling devices, smoke detectors (ceiling and duct-mounted), fire alarm annunciators, fire alarm transmission devices, fire sprinkler flow switches and control valve supervisory switches on each of the floor plans; and

 (iv) areas protected with fire sprinkler systems (pendant, sidewall or upright, normal or quick response, and temperature rating shall be indicated), stand pipe system risers and sizes with valves and inside and outside fire department connections, fire sprinkler risers and sizes, location and type of portable fire extinguishers.

 (C) Equipment drawings shall include:

 (i) all equipment necessary for the operation of the facility as planned and provisions for the installation of large and special items of equipment and for service accessibility;

 (ii) fixed equipment (equipment which is permanently affixed to the building or which shall be permanently connected to a service distribution system designed and installed during construction for the specific use of the equipment). The term fixed equipment includes items such as laundry extractors, communication systems, and built-in casework (cabinets);

 (iii) movable equipment (equipment not described in clause (ii) of this subparagraph as fixed), including wheeled equipment, plug-in type monitoring equipment, and relocatable items; and

 (iv) equipment which is not included in the construction contract, but which requires mechanical or electrical service connections or construction modifications, which shall be identified on the drawings to ensure its coordination with the architectural, mechanical, and electrical phases of construction.

 (D) Structural drawings shall include:

 (i) plans for foundations, floors, roofs, and all intermediate levels;

 (ii) a complete design with sizes, sections, and the relative location of the various members;

 (iii) a schedule of beams, girders, and columns;

 (iv) dimensioned floor levels, column centers, and offsets;

 (v) details of all special connections, assemblies, and expansion joints; and

 (vi) special openings and pipe sleeves dimensioned or otherwise noted for easy reference.

 (E) Mechanical drawings shall include:

 (i) complete ventilation systems (supply, return, exhaust), all fire and smoke partitions, locations of all dampers, registers, and grilles, air volume flow at each device, and identification of all spaces (e.g., corridor, patient room);

 (ii) boilers, chillers, heating and cooling piping systems (steam piping, hot water, chilled water), and associated pumps;

 (iii) cold and warm water supply systems, water heaters, storage tanks, circulating pumps, plumbing fixtures, emergency water storage tanks (if provided), and special piping systems such as for deionized water;

 (iv) nonflammable medical gas piping (oxygen, compressed medical air, vacuum systems, nitrous oxide), emergency shutoff valves, pressure gages, alarm modules, gas outlets;

 (v) drain piping systems (waste and soiled piping systems, laboratory drain systems, roof drain systems);

 (vi) fire protection piping systems (sprinkler piping systems, fire standpipe systems, water or chemical extinguisher piping system for cooking equipment);

 (vii) piping riser diagrams, equipment schedules, control diagrams or narrative description of controls, filters, and location of all duct-mounted smoke detectors; and

 (viii) laboratory exhaust and safety cabinets.

 (F) Electrical drawings shall include:

 (i) electrical service entrance with service switches, service feeders to the public service feeders, and characteristics of the light and power current including transformers and their connections;

 (ii) location of all normal electrical system and essential electrical system conduits, wiring, receptacles, light fixtures, switches and equipment which require permanent electrical connections, on plans of each building level:

 (I) light fixtures marked distinctly to indicate connection to critical or life safety branch circuits or to normal lighting circuits; and

 (II) outlets marked distinctly to indicate connection to critical, life safety, or normal power circuits;

 (iii) telephone and communication, fixed computers, terminals, connections, outlets, and equipment;

 (iv) nurses calling system showing all stations, signals, and annunciators on the plans;

 (v) in addition to electrical plans, single line diagrams prepared for:

 (I) complete electrical system consisting of the normal electrical system and the essential electrical system including the on-site generators, transfer switches, emergency system, panels, subpanels, transformers, conduit, wire sizes, main switchboard, power panels, light panels, and equipment for additions to existing buildings, proposed new facilities, and remodeled portions of existing facilities, which show feeder and conduit sizes with schedule of feeder breakers or switches;

 (II) complete nurses calling system with all stations, signals, annunciators, etc. with room number noted by each device and indicating the type of system (nurses emergency calling system, or staff emergency assistance calling system);

 (III) a single line diagram of the complete fire alarm system showing all control panels, signaling and detection devices, and the room number where each device is located; and

 (vi) schedules of all panels indicating connection to emergency system or normal system and connected load at each panel.

 (3) Any changes to the final construction documents which affect or change the function, design, or designated use of an area shall be submitted to HHSC for approval prior to authorization of the modifications.

(g) Special submittals.

 (1) Self-certification.

 (A) In an effort to shorten the plan review and approval process, the ESRD facility owner, operator, or representative may request approval of final construction documents under the self-certification review process.

 (i) The owner or operator shall submit the items in subsection (b)(1)(A) - (C) of this section and a completed self-certification form, signed by the ESRD facility owner or operator, architect of record, and engineer of record attesting that the plans and specifications are based upon and comply with the requirements of this chapter.

 (ii) By signing and submitting the self-certification form, the ESRD facility owner or operator accepts the following conditions.

 (I) HHSC retains the right to review the final construction documents, conduct inspections of the project, and withdraw its approval.

 (II) The ESRD facility owner or operator has a continuing obligation to make any changes HHSC requires to comply with the licensing rules, whether or not physical plant construction or alterations have been completed.

 (III) The ESRD facility owner or operator is ultimately responsible for compliance with Texas Health and Safety Code, Chapter 251, End Stage Renal Disease Facilities, and this chapter.

 (B) HHSC shall review the request for self-certification and notify the ESRD facility owner or operator if the request is approved or denied. If denied, HHSC shall review the final construction documents in the chronological order in which the documents were received. Construction shall not begin until the final construction documents have been reviewed and approved.

 (2) If an ESRD facility owner or operator believes that a proposed project is a minor project, the ESRD facility owner or operator shall provide to HHSC a brief written description of the proposed project and floor plans of the areas of work.

 (A) If it is determined that the proposed project is a minor project, HHSC shall notify the ESRD facility owner or operator of the approval and state the number of inspections that shall be required. A minimum of one inspection shall be conducted.

 (B) HHSC shall notify the ESRD facility owner or operator that a proposed project is not approved as a minor project, if the project involves any of the following:

 (i) remodeling or alterations which involve alterations to load bearing members or partitions;

 (ii) a change in functional operation;

 (iii) affecting fire safety (e.g., modifications to the fire, smoke, and corridor walls);

 (iv) adding services for which the ESRD facility is not currently licensed; and

 (v) significantly changing the mechanical, electrical, plumbing, or fire protection.

 (C) The ESRD facility owner or operator shall submit final construction documents in accordance with subsection (f) of this section if HHSC determines the project is not a minor project.

 (3) Fire sprinkler systems.

 (A) When the sole purpose of a project is installation of a sprinkler system, whether a partial or complete system, the ESRD facility owner or operator shall submit to HHSC for approval the items in subsection (b)(1)(A) - (C) of this section and sprinkler documents.

 (B) Fire sprinkler systems shall comply with the requirements of National Fire Protection Association 13, Standard for the Installation of Sprinkler Systems, 2002 Edition (NFPA 13), and shall be designed or reviewed by an engineer who is registered by the Texas Board of Professional Engineers in fire protection specialty or is experienced in hydraulic design and fire sprinkler system installation. A short resume shall be submitted if registration is not in fire protection specialty.

 (i) Fire sprinkler working plans, complete hydraulic calculations and water supply information shall be prepared in accordance with NFPA 13, §§14.1, 14.2 and 14.3, for new fire sprinkler systems, alterations of and additions to existing ones.

 (ii) One set of fire sprinkler working plans, calculations, and water supply information shall be forwarded to HHSC together with the professional engineer's (P.E. licensed in the State of Texas) certification letter stating that the sprinkler system design complies with the requirements of NFPA 13. Certification of the fire sprinkler system shall be submitted prior to system installation.

 (iii) Upon completion of the fire sprinkler system installation and any required corrections, written certification by the engineer, stating that the fire sprinkler system is installed in accordance with NFPA 13 requirements, shall be submitted prior to or with the written request for the final construction inspection of the project.

(h) Retention of drawings, manuals, and design data.

 (1) Upon occupancy of the building or portion thereof, the owner shall retain as part of the ESRD facility's permanent records, a complete set of legible architectural plans of each building level, fire safety plans as described in subsection (f)(2)(B) of this section for each floor reflecting fire safety requirements, and all single line diagrams described in subsection (f)(2)(F)(v) of this section, drawings for fixed equipment, and mechanical and electrical systems, as installed or built.

 (2) Upon completion of the contract, the owner shall retain as part of the ESRD facility's permanent records a complete set of manufacturers' operating, maintenance, and preventive maintenance instructions; parts lists; and procurement information with numbers and a description for each piece of equipment. Facility staff shall also be provided with instructions on how to properly operate systems and equipment. Required information shall include energy ratings as needed for future conservation calculations.

 (3) The owner shall retain in the ESRD facility's permanent records complete design data for the facility. This shall include structural design loadings; summary of heat loss assumption and calculations; estimated water consumption; medical gas outlet listing; list of applicable codes; and electric power requirements of installed equipment. All such data shall be supplied to facilitate future alterations, additions, and changes, including energy audits and retrofit for energy conservation.

§507.105. Construction, Inspections, and Approval of Project.

(a) Construction.

 (1) Construction, other than minor alterations, shall not commence until the final plan review deficiencies have been satisfactorily resolved, the appropriate licensing fee has been paid, and HHSC has issued a letter granting approval to begin construction. Such authorization does not constitute release from the requirements contained in this chapter. If the construction takes place in or near occupied areas, adequate provision shall be made for the safety and comfort of occupants.

 (2) The architect of record, or the ESRD facility owner or operator, shall provide written notification to HHSC when construction will commence. HHSC shall be notified in writing of any change in the completion schedules.

 (3) Construction shall be completed in compliance with the construction documents including all addenda or modifications approved for the project.

(b) All ESRD facilities, including those which maintain certification under Title XVIII of the Social Security Act (42 United States Code, §§1395 et seq.), are subject to construction inspections.

 (1) A minimum of two construction inspections of the project is generally required for verifying compliance with subchapters G and H of this chapter and the approved plans and specifications. The final plan approval letter shall inform the architect of record and the owner as to the minimum number of inspections required for the project.

 (2) The architect of record or the ESRD facility owner or operator shall request an inspection by submitting, at least three weeks in advance of the requested inspection date, an application for inspection for each intermediate inspection, final inspection, and reinspection requested. Inspection requests by contractors shall not be honored.

 (A) The architect of record or the ESRD facility owner or operator shall request an intermediate construction inspection to occur at approximately 80 percent completion. All major work above the ceiling shall be completed at the time of the intermediate inspection, however, ceilings shall not be installed.

 (B) The architect of record or the ESRD facility owner or operator shall request a final construction inspection at 100 percent completion. One hundred percent completion means that the project is completed to the extent that all equipment is operating in accordance with specifications, all necessary furnishings are in place, and patients could be admitted and treated in all areas of the project.

 (3) Depending upon the number and nature of the deficiencies cited during the final inspection, the inspector may require that a reinspection be conducted to confirm correction of all deficiencies cited. The inspector may also require a reinspection, if he determines that the project was not sufficiently complete to warrant a final inspection. The request for reinspection shall be submitted in accordance with paragraph (2) of this subsection.

(c) Patients and staff shall not occupy a new structure or remodeled or renovated space until approval has been received from the local building and fire authorities and HHSC.

 (1) The ESRD facility owner or operator shall submit the following documents to HHSC before the project will be approved:

 (A) written approval of the project by the fire authority;

 (B) a certificate of occupancy for the project issued by the local building authority;

 (C) a copy of a letter or certification from a professional engineer (P.E.) licensed in the State of Texas indicating the fire sprinkler working plans, hydraulic calculation, the testing, and field inspection of the installation of the new or modified sprinkler system complies with the requirements of NFPA 13, Standard for the Installation of Sprinkler Systems, 2002 Edition, if applicable. A copy of a letter or certification of changes in existing fire sprinkler system is not required, when relocation of not more than twenty sprinkler heads and hydraulic calculation is not involved;

 (D) fire alarm system certification (form FML-009A of the State Fire Marshal's Office), if applicable;

 (E) a copy of the test and a letter from the electrical contractor certifying that the electrical system was tested and complies with the standards of NFPA 99, Health Care Facilities, 2002 Edition, §4.3.2.2.8 (Special Grounding) and §4.3.3.1 (Grounding System Testing), if applicable to the project;

 (F) a copy of documentation indicating the flame spread rating and the smoke development rating of any wall covering installed in this project. A signed letter or statement corroborating the installation of the product in the project shall be provided;

 (G) a copy of documentation indicating that draperies, curtains (including cubicle curtains), and other similar loosely hanging furnishings and decorations are flame-resistant as demonstrated by passing both the small and large-scale tests of NFPA 701, Standard Methods of Fire Tests for Flame-Resistant Textiles and Films, 1999 Edition, as required by NFPA 101, §20-7.5, and a signed letter or statement corroborating the installation of the product in the project;

 (H) a written plan of correction signed by the ESRD facility owner or operator for any deficiencies noted during the final inspection; and

 (I) any other documentation or information required or requested due to the type of the project.

 (2) Architectural approval.

 (A) If, during the final inspection, the inspector finds only a few minor deficiencies that do not jeopardize patient health, safety and welfare, the inspector may grant architectural approval contingent upon the documents listed in paragraph (1)(A) - (D) of this subsection being provided to and approved by the inspector at the time of the final inspection.

 (B) Architectural approval allows the ESRD facility owner or operator to proceed with licensing. Patients may not be admitted, nor patient services provided until a license or modified license has been issued to the facility by HHSC. However, the ESRD facility owner or operator shall submit the documents required in paragraph (1)(E) - (I) of this subsection before the project receives final approval.

 (3) Upon its receipt and acceptance of the documents required in paragraph (1) of this subsection and receipt of an acceptable Plan of Correction of the final inspection report, HHSC shall issue written final approval of the project.

§507.106. Tables.

Figure: 26 TAC §507.106. Staffing Levels of Direct Care Staff.

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| **MINIMUM STAFFING LEVELS FOR PATIENT CARE STAFF** |
| **Patients receiving treatment** | **Charge Nurse (RN)*****Note: This RN may perform unassigned patient care* (\*Exception 1-6 patients)** | **RN or Staff RN*****Note: This RN is allowed to perform unassigned patient care*** | **Direct Care Staff****RN, Staff RN or LVN**  | **Direct Care Staff****PCT, LVN or RN** | **Total Clinical Staff*****(Including Charge Nurse)*** |
| 1-6 | \*1 |   |   | 1 | 2 |
| 7 | 1 |   | 1 | 1 | 3 |
| 8 | 1 |   | 1 | 1 | 3 |
| 9 | 1 |   | 1 | 2 | 4 |
| 10 | 1 |   | 1 | 2 | 4 |
| 11 | 1 |   | 1 | 2 | 4 |
| 12 | 1 |   | 1 | 2 | 4 |
| 13 | 1 | 1 |   | 4 | 6 |
| 14 | 1 | 1 |   | 4 | 6 |
| 15 | 1 | 1 |   | 4 | 6 |
| 16 | 1 | 1 |   | 4 | 6 |
| 17 | 1 | 1 |   | 5 | 7 |
| 18 | 1 | 1 |   | 5 | 7 |
| 19 | 1 | 1 |   | 5 | 7 |
| 20 | 1 | 1 |   | 5 | 7 |
| 21 | 1 | 1 |   | 6 | 8 |
| 22 | 1 | 1 |   | 6 | 8 |
| 23 | 1 | 1 |   | 6 | 8 |
| 24 | 1 | 1 |   | 6 | 8 |
| 25 | 2 | 1 |   | 7 | 10 |
| 26 | 2 | 1 |   | 7 | 10 |
| 27 | 2 | 1 |   | 7 | 10 |
| 28 | 2 | 1 |   | 7 | 10 |
| 29 | 2 | 1 |   | 8 | 11 |
| 30 | 2 | 1 |   | 8 | 11 |
| 31 | 2 | 1 |   | 8 | 11 |
| 32 | 2 | 1 |   | 8 | 11 |
| 33 | 2 | 1 |   | 9 | 12 |
| 34 | 2 | 1 |   | 9 | 12 |
| 35 | 2 | 1 |   | 9 | 12 |
| 36 | 2 | 1 |   | 9 | 12 |
| 37 | 3 | 1 |   | 10 | 14 |
| 38 | 3 | 1 |   | 10 | 14 |
| 39 | 3 | 1 |   | 10 | 14 |
| 40 | 3 | 1 |   | 10 | 14 |
| 41 | 3 | 1 |   | 11 | 15 |
| 42 | 3 | 1 |   | 11 | 15 |
| 43 | 3 | 1 |   | 11 | 15 |
| 44 | 3 | 1 |   | 11 | 15 |
| 45 | 3 | 1 |   | 12 | 16 |
| 46 | 3 | 1 |   | 12 | 16 |
| 47 | 3 | 1 |   | 12 | 16 |
| 48 | 3 | 1 |   | 12 | 16 |
| 49 | 4 | 1 |   | 13 | 18 |
| 50 | 4 | 1 |   | 13 | 18 |