

**Department of State Health Services
Council Agenda Memo for State Health Services Council
November 4, 2009**

Agenda Item Title: Repeal of rules and new rules concerning the regulation of end stage renal disease facilities

Agenda Number: 7b

Recommended Council Action:

For Discussion Only

For Discussion and Action by the Council

Background: Pursuant to Health and Safety Code Chapter 251, the Texas Department of State Health Services (DSHS) regulates end stage renal disease (ESRD) facilities to protect and promote the public health and safety of individuals receiving services in these facilities. DSHS issues licenses to these facilities and conducts inspections to determine compliance with regulations. Findings of noncompliance result in referral for enforcement action. There are 483 licensed ESRD facilities.

Per Health and Safety Code, Chapter 251, DSHS may use the referral process with the Medical Review Board / ESRD network in lieu of enforcement. In fiscal year 2009, 23 ESRD facilities were placed on DSHS-directed Corrective Action Plans (CAPs). Temporary managers and nurse monitors are used to oversee and help facilities implement CAPs, which usually last at least six months. The law requires us to use the CAP process in lieu of enforcement unless DSHS justifies why the CAP is not appropriate and enforcement is appropriate. DSHS rarely has ESRD cases taken to escalated enforcement. In the past four fiscal years, there has only been one such case. DSHS received 89 complaints against ESRD facilities and conducted 82 ESRD facility complaint investigations. Overall, DSHS conducted 253 federal and state surveys and complaint investigations in fiscal year 2009.

The ESRD fee is deposited in general revenue (Comptroller's Fund # 0001). Per the 2008 Fee Resource Manual, the ESRD fee generated \$1,066,113 in revenue and the cost associated with the program was \$415,034.

Summary: The purpose of the repeals and new rules is to clarify language to be consistent with state and federal regulations; update references to statutes, rules, and agency names; and revise, delete, or add definitions for governing ESRD facilities. The proposed rules reflect improvements in order to protect the health, safety, and welfare of patients receiving end stage renal dialysis care and have a positive impact on ESRD facilities and the organizations that represent them.

The proposed rules implement Health and Safety Code, Chapter 251, which requires ESRD facilities to be licensed by DSHS, and incorporate revisions made by Senate Bill 1932, 81st Legislature, Regular Session, 2009, which relates to hospitals temporarily providing outpatient dialysis services to a person because of a disaster. The review of the rules complies with the four-year agency review required by Government Code, Section 2001.039.

The rules:

- require facilities to comply with American Association of Medical Instrumentation Standard RD52 2004 and follow the Morbidity and Mortality Weekly Report from the Centers for Disease Control and Prevention;
- require a review of a patient's plan of care more frequently than monthly;
- expand a facility's responsibility for disaster preparedness and require an emergency contingency plan, part of which consists of four possibilities related to supplying emergency power;
- expand incident reporting to include patient deaths, involuntary discharge of patients, and hospital transfers;
- require equipment to be FDA approved, operated in accordance with the manufacturer's direction for use

and maintained free of defects, and standardize the qualifications for staff who conduct maintenance and repair of equipment;

- update the interdisciplinary quality assessment and performance improvement program to be consistent with federal standards;
- clarify that an LVN is not qualified to serve as charge nurse in a facility, in accordance with the Board of Nursing guidelines;
- require that an RN be in the facility whenever patients are in the facility, not just when patients are actively dialyzing;
- modify design and spacing requirements; and
- require new facilities or existing facilities expanding capacity of treatment stations to have isolation treatment rooms (for hepatitis B patients) as required by the Centers for Medicare and Medicaid Services (CMS); however, facilities can request a waiver to the requirement. (Some facilities are already in compliance with this requirement. Facilities can opt to have hepatitis B patients treated at other facilities. Those facilities not CMS certified can request a temporary exception while awaiting initial survey for Medicare certification.)

Summary of Input from Stakeholder Groups: Stakeholders were contacted by mail or e-mail in September 2008 of a meeting held on October 17, 2008. The draft proposed rules were posted on the DSHS website and stakeholders were solicited for comments in November 2008. The stakeholders included: all licensed ESRD facilities; End Stage Renal Disease Network of Texas; Council of Nephrology Social Workers; Texas Board of Nursing; Texas Hospital Association; Coalition for Nurses in Advanced Practice; Texas Medical Foundation Health Quality Institute; Camden Design Group; K & L Gates LLC; Braswell & Carruthers; Harris County Hospital District Biomed; Baxter Healthcare; Dialysis Resources Inc.; NxStage; Abbott Labs; independent physician, nurse, dietician, and social worker monitors; and independent consultants.

The stakeholders were notified by e-mail in November 2008 and January 2009 of meetings held on December 5, 2008, and January 30, 2009, regarding draft revisions of the rules, which were also posted on the DSHS website.

Most of the stakeholder issues pertained to design and space and disaster preparedness requirements, including the need for equipment (generator or transfer switch) or transfer agreement for facility patients.

Dietitians and social workers requested their ratio to patients to be 1:100 instead of 1:125. The ratio was unchanged, but the facility assigns personnel to assist the social worker with ancillary tasks (e.g., assistance with financial services, transportation, administrative, clerical, etc.) when the patient load exceeds 100 patients. The requirement is now for assistive personnel when the ratio exceeds 1:100 in the particular facility where the social worker is employed. No change for dietitians.

Other changes based upon stakeholder feedback were related to:

- water and equipment for peritoneal dialysis and home dialysis,
- complaints against a DSHS surveyor,
- requirements for EKG equipment,
- three options for the provisions of electricity and water in the emergency contingency plan, and
- deleting a requirement for weekly testing of water every four weeks if the facility replaces components that are designed to be replaced on a routine schedule such as filters, ultrafilters and ultraviolet lamps.

Proposed Motion: Motion to recommend HHSC approval for publication of rules contained in agenda item #7b

Approved by Assistant Commissioner/Director: Kathryn C. Perkins **Date:** 10/1/09

Presenter: Beth Albro-Pratt **Program:** Health Care Quality Section **Phone No.:** 834-6752

Approved by CPCPI: Carolyn Bivens **Date:** 10/01/2009

Title 25. HEALTH SERVICES

Part 1. DEPARTMENT OF STATE HEALTH SERVICES

Chapter 117. End Stage Renal Disease Facilities

Subchapter A. General Provisions

Repeal §§117.1 – 117.2

New §§117.1 – 117.2

Subchapter B. Facility Licensing

Repeals §§117.11 – 117.18

Subchapter B. Application and Issuance of a License

New §§117.11 – 117.19

Subchapter C. Minimum Standards for [Design and Space,] Equipment, Water Treatment and

Reuse, and Sanitary and Hygienic Conditions

Repeal §§117.31 – 117.34

New §§117.31 – 117.33

Subchapter D. Minimum Standards for Patient Care and Treatment

Repeal §§117.41 – 117.46

New §§117.41 – 117.48

Subchapter E. Dialysis Technicians

Repeal §§117.61 – 117.65

New §§117.61 – 117.65

Subchapter F. Corrective Action Plan and Enforcement

Repeal §§117.81 – 117.86

New §§117.81 – 117.86

Subchapter G. Fire Prevention, Protection, and Emergency Contingency Plan

New §§117.91 – 117.93

Subchapter H. Physical Plant and Construction Requirements

New §§117.101 – 117.106

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission on behalf of the Department of State Health Services (department) proposes the repeal of §§117.1 – 117.2, 117.11 – 117.18, 117.31 – 117.34, 117.41 – 117.46, 117.61 – 117.65, and 117.81 - 117.86, and new §§117.1 – 117.2, 117.11 – 117.19, 117.31 – 117.33, 117.41 – 117.48, 117.61 – 117.65, 117.81 – 117.86, 117.91 - 117.93, and 117.101 - 117.106, concerning the regulation of end stage renal disease facilities.

BACKGROUND AND PURPOSE

The repeals and new sections are necessary to update, reorganize, and clarify the rules and to implement legislation by the 81st Legislature, Regular Session, 2009, specifically, the amendment to Health and Safety Code, Chapter 251, (Senate Bill 1932) relating to the licensing requirements of hospitals temporarily providing outpatient dialysis services to a person because of a disaster.

Government Code, §2001.039, requires that each state agency review and consider for re-adoption each rule adopted by that agency pursuant to the Government Code, Chapter 2001 (Administrative Procedure Act). Sections 117.1 – 117.2, 117.11 – 117.18, 117.31 – 117.34, 117.41 – 117.46, 117.61 – 117.65, and 117.81 - 117.86 have been reviewed and the department has determined that reasons for adopting the sections continue to exist because rules on this subject are needed.

SECTION-BY-SECTION SUMMARY

Proposed new §§117.1 – 117.2, 117.11 – 117.19, 117.31 – 117.33, 117.41 – 117.48, 117.61 – 117.65, 117.81 – 117.86, 117.91 – 117.93, and 117.101 – 117.106 provide clarification to the rules, update references to statutes, rules, codes, guidelines and standards, the names and contact information of associations, boards, commissions, conferences, societies and the department programs. The new §117.2 deletes definitions not used in the rules, adds definitions and revises the definition of individual, advanced practice registered nurse, licensed vocational nurse, physician, and registered nurse.

The new §117.11 adds facilities exempt from licensing. The new §117.12 is reordered to update initial licensure requirements and adds a requirement for new facilities to have an isolation treatment room for hepatitis B patients or be granted a waiver by the Centers for Medicare and Medicaid Services (CMS), requires document submittal to include complete chemical analysis of the product water. The new §117.13 changes the date the department may send renewal notices from 60 to 90 days and updates the license renewal period to 24 months. The new §117.14 reorders the requirements for a change of ownership and facility relocation, and adds the requirement for a hepatitis B isolation treatment room for facilities increasing services or stations. The new §117.15 adds requirements for facilities in which services are not provided more than 60 days to request inactive status, and requires facilities to notify the department upon closure of an end stage renal dialysis (ESRD) facility. The new §117.18 adds that surveyors may interview patients and staff, clarifies the basis for the department conducting inspections and requires the surveyor to inform the facility representative during the exit conference of any preliminary findings which are potentially serious, serious, or life-threatening, clarifies that the surveyor may submit a written summary to the medical review board, clarifies when and how the department provides the facility a statement of deficiencies, clarifies requirements and timelines related to unacceptable corrective action plans submitted by a facility, adds that the department may assess administrative penalties, and adds the process for complaints against a department surveyor. The new §117.19 adds the requirement that equipment is Food and Drug Administration (FDA) approved, and deletes the requirement for an electrocardiograph.

The new §117.31 adds requirements for equipment, including FDA approval, preventive maintenance, emergency equipment and back up machines. The new §117.32 adds facility owner and medical director responsibility for contaminants in water, adds requirements for a continuous recirculation loop and monitoring the performance, to prevent retrograde flow of water, to eliminate trapped fluid to enforce policies and procedures and to minimize the likelihood of inadvertent bypass, to regulate the metering pump, to ensure disinfection of devices regenerated or reconstituted off site, adds that regenerated carbon shall not be used, adds the requirements to document results of all absence testing, for regular disinfection of the machine supply line,

clarified the requirement for water analysis and that samples shall be taken from each machine direct feed systems flow and equipment necessary for monitoring as determined by the facility medical director, adds requirement for direct feed systems to prevent retrograde flow of water, clarifies that dead-end piping is not allowed, adds water treatment policies and procedures to be approved by the medical director implemented and enforced, clarifies bypass valves procedures, adds that systems shall be monitored according to manufacturer's instructions with documented test procedures related to chemicals in the water, adds the requirement for alarms in the patient care area, clarifies use and monitoring of deionization tanks, adds a requirement for facilities regarding devices that are regenerated or reconstituted off site, updated type of carbon in carbon tanks, clarifies flow rate for total empty bed contact time (EBCT), adds specific criteria for when water from carbon tanks port should be tested, adds a requirement for endotoxin reducing filter downstream of ultraviolet lights, clarifies the schedule for routine microbiological testing, adds responsibility to notify medical director of action levels are in product water, adds requirements for ozone generators if used, clarifies use of Association for the Advancement of Medical Instrumentation (AAMI) for hot water disinfection systems, adds requirement for absence testing to be documented, adds requirement for procedure for disinfection of lines, adds requirements for chemical analysis of product water, adds Quality Assessment/Performance Improvement (QAPI) procedure requirements, adds requirement for newly installed bicarbonate concentrate mixing and delivery systems testing and notification of medical director when action levels are exceeded, defined dialysate components, adds integral system requirements for tank plumbing, adds documentation requirement for results of concentrates tests, including establishment of acceptable limits, adds mixed solution storage requirements related to tanks and containers, adds requirements for pick-up tubes handling, clarifies the location for centralized reprocessing, and requires direct communication between facility and reprocessing medical directors. The new §117.33 adds the requirement to follow standard infection control precautions, provides specific resources, adds infection control precautions for all patients, to include requirements for disposable gloves, hand washing, waterless antiseptic hand rub, protective equipment, activities related to eating, drinking and smoking, items taken to dialysis station, nondisposable items, unused medications, designation of clean areas and contaminated areas, multiple dose medication vials, common medication carts, carts with cleaning supplies, and transporting medications and supplies, adds that the facility should provide a safe, functional, comfortable environment for all patients and visitors and the public, adds a requirement for fixing or replacing damaged wall baseboard and floor tiles and documentation, adds reprocessing room to area where portable or ceiling fans are not allowed, adds that dedicated cleaning supplies should be used for blood spills, adds requirement for documentation of disinfection of dialysis machines, adds cleaning between patient shifts of individual televisions sets at each treatment station, adds requirements for waste containers, to include locations, cleaning, type, and strength, clarifies need for order from nephrologists to provide hepatitis B vaccine to patients, adds isolation procedures for HBs-AG positive patients to include separate treatment rooms and dedicated supplies and equipment, labeling of supplies and equipment refillable containers and pick-up tubes, disinfection of refillable containers and pick-up tubes, procedures for wearing gowns, dedicated cleaning supplies, updated term "caregiver" with "direct patient care staff member", updates term "isolated air handling system" with "dedicated exhaust system", and adds requirement to adopt, implement and enforce policy for offering and providing pneumococcal and influenza vaccines for elderly persons per Center for Disease Control annual

recommendations including procedures for administering, documentation and waiving the requirement.

The new §117.41 adds, reorders and clarifies requirements and responsibilities for an ESRD facility governing body including the adoption, implementation and enforcement of policies, procedures, by-laws, rules, and regulations. The new §117.42 deletes the requirement that a facility must inform a patient of all rules and regulations governing patient conduct and responsibilities and provide a written copy of patient's rights and responsibilities to the patient upon admission. The new §117.43 adds a requirement for a facility to develop, implement, maintain, and evaluate an effective, ongoing, facility-wide, data-driven, interdisciplinary quality assessment and performance improvement (QAPI) program, requires that core staff members participate, provides specific minimal indicators to be measured analyzed and tracked on a monthly basis, and allows a department surveyor to review QAPI activities to ensure compliance. The new §117.44 clarifies the requirement for the submission of an annual report to the department required by the Centers for Medicare and Medicaid Services which includes aggregate data on specified indicators of quality of care provided to patients, deletes certain examples of indicators, and deletes the requirement that the department determines the specific data to submit. The new §117.45 adds requirements for the patient's plan of care to include the process, coordination using an interdisciplinary team approach, for including measurable and expected outcomes and estimated timetables for outcomes, for the patient's plan of care including coordination, time lines, outcomes and monitoring, adds outpatient treatments timeline for patient plan of care, requires revision of the plan of care for lack of progress, deterioration or significant changes, adds a minimum of monthly monitoring of the plan of care; adds a requirement for an ESRD facility to maintain information on the department approved reporting system; adds that an attending physician can order medications, clarifies that physician orders must be in compliance within the licensed professional's scope of practice, adds the requirement that medication vials may not be taken to patient stations and that intravenous medication vials labeled for single-use may not be punctured more than once, clarifies that a contract staff person is not considered an employee and cannot be considered as the full-time supervising nurse, adds the requirement that a registered nurse shall be in the facility when patients are present in the facility, clarifies when a patient assessment is required by a registered nurse, adds that a registered nurse functioning as charge nurse shall be present during all dialysis treatments, adds the requirement that a licensed nurse assigned direct patient care responsibility for four patients shall not be assigned responsibility for additional patients, clarifies the requirement that patients are in view of staff during hemodialysis treatments, adds a requirement for written policies and procedures to guide nursing actions in the event a patient's condition deteriorates during treatment, clarifies the requirement that a registered nurse conducts the initial patient assessment at the time of the initial dialysis treatment, clarifies when a nutrition reassessment shall be conducted, clarifies the maximum patient load per full-time equivalent of qualified dietitian time shall not exceed 125 patients, adds requirements for physician standing orders authorizing delegation of responsibilities for the dietitian, adds requirement that medication algorithms and protocols be individualized, adds requirement for social workers to include health-related quality of life surveys, adds counseling to social worker interventions, adds a requirement for social workers to make rehabilitation referrals as appropriate, clarifies when a psychosocial reassessment shall be conducted, clarifies the requirement that personnel shall be assigned to assist a social worker(s) with ancillary tasks when the patient load exceeds 100 patients, clarifies

the requirement that the maximum patient load per full-time equivalent of qualified social worker time shall not exceed 125 patients; adds that home dialysis patients may be seen by advanced practice registered nurse or physician's assistant, clarifies that 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, adds that the advanced practice registered nurse or physician assistant may not replace the physician for the every two week evaluation of the in-center dialysis patient, adds that an advanced practice registered nurse shall meet the requirements of the Texas Board of Nursing and a physician assistant shall meet the requirements established by the Texas Medical Board, adds the role of jointly developed and signed mechanisms which provide authority for an advanced practice registered nurse or a physician's assistant to provide medical aspects of care which are reviewed at least annually, adds the requirement that home dialysis services are at least equivalent to those provided to in-facility patients, adds a requirement for a separate room for home dialysis services, adds a requirement that each individual home dialysis patient shall use one machine exclusively, adds a requirement for one full-time equivalent registered nurse per 20 patients, or portion thereof, adds requirements for training curriculum approved by the medical director for the facility that provides home dialysis training and support to include medication administration, training the patient and/or caregiver, and documentation requirements, adds a requirement that the interdisciplinary team shall oversee training of the home dialysis patient and designated caregiver and monitor home dialysis monitoring data at least every two months, adds the requirement for services for the home dialysis patient to include initial and annual monitoring visit to the patient's home, visit schedule of the physician, advanced practice registered nurse or physician's assistant of no less than one time a month and a requirement for the physician to see the patient at least one time every three months, adds the requirement of the development and periodic review of the patient's individual plan of care to address patient's needs, adds a requirement for the home dialysis facility to monitor the quality of water and dialysate used by a home hemodialysis patient on-site and to correct any water and dialysate problem for the home hemodialysis patient or arrange for backup dialysis, expands the dialysis facility's responsibility for home dialysis supplies and equipment and emergency backup services when needed, adds requirements for home dialysis machines to be cultured, maintenance logs, specifies equipment allowed, clarifies the requirement for separate home dialysis training room for existing and new facilities, and deletes the requirements for temporary admissions. The new §117.46 adds the requirement that facility staff shall meet qualifications and demonstrate and sustain skills needed to perform the specific duties of their positions, adds that newly employed dialysis technician must be certified under a national certification program within 18 months of being hired and dialysis technicians employed on October 14, 2008 or later must be certified within 18 months of that date, adds the requirement that each registered nurse assigned to charge nurse shall have at least 12 months of clinical experience and have six months experience in hemodialysis subsequent to completion of the facility's training program, deletes requirements related to a licensed vocational nurse functioning in the charge nurse role, and adds a requirement for documentation of qualifications of other personnel assisting in the training of a patient and patient's caregiver. The new §117.47 adds a requirement for clinical records to be secured from unauthorized access, adds a requirement for patient's clinical records to include complete and pertinent information and shall be accessible to every authorized member of the interdisciplinary team, deletes requirement for adequate space for transcribing records in electronic format, and deletes the requirement for the comprehensive medical history and physical to be completed

within two weeks after any patient's admission to the facility. The new §117.48 adds hospital transfers, involuntary transfer or discharge of a patient, and a fire in the facility to the occurrences required to be reported to the department.

The new §117.61-117.64 adds requirements for dialysis technicians to include general requirements, training and curriculum, competency evaluation, and documentation of competency. The new §117.65 prohibits acts by a dialysis technician who is not a licensed vocational nurse.

The new §117.81-117.86 adds requirements for corrective action plans, voluntary and involuntary appointment of a temporary manager, disciplinary action, administrative penalties, and recovery of costs.

The new §117.91 adds a requirement for a fire prevention, protection and emergency contingency plan, adopting, implementing and enforcing policies related to fire fighting equipment, fire extinguishers and, if installed, sprinkler systems, a posted plan for patient protection and evacuation in the event of fire, a fire alarm system, to include staff training and fire drill requirements, a system for communication with and providing information to the fire department, arrangements with fire department when outside of service area, an emergency contingency plan for continuity of emergency essential building systems including an emergency power source and potable water, consisting of an emergency generator or an executed contract with an outside supplier/vendor or an executed contract with another licensed ESRD facility within a 100 miles radius to provide emergency contingency care for the patient(s). The new §117.92 adds a requirement for a physical environment that protects the health, safety and welfare of patients, personnel and the public, adds a requirement that the physical premises and the physical environment of the facility shall meet the local building and fire safety codes, adds a requirement for a self-sufficient emergency communication system with the capability of communication with community or state emergency networks, including police and fire departments, restricts portable and ceiling fans, extension cords and cables, adds a requirement for a nurses emergency calling system in all patient waiting areas, treatment, exam rooms, isolation and toilet rooms, clarifies door lock requirements, and adds requirements for safety and comfort of patients during construction at the facility. The new §117.93 adds requirements for the handling and storage of gases and flammable liquids in accordance with the National Fire Protection Association standards, adds requirements for the use of alcohol-based hand rubs, and restricts the use of motor vehicles in the ESRD facility.

The new §117.101 adds construction requirements for existing ESRD facilities related to National Fire Protection Association, adds a requirement that all major remodeling, renovations, additions and alterations to an existing ESRD facility must be in accordance with the requirements for new construction and all areas of an existing ESRD facility not part of a major remodel, renovation, addition or alteration are not requirement to meet the new construction requirements, adds that the department may grant a condition approval of minor deviations from the requirements, adds the requirement that new building equipment shall comply with the requirements for new construction and complete plans and specifications must be submitted, reviewed and approved by the department, adds the requirement that minor remodeling or alterations within an existing ESRD facility require evaluation and approval by the department

after submission of a written request and floor plan, brief description and sketches of the area being remodeled, adds the requirement that remodeling or alterations which involve load bearing members or partitions, change functional operation, add treatment states, or affect fire safety are major projects and shall submit plans for approval prior to beginning construction of major projects, adds the requirement that new facilities or expanding the capacity of treatment stations in existing facilities shall have an isolation room or be granted a waiver by Centers for Medicare and Medicaid Services, adds requirements for phasing of construction in existing facilities to minimize disruptions of existing functions, and adds the requirement that previously licensed ESRD facility which has been vacated or used for other purposes shall comply with all the requirements for new construction. The new §117.102 adds the requirement for new ESRD facilities including accessibility, prohibits ESRD facilities in proximity to hazardous or undesirable locations, adds the requirement and specifications for means of egress from the building, adds the requirement for facilities constructed in a designated 100-year flood plain, adds the requirement for paved roads, walkways, parking and disability requirements, adds the requirement to design and construct buildings to sustain all dead and live loads in accordance with accepted engineering practices and standards and the local governing building codes, adds the requirement that all construction shall comply with New Ambulatory Health Care Occupancies of the National Fire Protection Association, adds requirements for ESRD facilities which are part of multiple building occupancy, adds spatial requirements for the physical plant, including administration, public areas, equipment rooms, examination rooms, hepatitis B isolation rooms, home or peritoneal dialysis training rooms, janitor's closets, laboratory services, linen and laundry processing area, waste storage and disposal, medication areas, reuse rooms, and treatment areas, adds spatial requirements for service areas, including clean storage room or closet, emergency eyewash, on-site mixing room, patient toilet rooms, staff toilet rooms, and the water room, adds a requirement for details and finishes including additions and alterations, exit corridors and doors, general finish requirements, including portable privacy screens, interior finishes, flooring, wall finishes, ceilings, floor, wall and ceiling penetration or openings, and toilet/restroom signage, adds requirements for mechanical systems, steam and hot and cold water systems, air conditioning, heating and ventilating systems, and thermal and acoustical insulation, to include mounting mechanical equipment on vibration isolators, adds a requirement for testing, balancing and operating all mechanical systems prior to completion and acceptance of the facility, adds a requirement for all heating, ventilating and air condition systems to comply with and be installed in accordance with the National Fire Protection Association, adds a requirement for all rooms and areas in the ESRD facility to have a provision for positive ventilation, adds requirements for the ventilation systems for the reuse room, airborne isolation room, and toilet exhaust, adds that facility design may utilize energy conserving procedures and may present innovative design that provides additional energy conservation to the department for consideration, adds a requirement that outside air intakes shall be located at least 25 feet from exhaust outlets or areas which may collect vehicular exhaust or other noxious fumes, adds requirements for fully ducted supply, return and exhaust air for HVAC systems. The new §117.103 adds requirements for elevators, escalators, and conveyors. The new §117.104 adds requirements for the preparation, submittal, review and approval of plans, and the retention of records for construction of new buildings, additions, renovations or conversions of existing buildings for ESRD facilities. The new §117.105 adds new requirements for construction, inspections, and the approval of projects. The new §117.106 adds a table depicting nursing staffing levels.

FISCAL NOTE

Renee Clack, Section Director, Health Care Quality Section, has determined that for each year of the first five-year period that the sections will be in effect, there will not be fiscal implications to state or local governments as a result of enforcing and administering the sections as proposed.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Ms. Clack has also determined that there may be an adverse economic impact on small businesses or micro-businesses required to comply with the sections as proposed. This was determined by interpretation of the rules that small businesses and micro-businesses may incur economic costs in adding an isolation treatment room (for hepatitis B patients) if a business decision is made by the facility to expand the capacity of treatment stations. Small businesses and micro-businesses may incur an additional expense in order to comply with emergency contingency plan requirements for supplying emergency power to the facility, depending on which of four options the business chooses to implement (purchase of a generator, installation of transfer switches and plug-ins, or an executed contract and transfer agreement with another licensed facility). Small businesses and micro-businesses may incur expense to comply with federal regulations and current Texas Board of Nursing rules which do not allow a licensed vocational nurse to function as a charge nurse due to scope of practice, effective 2004.

ECONOMIC COSTS TO PERSONS AND IMPACT ON LOCAL EMPLOYMENT

There may be economic costs to persons who are required to comply with the sections as stated in the small and micro-business impact analysis. There is no anticipated impact on local employment.

REGULATORY ANALYSIS

Many of the rule changes are necessary to incorporate new federal requirements for those facilities that have voluntarily chosen to participate in the Medicare certification program. Other changes reflect improvements to protect the health, safety, and welfare of patients receiving dialysis services, personnel and the public. These changes make the rules consistent with state and federal regulations. Alternative methods of compliance have been provided in these rules to allow facilities the flexibility to make business decisions based on their needs.

PUBLIC BENEFIT

In addition, Ms. Clack has also determined that for each year of the first five years the sections are in effect, the public will benefit from adoption of the sections. The public benefit anticipated as a result of enforcing or administering the sections is to ensure patient health and safety when end stage renal dialysis care is necessary.

REGULATORY ANALYSIS

The department has determined that this proposal is not a "major environmental rule" as defined by Government Code, §2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

TAKINGS IMPACT ASSESSMENT

The department has determined that the proposal does not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal may be submitted to Beth Albro-Pratt, Health Care Quality Section, Division of Regulatory Services, Department of State Health Services, P.O. Box 149347, Mail Code 2822, Austin, Texas 78714-9347, (512) 834-6752 or by email to beth.albro-pratt@dshs.state.tx.us. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register*.

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the proposed rules have been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

STATUTORY AUTHORITY

The proposed repeals and new sections are authorized by Health and Safety Code, §251.003, concerning rules and minimum standards to protect and promote the public health and welfare by providing for the issuance, renewal, denial, suspension, and revocation of each license; Health and Safety Code, Chapter 251, and Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001. Review of the rules implements Government Code, §2001.039.

The proposed repeals and new sections affect the Health and Safety Code, Chapters 251 and 1001; and Government Code, Chapter 531.

Sections for repeal.

Subchapter A. General Provisions.

§117.1. Purpose.

§117.2. Definitions.

Subchapter B. Facility Licensing

- §117.11. General Requirements for a License.
- §117.12. Application and Issuance of Initial License.
- §117.13. Application and Issuance of Renewal License.
- §117.14. Fees.
- §117.15. Time Periods for Processing and Issuing a License.
- §117.16. Inspections.
- §117.17. Optional Plan Review and Inspection.
- §117.18. Exceptions to These Rules.

Subchapter C. Minimum Standards for Design and Space, Equipment, Water Treatment and Reuse, and Sanitary and Hygienic Conditions

- §117.31. Design and Space Requirements.
- §117.32. Equipment.
- §117.33. Water Treatment, Dialysis Concentrates and Reuse.
- §117.34. Sanitary Conditions and Hygienic Practices.

Subchapter D. Minimum Standards for patient Care and Treatment

- §117.41. Quality Assurance for Patient Care.
- §117.42. Indicators of Quality of Care.
- §117.43. Provision and Coordination of Treatment and Services.
- §117.44. Qualifications of Staff.
- §117.45. Clinical Records.
- §117.46. Reports to the Director.

Subchapter E. Dialysis Technicians

- §117.61. General Requirements.
- §117.62. Training Curricula and Instructors.
- §117.63. Competency Evaluation.
- §117.64. Documentation of Competency.
- §117.65. Prohibited Acts.

Subchapter F. Corrective Action Plan and Enforcement

- §117.81. Corrective Action Plan.
- §117.82. Voluntary Appointment of a Temporary Manager.
- §117.83. Involuntary Appointment of a Temporary Manager.
- §117.84. Disciplinary Action.
- §117.85. Administrative Penalties.
- §117.86. Recovery of Costs.

Legend: (Proposed New Rules)
Regular Print = Proposed new language

Subchapter A. General Provisions.

§117.1. Purpose.

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

(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; enforcement standards, fire prevention and safety requirements; and physical plant and construction requirements.

(c) Compliance with this chapter does not constitute release from the more stringent requirements of other applicable federal, state, or local codes and ordinances. This chapter shall be followed where it is more stringent than other codes and ordinances.

§117.2. 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 by the Texas Board of Nursing to practice.

(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) Affiliate--An applicant or owner which is:

(A) a corporation--includes each officer, consultant, stockholder with a direct ownership of at least 5.0%, subsidiary, and parent company;

(B) a limited liability company--includes each officer, member, and parent company;

(C) an individual--includes:

(i) an individual;

(ii) an individual's spouse if the spouse is actively involved in the management of the facility;

(iii) each partnership and each partner thereof of which the individual or any affiliate of the individual is a partner; and

(iv) each corporation in which the individual is an officer, consultant, or stockholder with direct ownership of at least 5.0%.

(D) a partnership--includes each partner and any parent company; and

(E) a group of co-owners under any other business arrangement--includes each officer, consultant, or the equivalent under the specific business arrangement and each parent company.

(6) Applicant--The owner of an end stage renal disease facility which is applying for a license under the statute. This is the person in whose name the license is issued.

(7) 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.

(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 sole proprietor who transfers all or part of the facility's ownership to another person or persons; the removal, addition, or substitution of a person or persons as a partner in a facility owned by a partnership and the tax identification number of the partnership changes; or a corporate sale, transfer, reorganization, or merger of the corporation which owns the facility if sale, transfer, reorganization, or merger causes a change in the facility's ownership to another person or persons and the tax identification number of the corporation changes.

(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 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, which uses sterile manufactured bagged dialysate, or dialysate solution.

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

(13) Commissioner--The commissioner of the Department of State Health Services.

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

(16) Core staff members--The facility's medical director, supervising nurse, dietitian, social worker, administrator, and chief technician.

(17) Corrective action plan--A written strategy for correcting a licensing violation. The corrective action plan is developed by the facility and addresses the system(s) operation(s) of the facility as the system(s) operation(s) applies to the deficiency.

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

(19) Department--The Department of State Health Services.

(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 which 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. It 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 provides hands on dialysis care to specifically assigned patients during their dialysis treatment under the direct supervision of a registered nurse. If unlicensed, this individual may also be known as a patient care technician.

(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).

(26) Director--The director of the Patient Quality Care Unit of the department or his or her designee.

(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. $EBCT = (7.48 \times V)/Q$ where V is the volume of particles in the bed (feet³), Q is the flow rate of the water through the bed (gallon/minute), and 7.48 is the conversion factor for gallons to feet³.

(28) End stage renal disease (ESRD)--That stage of renal impairment 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) 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.

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

(35) Governing body--An identified group, which includes the medical director and a representative(s) of the owner of the facility, with full legal authority and responsibility for the governance and operation of the facility.

(36) Ground fault circuit interrupters (GFCI)--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 National Fire Protection Association (NFPA) 70, §§517.20 and 517.21, shall be GFCI protected regardless of the branch of the electrical system serving the receptacle.

(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) 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 §117.45(j) of this title (relating to Provision and Coordination of Treatment and Services).

(39) Hospital--A facility that is licensed under the Texas Hospital Licensing Law, 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.).

(40) 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.

(41) Inspection--An investigation or survey conducted by a representative of the department to determine if an applicant or licensee is in compliance with this chapter.

(42) Integrated dialysis system--A preconfigured system which incorporates water treatment and dialysis preparation and delivery into one system.

(43) 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.

(44) Intermediate-level disinfection--A surface treatment using chemical germicides or disinfectants which are capable of inactivating various classes of microorganisms including, but not limited to, 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% ethanol or isopropanol, and certain phenolic or iodophor preparations.

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

(46) 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.

(47) Manager--An individual approved or selected by the department who assumes overall management of an end stage renal disease facility to ensure adequate and safe services are provided to patients.

(48) 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.

(49) Medical review board (MRB)--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.

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

(51) Monitor--An individual approved or selected by the department who observes, supervises, consults, and educates a facility to correct identified violations of the statute or this chapter.

(52) Owner--One of the following which holds or will hold a license issued under the statute in the person's name or the person's assumed name:

(A) a corporation;

(B) a limited liability company;

(C) an individual;

(D) a partnership if a partnership name is stated in a written partnership agreement or an assumed name certificate;

(E) all partners in a partnership if a partnership name is not stated in a written partnership agreement or an assumed name certificate; or

(F) all co-owners under any other business arrangement.

(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/or family member 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.

(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.

(60) Presurvey conference--A conference held with department staff and the applicant or his or her representatives to review licensure standards and survey documents and provide consultation prior to the issuance of the license. The applicant's representatives shall include an individual who will be responsible for the day-to-day supervision of care by the facility.

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

(62) 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 period of time.

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

(64) Quality assessment and performance improvement (QAPI)--An ongoing program which measures, analyzes, and tracks quality indicators related to improve health

outcomes. The program implements improvement plans and evaluates the implementation until resolution is achieved.

(65) 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.

(66) Self-care patients--In-center patients who perform all or part of their dialysis treatments.

(67) Social worker--A person who:

(A) is currently licensed as a social worker under the 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 September 1, 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.

(68) 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.

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

(70) Statute--The Health and Safety Code, Chapter 251.

(71) Supervising nurse (also may be known as the 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 which 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.

(72) 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. Immediate supervision means the supervisor is actually observing the task or activity as it is performed. Direct supervision means the supervisor is on the premises but not necessarily immediately physically present where the task or activity is being performed. Indirect supervision means the supervisor is not on the premises

but is accessible by two-way communication and able to respond to an inquiry when made, and is readily available for consultation.

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

(74) Training--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.

(75) 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% rejection. Ultrafilters with a nominal MWCO of 20,000 or less are generally adequate for endotoxin removal.

(76) Water distribution systems--Components to 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.

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

(78) Working day--Any day of the calendar week excluding Saturday or Sunday or holidays.

Subchapter B. Facility Licensing.

§117.11. General Requirements for a License.

- (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 §117.12(a) of this title (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 Health and Safety Code, Chapter 142, Subchapter A, with a home dialysis designation;

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

(A) individuals receiving inpatient services from the hospital; or

(B) individuals temporarily receiving outpatient services from the hospital 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; or

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

§117.12. 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 §117.16 of this title (relating to Fees); and

(3) as of February 9, 2009, the applicant for a new facility or for an existing facility that is expanding the capacity of treatment stations (in-center dialysis, peritoneal dialysis or home hemodialysis teaching rooms) in existing facilities shall have an isolation room or shall provide a waiver by the Centers for Medicare and Medicaid Services. The waiver shall demonstrate that there is sufficient capacity in the geographic area for isolation rooms for hepatitis B positive patients. An applicant may submit a written request for waiver through the Texas Department of State Health Services, Health Facility Compliance Group, Mail Code 1979, P.O. Box 149347, Austin, Texas, 78714-9347 for transmission to CMS.

(b) The applicant or the applicant's representative shall attend a presurvey conference at the office designated by the department. The purpose of the presurvey conference, which is conducted by department staff, is to review facility staff qualifications, survey documents and licensure rules, and to provide consultation prior to the on-site licensure survey. The department staff conducting the presurvey conference is responsible for making a recommendation regarding the issuance of the initial license. The department may waive the presurvey conference requirement.

(c) In addition to the document submittal requirements in subsection (a) of this section, the following shall be completed prior to the issuance of an ESRD facility license to newly constructed ESRD facility or ESRD facility from conversion of non-ESRD building.

(1) Final construction documents shall be reviewed and approved by the department in accordance with §117.104 of this title (relating to Preparation, Submittal, Review and Approval of Plans and Retention of Records).

(2) For new construction, necessary intermediate inspections and final construction inspections shall be conducted by the department in accordance with §117.105(b) of this title (relating to Construction, Inspections, and Approval of Project) to determine that the ESRD facility was constructed in compliance with this chapter.

(3) When an applicant intends to reopen and relicense a building formerly licensed as a ESRD facility, an on-site inspection shall be conducted by the department in accordance with §117.105 of this title to determine compliance with applicable construction and fire safety requirements.

(4) A certificate of occupancy for the project issued by the local building authority, if applicable and a written approval of the project by the fire authority.

(5) A complete and accurate Final Construction Approval form shall be submitted to the department.

(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 in compliance with §117.32 of this title (relating to Water Treatment, Dialysate Concentrates, and Reuse). The reports shall be kept on file at the facility and made available to department staff during the on-site inspection.

(e) When it is determined that the facility has complied with subsections (a) - (d) of this section, the department shall issue the license to the applicant.

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

(2) Expiration date.

(A) If the effective date of the license is the first day of a month, the license expires on the last day of the 23rd month after issuance.

(B) If the effective date of the license is the second or any subsequent day of a month, the license expires on the last day of the 24th month after issuance.

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

(g) Denial of a license shall be governed by §117.84 of this title (relating to Disciplinary Action).

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

(1) A facility shall request an on-site inspection to be conducted after at least one patient has been admitted and provided services.

(2) A facility shall be providing services to at least one patient at the time of the inspection. The department may interview patients at the time of the inspection in the patient's home or at the facility.

§117.13. Application and Issuance of Renewal License.

(a) The department 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 the department at least 30 calendar days before the expiration date, the facility shall notify the department 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, the department shall send to the facility a letter advising that, unless the license is renewed, the facility shall cease operations upon the expiration of the license.

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

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

(A) a complete and accurate application form;

(B) a copy of a fire safety survey indicating approval by the local fire authority in whose jurisdiction the facility is based. The facility fire safety survey shall be conducted annually and both surveys shall be submitted;

(C) the renewal license fee; and

(D) verification that the facility submitted the annual report required by §117.44 of this title (relating to Indicators of Quality of Care).

(2) The department may conduct an inspection prior to issuing a renewal license in accordance with §117.18 of this title (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, the department shall notify the facility that it shall cease operation and immediately return the license to the department. If the facility wishes to provide services after the expiration date of the license, it shall apply for a license under §117.12 of this title (relating to Application and Issuance of Initial License).

§117.14. Changes 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 department 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 the department at least 60 days before the date of the change of ownership. The application shall be in accordance with subsections (a) - (b) of this section. The applicant shall include the effective date of the change of ownership. 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 the department.

(3) When the new owner has complied with the provisions of subsections (a) - (b) of this section, the department 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 subsection (e)(2) of this section.

(5) The previous owner's license shall be void on the effective date of the new owner's license.

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

(1) The facility shall submit an application for an initial license to the department 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 the department.

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

(4) The expiration date of the license shall be in accordance with subsection (e)(2) of this section.

(5) The previous facility license shall be void on the effective date of the relocation.

(c) Changes which affect the license.

(1) A facility shall notify the department in writing at least 30 days before the occurrence of any of the following:

(A) any remodeling, renovations, additions and alterations, shall comply with the provisions of §117.101(b) of this title (relating to Construction Requirements for an Existing End Stage Renal Disease Facility);

(B) change in facility name, mailing address, telephone number, fax number, or administrator; or

(C) cessation of operation of the facility.

(2) A facility shall obtain written approval from the department prior to the utilization of added services or an increased number of stations. The written request shall be submitted 30 days prior to the planned change.

(A) For an additional service or increase in stations, the department may request that the facility provide evidence of appropriate staffing and policies and procedures which demonstrate the intent to comply with the applicable requirements, and 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) The department may conduct an on-site inspection prior to taking action on the requested change.

(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 in compliance with §117.32 of this title (relating to Water Treatment, Dialysate Concentrates, and Reuse). The reports shall be kept on file at the facility and made available to department staff during the next on-site inspection.

(E) The department shall send the facility written notice of the approval or disapproval of the requested change.

(F) As of February 9, 2009, all existing facilities expanding the capacity of treatment stations (in-center dialysis, peritoneal dialysis or home hemodialysis teaching rooms) shall have an isolation room or be granted a waiver by the Centers for Medicare and Medicaid Services. 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 Texas Department of State Health Services, Health Facility Compliance Group, Mail Code 1979, P.O. Box 149347, Austin, Texas, 78714-9347 for transmission to CMS.

(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 in compliance with §117.32 of this title (relating to Water Treatment, Dialysate Concentrates, and Reuse). The reports shall be kept on file at the facility and made available to department staff during the on-site inspection.

(e) When it is determined that the facility has complied with subsections (a) - (d) of this section, the department shall issue the license to the applicant.

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

(2) Expiration date.

(A) If the effective date of the license is the first day of a month, the license expires on the last day of the 23rd month after issuance.

(B) If the effective date of the license is the second or any subsequent day of a month, the license expires on the last day of the 24th month after issuance.

(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 §117.84 of this title (relating to Disciplinary Action).

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

(1) A facility shall request an on-site inspection to be conducted after at least one patient has been admitted and provided services.

(2) A facility shall be providing services to at least one patient at the time of the inspection. The department may interview patients at the time of the inspection in the patient's home or at the facility.

§117.15 Inactive Status and Closure.

(a) The department will automatically retire the license of an ESRD facility in which services are suspended or not provided for more than 60 days, unless the facility sends a written request to place the license on inactive status. To be eligible for inactive status, the facility must be in good standing with no pending legal actions or investigations.

(1) If granted, inactive status is limited to 60 days. The licensee is responsible for all licensure fees and for proper maintenance of client records while on inactive status.

(2) To reactivate the license, the facility shall submit a written request to reactivate the license no later than the date the inactivation period expires.

(3) If the license is not reactivated, it will be automatically retired at the end of the 60 day deactivation period.

(b) The facility shall notify the facility licensure department 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 facility licensure department 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 and department rules.

§117.16. Fees.

(a) General.

(1) All fees paid to the department are nonrefundable.

(2) All fees shall be paid to the department.

(b) License fees.

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

(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, the department 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 Government Code, §2054.111.

§117.17. 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 department.

(2) An application for an initial license is complete when the department has received, reviewed, and found acceptable the information described in §117.12 of this title (relating to Application and Issuance of Initial License).

(3) An application for a renewal license is complete when the department has received, reviewed and found acceptable the information described in §117.13 of this title (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 begins on the date the department receives the application and ends on the date the license is issued, or if the application is received incomplete, the period ends on the date the facility is issued a written notice that the application is incomplete. The written notice shall describe the specific information that is required before the application is considered complete. The first time period is 45 calendar days.

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

(c) Reimbursement of fees.

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

(2) Good cause for exceeding the period established is considered to exist if:

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

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

(C) other conditions existed giving good cause for 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. The department 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 the department.

§117.18. Inspections.

(a) The department may conduct an inspection at any time to verify compliance with the statute or this chapter. By applying for or holding a license, the facility consents to entry and inspection of the facility by the department or representative of the department in accordance with the statute and this chapter.

(1) An authorized representative of the department (surveyor) may enter the premises of a license applicant or license holder at reasonable times during business hours to conduct an on-site inspection incidental to the issuance of a license, and at other times as the department considers necessary to ensure compliance with:

(A) the statute or this chapter;

(B) an order of the commissioner;

(C) a court order granting injunctive relief;

(D) a corrective action plan; or

(E) other enforcement action(s).

(2) The surveyor is entitled to access all books, records, or other documents maintained by or on behalf of the facility, interview patients and staff to the extent necessary to ensure compliance with the statute, this chapter, an order of the commissioner, a court order granting injunctive relief, a corrective action plan, or other enforcement action. The department shall maintain the confidentiality of facility records as applicable under federal or state law. Ensuring compliance includes permitting photocopying by the department or providing photocopies to a department surveyor of any records or other information by or on behalf of the department as necessary to determine or verify compliance with the statute or this chapter.

(b) Types of inspections.

(1) Construction inspection.

(A) The department shall conduct an inspection to determine compliance with the spatial, physical plant, and system requirements described in §117.102 of this title (relating to Construction Requirements for a New End Stage Renal Disease Facility), the requirements in §117.31(a) and (c) of this title (relating to Equipment), and §117.32(b) and (c) of this title (relating to Water Treatment, Dialysate Concentrates, and Reuse) prior to issuance of the initial license.

(B) During any license period, the department may conduct a construction inspection to determine whether modifications or renovations comply with §117.102 of this title.

(2) A department surveyor may conduct an initial inspection after the date of issuance of the initial license to determine if the facility meets the requirements of the statute and this chapter. The initial inspection is an evaluation of compliance with all requirements of the statute and this chapter.

(3) At the department's discretion, a department surveyor may perform an on-site inspection prior to renewal of a facility license to verify compliance with the statute and this chapter. The renewal inspection may include an evaluation of compliance with all requirements of the statute and this chapter.

(4) The department surveyor shall perform an inspection of a facility on site or by mail, if the facility has demonstrated noncompliance with the statute or this chapter, or to investigate a complaint received by the department.

(5) After review of a facility's annual report, the department may request additional information, or conduct an inspection by mail or on site to determine compliance with the statute and this chapter.

(6) The department may conduct an inspection incidental to an incident report as described in §117.48 of this title (relating to Incident Reports).

(7) A department surveyor shall perform an inspection on site or by mail to verify completion of a corrective action plan(s) for deficiencies cited during any of the inspections described in paragraphs (1) - (6) of this subsection.

(c) Inspection procedures.

(1) The department's surveyor shall hold an entrance conference with the person who is in charge of the facility prior to commencing the inspection for the purpose of explaining the nature and scope of the inspection.

(2) Except for the purposes of conducting an inspection under subsection (b)(1), (4), (6), or (7) of this section, an on-site inspection shall include an evaluation to determine compliance with the statute and this chapter.

(3) Following an inspection of a facility the surveyor shall hold an exit conference with the facility administrator or his or her designee. During the exit conference, the surveyor shall;

(A) fully inform the facility representative of the preliminary finding(s) of the inspection;

(B) inform the facility representative regarding the preliminary finding(s) of the inspection of those circumstances which are potentially serious, serious, or life-threatening;

(C) give the facility representative a reasonable opportunity to submit additional facts or other information to the surveyor in response to those findings before the surveyor exits the facility; and

(D) identify any records that were duplicated.

(4) Written notice of findings.

(A) The surveyor shall:

(i) prepare and provide the facility administrator or his or her designee specific and timely written notice of the findings in accordance with subparagraphs (B) and (C) of this paragraph; and

(ii) if the findings result in a referral described in §117.81(a) of this title (relating to Corrective Action Plan), the surveyor may submit a written summary of the findings to the medical review board for its review and recommendation for appropriate action by the department.

(B) If no deficiencies are found during an inspection, the department shall provide a statement indicating this fact.

(C) If the written notice of findings includes deficiencies, the department and the facility shall comply with the procedure set out in this subparagraph.

(i) The department shall provide the facility with a statement of the deficiencies not later than the 10th working day after the exit conference.

(ii) The facility administrator or administrator's designee shall sign the written statement of deficiencies and return it to the department with an acceptable corrective action plan(s) for each deficiency no later than 10 working days of the facility's initial receipt of the statement of deficiencies. The signature does not indicate the administrator's or designee's agreement with deficiencies stated on the form. If the corrective action plan(s) is not acceptable to the department, the department shall notify the facility in writing and request that the corrective action plan(s) be modified and resubmitted no later than 10 working days from the facility's receipt of such request.

(iii) The facility shall come into compliance 60 calendar days prior to the expiration date of the license or no later than the dates designated in the corrective action plan(s), whichever comes first.

(iv) The requirements in clause (i) of this subparagraph do not apply if the surveyor's written notice of findings results in a referral to the medical review board as described in subparagraph (A)(ii) of this paragraph.

(v) A corrective action plan completion date shall not exceed 45 calendar days from the date the deficiency(ies) is cited (exit date of the survey).

(vi) The facility may challenge any deficiency cited after receipt of the statement of deficiencies. A challenge to a deficiency(ies) shall be in accordance with this subparagraph.

(I) The facility shall comply with clause (ii) of this subparagraph regardless of its intent to challenge the deficiency(ies).

(II) An initial challenge to a deficiency(ies) shall be submitted in writing no later than five working days from the facility's receipt of the statement of deficiencies to the applicable zone office.

(III) If the initial challenge is favorable to the department, the facility may request a review of the initial challenge by submitting a written request to the Director or his or her designee, Patient Quality Care Unit, Department of State Health Services. The facility shall submit its written request for review of the initial challenge no later than five working days from its receipt of the department's response to the initial challenge. The department shall not accept or review any documents that were not submitted with the initial challenge. A determination by the director of the patient quality care unit relating to a challenge to a deficiency(ies) is the department's final determination concerning the challenge.

(IV) The department shall respond to any written challenge submitted under subclause (II) or (III) of this clause no later than 15 working days from its receipt.

(V) The department shall determine if a written corrective action plan(s) is acceptable. If the corrective action plan(s) is not acceptable to the department, the department shall notify the facility in writing and request that the corrective action plan(s) be modified and resubmitted no later than 10 working days from the facility's receipt of such request.

(vii) If the facility does not come into compliance by the required date of correction reflected on the corrective action plan(s), the department may:

(I) appoint a monitor as described in §117.81 of this title (relating to Corrective Action Plan);

(II) appoint a temporary manager as described in §117.83 of this title (relating to Involuntary Appointment of Temporary Manager);

(III) propose to deny, suspend, or revoke the license in accordance with §117.84 of this title (relating to Disciplinary Action).

(IV) assess an administrative penalty(ies) in accordance with §117.85 of this title (relating to Administrative Penalties); or

(V) take all of the actions described in items (I) - (IV) of this subclause.

(viii) The department shall verify the correction of deficiencies by mail or on-site inspection.

(ix) Acceptance of a corrective action plan does not preclude the department from taking enforcement action as appropriate under §§117.83, 117.84, or 117.85 of this title.

(x) The department shall refer issues and complaints relating to the conduct of or action(s) by licensed health care professionals to the appropriate licensing board(s).

(d) Complaint against a department surveyor.

(1) An ESRD facility may register a complaint against a Department of State Health Services surveyor who conducts an inspection or investigation.

(2) A complaint against a surveyor shall be registered with the Patient Quality Care Unit, Department of State Health Services, Mail Code 1979, P.O. Box 149347, Austin, Texas 78714-9347, telephone (512) 834-6650 or (888) 973-0022.

(A) A complaint against a surveyor which is received by telephone will be referred not later than the second working day to the appropriate supervisor. The caller will be requested to submit the complaint in writing.

(B) When a complaint is received in writing, it will be forwarded to the appropriate supervisor not later than the second working day. Not later than the 10th calendar day after the department receives the complaint, the department will inform the complainant in writing that the complaint has been forwarded to the appropriate supervisor.

(C) Not later than the 10th calendar day after the supervisor receives the complaint, the supervisor will notify the complainant in writing that an investigation will be done.

(D) The supervisor will review the documentation in the survey packet and interview the surveyor identified in the complaint to obtain facts and assess the objectivity of the surveyor in the surveyor's application of this chapter during the ESRD facility's inspection or investigation.

(E) The supervisor will review the applicable rules, personnel policies, and review the training and qualifications of the surveyor as it relates to the inspection or investigation.

(F) The supervisor will document the investigation. A report of the investigation will be placed in the ESRD facility file if the complaint and investigation affected the inspection process. A counseling form will be used and placed in the surveyor's personnel file if the complaint relates to personnel performance.

(G) The supervisor shall offer to meet with the complainant to resolve the issue. The surveyor identified in the complaint will participate in the discussion. The resolution meeting may be conducted at the division's office or during an on-site follow-up visit to the hospital.

(H) Changes and deletions will be made to the inspection report, if necessary.

(I) The supervisor will notify the complainant in writing of the status of the investigation not later than the 30th calendar day after the date the supervisor received the complaint.

(J) The supervisor will forward all final documentation to the director of the Patient Quality Care Unit and notify the complainant of the results.

§117.19. Exceptions to These Rules.

(a) All ESRD facilities are required to maintain continuous compliance with these rules. The rules do not prohibit the request for temporary exceptions. These may include alternative concepts, methods, procedures, techniques, Food and Drug Administration (FDA) approved equipment, facilities during an emergency disaster situation, or for the conducting of pilot projects or research. Requests for temporary exceptions to these rules shall:

(1) be submitted to the department 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 alternatives (including compliance with the rule) were not selected;

(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) requests for exceptions for facilities during emergency disaster situations shall be submitted to Health Facility Compliance Group of the Patient Quality Care Unit for the department:

(A) may only be granted in an emergency situation 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 the staffing crisis situation;

(C) the facility shall submit the action plan to the department not later than the 60th calendar day after the department 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 on a monthly basis to the department; and

(E) an exemption from clinical records for evacuees; except that the facility shall assess and document the hepatitis and tuberculosis status of the affected patient(s). The following items shall be obtained at a minimum;

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

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

(b) Requests for exceptions to the rules shall be submitted to the Facility Licensing Group, Regulatory Licensing Unit, Department of State Health Services, Mail Code 2835, P.O. Box 149347, Austin, TX 78714-9347.

(c) The department may conduct a survey and may consult with the medical review board (MRB) prior to approving an exception.

(d) Upon finding that the facility has satisfied the conditions of this rule, the department may grant an exception, to include the duration of the exception. The department will respond to a waiver request within 90 days.

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

(f) Granting of an exception is considered public information, is subject to disclosure, and may be posted on the department web site (<http://www.dshs.state.tx.us/hfp/apps.shtm>).

Subchapter C. Minimum Standards for Equipment, Water Treatment and Reuse, and Sanitary and Hygienic Conditions.

§117.31. Equipment.

(a) All equipment used by a facility, including backup equipment, shall be FDA approved, operated in accordance with the manufacturer's direction for use, and maintained free of defects which could be a potential hazard to patients, staff, or visitors. Maintenance and repair of all equipment shall be performed by qualified staff or contract personnel.

(1) Staff shall be able to identify malfunctioning equipment and report such equipment to the appropriate staff for immediate repair.

(2) Medical equipment that malfunctions shall be clearly labeled and immediately removed from service until the malfunction is identified and corrected.

(3) Written evidence of all maintenance and repairs shall be maintained.

(4) After repairs or alterations are made to any equipment or system, the equipment or system shall be thoroughly tested for proper operation and disinfected before returning to service.

(5) A facility shall comply with the Federal Food, Drug, and Cosmetic Act, 21 United States Code (USC), §360i(b), concerning reporting when a medical device as defined in 21 USC §321(h) has or may have caused or contributed to the injury or death of a patient of the facility.

(6) Completion of the requirements listed in paragraphs (1) – (5) of this subsection shall be documented on the facility’s equipment or system repair log.

(b) A facility shall develop, implement, and enforce a written preventive maintenance program to ensure patient care related equipment used in a facility or provided by a facility for use by the patient in the patient’s home receives electrical safety inspections, if appropriate, and maintenance at least annually or more frequently in accordance with the manufacturer’s direction for use. The preventive maintenance may be provided by facility staff or by contract personnel.

(c) At least one complete dialysis machine shall be available on site as backup for every ten dialysis machines in use. At least one of these backup machines shall be completely operational during hours of treatment. Machines not in use during a patient shift may be counted as backup except at the time of an initial or an expansion survey.

(d) If pediatric patients are treated, a facility shall use equipment and supplies, to include blood pressure cuffs, dialyzers, and blood tubing, appropriate for this special population.

(e) All equipment and appliances shall be properly grounded in accordance with the National Fire Protection Association 99, Standard for Health Care Facilities, §4.3.2.2.2, 2002 Edition (NFPA 99), published by the NFPA. 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: National Fire Protection Association, 1 Batterymarch Park, Quincy, Massachusetts 02269-9101 or (800) 344-3555.

(f) An ESRD facility shall have emergency equipment and supplies immediately accessible in the treatment area.

(1) At a minimum, the emergency equipment and supplies shall include the following:

- (A) oxygen;
- (B) ventilatory assistance equipment, to include airways, manual breathing bag, and mask;
- (C) suction equipment;
- (D) supplies specified by the medical director; and
- (E) automated external defibrillator.

(2) If pediatric patients are treated, the facility shall have the appropriate type and size emergency equipment and supplies listed in paragraph (1) of this subsection for this special population.

(3) A facility shall establish, implement, and enforce a policy for the periodic testing and maintenance of the emergency equipment. Staff shall properly maintain and test the emergency equipment and supplies, and document the testing and maintenance.

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

(a) A facility shall meet the requirements of this section. 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 contaminants that may be found in water and improperly prepared dialysate, to ensure that 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 operator(s), 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 described in 30 Texas Administrative Code, §290.104 (relating to Summary of Maximum Contaminant Levels, Maximum Residual Disinfectant Levels, Treatment Techniques, and Action Levels), and §290.109 (relating to Microbial Contaminants) as adopted by the Texas Commission on Environmental Quality.

(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. Water distribution systems shall be configured as a continuous recirculation loop, and to minimize biofilm formation, there shall always be flow in a piping system.

(A) For indirect feed systems a minimum of three feet per second water flow shall be achieved in the distribution loop. This rule shall apply to facilities licensed on or after September 1, 2003 or any facility making design changes or reconfiguration of the water distribution system.

(B) For direct feed systems a minimum of 1.5 feet per second water flow shall be achieved in the distribution loop. This rule shall apply to facilities licensed on or after September 1, 2003 or any facility making design changes or reconfiguration of the water distribution system.

(C) This rule shall not apply to facilities providing only home training and support services utilizing single patient devices.

(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 in §4.1.1 (concerning Maximum level of chemical contaminants in water) and §4.1.2 (concerning Bacteriology of water) of the American National Standards Institute (ANSI), Water Treatment Equipment for Hemodialysis Applications, RD52:2004 Edition, published by Association for the Advancement of Medical Instrumentation (AAMI). All documents published by the AAMI as referenced in this section may be obtained by writing the following address: 1110 North Glebe Road, Suite 220, Arlington, Virginia 22201.

(A) Direct feed systems shall include a means of verifiably preventing retrograde flow of water into the distribution loop from the feed side of the reverse osmosis unit.

(B) Dead-end piping (risers with no flow, branches with no fixture) shall not be installed. In any renovation work, dead-end piping shall be removed.

(5) Written policies and procedures for the operation of the water treatment system shall be developed, approved by the medical director, implemented, and enforced. 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; describes its function, how performance is verified, and actions to take in the event performance is not within an acceptable range. Facility's policy and/or procedure 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 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 so as 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 chemical. This control system shall be designed to tightly control addition of the chemical. The control system shall ensure that 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/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 in §6.2.7 (concerning Reverse Osmosis) of the American National Standards Institute, Dialysate for Hemodialysis RD 52:2004 Edition, published by the AAMI.

(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 that all devices that are regenerated or reconstituted off site, such as deionizers, shall be disinfected at the time of regeneration or reconstitution, so that 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. Regenerated carbon shall not be used.

(ii) A minimum of two carbon adsorption beds shall be installed in a series configuration.

(iii) The total empty bed contact time (EBCT) shall be at least ten 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) A sample port shall also be installed following the second bed for use in the event of free chlorine or chloramine breaking through the first bed. Water from this port(s) shall be tested for chlorine/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 during hours of operation.

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

(vi) 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 tank(s) and final tank(s) shall require testing to be performed at the final exit and replacement of the initial tank(s). Testing equipment, supplies and procedures shall be used in accordance with the manufacturer's directions for use.

(vii) In a system without a holding tank, if test results at the exit of the final tank(s) 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/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.

(viii) If means other than granulated carbon are used to remove chlorine/chloramine, the facility's governing body shall approve such use in writing after review of the safety of the intended method 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 face(s) of timer(s) used to control any component of the water treatment or dialysate delivery system shall be visible to the operator at all times. 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 down stream of the device. A log sheet shall be used to record monitoring.

(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.

(18) A facility shall maintain written logs 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 has been made to an existing system, weekly testing shall be conducted for one month 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/disinfection of the water treatment system, and the dialysis machines. Water testing results shall be routinely trended and reviewed by the medical director in order 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 less than 200 colony forming units (CFU)/millimeter (ml) and an endotoxin concentration 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.

(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 on a log sheet in order 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. A mechanism shall be incorporated in the distribution system to ensure that disinfectant does not drain from pipes during the disinfection period.

(21) If used, hot water disinfection systems shall utilize 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 that disinfectant does not drain from pipes during the disinfection period.

(23) Users shall establish 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 are made to the water

treatment system, or if the percent rejection of a reverse osmosis system decreased 5.0% 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 evidence that 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 §117.46(f) of this title (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 or the concentrate family or concentrate manufacturer is changed, 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 one month 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 dialysis systems, shall be cultured monthly 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 §117.2(11) of this title (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 and/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.

(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 so as 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;

(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 a ground fault protected electrical outlet.

(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 (c)(11)(A) of this section.

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

(F) If 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 product 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 product 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, 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, 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, and inverted to dry. Pick-up tubes shall be rinsed free of residual disinfectant and allowed to air dry. 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 as to the contents.

(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/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, lot number(s) of powdered concentrate packages, the manufacturer of the powdered concentrate, date and time of mixing, test results, person performing mixing, and 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 the 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 AAMI.

(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 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 that 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 automated reprocessing facility;
- (3) maintain responsibility and accountability for the entire reuse process;
- (4) adopt, implement, and enforce policies to ensure that the transfer and transport of used and reprocessed dialyzers to and from the off-site location does not increase contamination of the dialyzers, staff, 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 department staff access to the off-site reprocessing site as part of a facility inspection.

§117.33. 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 Human Immunodeficiency Virus and Hepatitis B Virus by Health Care Workers).

(B) The facility shall demonstrate that it follows standard infection control precautions by implementing the Recommended Infection Control Practices for Hemodialysis Units at a Glance, with the exception of screening for Hepatitis C, found in Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients, Morbidity and Mortality Weekly Report, Volume 50, Number RR - 5, April 27, 2001, pages 18 through 22, 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 hand washing.

(iv) Staff members shall wear gowns, face shields, eye wear, or masks to protect themselves and prevent soiling of clothing when performing procedures during which spurling or splattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood).

(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) Nondisposable 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 medications 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 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.

(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 §117.43 of this title (relating to Quality Assessment and Performance Improvement). The record shall include trends, corrective actions, and improvement actions taken.

(b) Physical environment.

(1) General procedures.

(A) A facility shall develop implement and enforce policies and procedures to provide and actively monitor a safe, functional, comfortable, and sanitary environment which minimizes or prevents transmission of infectious diseases for all patients and visitors, and the public.

(i) Wall bases in patient treatment and other areas which are frequently subject to wet cleaning methods shall be tightly sealed to the floor and the wall, impervious to water, and constructed without voids that can harbor insects. Wall baseboard and floor tiles in all patient treatment care areas and bathrooms that are loose, torn, cracked, or not

sealed shall be fixed or replaced. The maintenance safety occurrence shall be recorded in the safety report or maintenance log records and maintained in the facility.

(ii) Wall finishes shall be washable and, in the immediate areas of plumbing fixtures, smooth and moisture resistant.

(iii) All exposed ceilings and ceiling structures in areas normally occupied by patients, staff, and visitors shall be finished so as to be cleanable with equipment used in daily housekeeping activities, and shall be replaced if stained with blood. No portable or ceiling fans shall be utilized in patient treatment areas, or in the reprocessing room.

(iv) Floors that are subject to traffic while wet shall have nonslip surfaces. Floor materials shall be easily cleanable and have wear resistance appropriate for the location involved. In all areas subject to wet cleaning methods, floor materials shall not be physically affected by germicidal and cleaning solutions. Floor and wall penetrations by pipes, ducts, and conduits shall be tightly sealed to minimize entry of rodents and insects. Joints of structural elements shall be similarly sealed.

(v) A facility shall utilize a ventilation system which provides adequate comfort to patients during treatment and which minimizes the potential of insect access.

(vi) All storage areas shall be kept clean and orderly at all times, with a separate space designated for wheelchair storage.

(B) Blood spills shall be cleaned immediately or as soon as is practical with a disposable cloth and an appropriate chemical disinfectant.

(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 utilize dedicated cleaning supplies (i.e., mop, 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. The facility personnel responsible for the disinfection of the dialysis machines shall document the date, and the time of the disinfection, and verify that the dialysis machines were rinsed and that 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 which become contaminated with blood shall be removed from service, disinfected, and allowed to dry prior to being returned to use.

(c) Waste and waste disposal.

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

(A) The ESRD facility shall comply with the requirements set forth by the department in §§1.131-1.137 of this title (relating to Definition, Treatment, and Disposition of Special Waste from Health Care-Related Facilities) and the Texas Commission on Environmental Quality (TCEQ) requirements in 30 Texas Administrative Code, §330.1207 (relating to Generators of Medical Waste).

(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 Title 30, Texas Administrative Code, Chapter 285 (relating to On-Site Sewage Facilities).

(2) Waste containers.

(A) Waste containers shall be conveniently available in all toilet rooms, patient areas, staff work areas, and waiting rooms. Receptacles shall be routinely emptied of their contents at a central location(s) into closed containers.

(B) Waste containers shall be cleaned and properly maintained and free of visible residue.

(C) All containers for other municipal solid waste shall be leak-resistant, have covers, be rodent-proof, and comply with local sanitation requirements.

(D) Nonreusable containers shall be of suitable strength to minimize animal scavenging or rupture during collection operations.

(d) Hepatitis B prevention.

(1) The facility shall offer hepatitis B vaccination to previously unvaccinated, susceptible new staff members in accordance with 29 Code of Federal Regulations, §1910.1030(f)(1) - (2) (concerning 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 vaccination.

(ii) The facility shall make available to patients literature describing the risks and benefits of the hepatitis B vaccination.

(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, provided that the facility's policy on this subject remains congruent with Appendices I and II of the National Surveillance of Dialysis Associated Disease in the United States, 2000, published by the United States Department of Health and Human Services.

(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 §117.101 of this title (relating to Construction Requirements for an Existing End Stage Renal Disease Facility). An ESRD facility which is licensed after the effective date of these rules shall treat patients positive for HBsAg in a separate treatment room which complies with §117.102(d)(4) of this title (relating to Construction Requirements for a New End Stage Renal Disease Facility).

(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/room, such as clamps, blood pressure cuffs, testing reagents, etc., shall be labeled “isolation” and not routinely removed from the isolation area/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/room and refilled at the door. Refillable bicarbonate concentrate containers shall be removed for cleaning and disinfection. In the disinfection area, containers labeled “isolation” container(s) and pick-up tube(s) 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/room and removed before leaving the isolation area/room. Any one entering the isolation area/room during the patient’s treatment must wear a protective gown.

(v) Dedicated cleaning supplies (i.e., mop, bucket) for the cleaning of the isolation area/room and blood spills shall be utilized 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 be assigned to the same staff member who is caring for the HBsAg-positive patient.

(viii) If an HBsAg-positive patient is discharged, the equipment which 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.

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

(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.

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

(1) establish that an elderly person, defined as 65 years of age or older, who receives ongoing care at the facility, is offered, to the extent possible as determined by the facility, the opportunity to receive the pneumococcal and influenza vaccines, if a physician, or an advanced practice registered nurse or physician assistant on behalf of a physician, determines that the vaccine is in the person's best interest. If the facility decides it is not feasible to offer the vaccine, the facility shall provide the person with information on other options for obtaining the vaccine.

(2) include provisions that the influenza vaccine shall be offered according to the Centers for Disease Control annual recommendations, and the pneumococcal vaccine shall be offered throughout the year;

(3) require that the person administering the vaccine ask the elderly 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;

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

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

Subchapter D. Minimum Standards for Patient Care and Treatment.

§117.41. 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 §117.2(48) of this title (relating to Definitions).

(1) A qualified medical director is a physician who is board certified in internal medicine by the American Board of Internal Medicine or pediatrics by the American Board of Pediatrics or 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 of more of the qualifications or if a physician who does meet these qualifications is not available to direct the facility. The waiver shall provide an explanation as to why a physician meeting the board certification requirement is not available and include a brief resume of the physician. A written request for waiver shall be made through the Texas Department of State Health Services, Health Facility Compliance Group, Mail Code 1979, P.O. Box 149347, Austin, Texas, 78714-9347 for transmission to CMS.

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

(c) The governing body shall ensure that the medical staff has current bylaws, rules and regulations that are adopted, implemented, and enforced.

(d) The governing body shall ensure that effective administrative rules, regulations, and policies designed to protect the health and safety of patients are implemented and reviewed annually.

(e) The governing body shall ensure that 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 that all facility staff are qualified (i.e., 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 must demonstrate and sustain the skills needed 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/staff ratio is appropriate to the level of dialysis care given and meets the needs of patients.

(h) The governing body shall review and approve the facility's training program for staff, patients, and/or patient's caregiver.

(i) The governing body shall develop, implement, and enforce policies and procedures relating to the facility's disaster preparedness plan, to meet the requirements of §117.45(b)(5) of this title (relating to Provision of 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 ESRD facility to provide emergency contingency care to patients to meet the requirements of §117.91(h) of this title (relating to Fire Prevention, Protection and Emergency Contingency Plan).

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

(k) The governing body shall ensure a physical environment that protects the health and safety of patients, personnel, and the public. The physical premises of the facility and those areas of the facility's surrounding physical structure that are used by the patients (including stairwells, corridors, and passageways) shall meet the local building and fire safety codes 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 personnel shall be assigned to assist a social worker(s) with ancillary tasks (e.g., assistance with financial services, transportation, administrative, clerical, etc.), when the patient load, including all modalities, exceeds 100 patients. The maximum patient load, including all modalities, per full-time equivalent qualified social worker, with assigned personnel assistance, is 125 patients.

§117.42. 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. Written patient information materials shall be available, with materials in languages other than English. In lieu of written materials in the patient's primary language, an interpreter, interpreter service, visual and hearing impaired assistance shall be provided. Staff shall document in the patient's clinical record how consent forms for treatment requiring a signature were explained, and the patient's consent obtained, and how patient rights and responsibilities were explained to the patient;

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

(6) informed of and receive education regarding all treatment modalities and settings, including self-care and transplant for the treatment of end stage renal disease on an annual basis;

(7) informed about and participates in, if desired, all aspects of care, including the right to refuse treatment, and informed of the medical consequences of such refusal;

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

(9) informed about the facility's reuse of dialysis supplies, including hemodialyzers. If printed materials such as brochures are used to describe a facility and its services, the brochures shall contain a statement with respect to reuse.

(10) 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;

(11) provided hours of dialysis that are scheduled for patient convenience whenever feasible or possible. Consideration shall be given to a patient's work or school schedule.

(12) 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. A patient shall be given 30 calendar days advance notice to ensure orderly transfer or discharge, except in cases where the patient presents an immediate risk to others; and

(13) given an opportunity and assistance to improve problematic behavior prior to dismissal from the facility. 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. The policy shall include the requirements at §117.45(a)(8) of this title (relating to Provision and Coordination of Treatment and Services).

(14) provided protection from abuse, neglect, or exploitation as those terms are defined in §1.204 of this title (relating to Investigations of Abuse, Neglect, or Exploitation of Children or Elderly or Disabled Persons).

(15) provided information regarding advance directives and allowed to formulate such directives to the extent permitted by law. This includes documents executed under the Health and Safety Code, Chapter 166, Advance Directives Act.

(16) aware of the mechanisms and agencies to express a complaint against the facility without fear of reprisal or denial of services. A facility shall provide to each individual who is admitted to the facility a written statement that informs the individual that a complaint against the facility may be directed to the department. The statement shall be provided at the time of admission and shall advise the patient that registration of complaints may be filed with the Department of State Health Services, Health Facility Compliance Group, Mail Code 2835, P.O. Box 149347, Austin, TX 78714-9347, (888) 973-0022. Correctional institutions shall not be required to include the 888 number in information provided to patients in these facilities.

(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. A written copy of the patient's rights and responsibilities shall be provided to each patient or the patient's legal representative upon admission, and a copy shall be posted with the facility license certificate.

(18) fully informed of the patient plan of care process, including but not limited to the necessary services outlined in the patient plan of care.

§117.43. 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 specific 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, but not be limited to, an ongoing program that achieves measurable improvement in health outcomes and reduction of medical errors by using indicators or performance measures associated with improved health outcomes and with the identification and reduction of medical errors.

(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 that 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.

(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;

(3) appointment of interdisciplinary improvement team(s) to:

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

(B) create and implement improvement plan(s);

(C) evaluate the implementation of the improvement plan(s); and

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

(4) establishment and monitoring of quality indicators related to improved health outcomes. 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 on a monthly basis:

(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 dialyzer(s), water, machine(s), 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 §117.48 of this title (relating to Incident Reports);

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

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

(J) staffing to include, but not limited to orientation, training, delegation, licensing and certification, and non-adherence to policies and procedures by facility staff;

(K) safety (fire and disaster preparedness, use of a department 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, 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.

(5) 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.

(h) The department shall review a facility's QAPI activities to determine compliance with this section.

(1) A department surveyor shall verify that the facility has a QAPI program which 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) The department shall require disclosure of QAPI program records when disclosure is necessary to determine compliance with this section.

§117.44. Indicators of Quality of Care.

(a) Each facility shall submit an annual report to the department through reports required by the Centers for Medicare and Medicaid Services or the department's designee to include aggregate data on specified indicators of the quality of care provided to patients. Examples of indicators include:

- (1) anemia management;
- (2) measures of the adequacy of dialysis;
- (3) vascular access management; and
- (4) hospitalization rate.

(b) Data from each facility shall be reviewed to identify opportunities to improve care. Assistance in improving care from the department or department's designee may include feedback of comparative data, a corrective action plan, or an on-site inspection.

§117.45. Provision and Coordination of Treatment and Services.

(a) Patient 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. 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 in order 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 plan of care shall include measurable and expected outcomes and estimated timetables to achieve these outcomes. The plan of care shall include, but not be limited to, 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. At a minimum, the patient plan of care shall demonstrate that the content was discussed with the patient or the patient's legal representative by a member of the interdisciplinary team.

(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 plan of care shall be revised due to the patient's 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 plan of care at least monthly to recognize and address any deviations from the plan of care as follows:

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

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

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

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

(b) Emergency preparedness.

(1) A facility shall implement written procedures which describe staff and patient actions to manage potential medical and nonmedical emergencies, including but not limited to fire, equipment failure, power outages, medical emergencies, and natural or other disasters which are likely to threaten the health, welfare, or safety of facility patients, the 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 which 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 effected 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 working 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 the department 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 117.91(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 the department 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 if such medication is ordered by the patient's physician or an attending physician.

(3) All verbal or telephone physician orders shall be received by a licensed nurse and shall be countersigned by the physician within 15 calendar days. All physician orders shall be in compliance within the licensed professional's scope of practice.

(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 be located in such a manner as to prevent contamination of medicines being prepared for administration and shall include a work counter and a sink.

(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 individual who prepared the medication.

(9) 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 §117.62 of this title (relating to Training Curricula and Instructors) and §117.63 of this title (relating to Competency Evaluation). Such administration by dialysis technicians shall be in compliance with Chapter 157 of the 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 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:

(A) be in the facility when patients are present in the facility;

(B) conduct admission nursing assessments;

(C) conduct 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;

(D) participate in the interdisciplinary team review of a patient's progress;

(E) recommend changes in treatment based on the patient's current needs;

(F) facilitate communication between the patient, patient's family or significant other, and other interdisciplinary members to ensure needed care is delivered;

(G) provide oversight and direction to dialysis technicians and licensed vocational nurses; and

(H) participate in the facility's QAPI activities.

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

(5) At least one licensed nurse shall be available on site to provide patient care, functioning in the nursing role (without direct patient care responsibilities) for every twelve patients or portion thereof. This may include the registered nurse(s) functioning in the charge role required by paragraph (4) of this subsection.

(6) 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.

(7) Sufficient direct care staff shall be on site to meet the needs of the patients.

(A) The staffing level for a facility shall not exceed four patients per licensed nurse or patient care technician per patient shift. The licensed nurse assigned direct patient care responsibilities for four patients shall not be assigned more responsibilities for additional patients. During treatment of eight or more patients, one of the licensed nurses

qualified to function in the charge role shall not be included in this ratio as demonstrated in Table 1 of 117.106 of this Title.

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

(8) A facility shall ensure that 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.

(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 actions to be taken by the nursing staff 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 at the time of 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 which meets the requirements in §117.62 of this title and §117.63 of this title.

(f) A dialysis technician providing direct patient care shall demonstrate knowledge and competency for the responsibilities specified in §117.62 of this title and §117.63 of this title .

(g) Nutrition services.

(1) Nutrition services shall be provided to a patient and the patient's caregiver(s) in order 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. 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. Measurement criteria include but are not limited to weight changes, blood chemistries, adequacy of dialysis, and medication changes which 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(s) to provide clinical nutrition services for each patient. One full-time equivalent of dietitian time shall be available for up to 100 patients with the maximum patient load per full-time equivalent of dietitian time being 125 patients for all modalities.

(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 State Board of Examiners of Dietitians licensure.

(8) If the facility is using a medication algorithm/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 in dealing with the 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 utilize 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 psychosocial reassessment shall be conducted no less than annually or more often when indicated by a significant change in 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(s) to meet the psychosocial needs of the patients Personnel shall be assigned to assist a social worker(s) with ancillary tasks (e.g., assistance with financial services, transportation, administrative, clerical, etc.), when the patient load, including all modalities, exceeds 100 patients. The maximum patient load, including all modalities, per full-time equivalent qualified social worker, with assigned personnel assistance, 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 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; and

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

(2) Medical staff.

(A) Each patient shall be under the care of a nephrologist 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 once every two weeks during the patient's treatment time. 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.

(D) 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.

(E) Orders for treatment shall be in writing and signed by the physician. Routine orders for treatment shall be updated at least annually.

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

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

(3) Physician Extenders.

(A) If advanced practice registered nurses or physician assistants are utilized:

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

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

(iii) the advanced practice registered nurse or physician assistant may not replace the physician for the every two week evaluation of the in-center dialysis patient.

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

(v) if an advanced practice registered nurse or physician assistant is utilized, 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); and

(vi) if an advanced practice registered nurse or a physician assistant is utilized such individuals shall utilize mechanisms which provide authority for that care. These mechanisms shall include, but are not limited to protocols or other written authorization. The protocols or other written authorization shall be jointly developed by the practitioner and the appropriate physician(s), be signed by both the practitioner and the physician(s), be reviewed and re-signed at least annually, be maintained in the practice setting of the practitioner, and be made available as necessary to the department to verify authority to provide medical aspects of care.

(j) Home dialysis service.

(1) A dialysis 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 to that 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) For all home dialysis patients, regardless of modality, there shall be one machine used exclusively for each individual home dialysis patient.

(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, but not be limited to, the following:

(A) be conducted by a registered nurse with at least 12 months clinical experience and six months experience in the specific modality with the responsibility for training the patient, and the patient's caregiver;

(B) be conducted for each home dialysis patient and address the specific needs of the patient, in the nature and management of end stage renal disease;

(C) include 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/or caregiver regarding the effective, and safe administration of erythropoiesis-stimulating agent(s) (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/or caregiver how to detect, report, and manage potential dialysis complications, including water treatment problems;

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

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

(H) training of the patient, and/or caregiver how to handle medical and nonmedical emergencies;

(I) training of the patient, and/or caregiver regarding infection control precautions;

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

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

(L) training of the patient, and/or caregiver that non-medical electrical equipment shall not be used within 6 feet of the home hemodialysis machine; and

(M) maintain the 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-patient or their designated caregiver(s) 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) Services include, but are not limited to, the following:

(A) initial monitoring visit of the patient's home adaptation, including visits to the patient's home by facility personnel (including, but not limited to, the registered nurse responsible for training the patient in the chosen modality and technical staff as appropriate) 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 on a monthly basis. This visit may be conducted in the dialysis facility, at the physician's office, or in the patient's home.

(C) The development and periodic review of the patient's individualized comprehensive plan of care that specifies the services necessary to address the patient's needs and meets the measurable and expected outcomes, 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.

(A) An AAMI analysis of the product water used for dialysate preparation shall be performed every six months.

(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 dialysis system designed, tested, and validated to meet AAMI quality (which includes standards for chemical and chlorine/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.

(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.

(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 purchase, lease, or rent, and delivery, installation, repair, and shall maintain medically necessary home dialysis 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, if the machine is to be disinfected.

(16) All dialysis machines and dialysis equipment shall have maintenance logs maintained at the dialysis facility.

(17) The electrical connection for the home hemodialysis machines shall be connected to a GFCI receptacle in accordance with §117.102(i)(8)(F) of this title (relating to Construction Requirements for a New End Stage Renal Disease Facility).

(18) Equipment for home hemodialysis includes the conventional (single pass) dialysis machine, the integrated dialysis system, the dialysis system which uses manufactured bagged dialysate, the peritoneal dialysis system which uses manufactured bagged dialysis solution, and the sorbent regeneration system.

(A) The conventional (single pass) dialysis machine shall comply with the requirements at §117.31 of this title (relating to Equipment), and §117.32 of this title (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.

(B) Integrated dialysis 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 every six months 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 dialysis system to ensure that the product water meets the primary standards of AAMI RD 52:2004.

(iii) A means shall be provided to sample the product water to test for chlorine/chloramines levels immediately prior to using the dialysate. Chlorine/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 §117.32 of this title.

(C) The dialysis system, which uses sterile manufactured bagged dialysate, in its existing form, shall be used according to manufacturer's directions for use.

(D) The peritoneal dialysis system, which uses manufactured bagged dialysis solution, shall be used according to manufacturer's directions for use.

(E) When sorbent technology is used, the quantity of water used shall not exceed six liters per treatment; and testing for chlorine/chloramines is not required. 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 every six months or if there is a change in the source water.

(19) An ESRD facility which was licensed prior to the effective date of these rules shall comply with §117.101 of this title (relating to Construction Requirements for an Existing End Stage Renal Disease Facility). An ESRD facility which is licensed after the effective date of these rules shall provide a separate training room for home dialysis patients in compliance with §117.102(d)(5) of this title.

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

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

(2) The facility shall obtain the information described in §117.47(e) of this title (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) evidence of evaluation of the patient by a physician on the staff of the facility;

(B) orders for treatment;

(C) hepatitis B status;

(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 §117.47(e) of this title.

(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 Occupations Code, Chapter 102, concerning the prohibition on soliciting patients or patronage.

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

(o) A facility or its corporate ownership, shall develop, implement, and enforce a compliance policy for monitoring its receipt and expenditure of state or federal funds.

(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. If the student is licensed (e.g., a licensed vocational nurse attending a registered nurse program for licensure as a registered nurse) the facility shall ensure that the administration of any medication(s) is within the student's licensed scope of practice.

(2) A student may administer medications only if:

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

(B) the instructor is on the premises and immediately supervises the administration of medication by an unlicensed student and the administration of such medication is within the instructor's licensed scope of practice.

(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.

(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.

§117.46. 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. The facility shall:

(1) 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.

(2) 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. The orientation 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 orientation program shall be two weeks plus additional orientation time as determined by the facility.

(3) 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.

(4) The facility shall ensure that registered nurses with no previous dialysis experience shall be provided an orientation program of a minimum of six weeks. For these registered nurses, the six-week orientation 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:

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

(B) kidney disease and treatment;

(C) dietary management of kidney disease;

- (D) principles of dialysis;
- (E) dialysis technology;
- (F) venipuncture technique;
- (G) care of the dialysis patient;
- (H) psychological, social, financial, and physical complications of long-term dialysis;
- (I) prevention of hepatitis and other infectious diseases; and
- (J) risks and benefits of reuse (if reuse is practiced).

(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. Newly employed dialysis technicians must be certified under a national commercially available certification program, within 18 months of being hired as a dialysis technician. Dialysis technicians employed on October 14, 2008 must be certified under a national commercially available certification program within 18 months after such date.

(6) The facility shall ensure that documentation shall be maintained to demonstrate that each staff member providing patient care completes at least five hours of continuing education related to end stage renal disease 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.

(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 utilized, such individuals shall meet the requirements established by the Texas Board of Nursing in Texas Administrative Code, Title 22, Part 11, Chapter 221, Advanced Practice Registered Nurses.

(4) If a physician assistant is utilized, such individuals shall meet the requirements established by the Texas Medical Board in Texas Administrative Code, Title 22, 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.

(2) Each registered nurse assigned charge nurse responsibilities shall have at least 12 months of clinical experience and have six months experience in hemodialysis subsequent to completion of the facility's training program. 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, and be consistent with the Texas Medical Board statutes and rules, and the Texas Board of Nursing practice act, rules, and policy statements for registered nurses and licensed vocational nurses.

(4) If patient self-care 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.

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

(e) Each social worker shall:

(1) be licensed as a social worker under the Occupations Code, Chapter 505, and hold a masters 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 September 1, 1976, and have established a consultative relationship with a social worker who has a masters degree in social work from a graduate school of social work accredited by the Council on Social Work Education.

(f) 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(s) meets the minimum qualifications for each required level of responsibility as described in this subsection.

(1) Only individuals qualified by training, education, or experience may operate, repair, or replace components of the systems utilized 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. For technical staff employed by the facility for two or more years prior to April 11, 1999, this requirement is waived; 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 §117.62(a) and (b) of this title (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.

(2) The technical supervisor is responsible for the 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 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 course(s) as established for each technical area.

(ii) The training course(s) 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.

(3) 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 so as 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 which 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.

(4) 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 the following minimum components:

(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.

(5) 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 which 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, 1110 North Glebe Road, Suite 220, Arlington, Virginia 22201; and

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

§117.47. 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 which 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. Computerized 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 on microfilm, optical disc, or other electronic means, and may be stored off site as long as security is maintained and the record is readily retrievable for review by the department or the department'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 the course of 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 clinical record shall include this data.

(c) The 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. Such reports 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 the department written notification of the location of the clinical records and the name and address of the clinical records custodian.

§117.48. Incident Reports.

(a) A facility shall report the following incident(s) to the department within ten working days:

(1) death of a dialysis patient, which occurs in the facility, at home, or in a hospital;

(2) hospital transfers;

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

(4) involuntary transfer or discharge of a patient; and

(5) a fire in the facility.

(b) An incident listed in subsection (a) of this section shall be reported to the Facility Licensing Group, Regulatory Licensing Unit, Department of State Health Services, Mail Code 2835, P.O. Box 149347, Austin, TX 78714-9347. The incident report shall be on a form provided by the department and include the information requested on the form. The facility may reproduce the form as needed to maintain an adequate supply.

Subchapter E. Dialysis Technicians.

§117.61. 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.

§117.62. 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 as follows:

- (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 which may result in inadequate treatment;
- (D) observing and reporting patient reactions to treatment;
- (E) glucose monitoring and hemoglobin/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:

- dialysis;
- (A) theory and practice of conventional, high efficiency, and high flux
 - (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, Dialysate for Hemodialysis RD 52:2004 Edition, published by the AAMI, 1110 North Glebe Road, Suite 220, Arlington, Virginia 22201;
 - (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;
- (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 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 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. If the dialysis technician trainee will cannulate access and administer medications, the examination shall encompass the content described in subsection (c) of this section. A score of 80% is required on the written examination(s) 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; or

(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; or

(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.

§117.63. 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 instructor(s) and preceptor(s), and validate that the trainee has successfully completed the training program.

(b) An individual who completed the facility's orientation program and was determined by the facility to be qualified to deliver dialysis patient care before September 1, 1996, may qualify as a dialysis technician by passing the written examination described in §117.62(f) of this title (relating to Training Curricula and Instructors) and demonstrating competency by completion of the skills checklist described in subsection (c) of this section. Current certification as a dialysis technician by a nationally recognized testing organization may be substituted for the written examination.

(c) The supervising nurse or a registered nurse who qualifies as an instructor under §117.62(g)(2) of this title 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 predialysis 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 postdialysis 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) obtaining 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;

(6) performing a transfer tubing change; and

(7) 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; and

(H) securing needles;

(2) administration of heparin 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 to include:

(A) checking the patient's prescription;

(B) identifying the correct vial of 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 other than a licensed vocational nurse is to cannulate a dialysis access, administer normal saline, heparin, lidocaine, 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 Occupations Code, Chapter 157.

§117.64. Documentation of Competency.

(a) A training program is required to provide a document to the trainee on the 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 §117.63(c), (d), and (e) of this title (relating to Competency Evaluation) within two weeks of hire.

§117.65. Prohibited Acts.

Performance of the following acts by any dialysis technician who is not a licensed vocational nurse is prohibited:

- (1) initiation of patient education;
- (2) alteration of ordered treatment, including shortening of 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, lidocaine, or oxygen, which may only be administered in the course of 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 less than 35 kilograms;
- (9) alteration of the level of electrolytes in dialysate through the use of additive(s) ("spiking"); and
- (10) initiation or discontinuation of dialysis via an implantable port.

Subchapter F. Corrective Action Plan and Enforcement.

§117.81. Corrective Action Plan.

(a) The medical review board (MRB) may assist the department 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, the department 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 Health and Safety Code, §251.061. This subsection is consistent with Health and Safety Code, §251.061.

(1) The department may use a corrective action plan as an alternative to enforcement action under the statute.

(2) Before taking enforcement action, the department 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.

(3) The department may use a level one, level two, or level three corrective action plan, as determined by the department in accordance with this subsection, after inspection of the facility.

(A) If deficiencies are identified after an inspection, the surveyor may request a corrective action plan. The surveyor shall identify the level of corrective action plan required.

(B) The facility shall develop and implement a corrective action plan approved by the department. The facility shall provide the corrective action plan within the time frames specified by the department. A corrective action plan shall identify dates by which compliance will be accomplished. The dates by which compliance will be accomplished on a corrective action plan shall not exceed 45 days from the date the deficiency is cited.

(C) The department shall review and approve the corrective action plan. If the corrective action plan is not acceptable, the department shall notify the facility of changes needed in order for the department to approve the plan.

(D) The facility shall come into compliance within the time frames set out in the corrective action plan. The department will keep a corrective action plan in place as long as necessary or as long as it takes for the facility to come into compliance.

(E) The department shall verify the correction of deficiencies by mail or on-site inspection.

(F) Acceptance of a corrective action plan does not preclude the department from taking other enforcement action as appropriate under this subchapter.

(4) A level one corrective action plan is appropriate, if the department finds that the facility is not in compliance with the statute or this chapter, but the circumstances are not serious or life-threatening. The department or a monitor may supervise the implementation of the plan.

(5) A level two corrective action plan is appropriate, if the department 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 the department finds that the facility failed to implement or comply with a level one corrective action plan. The department 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.

(6) A level three corrective action plan is appropriate, if the department finds that the facility is not in compliance with the statute or this chapter and the circumstances are serious or life-threatening, or if the department finds that the facility failed to comply with a level two corrective action plan or to cooperate with the department in connection with that plan. The department 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 §117.82 of this title (relating to Voluntary Appointment of a Temporary Manager). Involuntary appointment of a temporary manager shall be in accordance with §117.83 of this title (relating to Involuntary Appointment of a Temporary Manager).

(7) A corrective action plan is not confidential. Information contained in the plan may be excepted from required disclosure under the Government Code, Chapter 552 or other applicable law.

(8) The department 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 MRB.

(A) The monitor may not be or include individuals who are current or former employees of the facility that is the subject of the corrective action plan or of an affiliated facility.

(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.

(C) The facility shall pay the cost of the monitor.

§117.82. Voluntary Appointment of a Temporary Manager.

(a) A person holding a controlling interest in a facility may, at any time, request the department to assume the management of the facility through the appointment of a temporary manager in accordance with Health and Safety Code, §251.091.

(b) After receiving the request, the department 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 the department 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.

§117.83. Involuntary Appointment of a Temporary Manager.

(a) Under Health and Safety Code, §251.092, the department 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) the department 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 the department determines that an imminent or reasonably foreseeable threat to the health and safety of a patient of the facility exists;

(4) the department 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) the department determines a level three corrective action plan under §117.81(b)(6) of this title (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 ESRD facilities or similar facilities.

(3) 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 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.

§117.84. Disciplinary Action.

(a) The department may deny, suspend, or revoke a license if the applicant or facility:

(1) fails to comply with any provision of the statute;

(2) fails to comply with any provision of this chapter;

(3) commits fraud, misrepresentation, or concealment of a material fact on any documents required to be submitted to the department or required to be maintained by the facility pursuant to this chapter;

(4) aids, abets, or permits the commission of an illegal act;

(5) fails to comply with an order of the commissioner or another enforcement procedure under the statute; or

(6) fails to comply with applicable requirements within a designated probation period.

(b) The department may deny a license if the applicant or licensee fails to provide the required license fee, application, or renewal information.

(c) The department 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, the department shall consider the provisions of 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 the department will promote the intent of the statute, this chapter, or 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 the department proposes to deny, suspend, or revoke a license, the department 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 tenth calendar day after the notice is mailed to the last address known to the department, 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 Department of State Health Services, Mail Code 1979, P O Box 149347, Austin, Texas 78714-9347.

(3) A hearing shall be conducted pursuant to the Administrative Procedure Act, 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 the department suspends a license, the suspension shall remain in effect until the department determines that the reason for suspension no longer exists. An authorized representative of the department shall investigate prior to making a determination.

(1) During the time of suspension, the suspended license holder shall return the license to the department.

(2) If a suspension overlaps a renewal date, the suspended license holder shall comply with the renewal procedures in this chapter; however, the department may not renew the license until the department determines that the reason for suspension no longer exists.

(f) If the department 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. The department 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 the department.

(h) The department may issue an emergency order to suspend a license issued under this chapter, if the department 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, the department shall conduct a hearing not earlier than the tenth 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 the department's rules for a contested case hearing and Government Code, Chapter 2001.

(i) The department may schedule the facility for a probation 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.

§117.85. Administrative Penalties.

(a) Under Health and Safety Code, §§251.066-251.070, the department 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, the department 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, Government Code, Chapter 2001.

(e) If after investigation of a possible violation and the facts surrounding that possible violation, the department determines that a violation has occurred, the department shall give written notice of the violation to the person alleged to have committed the violation. The notice shall include:

- (1) a brief 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 the department 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 the department, 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. The hearings examiner 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 a sworn 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 the department by certified mail.

(k) If the department receives a copy of an affidavit under subsection (j)(3)(B) of this section, the department may file with the court, within five calendar days after the date the copy is received, a contest to the affidavit.

§117.86. Recovery of Costs.

(a) The department 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) The department 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 the department, reasonable expenses and costs.

(e) For purposes of this section, "reasonable expenses and costs" include expenses incurred by the department and the attorney general in the investigation, initiation, or prosecution of an action, including reasonable investigative costs, court costs, attorney's fees, witness fees, and deposition expenses.

Subchapter G. Fire Prevention and Safety Requirements.

§117.91. Fire Prevention, Protection, and Emergency Contingency Plan.

(a) An 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 the Facility Licensing Group, Regulatory Licensing Unit, Department of State Health Services, Mail Code 2835, P.O. Box 149347, Austin, TX 78714-9347 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 fire fighting 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 fire fighting 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 through 21.7.2.3.

(4) All staff shall be familiar with the locations of fire fighting equipment. Fire fighting 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 provide the following:

(1) The ESRD facility shall maintain driveways, free from all obstructions, to main buildings for fire department apparatus use.

(2) Upon request, the ESRD facility shall submit a copy of the floor plans of the building to the local fire department officials.

(3) The ESRD facility shall 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 below.

(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(s) 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.

(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(s) and electrical transformer(s) 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/vendor that will provide a portable emergency generator(s) 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 1-1/2 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(s) with the supplier/vendor(s) in order to have portable emergency generator(s) 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 patient(s).

(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 1-1/2 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.

§117.92. General Safety.

(a) An 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 utilized 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 nurses 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 nurses emergency call system shall be accessible to a collapsed patient lying on the floor. Inclusion of a pull cord extending to within 6 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.

§117.93. Handling and Storage of Gases and Flammable Liquids.

(a) An 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.

Subchapter H. Physical Plant and Construction Requirements.

§117.101. Construction Requirements for an Existing End Stage Renal Disease Facility.

(a) All buildings in which existing ESRD facilities licensed by the department 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 §117.102 of this title (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, the department may grant a conditional approval of minor deviations from the requirements of §117.102 of this title, 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(s) which is not in compliance with these sections.

(1) Any alteration, modification, replacement, or any installation of new building equipment, such as mechanical, electrical, emergency power equipment, energy/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 the department, and the department has reviewed and approved the plans and specifications in accordance with §117.104 of this title (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 the department. An ESRD facility shall submit by mail or fax 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, the department shall evaluate and determine whether any additional submittals or inspections are required. The department 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 the department 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 §117.104 of this title (relating to Preparation, Submittal, Review and Approval of Plans, and Retention of Records) for all major remodeling or alterations.

(B) As of February 9, 2009, all new facilities or expanding the capacity of treatment stations (in-center dialysis, peritoneal dialysis or home hemodialysis teaching rooms) in existing facilities shall have an isolation room or be granted a waiver by Center for Medicare and Medicaid Services. 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 Texas Department of State Health Services, Health Facility Compliance Group, Mail Code 1979, P.O. Box 149347, Austin, Texas, 78714-9347 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 §117.102 of this title in order to be licensed.

§117.102. Construction Requirements for a New End Stage Renal Disease Facility.

(a) Any proposed new 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 which 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 but not limited to 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 right-of-ways serving dwellings and gas lines on property servicing gas meter(s) 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 subparagraph (B)(i) of this paragraph.

(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 subparagraph (B)(i) of this paragraph.

(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 Texas Administrative Code, §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, (888) 422-7233 5203.

(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 the department in accordance with §117.104 of this title (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 the department 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 §117.103 of this title (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) telephone(s) 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(s) shall be provided for business transactions, records, and administrative and professional staff.

(F) The facility shall provide an area for storage of clinical records which 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 2 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/chair and a wall/partition shall be a minimum of 3 feet. The clearance between sides of stations/chairs shall be a minimum of 4 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/chair clear floor space/area.

(D) The isolation treatment room shall have viewing panels in doors and/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 §117.33(d)(2)(C) of this title (relating to Sanitary Conditions and Hygienic Practices).

(G) As of February 9, 2009, all new facilities or expanding the capacity of treatment stations (in-center dialysis, peritoneal dialysis or home hemodialysis teaching rooms) in existing facilities shall have an isolation room or be granted a waiver by Centers for Medicare and Medicaid Services. 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 Texas Department of State Health Services, Health Facility Compliance Group, Mail Code 1979, P.O. Box 149347, Austin, Texas, 78714-9347 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 §117.45(l) of this title (relating to Provision and Coordination of Treatment and Services).

(A) The laboratory workroom/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. Clean linen storage 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 6 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 6 foot separation. The partition shall be a minimum of 5 feet in height from the finished floor and 2 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/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 §117.32(d) of this title (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/used dialyzers before processing occurs.

(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 use 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 area(s) or rooms shall be separate from the administrative area(s).

(A) When individual hemodialysis patient treatment room(s) is 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 8 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 3 feet, and the back of the extended chair and a wall shall be a minimum of 1 foot. A clear unobstructed width of 3 feet 8 inches shall be available at the foot of each treatment area(s) 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(s) 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(s) 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, clean and sterile supplies.

(2) Emergency eyewash shall be provided conveniently for staff use and 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(s) and include hand washing sink(s) with hands-free operable controls. Patient toilet room shall be at a ratio of 1 toilet room for every 40 treatment stations or fraction thereof.

(5) Staff toilet room(s) shall be provided and include hand washing sink(s) 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 an enclosed room. The water room shall be designed and house the water treatment system and meet the requirements of §117.32(b) of this title.

(f) Details and finishes in new construction projects, including additions and alterations, shall be in compliance 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 §117.101 of this title (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 area(s) 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/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 which 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, shall have either one and one-fourth or one and one-half inches clearance to walls, and shall 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. Particular 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/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 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/ceiling assembly or a floor/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 are required in all areas or rooms in the ESRD facility unless a requirement requires a specific type of ceiling for such space. This 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; and

(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.

(iv) no finished ceiling is required 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/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/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/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% and 60%.

(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%.

(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 (h)(10) of this section.

(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 utilize 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 the department 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% or equal minimum efficient rating value (merv) of 8 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, the department 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% or equal to 8 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, provided that 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. Nonrecirculated 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 tank(s) 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 contaminants/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 §117.105(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 the following:

(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. Insulation on cold surfaces shall include an exterior vapor barrier; and

(V) 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 nonabsorptive 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 which 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 utilized.

(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 gridded drain cover to prevent entry of large particles of waste which might cause stoppages.

(I) Under counter piping and above floor drains shall be arranged (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) This subsection contains 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 arranged (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 (i.e., 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/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/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 receptacle(s) 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 nurses 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 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 nurses emergency call system shall be accessible to a collapsed patient lying on the floor. Inclusion of a pull cord extending to within 6 inches of the floor will satisfy this requirement.

(10) The ESRD facility shall provide, at submission of construction documents/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 below.

(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 [2], and National Fire Protection Association 110, Standard for Emergency and Standby Power Systems, 2002 Edition.

(i) An emergency generator standby power system(s) 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(s) and electrical transformer(s) 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 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.

(B) A executed contract with an outside supplier/vendor(s) that will provide a portable emergency generator(s) 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 1-1/2 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.

(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(s) with the supplier/vendor(s) in order to have portable emergency generator(s) 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 1-1/2 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.

(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 as follows:

(A) A fire alarm control panel (FACP) shall be installed at a visible central location.

(B) Manual fire alarm pull stations shall be installed in accordance with NFPA 101, §18.3.4.

(C) Smoke detectors for door release service shall be 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 shall be 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 shall be 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 shall be 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 shall be installed in accordance with the requirements of NFPA 72, §6.8.5.5.

(H) Audible alarm indicating devices shall be 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 (b)(2)(B) of this section and NFPA 72, §7.5, shall be provided.

(J) Devices for transmitting alarm for alerting the local fire brigade or municipal fire department of fire or other emergency shall be provided. The devices shall be listed for the fire alarm service by a nationally recognized laboratory, and be 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, shall be provided to alert occupants of fire or other emergency.

(L) Wiring for fire alarm detection circuits and fire alarm notification circuits shall comply with requirements of NFPA 70, Article 760.

(M) Smoke detector(s) for shutdown of air handling units shall be provided. The detectors shall be installed in accordance with NFPA 90A, §6.4.3.

(N) Telecommunications and information systems central equipment shall be installed in a separate location designed for the intended purpose. Special air conditioning and voltage regulation shall be provided as recommended by the manufacturer.

(O) When installed, lightning protection systems shall comply with National Fire Protection Association 780, Standard for the Installation of Lightning Protection Systems, 2000 Edition.

§117.103. 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 be in compliance 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 fire fighting or rescue purposes shall conform to Fire Fighters' Service Requirements of ASME/ANSI A17.3 as required by NFPA 101, §9.4.3.

§117.104. Preparation, Submittal, Review and Approval of Plans, and Retention of Records.

(a) General.

(1) ESRD facility owners or operators shall not begin construction of a new building, additions to, or renovations, or conversions of existing buildings until the department 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 and/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) The department 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 the department.

(6) Once final construction documents are approved, the ESRD facility owner or operator shall request inspections in accordance with §117.105 of this title (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 the department 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 the department when a project has been placed on hold, canceled, or abandoned.

(9) The department 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 the department 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. The application for plan review may be obtained by calling the department or by visiting the department's website at www.dshs.state.tx.us/hfp;

(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 §117.102(i)(10) of this title (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 the department has determined that the submission required in paragraph (1) of this subsection is complete, the department 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 the department 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 the department'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 the department.

(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 the department.

(d) The ESRD facility owner or operator shall submit a functional program narrative to the department 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) The department may request preliminary documents. If requested by the department, 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 usage of all spaces, areas, and rooms on every floor level.

(f) Final construction documents and specifications shall be submitted to the department 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 engineer(s) licensed by the State of Texas.

(1) The ESRD facility owner or operator shall submit to the department 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 the following:

(i) a map of the area within a 500 foot radius of the facility site shall be provided and any hazardous and undesirable location noted in §117.102(a) of this title shall be identified;

(ii) 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, and the extent of the areas to be landscaped. All structures which are to be removed under the construction contract and improvements shall be shown. A general description of the immediate area surrounding the site shall be provided;

(iii) 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 the following information:

(i) separate fire safety plans (preferably one floor plan per sheet) shall indicate 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;

(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 the following:

(i) all equipment necessary for the operation of the facility as planned. The design shall indicate 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). The term moveable equipment includes 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. The equipment described in this clause 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 tank(s) (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 generator(s), transfer switch(es), 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. Feeder and conduit sizes shall be shown 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 the department 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(s) 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) The department 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 the department 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 Health and Safety Code, Chapter 251, End Stage Renal Disease Facilities, and this chapter.

(B) The department shall review the request for self-certification and notify the ESRD facility owner or operator if the request is approved or denied. If denied, the department 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 the department a brief written description of the proposed project and floor plans of the areas of work. The minor project request shall be mailed or faxed.

(A) If it is determined that the proposed project is a minor project, the department 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) The department 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) affects fire safety (e.g., modifications to the fire, smoke, and corridor walls);

(iv) adds services for which the ESRD facility is not currently licensed; and

(v) significantly changes 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 the department 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 the department 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 the department 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, but not limited to, energy audits and retrofit for energy conservation.

§117.105. 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 the department 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 the department when construction will commence. The department 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 the purpose of 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% 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% 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 the department.

(1) The ESRD facility owner or operator shall submit the following documents to the department 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 is in compliance 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 the department. 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, the department shall issue written final approval of the project.

§117.106. Tables.

Table 1. Staffing Levels of Direct Care Staff.

**TABLE 1
STAFFING LEVELS OF DIRECT CARE STAFF**

Patients receiving treatment	RN	RN or LVN	PCT, LVN or RN	Charge RN
1-7	1		1	
8	1		2	
9	1		3	
10	1		3	
11	1		3	
12	1		3	
13	1	1	4	
14	1	1	4	
15	1	1	4	
16	1	1	4	
17	1	1	5	
18	1	1	5	
19	1	1	5	
20	1	1	5	
21	1	1	6	
Etc.				

§117.1. Purpose.

~~(a) The purpose of this chapter is to implement 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 Department of Health.~~

~~(b) This chapter provides minimum standards for the design and space requirements; equipment used by the facility; water treatment and reuse; sanitary and hygienic conditions; quality assurance for patient care; indicators of quality 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; and the competency evaluation of dialysis technicians.~~

~~(c) Compliance with this chapter does not constitute release from the requirements of other applicable federal, state, or local codes and ordinances. This chapter must be followed where it exceeds other codes and ordinances.~~

§117.2. 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 should be taken to interrupt the trend towards unacceptable levels.~~

~~(2) Advanced practice nurse—A registered nurse approved by the Board of Nurse Examiners for the State of Texas to practice as an advanced practice nurse.~~

~~(3) 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.~~

~~(4) Affiliate—An applicant or owner which is:~~

~~(A) a corporation—includes each officer, consultant, stockholder with a direct ownership of at least 5.0%, subsidiary, and parent company;~~

~~(B) a limited liability company—includes each officer, member, and parent company;~~

~~(C) an individual—includes:~~

~~(i) the individual's spouse;~~

~~(ii) each partnership and each partner thereof of which the individual or any affiliate of the individual is a partner; and~~

~~(iii) each corporation in which the individual is an officer, consultant, or stockholder with a direct ownership of at least 5.0%;~~

~~(D) a partnership includes each partner and any parent company; and~~

~~(E) a group of co-owners under any other business arrangement includes each officer, consultant, or the equivalent under the specific business arrangement and each parent company.~~

~~(5) Applicant—The owner of an end stage renal disease facility which is applying for a license under the statute. This is the person in whose name the license is issued.~~

~~(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.~~

~~(7) Board—The Texas Board of Health.~~

~~(8) Change of ownership—A sole proprietor who transfers all or part of the facility's ownership to another person or persons; the removal, addition, or substitution of a person or persons as a partner in a facility owned by a partnership and the tax identification number of the partnership changes; or a corporate sale, transfer, reorganization, or merger of the corporation which owns the facility if sale, transfer, reorganization, or merger causes a change in the facility's ownership to another person or persons and the tax identification number of the corporation changes.~~

~~(9) Charge nurse—A registered professional 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 of patient care, monitoring patients for changes in condition, and/or communicating with the physician, dietician, and social worker regarding patient needs.~~

~~(10) Commissioner—The commissioner of health.~~

~~(11) Competency—The demonstrated ability to carry out specified tasks or activities with reasonable skill and safety that adheres to the prevailing standard of practice.~~

~~(12) Core staff members—The facility's medical director, supervising nurse, dietitian, social worker, administrator, and chief technician.~~

~~(13) Corrective action plan—A written strategy for correcting a licensing violation. The corrective action plan is developed by the facility and addresses the system(s) operation(s) of the facility as the system(s) operation(s) applies to the deficiency.~~

~~(14) Delegation—The transfer to a qualified and properly trained individual of the authority to perform a selected task or activity in a selected situation.~~

~~(15) Department—The Texas Department of Health.~~

~~(16) 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 which 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. It does not include peritoneal dialysis fluid.~~

~~(17) 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.~~

~~(18) 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.~~

~~(19) Dialysis technician—An individual who is not a registered nurse or physician and who provides dialysis care under the direct supervision of a registered nurse or physician. If unlicensed, this individual may also be known as a patient care technician.~~

~~(20) Dietitian—A person who is currently licensed under the laws of this state to use the title of licensed dietitian, is eligible to be a registered dietitian, and has one year of experience in clinical dietetics after becoming eligible to be a registered dietitian.~~

~~(21) Director—The director of the Health Facility Licensing and Compliance Division of the department or his or her designee.~~

~~(22) 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.~~

~~(23) End stage renal disease—That stage of renal impairment that appears irreversible and permanent and that requires a regular course of dialysis or kidney transplantation to maintain life.~~

~~(24) End stage renal disease (ESRD) facility—A facility that provides dialysis treatment or dialysis training to individuals with end stage renal disease.~~

~~(25) 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.~~

~~(26) Full-time equivalent—Work time equivalent to 2,080 hours per 12 consecutive months.~~

~~(27) Health care facility—Any type of facility or home and community support services agency licensed to provide health care in any state or is certified for Medicare (Title XVIII) or Medicaid (Title XIX) participation in any state.~~

~~(28) Governing body—An identified group, which includes the medical director and a representative(s) of the owner of the facility, with full legal authority and responsibility for the governance and operation of the facility.~~

~~(29) Hospital—A facility that is licensed under the Texas Hospital Licensing Law, 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.).~~

~~(30) Interdisciplinary team—A group composed of the primary physician, the registered nurse, the dietitian and the social worker who are responsible for planning care for the patient.~~

~~(31) Intermediate level disinfection—A surface treatment using chemical germicides or disinfectants which are capable of inactivating various classes of microorganisms including, but not limited to, 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 instructions 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% ethanol or isopropanol, and certain phenolic or iodophor preparations.~~

~~(32) Inspection—An investigation or survey conducted by a representative of the department to determine if an applicant or licensee is in compliance with this chapter.~~

~~(33) LAL (Limulus Amoebocyte Lysate) test—An assay used to detect endotoxin which exploits the immune response of the horse shoe crab (Limulus polyphemus).~~

~~(34) Licensed nurse—A registered nurse or licensed vocational nurse.~~

~~(35) Licensed vocational nurse (LVN)—A person who is currently licensed under Texas Civil Statutes, Article 4528c to use the title licensed vocational nurse and who may provide dialysis treatment after meeting the competency requirements specified for dialysis technicians.~~

~~(36) Manager—An individual approved or selected by the department who assumes overall management of an end stage renal disease facility to ensure adequate and safe services are provided to patients.~~

~~(37) Medical director—A physician who:~~

~~(A) is board eligible or board certified in nephrology or pediatric nephrology by a professional board; or~~

~~(B) during the five year period prior to September 1, 1996, has served for at least 12 months as director of a dialysis program.~~

~~(38) Medical review board (MRB)—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.~~

~~(39) Monitor—An individual approved or selected by the department who observes, supervises, consults, and educates a facility to correct identified violations of the statute or this chapter.~~

~~(40) Notarized copy(ies)—A sworn affidavit stating that attached copy(ies) is a true and correct copy(ies) of the original documents.~~

~~(41) Owner—One of the following which holds or will hold a license issued under the statute in the person's name or the person's assumed name:~~

~~(A) a corporation;~~

~~(B) a limited liability company;~~

~~(C) an individual;~~

~~(D) a partnership if a partnership name is stated in a written partnership agreement or an assumed name certificate;~~

~~(E) all partners in a partnership if a partnership name is not stated in a written partnership agreement or an assumed name certificate; or~~

~~(F) all co-owners under any other business arrangement.~~

~~(42) Patient—An individual receiving dialysis treatment or training from an end stage renal disease facility.~~

~~(43) Patient care plan—Documentation of the interactive process whereby the interdisciplinary team and the patient and/or family member or guardian develop a plan to assist the end-stage renal disease patient in managing the disease and its complications.~~

~~(44) Pediatric patient—An individual 18 years of age or younger under the care of a facility.~~

~~(45) Person—An individual, corporation, or other legal entity.~~

~~(46) Physician—An individual who is licensed to practice medicine under the Medical Practice Act, Texas Civil Statutes, Article 4495b.~~

~~(47) Physician assistant—A person who is licensed as a physician assistant under the Physician Assistant Licensing Act, Texas Civil Statutes, Article 4495b-1.~~

~~(48) Presurvey conference—A conference held with department staff and the applicant or his or her representatives to review licensure standards and survey documents and provide consultation prior to the issuance of the temporary license. The applicant's representatives shall include an individual who will be responsible for the day-to-day supervision of care by the facility.~~

~~(49) Product water—The effluent water from the last component of the facility's water treatment system.~~

~~(50) Progress note—A dated and signed written notation by a facility staff member summarizing facts about care and a patient's response during a given period of time.~~

~~(51) Quality—The degree to which health services for individuals and populations increase the likelihood of desired outcomes that are consistent with current professional knowledge.~~

~~(52) Quality assurance—An ongoing, objective, and systematic process of monitoring, evaluating, and improving the quality, appropriateness, and effectiveness of care. The term includes the quality management and quality improvement processes.~~

~~(53) Quality management—A management philosophy used to plan and achieve desired processes and outcomes based upon a quality plan, which establishes quality objectives and the means to achieve; quality control, which is a process to evaluate actual performance against expected performance; and quality improvement, which is a process to identify, plan, and implement change for improvement.~~

~~(54) Registered nurse (RN)—A person who is currently licensed under the Nursing Practice Act, Texas Civil Statutes, Article 4513 et seq. as a registered nurse.~~

~~(55) Social worker—A person who:~~

~~(A) is currently licensed as a social worker under the Human Resources Code, Chapter 50, and holds a masters 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 September 1, 1976, and has established a consultative relationship with a social worker who has a masters degree from a graduate school of social work accredited by the Council on Social Work Education.~~

~~(56) Supervising nurse (also may be known as the director of nursing)—An RN who:~~

~~(A) has at least 18 months experience as an RN, which includes at least 12 months experience in dialysis which 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.~~

~~(57) 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. Immediate supervision means the supervisor is actually observing the task or activity as it is performed. Direct supervision means the supervisor is on the premises but not necessarily immediately physically present where the task or activity is being performed. Indirect supervision means the supervisor is not on the premises but is accessible by two-way communication and able to respond to an inquiry when made, and is readily available for consultation.~~

~~(58) Statute—The Health and Safety Code, Chapter 251.~~

~~(59) Training—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.~~

~~(60) Technical supervisor—The supervisor of the facility's mechanical, reuse and water treatment systems.~~

~~(61) Ultrafilter—A membrane filter with a pore size in the range 0.001 to 0.05 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% rejection. Ultrafilters with a nominal MWCO of 20,000 or less are generally adequate for endotoxin removal.~~

~~(62) Water distribution systems—Components to 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.~~

~~(63) Water treatment system—A collection of water purification devices and associated piping, pumps, valves, gauges, etc., that together produce purified water for hemodialysis applications and deliver it to the point of use.~~

~~(64) Working day—Any day of the calendar week excluding Saturday or Sunday.~~

~~§117.11. General Requirements for a License.~~

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

~~(b) Display. 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) Alteration. A facility license shall not be altered.~~

~~(d) Transfer or assignment prohibited. A facility license shall not be transferred or assigned. The facility shall comply with the provisions of §117.12(h) of this title (relating to Application and Issuance of Initial License) in the event of a change in the ownership.~~

~~(e) Changes which affect the license.~~

~~(1) A facility shall notify the department in writing prior to the occurrence of any of the following:~~

~~(A) any construction, renovation, or modification of the facility buildings;~~

~~(B) cessation of operation of the facility; or~~

~~(C) change in facility name, telephone number or administrator.~~

~~(2) A facility shall obtain written approval from the department prior to the utilization of added services or an increased number of stations. The written request shall be submitted 30 calendar days prior to the planned change.~~

~~(A) For an additional service or increase in stations, the department may request that the facility provide evidence of appropriate staffing and policies and procedures which demonstrate the intent to comply with the applicable requirements, and 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) The department may conduct on on-site inspection prior to taking action on the requested change.~~

~~(D) No later than three weeks after initiating the use of the new stations, the facility is required to complete chemical and bacteriological cultures of the product water to ensure they are in compliance with §4.2.1 (relating to Water Bacteriology) and §4.2.2 (relating to Maximum Level of Chemical Contaminants) of the American National Standard, Water Treatment Equipment for Hemodialysis Applications, August 2001 Edition, published by the Association for the Advancement of Medical Instrumentation, 1110 North Glebe Road, Suite 200, Arlington, Virginia 22201, 703-525-4890. Deviations from acceptable levels must be immediately reported to the department. The reports must be kept on file at the facility and made available to department staff during the next on-site inspection.~~

~~(3) The department shall send the facility written notice of the approval or disapproval of the requested change.~~

~~(f) Facility relocation.~~

~~(1) A facility planning to relocate shall notify the department a minimum of 60 days prior to the planned relocation. Relocations must be within the same geographical area, and services shall continue to be provided to the facility's existing patient population.~~

~~(2) The facility shall submit the following to the department:~~

~~(A) a copy of a current fire safety survey indicating approval by the local fire authority in whose jurisdiction the new location is based;~~

~~(B) results of chemical and bacteriological cultures of the product water at the new location to ensure they are in compliance with §§4.2.1 (relating to Water Bacteriology) and 4.2.2 (relating to Maximum Level of Chemical Contaminants) of the American National Standard, Water Treatment Equipment for Hemodialysis Applications, August 2001 Edition, published by the Association for the Advancement of Medical Instrumentation, 1110 North Glebe Road, Suite 200, Arlington, Virginia 22201, (703) 525-4890;~~

~~(C) documentation verifying compliance with paragraph (1) of this subsection; and~~

~~(D) a written plan for the orderly transition of all patient services to the new location.~~

~~(3) The department shall conduct the design and space inspection described in §117.16(b)(1)(A) of this title (relating to Inspections) prior to issuance of the initial license, unless the department waives the requirement.~~

~~(4) The department may conduct additional on-site inspections, or request additional information, before approving the relocation.~~

~~(5) The department will notify the facility in writing of the approval or disapproval of relocation. If approved, the license will be reissued for the new location effective on the day that patient services are transferred to the new location.~~

~~§117.12. Application and Issuance of Initial License.~~

~~(a) Application submittal. The applicant shall submit the following documents to the department no earlier than 60 calendar days prior to the projected opening date of the facility:~~

- ~~(1) an accurate and complete application form;~~
- ~~(2) an approved fire safety report from the local fire authority; and~~
- ~~(3) the appropriate license fee as required in §117.14 of this title (relating to Fees).~~

~~(b) Design and space inspection. The department shall conduct the design and space inspection described in §117.16(b)(1)(A) of this title (relating to Inspections) prior to issuance of the initial license, unless the department waives the requirement.~~

~~(c) Presurvey conference. The applicant or the applicant's representative shall attend a presurvey conference at the office designated by the department. The purpose of the presurvey conference, which is conducted by department staff, is to review facility staff qualifications, facility policies and procedures, results of water cultures and analysis of product water, survey documents and licensure rules, and to provide consultation prior to the on-site licensure survey. The department staff conducting the presurvey conference is responsible for making a recommendation regarding the issuance of the initial license. The department may waive the presurvey conference requirement.~~

~~(d) Issuance of license. When it is determined that the facility has complied with subsections (a)–(c) of this section, the department shall issue the license to the applicant.~~

~~(1) Effective date. The license shall be effective on the date the facility is determined to be in compliance with subsections (a)–(c) of this section.~~

~~(2) Expiration date.~~

~~(A) For initial licenses issued prior to January 1, 2005.~~

~~(i) If the effective date of the license is the first day of a month, the license expires on the last day of the 11th month after issuance.~~

~~(ii) If the effective date of the license is the second or any subsequent day of a month, the license expires on the last day of the 12th month after issuance.~~

~~(B) For initial licenses issued January 1, 2005, or after.~~

~~(i) If the effective date of the license is the first day of a month, the license expires on the last day of the 23rd month after issuance.~~

~~(ii) If the effective date of the license is the second or any subsequent day of a month, the license expires on the last day of the 24th month after issuance.~~

~~(e) Withdrawal of application. If an applicant decides not to continue the application process for a license or renewal of a license, the application may be withdrawn. The department shall acknowledge receipt of the request to withdraw.~~

~~(f) Denial of a license. Denial of a license shall be governed by §117.84 of this title (relating to Enforcement).~~

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

~~(1) A facility shall request an on-site inspection to be conducted after one inpatient has been admitted and provided services.~~

~~(2) A facility shall be providing services to at least one inpatient in the facility at the time of the inspection.~~

~~(h) Change of ownership. 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 and the tax identification number does not change, this subsection does not apply, except that the corporation must notify the department within 10 calendar days after the effective date of the name change. The sale of stock of a corporate licensee does not cause this subsection to apply. A change of ownership requires submission of an initial license application.~~

~~(1) The new owner shall submit an application for an initial license to the department prior to the date of the change of ownership or not later than 10 calendar days following the date of a change of ownership. The application shall be in accordance with subsections (a)–(e) of this section. The applicant shall include the effective date of the change of ownership.~~

~~(2) Inspections. The design and space and health inspections required by subsections (b) and (g) of this section may be waived by the department.~~

~~(3) Issuance of license. When the new owner has complied with the provisions of subsections (a)–(e) of this section, the department shall issue a license which shall be effective the date of the change of ownership.~~

~~(4) Expiration of license. The expiration date of the license shall be in accordance with subsection (d) of this section.~~

~~(5) License void. The previous owner's license shall be void on the effective date of the new owner's license.~~

~~(i) Temporary initial license. The department may issue a temporary initial license in lieu of the initial license.~~

~~§117.13. Application and Issuance of Renewal License.~~

~~(a) Renewal notice. The department may send a renewal notice to a facility up to 60 calendar days before the expiration date of a license.~~

~~(1) If the facility has not received the renewal notice from the department within 30 calendar days prior to the expiration date, it is the duty of the facility to notify the department and request a renewal application for a license.~~

~~(2) If the facility fails to submit the application and fee within 15 calendar days prior to the expiration date of the license, the department shall send to the facility a letter advising that unless the license is renewed, the facility must cease operations upon the expiration of the license.~~

~~(b) Renewal license. The department shall issue a renewal license to a facility that meets the minimum requirements for a license.~~

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

~~(A) a complete and accurate application form;~~

~~(B) a copy of a fire safety survey indicating approval by the local fire authority in whose jurisdiction the facility is based that is dated no earlier than one year prior to the application date;~~

~~(C) the renewal license fee; and~~

~~(D) verification that the facility submitted the annual reports required by §117.42 of this title (relating to Indicators of Quality of Care).~~

~~(2) The department may conduct an inspection prior to issuing a renewal license in accordance with §117.16 of this title (relating to Inspections).~~

~~(3) Renewal licenses issued prior to January 1, 2005, will be valid for 12 months.~~

~~(4) Renewal licenses issued January 1, 2005, through December 31, 2005, will be valid for either 12 or 24 months, to be determined by the department prior to the time of license renewal.~~

~~(5) Renewal licenses issued January 1, 2006, or after will be valid for 24 months.~~

~~(c) Notice to cease operation and return license. If a facility fails to submit the application, documents, and fee by the expiration date of the license, the department shall notify the facility that it must cease operation and immediately return the license by certified mail to the department. If the facility wishes to provide services after the expiration date of the license, it shall apply for a license under §117.12 of this title (relating to Application and Issuance of Initial License).~~

~~§117.14. Fees.~~

~~(a) General.~~

~~(1) All fees paid to the department are nonrefundable.~~

~~(2) All fees shall be paid to the department.~~

~~(b) License fees.~~

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

~~(A) \$3,500 for facilities licensed for 0 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) Other fees. For all applications and renewal applications, the department 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.~~

~~§117.15. 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 Department of Health (department).~~

~~(2) An application for an initial license is complete when the department has received, reviewed, and found acceptable the information described in §117.12 of this title (relating to Application and Issuance of Initial License).~~

~~(3) An application for an annual renewal license is complete when the department has received, reviewed and found acceptable the information described in §117.13 of this title (relating to Application and Issuance of Renewal License).~~

~~(b) Time Periods. 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 begins on the date the department receives the application and ends on the date the license is issued, or if the application is received incomplete, the period ends on the date the facility is issued a written notice that the application is incomplete. The written notice shall describe the specific information that is required before the application is considered complete. The first time period is 45 calendar days.~~

~~(2) The second time period begins on the date the last item necessary to complete the application is received and ends on the date the license is issued. The second time period is 45 calendar days.~~

~~(c) Reimbursement of fees.~~

~~(1) In the event the application is not processed in the time periods stated in subsection (b) of this section, the applicant has the right to request that the department reimburse in full the fee paid in that particular application process. If the department does not agree that the established periods have been violated or finds that good cause existed for exceeding the established periods, the request will be denied.~~

~~(2) Good cause for exceeding the period established is considered to exist if:~~

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

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

~~(C) other conditions existed giving good cause for exceeding the established periods.~~

~~(d) Appeal. If the request for reimbursement as authorized by subsection (c) of this section is denied, the applicant may then appeal to the commissioner of health 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. The department 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 will make the final decision and provide written notification of the decision to the applicant and the director.~~

~~(e) Hearings. If a hearing is proposed during the processing of the application, the hearing shall be conducted pursuant to the Administrative Procedure Act, Texas Government Code, Chapter 2001, and the department's formal hearing procedures in Chapter 1 of this title (relating to the Texas Board of Health).~~

~~§117.16. Inspections.~~

~~(a) General. The Texas Department of Health (department) may conduct an inspection at any time to verify compliance with the statute or this chapter. By applying for or holding a license, the facility consents to entry and inspection of the facility by the department or representative of the department in accordance with the statute and this chapter.~~

~~(1) An authorized representative of the department (surveyor) may enter the premises of a license applicant or license holder at reasonable times during business hours to conduct an on-site inspection incidental to the issuance of a license, and at other times as the department considers necessary to ensure compliance with:~~

~~(A) the statute or this chapter;~~

~~(B) an order of the commissioner of health (commissioner);~~

~~(C) a court order granting injunctive relief;~~

~~(D) a corrective action plan; or~~

~~(E) other enforcement action(s).~~

~~(2) The surveyor is entitled to access all books, records, or other documents maintained by or on behalf of the facility to the extent necessary to ensure compliance with the statute, this chapter, an order of the commissioner, a court order granting injunctive relief, a corrective action plan, or other enforcement action. The department shall maintain the confidentiality of facility records as applicable under federal or state law. Ensuring compliance includes permitting photocopying by the department or providing photocopies to a department surveyor of any records or other information by or on behalf of the department as necessary to determine or verify compliance with the statute or this chapter.~~

~~(b) Types of inspections.~~

~~(1) Design and space inspection.~~

~~(A) The department shall conduct an inspection to determine compliance with the design and space requirements described in §117.31 of this title (relating to Design and Space Requirements), the requirements in §117.32(a), (c), (e), and (g) of this title (relating to Equipment), and §117.33(b)(1) and (3)–(10) of this title (relating to Water Treatment and Reuse) prior to issuance of the temporary initial license, unless the department waives the requirement.~~

~~(B) During any license period, the department may conduct a design and space inspection to determine whether modifications or renovations comply with §117.31 of this title.~~

~~(2) Initial inspection for the issuance of the initial license. A department surveyor may conduct an initial inspection after the date of issuance of the initial license to determine if the facility meets the requirements of the statute and this chapter. The initial inspection is an evaluation of compliance with all requirements of the statute and this chapter.~~

~~(3) Renewal inspection. At the department's discretion, a department surveyor may perform an on-site inspection prior to renewal of a facility license to verify compliance with the statute and this chapter. The renewal inspection may include an evaluation of compliance with all requirements of the statute and this chapter.~~

~~(4) Inspection to investigate a complaint. The department surveyor shall perform an inspection of a facility on-site or by mail if the facility has demonstrated noncompliance with the statute or this chapter, or to investigate a complaint received by the department.~~

~~(5) Inspection based on annual report. After review of a facility's annual report, the department may request additional information or conduct an inspection by mail or on-site to determine compliance with the statute and this chapter.~~

~~(6) Inspection related to a report(s) to the director. The department may conduct an inspection incidental to a report to the director described in §117.46 of this title (relating to Reports to the Director).~~

~~(7) Follow-up inspection. A department surveyor shall perform an inspection on-site or by mail to verify completion of a corrective action plan(s) for deficiencies cited during any of the inspections described in paragraphs (1)–(6) of this subsection.~~

~~(c) Inspection procedures:~~

~~(1) Entrance conference. The department's surveyor shall hold a conference with the person who is in charge of the facility prior to commencing the inspection for the purpose of explaining the nature and scope of the inspection.~~

~~(2) Evaluation of compliance. Except for the purposes of conducting an inspection under subsection (b)(1), (4), (6), or (7) of this section, an onsite inspection will include an evaluation to determine compliance with the statute and this chapter.~~

~~(3) Exit conference. After an inspection of a facility the surveyor shall hold an exit conference with the facility administrator or his or her designee. During the exit conference, the surveyor shall:~~

~~(A) fully inform the facility representative of the preliminary finding(s) of the inspection;~~

~~(B) give the person a reasonable opportunity to submit additional facts or other information to the surveyor in response to those findings; and~~

~~(C) identify any records that were duplicated.~~

~~(4) Written notice of findings.~~

~~(A) The surveyor shall:~~

~~(i) prepare and provide the facility administrator or his or her designee specific and timely written notice of the findings in accordance with subparagraphs (B) and (C) of this paragraph; or~~

~~(ii) if the findings result in a referral described in §117.81(a)(1) of this title (relating to Corrective Action Plan), submit a written summary of the findings to the medical review board for its review and recommendation for appropriate action by the department.~~

~~(B) If no deficiencies are found during an inspection, the department shall provide a statement indicating this fact.~~

~~(C) If the written notice of findings includes deficiencies, the department and the facility shall comply with the procedure set out in this subparagraph.~~

~~(i) The department shall provide the facility with a statement of the deficiencies at the time of the exit conference or within 10 working days after the exit conference.~~

~~(ii) The facility administrator or administrator's designee shall sign the written statement of deficiencies and return it to the department with a corrective action plan(s) for each deficiency no later than 10 working days of its receipt of the statement of deficiencies. The signature does not indicate the administrator's or designee's agreement with deficiencies stated on the form.~~

~~(iii) The facility shall come into compliance 60 calendar days prior to the expiration date of the license or no later than the dates designated in the corrective action plan(s), whichever comes first.~~

~~(iv) The requirements in clause (i) of this subparagraph do not apply if the surveyor's written notice of findings results in a referral to the medical review board as described in subparagraph (A)(ii) of this paragraph.~~

~~(v) A corrective action plan completion date shall not exceed 45 calendar days from the date the deficiency(ies) is cited (exit date of the survey).~~

~~(vi) The facility may challenge any deficiency cited after receipt of the statement of deficiencies. A challenge to a deficiency(ies) shall be in accordance with this subparagraph.~~

~~(I) The facility shall comply with clause (ii) of this subparagraph regardless of its intent to challenge the deficiency(ies).~~

~~(II) An initial challenge to a deficiency(ies) shall be submitted in writing no later than five working days from the facility's receipt of the statement of deficiencies to the Program Director, End Stage Renal Disease Licensing Program or his or her designee, Health Facility Licensing and Compliance Division, Texas Department of Health, 1100 West 49th Street, Austin, Texas, 78756-3199, (512) 834-6646.~~

~~(III) If the initial challenge is favorable to the department, the facility may request a review of the initial challenge by submitting a written request to the Director or his or her designee, Health Facility Licensing and Compliance Division, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756-3199. The facility shall submit its written request for review of the initial challenge no later than five working days of its receipt of the department's response to the initial challenge. The department will not accept or review any documents that were not submitted with the initial challenge. A determination by the Director of the Health Facility Licensing and Compliance Division relating to a challenge to a deficiency(ies) is the department's final determination concerning the challenge.~~

~~(IV) The department shall respond to any written challenge submitted under subclause (II) or (III) of this clause no later than 15 working days from its receipt.~~

~~(V) The department shall determine if a written corrective action plan(s) is acceptable. If the corrective action plan(s) is not acceptable to the department, the department shall notify the facility by telephone and request that the corrective action plan(s) be modified and resubmitted no later than 10 working days from the facility's receipt of such request.~~

~~(VI) If the facility does not come into compliance by the required date of correction reflected on the corrective action plan(s), the department may:~~

~~(a) appoint a monitor as described in §117.81 of this title;~~

~~(b) appoint a temporary manager as described in §117.83 of this title (relating to Involuntary Appointment of Temporary Manager);~~

~~(c) propose to deny, suspend, or revoke the license in accordance with §117.84 of this title (relating to Enforcement);~~

~~(d) assess an administrative penalty(ies) in accordance with §117.85 of this title (relating to Administrative Penalties); or~~

~~(e) take all of the actions described in items (a)–(d) of this subclause.~~

~~(VII) The department shall verify the correction of deficiencies by mail or on-site inspection.~~

~~(VIII) Acceptance of a corrective action plan does not preclude the department from taking enforcement action as appropriate under §§117.83, 117.84, or 117.85 of this title.~~

~~(IX) The department shall refer issues and complaints relating to the conduct of or action(s) by licensed health care professionals to the appropriate licensing board(s).~~

~~§117.17. Optional Plan Review and Inspection.~~

~~(a) Request for a plan review. Plans and specifications covering the construction of new buildings or alterations, additions, conversions, modernizations or renovations to existing buildings may be submitted to the Texas Department of Health (department) for review to determine compliance with this chapter. Submission of plans and specifications is not mandatory.~~

~~(1) If a plan review is requested by the facility, plans and specifications shall be submitted in accordance with this section.~~

~~(2) A review of minor alterations or remodeling changes which do not include alterations to load-bearing members of partitions, change functional operation, affect fire safety, or add additional stations may be requested. The request for review shall be in writing to the department with a brief description of the proposed changes.~~

~~(3) If review of preliminary plans and outline specifications is requested, the submittal shall contain sufficient information to establish the scope of the project and compliance with the design and space requirements in this chapter.~~

~~(4) If review of final drawings and specifications is requested, one complete set of drawings shall be submitted. All working drawings shall be well prepared so that clear and distinct prints may be obtained, be accurately dimensioned, and include all necessary explanatory~~

notes, schedules, and legends. Final drawings shall be complete and adequate for construction contract purposes. All final plans and specifications shall be appropriately sealed and signed by a registered architect and professional engineer licensed by the State of Texas. Drawings and specifications shall comply with the design and space requirements in this chapter.

(b) Inspection. At 100% completion of construction and prior to occupancy, the department may schedule a construction inspection at the department's convenience for the purpose of verifying compliance with design and space requirements in this chapter.

~~§117.18. Exceptions to These Rules.~~

~~(a) While all subject ESRD facilities are required to maintain continuous compliance with these rules, these rules do not prohibit the use of alternative concepts, methods, procedures, techniques, equipment, facilities, personnel qualifications of the conducting of pilot projects or research. Requests for temporary exceptions to these rules must:~~

~~(1) be submitted to the department 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 alternatives (including compliance with the rule) were not selected;~~

~~(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; and~~

~~(6) describe the proposed duration of the exception.~~

~~(7) exceptions to staffing requirements:~~

~~(A) may only be granted in an emergency situation 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 the staffing crisis situation;~~

~~(C) the facility shall submit the action plan to the department within 60 days of the granting of the exception; and~~

~~(D) during the period of exception to staffing requirements, the facility shall monitor outcome data related to quality of care and report these outcomes on a monthly basis to the department.~~

~~(b) Requests for exceptions to the rules shall be submitted to the applicable zone office.~~

~~(c) The department may conduct a survey and consult with the MRB prior to approving an exception.~~

~~(d) Upon finding that the facility has satisfied the conditions of this rule, the department may grant an exception, to include the duration of the exception. The department will respond to a waiver request within 90 days.~~

~~(e) The facility may implement an exception only after written approval from the department.~~

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

~~§117.31. Design and Space Requirements.~~

~~(a) General.~~

~~(1) The standards in this section shall apply to all facilities that provide outpatient dialysis services. Dialysis facilities in operation on or before September 1, 2003 shall meet the design and space requirements of this section which were in effect at the time the facility was constructed.~~

~~(2) A facility must provide a physical environment that protects the health and safety of patients, personnel and the public. The physical premises 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) must meet the local building and fire safety codes as they relate to design and space requirements for safe access and patient privacy.~~

~~(3) A facility shall comply with Chapter 38 of the National Fire Protection Association 101, Code for Safety to Life from Fire in Buildings and Structures, 2000 Edition (NFPA 101), relating to new business occupancies, 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, Batterymarch Park, Quincy, Massachusetts 02169, 1-800-344-3555.~~

~~(4) Water distribution systems shall be configured as a continuous recirculation loop and designed to minimize bacterial proliferation and biofilm. A minimum of three feet per second water flow must be achieved in the distribution loop. This rule shall apply only to new facilities.~~

~~(5) Water treatment systems shall include a minimum of two carbon tanks in a series, with the total empty bed contact time (EBCT) of at least ten minutes, and the final tank providing at least five minutes EBCT.~~

~~(6) A facility shall provide a reception and information counter or desk and a waiting room separate from the patient treatment area. The waiting room shall provide adequate seating.~~

~~(7) The patient treatment area shall be designed and equipped to provide proper and safe treatment as well as privacy and comfort for patients. At a minimum, patient treatment stations shall be 70 square feet, with the smallest dimension at seven feet. The 70 square feet may include aisles or counters.~~

~~(8) If hepatitis B positive patients are treated, a separate room with its own designated machine(s), clamp(s), blood pressure cuff(s), sink(s) and other equipment shall be used.~~

~~(9) A facility shall provide a call system in patient areas outside the treatment area (e.g., patient restrooms, training rooms, and examination rooms) which is usable by a collapsed patient lying on the floor (e.g., inclusion of a pull cord). Calls shall register at and activate a visible signal in the central nurses station. Call systems which provide two-way communication shall be equipped with an indicating light at each call station which lights and remains lighted as long as the voice circuit is operating.~~

~~(10) A facility shall have separate toilet and lavatory facilities for staff and patients.~~

~~(11) A facility shall provide a private area for meetings with patients or family members.~~

~~(12) A facility shall have a room for medical examinations which includes an examination table, a work counter, and a hand washing sink or lavatory.~~

~~(13) Telephone access shall be available in the facility to patients and family members.~~

~~(14) A facility located above the ground floor must have an elevator of sufficient size to accommodate a gurney available at all times.~~

~~(15) A facility shall provide two exits remote from each other in accordance with NFPA 101, §7-5.1.3. 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.~~

~~(16) A facility shall provide a separate room for peritoneal dialysis patients if the facility provides on-site peritoneal dialysis training. This room shall include a lavatory or sink for hand washing.~~

~~(17) Doors to an isolation room or peritoneal dialysis room shall not be lockable from inside the room.~~

~~(18) Public corridor widths and all other areas where patients may traverse shall accommodate wheel chair or gurney passage.~~

~~(19) Items such as drinking fountains, telephone booths, vending machines and portable equipment (including patient care equipment) shall be located so that they do not project into, restrict, or obstruct exit corridor traffic.~~

~~(20) A facility shall utilize a ventilation system which provides adequate comfort to patients during treatment and which minimizes the potential of insect access.~~

~~(21) Floors that are subject to traffic while wet shall have nonslip surfaces.~~

~~(b) Storage areas.~~

~~(1) All storage areas shall be kept clean and orderly at all times.~~

~~(2) A facility premises shall be kept free from accumulations of combustible materials not necessary for immediate operation of the facility. Local supplies of combustible liquids shall be stored in cabinets or shelves which are well-ventilated from top to bottom.~~

~~(3) A facility shall have a separate space for wheel chair storage.~~

~~(4) A facility shall store oxygen in compliance with §4-3 of the National Fire Protection Association 99, Standard for Health Care Facilities, 1999 Edition (NFPA 99) published by the National Fire Protection Association.~~

~~(c) Provisions for the handicapped.~~

~~(1) If Texas Civil Statutes, Article 9102 applies, a facility shall be designed in accordance with 16 Texas Administrative Code, Chapter 68 (Elimination of Architectural Barriers) administered by the Texas Department of Licensing and Regulation, effective April 1, 1994.~~

~~(2) A facility shall meet applicable requirements of 29 United States Code, §794. When federal funds are used for construction, for program requirements, or for client services, the handicapped requirements of §794 will apply.~~

~~(3) A facility shall comply with the design and space requirements of the Americans with Disabilities Act, 42 United States Code, §12182(b)(2)(A)(iv) and (v) and §12183, and the regulations and guidelines promulgated under §12186(b) and (c) and §12204, effective July 28, 1991.~~

~~(d) Fire protection.~~

~~(1) All sprinkler systems, smoke detectors, and other fire fighting equipment shall be inspected and tested at least once each year to maintain it in serviceable condition. If a facility has a sprinkler system, the sprinkler system shall be installed and maintained in accordance with the National Fire Protection Association 13, Standard for the Installation of Sprinkler Systems, 1999 Edition, published by the National Fire Protection Association.~~

~~(2) A facility shall have an emergency lighting system capable of providing sufficient illumination to allow safe evacuation from the building. Battery pack systems shall be maintained and tested quarterly. If a facility maintains a back-up generator, the generator must be installed, tested and maintained in accordance with the National Fire Protection Association 110, Standard for Emergency and Standby Power Systems, 1999 Edition (NFPA 110), published by the National Fire Protection Association.~~

~~(3) A facility housed in or adjacent to a building classified as a "high hazard industrial occupancy," as defined in §40-1.4.1 of the NFPA 101, must have a special feature such as a two-hour fire wall between the facility and the other occupancy and written approval by the fire authority having jurisdiction.~~

~~(e) Construction. If construction takes place in or near occupied areas, adequate provision shall be made for the safety and comfort of patients during the construction.~~

~~(f) Other standards. A facility may impose more stringent design and space standards than the minimum standards in this section.~~

~~§117.32. Equipment.~~

~~(a) All equipment used by a facility, including backup equipment, shall be operated within manufacturer's specifications, and maintained free of defects which could be a potential hazard to patients, staff, or visitors. Maintenance and repair of all equipment shall be performed by qualified staff or contract personnel.~~

~~(1) Staff shall be able to identify malfunctioning equipment and report such equipment to the appropriate staff for immediate repair.~~

~~(2) Medical equipment that malfunctions must be clearly labeled and immediately removed from service until the malfunction is identified and corrected.~~

~~(3) Written evidence of all maintenance and repairs shall be maintained.~~

~~(4) After repairs or alterations are made to any equipment or system, the equipment or system shall be thoroughly tested for proper operation before returning to service. This testing must be documented.~~

~~(5) A facility shall comply with the federal Food, Drug, and Cosmetic Act, 21 United States Code (USC), §360i(b), concerning reporting when a medical device as defined in~~

~~21 USC §321(h) has or may have caused or contributed to the injury or death of a patient of the facility.~~

~~(b) A facility shall develop, implement and enforce a written preventive maintenance program to ensure patient care related equipment used in a facility or provided by a facility for use by the patient in the patient's home receives electrical safety inspections, if appropriate, and maintenance at least annually or more frequently as recommended by the manufacturer. The preventive maintenance may be provided by facility staff or by contract.~~

~~(c) At least one complete dialysis machine shall be available on-site as backup for every ten dialysis machines in use. At least one of these backup machines must be completely operational during hours of treatment. Machines not in use during a patient shift may be counted as backup except at the time of an initial or an expansion survey.~~

~~(d) If pediatric patients are treated, a facility shall use equipment and supplies, to include blood pressure cuffs, dialyzers, and blood tubing, appropriate for this special population.~~

~~(e) All equipment and appliances shall be properly grounded in accordance with the National Fire Protection Association 99, Standard for Health Care Facilities, §§3-3.2.1.2(a)(2) and 7-5.1, 1999 Edition (NFPA 99), 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, Batterymarch Park, Quincy, Massachusetts 02169, 1-800-344-3555.~~

~~(f) Extension cords and cables shall not be used for permanent wiring.~~

~~(g) A facility shall have emergency equipment and supplies immediately accessible in the treatment area:~~

~~(1) At a minimum, the emergency equipment and supplies shall include the following:~~

- ~~(A) oxygen;~~
- ~~(B) ventilatory assistance equipment, to include airways, manual breathing bag, and mask;~~
- ~~(C) suction equipment;~~
- ~~(D) supplies specified by the medical director;~~
- ~~(E) electrocardiograph; and~~
- ~~(F) automated external defibrillator.~~

~~(2) If pediatric patients are treated, the facility shall have the appropriate type and size emergency equipment and supplies listed in paragraph (1) of this subsection for this special population.~~

~~(3) A facility shall establish, implement, and enforce a policy for the periodic testing and maintenance of the emergency equipment. Staff shall properly maintain and test the emergency equipment and supplies and document the testing and maintenance.~~

~~§117.33. Water Treatment, Dialysate Concentrates and Reuse.~~

~~(a) Compliance required. A facility shall meet the requirements of this section. 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 contaminants that may be found in improperly prepared dialysate, to ensure that the dialysate is correctly formulated and meets the requirements of all applicable quality standards.~~

~~(2) The facility owner and medical director must each assure that policies and procedures related to water treatment, dialysate and reuse are understandable and accessible to the operator(s) 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 must be informed prior to any alteration of, or any device being added to, the water system.~~

~~(b) Water treatment. 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 described in 30 Texas Administrative Code, §290.104 (Control Tests), §290.105 (Maximum Contaminant Levels (MCLs) for Microbiological Contaminants), and §290.106 (Bacteriological Monitoring) as adopted by the Texas Commission on Environmental Quality.~~

~~(3) The physical space in which the water treatment system is located must be adequate to allow for maintenance, testing, and repair of equipment. If mixing of dialysate is performed in the same area, the physical space must also be adequate to house and allow for the maintenance, testing, and repair of the mixing equipment and for performing the mixing procedure.~~

~~(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 in §4.2.1 (concerning Water Bacteriology) and §4.2.2 (concerning Maximum Level of Chemical Contaminants) of the American National Standard, Water Treatment Equipment for Hemodialysis Applications, August 2001 Edition, published by the Association for the Advancement of Medical Instrumentation (AAMI). All documents published by the AAMI as referenced in this section may be obtained by writing the following address: 1110 North Glebe Road, Suite 220, Arlington, Virginia 22201.~~

~~(5) Written policies and procedures for the operation of the water treatment system must be developed and implemented. Parameters for the operation of each component of the water treatment system must be developed in writing and known to the operator. Each major water system component shall be labeled in a manner that identifies the device; describes its function, how performance is verified and actions to take in the event performance is not within an acceptable range.~~

~~(6) The materials of any components of water treatment systems (including piping, storage, filters and distribution systems) that contact the purified water shall not interact chemically or physically so as 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.~~

~~(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. Monitors or specific test procedures to verify removal of additives shall be provided and documented.~~

~~(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/chloramine, the water treatment system shall include reverse osmosis membranes or deionization tanks and a minimum of one carbon tank.~~

~~(A) Reverse osmosis membranes, if used, shall meet the standards in §4.3.7 (concerning Reverse Osmosis) of the American National Standard, Water Treatment Equipment for Hemodialysis Applications, August 2001 Edition, published by the AAMI.~~

~~(B) Deionization systems.~~

~~(i) Deionization systems, if used, shall be monitored continuously to produce water of one megohm-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 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 deionizer.~~

~~(iii) A minimum of two deionization (DI) tanks in series shall be used with resistivity monitors including audible and visual alarms placed pre and post the final DI tank in the system. The alarms must be 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.~~

~~(C) Carbon tanks.~~

~~(i) The carbon tanks must contain acid washed carbon, 30-mesh or smaller with a minimum iodine number of 900.~~

~~(ii) A minimum of two carbon adsorption beds shall be installed in a series configuration.~~

~~(iii) The total empty bed contact time (EBCT) shall be at least ten minutes, with the final tank providing at least five minutes EBCT. 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 mg/l is verified before each treatment.~~

~~(iv) A means shall be provided to sample the product water immediately prior to the final bed(s). Water from this port(s) must be tested for chlorine/chloramine levels immediately prior to each patient shift.~~

~~(v) All samples for chlorine/chloramine testing must be drawn when the water treatment system has been operating for at least 15 minutes.~~

~~(vi) 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/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 tank(s) and final tank(s) shall require testing to be performed at the final exit and replacement of the initial tank(s).~~

~~(vii) In a system without a holding tank, if test results at the exit of the final tank(s) 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/chloramine and the medical director shall be notified. In systems with holding tanks, if the holding tank tests <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.

~~(viii) If means other than granulated carbon are used to remove chlorine/chloramine, the facility's governing body must approve such use in writing after review of the safety of the intended method for use in hemodialysis applications. If such methods include the use of additives, there must 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) Timers. If used, the face(s) of timer(s) used to control any component of the water treatment or dialysate delivery system shall be visible to the operator at all times. Written evidence that timers are checked for operation and accuracy each day of operation must 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) Storage tanks. 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. 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 recommended by the manufacturer. A log sheet shall be used to record monitoring.~~

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

~~(16) The water treatment system must 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 as 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 must assure that the lowest rate accepted would provide product water in compliance with §4.2.2 (concerning Maximum Level of Chemical Contaminants) of the American National Standard, Water Treatment Equipment for Hemodialysis Applications, August 2001 Edition published by the AAMI.~~

~~(18) A facility shall maintain written logs 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.~~

~~(A) Frequency. Microbiological testing shall be conducted monthly and following any repair or change to the water treatment system. For a newly installed water distribution system, or when a change has been made to an existing system, weekly testing shall be conducted for one month to verify that bacteria and endotoxin levels are consistently within the allowed limits.~~

~~(B) Sample sites. 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 dialysate mixing, and the end of the distribution piping.~~

~~(C) Technique. Samples shall be collected immediately before sanitization/disinfection of the water treatment system and dialysis machines. Water testing results shall be routinely trended and reviewed by the Medical Director in order to determine if results seem questionable or if there is an opportunity for improvement. The Medical Director or the CQI Committee shall determine if there is a need for retesting. Repeated results of "no growth" 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) Expected results. Product water used to prepare dialysate, concentrates from powder, or to reprocess dialyzers for multiple use, shall contain a total viable microbial count less than 200 CFU/ml and an endotoxin concentration less than 2 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.~~

~~(E) Required action for unacceptable results. If the action levels described at paragraph (D) are observed in the product water, corrective measures shall be taken promptly to reduce the levels into an acceptable range.~~

~~(F) Records. All bacteria and endotoxin results shall be recorded on a log sheet in order to identify trends that may indicate the need for corrective action.~~

~~(20) Ozone generators. If ozone generators are used to disinfect any portion of the water or dialysate delivery system, 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. Records of all testing must be maintained in a log.

~~(21) Hot Water Disinfection Systems. If used, hot water disinfection systems shall be monitored for temperature and time of exposure to hot water as specified by the manufacturer. Temperature of the water shall be recorded 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.~~

~~(22) After chemical disinfection, means shall be provided to restore the equipment and the system in which it is installed to a safe condition relative to residual disinfectant prior to the product water being used for dialysis applications.~~

~~(23) Water Analysis. Samples of product water must be submitted for chemical analysis every six months and must demonstrate that the quality of the product water used to prepare dialysate, concentrates from powder, or to reprocess dialyzers for multiple use, meets §4.2.2 (concerning Maximum Level of Chemical Contaminants) of the American National Standard, Water Treatment Equipment for Hemodialysis Applications, August 2001 Edition, published by the AAMI.~~

~~(A) Samples for chemical analysis shall be collected at the end of the water treatment components and 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 must draw samples at the most distal point for each water distribution loop on a one time basis.~~

~~(B) Additional chemical analysis shall be submitted if substantial changes are made to the water treatment system or if the percent rejection of a reverse osmosis system decreased 5.0% or more from the percent rejection measured at the time the water sample for the preceding chemical analysis was taken.~~

~~(24) Facility records must include all test results and evidence that the medical director has reviewed the results of the water quality testing and directed corrective action when indicated.~~

~~(25) Only persons qualified by the education or experience described in §117.44(f) of this title (relating to Qualifications of Staff) may operate, repair, or replace components of the water treatment system.~~

~~(e) Dialysate.~~

~~(1) Quality control and quality assurance procedures shall be established 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, or the concentrate family or concentrate manufacturer is changed, samples shall be sent to a laboratory for verification.~~

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

~~(4) Bacteriological testing.~~

~~(A) Frequency. 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 shall be cultured monthly until results not exceeding 200 colony forming units per milliliter are obtained for three consecutive months, then quarterly samples shall be cultured.~~

~~(B) Acceptable limits. 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) Action to be taken. Disinfection and retesting shall be done when bacterial or endotoxin counts exceed the action levels. Additional samples shall be collected when there is a clinical indication of a pyrogenic reaction and/or septicemia.~~

~~(5) Only a 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.~~

~~(6) Materials compatibility. 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 so as 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) Storage of acid concentrates. Facility policies shall address means to protect stored acid concentrates from tampering or from degeneration due to exposure to extreme heat or cold.~~

~~(8) Bulk storage tanks. Procedures to control the transfer of acid concentrates from the delivery container to the storage tank and prevent the inadvertent mixing of different~~

concentrate formulations shall be developed, implemented and enforced. The storage tanks shall be clearly labeled.

~~(9) Concentrate mixing systems.~~

~~(A) Concentrate mixing systems shall include a purified water source, a suitable drain, and a ground fault protected electrical outlet.~~

~~(B) Operators of mixing systems shall use personal protective equipment as specified by the manufacturer during all mixing processes.~~

~~(C) The manufacturer's instructions 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.~~

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

~~(E) Systems for preparing either bicarbonate or acid concentrate from powder shall be monitored according to the manufacturer's instructions.~~

~~(F) Concentrates shall not be used, or transferred to holding tanks or distribution systems, until all tests are completed.~~

~~(G) If a facility designs its own system for mixing concentrates, procedures shall be developed and validated using an independent laboratory to ensure proper mixing.~~

~~(10) Acid concentrate mixing systems.~~

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

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

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

~~(D) 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.~~

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

~~(11) Bicarbonate concentrate mixing systems.~~

~~(A) 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.~~

~~(B) Bicarbonate concentrate mixing tanks shall not be pre-filled the night before use.~~

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

~~(D) Unused portions of bicarbonate concentrate shall not be mixed with fresh concentrate.~~

~~(E) At a minimum, bicarbonate distribution systems shall be disinfected weekly. More frequent disinfection shall be done if required by the manufacturer, or if dialysate culture results are above the action level.~~

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

~~(i) jugs shall be emptied of concentrate, rinsed and inverted to drain at the end of each treatment day;~~

~~(ii) at a minimum, jugs shall be disinfected weekly, more frequent disinfection shall be considered by the facility quality management committee if dialysate culture results are above the action level; and~~

~~(iii) following disinfection, jugs shall be drained, rinsed free of residual disinfectant, and inverted to dry. Testing for residual disinfectant should be done and documented.~~

~~(12) Labeling of concentrate containers. All mixing tanks, bulk storage tanks, dispensing tanks and containers for single hemodialysis treatments shall be labeled as to the contents.~~

~~(A) Mixing tanks. 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/dispensing tanks. These tanks shall be permanently labeled to identify the chemical composition or formulation of their contents.~~

~~(C) Single machine containers. 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) Records of concentrate mixing. Permanent records of batches produced shall be maintained to include the concentrate formula produced, the volume of the batch, lot number(s) of powdered concentrate packages, the manufacturer of the powdered concentrate, date and time of mixing, test results, person performing mixing, test results, and expiration date (if applicable).~~

~~(14) Maintenance of dialysate mixing systems. If dialysate concentrates are prepared in the facility, the manufacturers' recommendations shall be followed regarding any preventive maintenance. Records shall be maintained indicating the date, time, person performing the procedure, and the results (if applicable).~~

~~(d) Reuse of hemodialyzers and related devices.~~

~~(1) Reuse practice in a facility must comply with the American National Standard, Reuse of Hemodialyzers, 1993 Edition published by the AAMI.~~

~~(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.~~

~~(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 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 that 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, the opportunity to tour the reuse area, and the opportunity to have questions answered.~~

~~(10) A facility shall restrict the reprocessing room to authorized personnel.~~

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

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

~~(1) appoint a medical director for the centralized reprocessing facility;~~

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

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

~~(4) adopt, implement, and enforce policies to ensure that the transfer and transport of used and reprocessed dialyzers to and from the off-site location does not increase contamination of the dialyzers, staff, 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 department staff access to the off-site reprocessing site as part of a facility inspection.~~

~~§117.34. 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 HIV and Hepatitis B Virus by Health Care Workers).~~

~~(B) Facility staff shall wash their hands before and after each patient contact in which there is a potential exposure to blood or body fluids. Location and arrangement of hand washing facilities shall permit ease of access and proper use.~~

~~(i) Hand washing sinks shall be readily accessible in each patient care area.~~

~~(ii) All fixtures and lavatories shall be trimmed with valves which can be operated without the use of hands. There shall be sufficient clearance for the operation of blade type handles, if they are used.~~

~~(iii) Provisions for hand drying shall be included at all hand washing facilities.~~

~~(C) 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.~~

~~(2) Documentation and coordination of infection control activities.~~

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

~~(B) A facility shall develop and maintain 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 assurance program described in §117.41 of this title (relating to Quality Assurance for Patient Care). The record shall include trends, corrective actions, and improvement actions taken.~~

~~(3) Smoking policy. The facility shall establish, implement, and enforce a smoking policy.~~

~~(b) Environmental infection control.~~

~~(1) General procedures.~~

~~(A) A facility shall provide and actively monitor a sanitary environment which minimizes or prevents transmission of infectious diseases.~~

~~(i) The facility shall provide a janitor's closet with space for cleaning supplies and equipment.~~

~~(ii) Wall bases in patient treatment and other areas which are frequently subject to wet cleaning methods shall be tightly sealed to the floor and the wall, impervious to water and constructed without voids that can harbor insects.~~

~~(iii) Floor materials shall be easily cleanable and have wear resistance appropriate for the location involved. In all areas subject to wet cleaning methods, floor materials shall not be physically affected by germicidal and cleaning solutions.~~

~~(iv) Wall finishes shall be washable and, in the immediate areas of plumbing fixtures, smooth and moisture resistant.~~

~~(v) Floor and wall penetrations by pipes, ducts, and conduits shall be tightly sealed to minimize entry of rodents and insects. Joints of structural elements shall be similarly sealed.~~

~~(vi) All exposed ceilings and ceiling structures in areas normally occupied by patients, staff, and visitors shall be finished so as to be cleanable with equipment used in daily housekeeping activities. Ceiling tiles stained with blood shall be cleaned or replaced.~~

~~(vii) Ceiling fans shall not be utilized in patient treatment areas.~~

~~(B) Blood spills shall be cleaned immediately or as soon as is practical with a disposable cloth and an appropriate chemical disinfectant.~~

~~(i) The surface should be subjected to intermediate level disinfection in accordance with the manufacturer's instructions, 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 the surface to be treated must be compatible with this type of chemical treatment.~~

~~(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 and the disinfectant removed.~~

~~(B) Between patient shifts, facility staff shall clean machine exteriors, treatment chairs, tourniquets, and hemostats. Blood pressure cuffs which become contaminated with blood shall be removed from service, disinfected, and allowed to dry prior to being returned to use.~~

~~(c) Medical waste and liquid/sewage waste management.~~

~~(1) The facility shall comply with the requirements set forth by the department in §§1.131-1.137 of this title (relating to Definition, Treatment and Disposition of Special Waste~~

~~from Health Care Related Facilities) and the Texas Commission on Environmental Quality's requirements in Title 30, Texas Administrative Code, §330.1004 (Generators of Medical Waste).~~

~~(2) All sewage and liquid wastes shall be disposed of in a municipal sewerage system or a septic tank system permitted by the Texas Commission on Environmental Quality in accordance with Title 30, Texas Administrative Code, Chapter 285 (On-site Sewage Facilities).~~

~~(d) Hepatitis B prevention.~~

~~(1) Prevention requirements concerning staff. The facility shall offer hepatitis B vaccination to previously unvaccinated, susceptible new staff members in accordance with 29 Code of Federal Regulations, §1910.1030(f)(1) (2) (concerning 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 the advice and consent of a patient's attending 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 vaccination.~~

~~(ii) The facility shall make available to patients literature describing the risks and benefits of the hepatitis B vaccination.~~

~~(B) Serologic screening of patients.~~

~~(i) A patient new to dialysis or returning to a facility after extended hospitalization or absence of 30 calendar days or longer shall have been screened for HBsAg within one month before or at the time of admission to the facility or have a known 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.~~

~~(ii) 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 HBsAg.~~

~~(II) Screening of HBsAg positive or anti HBs positive patients may be performed on a less frequent basis, provided that the facility's policy on this subject remains congruent with Appendices i and ii of the National Surveillance of Dialysis Associated Disease in the United States, 1993, published by the United States Department of Health and Human Services.~~

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

~~(i) The facility shall treat patients positive for HBsAg in a segregated treatment area which includes a handwashing sink, a work area, patient care supplies and equipment, and sufficient space to prevent cross-contamination to other patients.~~

~~(ii) A patient who tests positive for HBsAg shall be dialyzed on equipment reserved and maintained for the HBsAg positive patient's use only.~~

~~(iii) When a caregiver is assigned to both HBsAg negative and HBsAg positive patients, the HBsAg negative patients assigned to this grouping must be Hepatitis B antibody positive. Hepatitis B antibody positive patients are to be seated at the treatment stations nearest the isolation station and be assigned to the same staff member who is caring for the HBsAg+ patient.~~

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

~~(v) 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) Prevention requirements concerning staff.~~

~~(A) Facility staff shall be screened for tuberculosis upon employment or receiving privileges as a member of the medical staff and prior to patient contact.~~

~~(B) Subsequent screening of facility staff shall be performed after any potential exposure to laryngeal or pulmonary tuberculosis.~~

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

~~(2) Prevention requirements concerning patients.~~

~~(A) If the facility treats active pulmonary tuberculosis patients, a separate room with an isolated air handling system shall be utilized for these patients.~~

~~(B) 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.~~

~~§117.41. Quality Assurance for Patient Care.~~

~~(a) A facility shall perform a systematic, ongoing, concurrent and comprehensive review of the care provided. The review shall be specific to the facility. A facility shall adopt, implement, and enforce a quality assurance system which meets the criteria and standards described in this section.~~

~~(b) The quality assurance system shall include a quality management program which is planned with the participation of the facility's governing body; a quality control mechanism for data management and analysis; and a quality improvement mechanism to identify opportunities for improvement, develop improvement plan(s), and evaluate the implementation of the improvement plan(s).~~

~~(c) The governing body is responsible for:~~

~~(1) establishing the facility's quality mission;~~

~~(2) conducting quality planning;~~

~~(3) providing guidance and revising goals to achieve the quality mission;~~

~~(4) assuring allocation of sufficient time and resources to support the quality management program; and~~

~~(5) reviewing and monitoring the quality management activities at least quarterly.~~

~~(d) Quality management activities 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. 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 quality management activities.~~

~~(f) A facility shall conduct quality management meetings monthly or more often as necessary to identify or correct problems. At a minimum, the facility's medical director, supervising nurse, and the technical supervisor described in §117.44(f)(2) of this title (relating to Qualifications of Staff) shall participate in the quality management meetings. The quality management meetings shall be conducted separately from a patient care conference and the meetings shall be documented.~~

~~(g) The facility's quality control and quality improvement mechanisms 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;~~

~~(3) appointment of interdisciplinary improvement team(s) to:~~

~~(A) identify variation from desired outcomes;~~

~~(B) create and implement improvement plan(s);~~

~~(C) evaluate the implementation of the improvement plan(s); and~~

~~(D) continue monitoring and improvement activities until goals are achieved and data demonstrates that improvement(s) have been made and maintained; and~~

~~(4) establishment and monitoring of quality assurance indicators for key aspects of care. For each quality assurance indicator, the facility shall establish and monitor a level of performance consistent with current professional knowledge. At a minimum, the following indicators shall be monitored on an ongoing basis:~~

~~(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 dialyzer(s), water, machine(s), and dialysate; pyrogen reactions; sepsis episodes; and peritonitis rate);~~

~~(E) incidents and rate of occurrence (accidents, medication errors, adverse drug reactions, and other occurrences affecting patient(s), patient(s) family member(s), visitor(s),~~

or staff). These occurrences shall include incidents required to be reported to the director under §117.46 of this title (relating to Reports to the Director). Review of these occurrences shall include analysis of the patient history and specific circumstances to identify potential ways to prevent recurrence;

~~(F) mortality (review of each death and monitoring modality specific mortality rate(s));~~

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

~~(H) staffing (orientation, training, licensing and certification, and workload);~~

~~(I) safety (fire and disaster preparedness and disposal of special waste);~~

~~(J) medical records;~~

~~(K) clinical outcomes (laboratory indicators, hospitalizations, vascular access complications, and transplantation; and~~

~~(L) patient's quality of life to include rehabilitation.~~

~~(h) The department may review a facility's quality assurance activities to determine compliance with this section.~~

~~(1) A department surveyor shall verify that the facility has a quality management program which addresses concerns relating to quality of care provided to its patients and that facility staff know how to access the program's process.~~

~~(2) The department may not require disclosure of quality management program records except when disclosure is necessary to determine compliance with this section.~~

~~(3) The department will not use good faith efforts by the quality management program to identify and correct deficiencies relating to quality as a basis for a deficiency(ies) cited under this chapter.~~

~~§117.42. Indicators of Quality of Care.~~

~~(a) Each facility shall submit an annual report to the Texas Department of Health (department) or the department's designee to include aggregate data on specified indicators of the quality of care provided to patients. Examples of indicators include:~~

~~(1) anemia management;~~

~~(2) albumin level;~~

- ~~(3) measures of the adequacy of dialysis;~~
- ~~(4) vascular access management;~~
- ~~(5) bone disease management;~~
- ~~(6) peritonitis rate; and~~
- ~~(7) hospitalization rate.~~

~~(b) The form and data to be submitted will be specified annually by the department. The department shall provide notice to a facility of the required content for the report in sufficient time to enable facility staff to collect the data. The form required by the department will be constructed in consideration of the reports required by the Centers for Medicare and Medicaid Services and Centers for Disease Control to reduce or eliminate redundancy. The department may request data to validate the aggregate information contained in the annual report. All information gathered will be available to the department for review.~~

~~(c) Data from each facility will be reviewed and compared with statewide and national aggregate data to identify opportunities to improve care. Assistance in improving care from the department or department's designee may include feedback of comparative data, a corrective action plan, or an onsite inspection.~~

~~(d) A renewal license will not be issued to a facility until the facility's current annual report is received complete.~~

~~§117.43. Provision and Coordination of Treatment and Services.~~

~~(a) 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 and comfortable treatment environment;~~

~~(4) provided information in a manner to facilitate understanding by the patient and the patient's legal representative, family or significant other. Written patient information materials shall be available, with materials in languages other than English if the census of the facility includes more than four patients who read that primary language. In lieu of written materials in the patient's primary language, an interpreter may be provided if documentation and patient interview support that information sufficient to allow the patient to participate in the treatment has been communicated;~~

- ~~(5) informed by a physician of the patient's medical status;~~
- ~~(6) informed of all treatment modalities and settings for the treatment of end-stage renal disease;~~
- ~~(7) informed about and participates in, if desired, all aspects of care, including the right to refuse treatment, and informed of the medical consequences of such refusal;~~
- ~~(8) aware of all services available in the facility and the charges for services provided;~~
- ~~(9) informed about the facility's reuse of dialysis supplies, including hemodialyzers. If printed materials such as brochures are used to describe a facility and its services, the brochures shall contain a statement with respect to reuse;~~
- ~~(10) 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;~~
- ~~(11) provided hours of dialysis that are scheduled for patient convenience whenever feasible or possible. Consideration shall be given to a patient's work or school schedule;~~
- ~~(12) 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. A patient shall be given 30 calendar days advance notice to ensure orderly transfer or discharge, except in cases where the patient presents an immediate risk to others;~~
- ~~(13) a facility shall establish, implement and enforce a policy whereby a disruptive patient or family member or non-compliant patient is given an opportunity and assistance to improve the problematic behavior prior to dismissal from the facility. The policy will include requirements at §117.43(b)(7);~~
- ~~(14) provided protection from abuse, neglect, or exploitation as those terms are defined in §1.204 of this title (relating to Abuse, Neglect, and Exploitation Defined);~~
- ~~(15) provided information regarding advance directives and allowed to formulate such directives to the extent permitted by law. This includes documents executed under the Natural Death Act, Health and Safety Code, Chapter 672; Civil Practice and Remedies Code, Chapter 135 concerning durable power of attorney for health care; and Health and Safety Code, Chapter 674 concerning out of hospital do not resuscitate;~~
- ~~(16) aware of the mechanisms and agencies to express a complaint against the facility without fear of reprisal or denial of services. A facility shall provide to each individual who is admitted to the facility a written statement that informs the individual that a complaint against the facility may be directed to the department. The statement shall be provided at the~~

time of admission and shall advise the patient that registration of complaints may be filed with the director, Health Facility Licensing and Compliance Division, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756-3199, 1-888-973-0022. Correctional institutions shall not be required to include the 1-888 number in information provided to patients in these facilities; and

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

(b) Patient care plan.

(1) A facility shall establish, implement, and enforce a policy whereby patient services are coordinated using an interdisciplinary team approach. The interdisciplinary team shall consist of the patient's primary dialysis physician, registered nurse, social worker, and dietitian.

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

(3) The patient care plan 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 safe care.

(4) The patient care plan shall include evidence of the patient's (or patient's legal representative's) input and participation, unless they refuse to participate. At a minimum, the patient care plan shall demonstrate that the content was discussed with the patient or the patient's legal representative by a member of the interdisciplinary team.

(5) The patient care plan shall be developed within 30 days from the patient's admission to the facility and updated as indicated by any change in the patient's medical, nutritional, or psychosocial condition, or at least every six months. Evidence of the review of the patient care plan with the patient and the interdisciplinary team to evaluate the patient's progress or lack of progress toward the goals of the care plan, and interventions taken when the goals are not achieved, shall be documented and included in the patient's clinical record.

(6) A team conference may be conducted via phone conferencing. A phone care plan conference conducted with the interdisciplinary team and the patient (or their legal representative) must be documented as a phone conference.

(7) In the case of disruptive patients or family members or patients who do not conform to the treatment plan, the facility will establish, implement and enforce a process for

~~more intensive 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.~~

~~(e) Emergency preparedness.~~

~~(1) A facility shall implement written procedures which describe staff and patient actions to manage potential medical and non-medical emergencies, including but not limited to, fire, equipment failure, power outages, medical emergencies, and natural or other disasters which are likely to threaten the health or safety of facility patients, the 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 clinical staff members shall maintain current certification and competency in BCLS.~~

~~(4) A facility shall have a transfer agreement with one or more hospitals which 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 will be accepted and treated in emergencies. There shall be reasonable assurances that:~~

~~(A) the transfer or referral of patients will be effected 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 will occur within one working day; and~~

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

~~(5) A facility shall establish, implement and enforce a written plan for the protection of patients in the event of a fire.~~

~~(A) An evacuation plan shall be developed and diagrams posted in conspicuous places.~~

~~(B) The facility shall provide approved fire extinguishing equipment adequate for the conditions involved. Every portable fire extinguisher maintained in the facility shall be installed and maintained in accordance with National Fire Protection Association 10, Standard for Portable Fire Extinguishers, 1994 Edition, and the National Fire Protection Association 101, Code for Safety to Life from Fire in Buildings and Structures, 1994 Edition,~~

~~§26-3.5, published by the National Fire Protection Association, Post Office Box 9101, Batterymarch Park, Quincy, Massachusetts 02169, 1-800-344-3555. Fire extinguishers shall be refilled when necessary, kept in condition for instant use, and tagged or labeled to indicate the name, address, and telephone number of the person recharging the unit and the date of the last inspection. The hose, nozzle, gaskets, and all other parts shall be maintained in good repair at all times.~~

~~(C) The facility shall conduct fire drills at least every six months for each patient shift to include the use of alarms and equipment, and discussion with patients, visitors, employees and staff about the evacuation plan. Written reports shall be maintained to include evidence of staff and patient participation.~~

~~(D) All staff shall be familiar with the locations of fire fighting equipment. Fire fighting equipment shall be located so that a person shall not have to travel more than 75 feet from any point to reach the equipment.~~

~~(6) 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. The plan shall be reviewed by the governing body at least annually. Contact shall be made annually with a local disaster management representative 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. 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.~~

~~(7) A facility shall have an emergency lighting system capable of providing sufficient illumination to allow safe discontinuation of treatments and safe evacuation from the building. Battery pack systems shall be maintained and tested quarterly. If a facility maintains a back-up generator, the generator must be installed, tested and maintained in accordance with the National Fire Protection Association 110, Standard for Emergency and Standby Power Systems, 1993 Edition (NFPA 110), published by the National Fire Protection Association.~~

~~(8) A facility shall develop and 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.~~

~~(d) Medication storage and administration.~~

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

~~(2) Medications shall be administered only if such medication is ordered by the patient's physician.~~

~~(3) All verbal or telephone orders shall be received by a licensed nurse or physician assistant. Orders relating to a specific service (e.g. dietary services), may be received by the licensed professional responsible for providing the service (e.g. dietitian) and countersigned by the physician within 15 calendar days.~~

~~(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 maintain appropriate temperatures for such storage.~~

~~(5) A facility shall maintain an emergency stock of 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 be located in such a manner as to prevent contamination of medicines being prepared for administration and shall include a work counter and a sink.~~

~~(7) Multi-dose vials shall not be taken to a patient station. Protocols approved by the Centers for Disease Control must be used in those cases where single-use vials are entered 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. All medications shall be administered by the individual who prepares them.~~

~~(9) 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 §117.62(b) and (f) of this title (relating to Training Curricula and Instructors) and §117.63(b), (c) and (e) of this title (relating to Competency Evaluation). Such administration by dialysis technicians shall be in compliance with Chapter 157 of the Texas Occupations Code concerning the delegation of medical acts by a licensed physician in the State of Texas.~~

~~(e) Nursing services.~~

~~(1) Nursing services to prevent or reduce complications and to maximize the patient's functional status shall be provided to a patient and the patient's family or significant other.~~

~~(2) A full time supervising nurse shall be employed to manage the provision of patient care.~~

~~(3) A registered nurse shall be responsible for:~~

~~(A) conducting admission nursing assessments;~~

~~(B) conducting assessments of a patient when indicated by a question relating to a change in the patient's status or at the patient's request;~~

~~(C) participating in team review of a patient's progress;~~

~~(D) recommending changes in treatment based on the patient's current needs;~~

~~(E) facilitating communication between the patient, patient's family or significant other, and other team members to ensure needed care is delivered;~~

~~(F) providing oversight and direction to dialysis technicians and licensed vocational nurses; and~~

~~(G) participating in continuous quality improvement activities.~~

~~(4) A nurse or nurses functioning in the charge role shall be on site and available to the treatment area to provide patient care during all dialysis treatments.~~

~~(5) At least one licensed nurse shall be available on-site to provide patient care for every twelve patients or portion thereof. This may include the nurse(s) functioning in the charge role required by paragraph (4) of this subsection.~~

~~(6) 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.~~

~~(7) Sufficient direct care staff shall be on-site to meet the needs of the patients.~~

~~(A) The staffing level for a facility shall not exceed four patients per licensed nurse or patient care technician per patient shift. During treatment of eight or more patients, one of the licensed nurses qualified to function in the charge role shall not be included in this ratio.~~

~~(B) For pediatric dialysis patients, one licensed nurse shall be provided on-site for each patient weighing less than ten kilograms and one licensed nurse provided on-site for every two patients weighing from ten to 20 kilograms.~~

~~(8) A facility shall provide a nursing station(s) to allow adequate visual monitoring of patients by nursing staff during treatment.~~

~~(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. Written protocols may 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) The initial patient evaluation shall be initiated by a licensed nurse qualified to function in the charge role or a registered nurse at the time of the first treatment in the facility and completed by a registered nurse within the first three treatments.~~

~~(f) Licensed vocational nurses. This chapter does not preclude a licensed vocational nurse (LVN) from practicing in accordance with the rules adopted by the Texas Board of Vocational Nurse Examiners. 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 which meets the requirements in §117.62 of this title (relating to Training Curricula) and §117.63 of this title (relating to Competency Evaluation).~~

~~(g) Dialysis technicians. A dialysis technician providing direct patient care shall demonstrate knowledge and competency for the responsibilities specified in §117.62 of this title and §117.63 of this title.~~

~~(h) Nutrition services.~~

~~(1) Nutrition services shall be provided to a patient and the patient's caregiver(s) in order 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 a 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. 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 continuous quality improvement activities; and~~

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

~~(3) The collection of objective and subjective data to assess nutrition status shall occur 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 admission to the facility, whichever occurs later.~~

~~(4) A nutrition reassessment shall be conducted annually or more often if indicated.~~

~~(5) Each facility shall employ or contract with a dietitian(s) to provide clinical nutrition services for each patient. One full-time equivalent of dietitian time shall be available for up to 100 patients with the maximum patient load per full-time equivalent of dietitian time being 125 patients.~~

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

~~(i) 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;~~

~~(B) participating in team review of patient progress;~~

~~(C) recommending changes in treatment based on the patient's current psychosocial needs;~~

~~(D) providing case work and group work services to patients and their families in dealing with the 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 utilize them; and~~

~~(F) participating in continuous quality improvement activities.~~

~~(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 psychosocial reassessment shall be conducted annually or more often if indicated.~~

~~(5) Each facility shall employ or contract with a social worker(s) to meet the psychosocial needs of the patients. One full-time equivalent of qualified social worker time shall be available for each 100 patients. If the facility provides additional staff who perform supportive services (e.g. assistance with financial services/ transportation), the maximum patient load per full-time equivalent of qualified social worker time may be 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.~~

~~(j) Medical services.~~

~~(1) Medical director. The medical director is responsible for:~~

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

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

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

~~(D) developing and implementing all policies required by this chapter.~~

~~(2) Medical staff.~~

~~(A) Each patient shall be under the care of a physician 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 once every two weeks during the patient's treatment time. Home patients shall be seen by a physician at least every three months. The record of these contacts shall include evidence of assessment for new and recurrent problems and review of dialysis adequacy, monthly for in facility patients and quarterly for home patients.~~

~~(D) 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.~~

~~(E) Orders for treatment shall be in writing and signed by the prescribing physician. Routine orders for treatment shall be updated at least annually.~~

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

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

~~(F) If advanced practice nurses or physician assistants are utilized:~~

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

~~(ii) the advanced practice nurse or physician assistant may not replace the physician in participating in patient care planning or in quality management activities; and~~

~~(iii) the treating physician shall be notified and direct the care of patient medical emergencies.~~

~~(k) Home dialysis (self dialysis):~~

~~(1) If a facility provides self dialysis training, a registered nurse with at least 12 months clinical experience and six months experience in home dialysis shall be responsible for training the patient or family. When other personnel assist in the training, supervision by the registered nurse shall be demonstrated.~~

~~(2) For a patient who performs self dialysis at home, the following services shall be provided:~~

~~(A) a yearly physical examination;~~

~~(B) monthly contact from facility staff by telephone calls or clinic visits;~~

~~(C) a clinic visit at least every three months;~~
~~(D) communication with the appropriate interdisciplinary team member(s);~~
~~(E) routine laboratory work according to facility policy;~~
~~(F) a mechanism to contact staff at any time in the event of an emergent need; and~~
~~(G) surveillance of the patient's home adaptation, including provisions for visits to the home.~~

~~(3) The facility shall provide directly or under arrangement the following services.~~

~~(A) For hemodialysis, the required services are:~~
~~(i) consultation for the patient with a registered nurse, social worker and a dietitian;~~
~~(ii) a record keeping system which assures continuity of care;~~
~~(iii) installation and maintenance of equipment;~~
~~(iv) testing and appropriate treating of the water used for dialysis;~~
~~and~~
~~(v) ordering of supplies on an ongoing basis.~~

~~(B) For continuous ambulatory peritoneal dialysis, the required services are:~~
~~(i) consultation for the patient with a registered nurse, a social worker and a dietitian;~~
~~(ii) a record keeping system which assures continuity of care; and~~
~~(iii) ordering of supplies on an ongoing basis.~~

~~(C) For continuous cycling peritoneal dialysis, the required services are:~~
~~(i) consultation for the patient with a registered nurse, a social worker and a dietitian;~~
~~(ii) a record keeping system which assures continuity of care;~~

~~(iii) installation and maintenance of equipment; and~~

~~(iv) ordering of supplies on an ongoing basis.~~

~~(1) Temporary and transient admissions.~~

~~(1) Temporary admissions. If a facility dialyzes a patient who is normally dialyzed in another local facility, the referring and receiving facilities shall meet the requirements in this paragraph.~~

~~(A) The individual to be treated by the receiving facility must be a patient of a physician who is a member of the medical staffs of the referring and receiving facilities.~~

~~(B) The referring and receiving facilities shall establish, implement, and enforce written policies and procedures for communication of medical information and transfer of clinical records between facilities.~~

~~(C) The receiving facility shall continuously evaluate staffing levels and utilize this information in determining whether to accept a temporary admission for treatment.~~

~~(D) The receiving facility shall obtain the information described in §117.45(e) of this title (relating to Clinical Records) prior to providing dialysis. However, if the referring facility is closed when the patient's need for dialysis treatment is identified, the receiving facility may provide dialysis with, at a minimum, the following information:~~

~~(i) orders for treatment;~~

~~(ii) hepatitis B status;~~

~~(iii) 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 §117.45(e) of this title.~~

~~(E) In the event a temporary 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.~~

~~(2) Transient admissions. If a facility dialyzes a patient who is normally dialyzed in a distant facility, the facility shall meet the requirements in this paragraph.~~

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

~~(B) The facility shall obtain the information described in §117.45(e) of this title (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:

~~(i) evidence of evaluation of the patient by a physician on the staff of the facility;~~

~~(ii) orders for treatment;~~

~~(iii) hepatitis B status;~~

~~(iv) 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 §117.45(e) of this title.~~

~~(C) 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.~~

~~(m) Laboratory services. 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.~~

~~(n) Illegal remuneration prohibited. A facility shall not violate the Health and Safety Code, §161.191, et seq. concerning the prohibition on illegal remuneration for the purpose of securing or soliciting patients or patronage.~~

~~(o) Do not resuscitate orders. The facility shall comply with the Health and Safety Code, Chapter 674 concerning out-of-hospital do not resuscitate orders.~~

~~(p) Audits of billing. A facility shall develop, implement, and enforce a compliance policy for monitoring its receipt and expenditure of state or federal funds.~~

~~(q) Student health care professionals. 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. If the student is licensed (e.g., a licensed vocational nurse attending a registered nurse program for licensure as a registered nurse) the facility shall ensure that the administration of any medication(s) is within the student's licensed scope of practice.~~

~~(2) A student may administer medications only if:~~

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

~~(B) the instructor is on the premises and immediately supervises the administration of medication by an unlicensed student and the administration of such medication is within the instructor's licensed scope of practice.~~

~~(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.~~

~~(r) Complaint resolution. 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 must be completed within 30 calendar days after the facility receives the complaint, unless the facility has and documents reasonable cause for a delay.~~

~~§117.44. Qualifications of Staff.~~

~~(a) General.~~

~~(1) A written orientation program to familiarize all new employees (including office staff) with the facility, its policies, and job responsibilities shall be developed and implemented.~~

~~(2) In order to assure that each new direct patient care staff member is provided sufficient time to become familiar with the facility, the orientation program provided by the facility shall be a minimum time of two weeks for individuals with previous dialysis experience. For new direct patient care staff members with no previous dialysis experience, the orientation program shall be two weeks plus additional orientation time as determined by the facility.~~

~~(3) 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 must be on file in each facility where the shared employee works.~~

~~(4) A facility shall provide registered nurses with no previous dialysis experience an orientation program of a minimum of six weeks. For these registered nurses, the six-week orientation 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:~~

~~(A) fluid, electrolyte and acid-base balance;~~

- ~~(B) kidney disease and treatment;~~
- ~~(C) dietary management of kidney disease;~~
- ~~(D) principles of dialysis;~~
- ~~(E) dialysis technology;~~
- ~~(F) venipuncture technique;~~
- ~~(G) care of the dialysis patient;~~
- ~~(H) psychological, social, financial, and physical complications of long-term dialysis;~~
- ~~(I) prevention of hepatitis and other infectious diseases; and~~
- ~~(J) risks and benefits of reuse (if reuse is practiced).~~

~~(5) Each licensed nurse and dialysis technician shall demonstrate competency through written and skills testing annually. 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.~~

~~(6) A facility shall maintain documentation to demonstrate that each staff member providing patient care completes at least five hours of continuing education related to end-stage renal disease annually. Continuing education may be provided by facility staff.~~

~~(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 governing body of a facility shall designate a medical director.~~

~~(3) 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.~~

~~(4) If an advanced practice nurse or physician assistant is utilized, such individuals shall meet the requirements established by the Board of Nurse Examiners (for an advanced practice nurse) or the Board of Medical Examiners (for a physician assistant).~~

~~(c) Nursing staff.~~

~~(1) Each licensed nurse shall have a current Texas license to practice nursing.~~

~~(2) Each nurse assigned charge responsibilities shall be a registered nurse and have six months experience in hemodialysis obtained within the last 24 months. An RN 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. The responsibilities of an RN functioning as a charge nurse shall include:~~

~~(A) making daily assignments based on patient needs;~~

~~(B) providing immediate supervision of direct patient care;~~

~~(C) making patient assessments when indicated; and~~

~~(D) communicating with the physician(s), social worker(s) and dietitian(s).~~

~~(3) The following provisions create an exception to the requirement that the licensed nurse functioning in the charge role be a registered nurse.~~

~~(A) A licensed vocational nurse (LVN) who meets one of the following requirements may function in the charge role:~~

~~(i) the LVN was employed in a facility as of September 1, 1996, and had two years full time experience functioning in the charge role in a facility prior to September 1, 1996; or~~

~~(ii) the LVN has two years full time experience in hemodialysis, is certified as a hemodialysis nurse by a nationally recognized board (e.g. Board of Nephrology Nurse and Technician Examination), has completed a facility based training program for the charge role, and has demonstrated competence in the charge role.~~

~~(B) The responsibilities of an LVN functioning in the charge role, as delegated by the medical director, shall include:~~

~~(i) making daily assignments based on protocols to allow change of assignments based on patient needs;~~

~~(ii) providing immediate supervision of the direct patient care provided by dialysis technicians;~~

~~(iii) monitoring patients for changes in condition and notifying a RN or physician of such changes;~~

~~(iv) communicating with the physician(s), social worker(s) and dietitian(s).~~

~~(C) A LVN with two years full time experience in dialysis may function in the charge role in the temporary absence of the nurse functioning in the charge role at the facility.~~

~~(D) If a LVN is functioning in the charge role, in order to provide the direct supervision of dialysis technicians required by the statute, the facility's full time supervising nurse shall establish written protocols addressing the supervision of the technicians. The implementation of the protocol shall be considered to constitute direct supervision of the technicians by the RN. In the alternative, an RN who is the instructor of the facility's dialysis technician course, another RN, or a physician may provide onsite, direct supervision of the dialysis technicians.~~

~~(E) If a facility uses LVNs in the charge role, there must be written protocols specific to the facility to guide actions to be taken by the LVN functioning in the charge role in the event a patient's condition changes during treatment. These protocols must be approved by the medical director and be congruent with the state practice acts for registered nurses and licensed vocational nurses.~~

~~(F) In accordance with Title 22, Texas Administrative Code (TAC), §217.12 relating to designations for registered nurse/titles deemed misleading, an LVN functioning in the charge role may not be titled a "charge nurse."~~

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

~~(d) Nutritional staff. Each dietitian shall be licensed in Texas, be eligible for registration by the Commission on Dietetic Registration of the American Dietetic Association, and have one year of experience in clinical dietetics after becoming eligible for registration.~~

~~(e) Social services staff. Each social worker shall:~~

~~(1) be licensed as a social worker under the Human Resources Code, Chapter 50, and hold a masters 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 September 1, 1976, and have established a consultative relationship with a social worker who has a masters degree in social work from a graduate school of social work accredited by the Council on Social Work Education.~~

~~(f) Technical staff. 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(s) meets the minimum qualifications for each required level of responsibility as described in this subsection.~~

~~(1) All staff assigned technical responsibilities. Only individuals qualified by training, education, or experience may operate, repair, or replace components of the systems utilized 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. For technical staff employed by the facility for two or more years prior to the effective date of these rules, this requirement is waived; 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 §117.62(a) and (b) of this title (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 written testing.~~

~~(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 written testing. 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. The continuing education may be obtained through informal or formal education programs and shall be documented in facility files.~~

~~(2) Technical supervisory staff. The technical supervisor is responsible for the 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 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 course(s) as established for each technical area.~~

~~(ii) The training course(s) 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.~~

~~(3) 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 so as 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 which 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;~~

dialysis;

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

(VI) current water standards;

(VII) source water characteristics;

water treatment vendors;

(VIII) communication with source water agencies and

(IX) selection of water treatment equipment;

carbon adsorption and reverse osmosis;

(X) water purification equipment to include filtration;

(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; and

(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.~~

~~(4) Equipment maintenance and repair staff. 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 the following minimum components:~~

~~(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.~~

~~(5) Reprocessing staff. 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 which includes the components in the American National Standard, Reuse of Hemodialyzers, 1993 Edition, §5.2.1 published by the Association for the Advancement of Medical Instrumentation, 3330 Washington Boulevard, Suite 400, Arlington, Virginia 22201; and~~

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

~~§117.45. Clinical Records.~~

~~(a) A facility shall establish and maintain 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 which is separate from all patient treatment areas. The clinical records area shall have adequate space for reviewing, dictating, sorting, or recording records. If electronic imaging devices are employed (i.e., microfilm or optical disc), the clinical records area shall have adequate space for transcribing records in the electronic format. 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 medical records are treated with confidentiality.~~

~~(4) Signature stamps may not be used to authenticate medical record entries.~~

~~(5) Clinical records may be preserved electronically. Computerized 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 on microfilm, optical disc or other electronic means and may be stored off-site as long as security is maintained and the record is readily retrievable for review by the department or the department's designee.~~

~~(7) 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) patient care plans, including evidence of 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 30 days before or within two weeks after any patient's admission to the facility. For a patient new to dialysis, the physician(s) responsible for the dialysis care shall complete the history and physical. For an established dialysis patient, the history and physical may be completed by a nurse practitioner or physician assistant. Prior to the first treatment in the facility, the physician shall inform the nurse functioning in the charge role of at least the patient's diagnoses, medications, hepatitis status, allergies, and dialysis prescription. The clinical record shall include this data.~~

~~(c) Progress notes shall provide an 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 or at least every six months.

~~(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. Such reports 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 patient care plan;~~

~~(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 patient care plan. 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 the department written~~

~~notification of the location of the clinical records and the name and address of the clinical records custodian.~~

~~§117.46. Reports to the Director.~~

~~(a) A facility shall report the following occurrence(s) to the department within ten working days of the occurrence(s):~~

~~(1) an accident or incident resulting in the death of a patient; or~~

~~(2) conversion of staff or a patient to HbsAg positive.~~

~~(b) An occurrence listed in subsection (a) of this section shall be reported to the Director, Health Facility Licensing and Compliance Division, 1100 West 49th Street, Austin, Texas, 78756-3199, telephone number 512-834-6646, fax number 512-834-4514. The report to the director shall be on a form provided by the department and include the information requested on the form. The facility may reproduce the form as needed to maintain an adequate supply.~~

~~§117.61. 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.~~

~~§117.62. Training Curricula and Instructors.~~

~~(a) Specific objectives for training curricula. Each training program for dialysis technicians shall develop a written curriculum with objectives specified for each section.~~

~~(b) Components of training curricula. The training curricula for dialysis technicians shall include the following minimum components:~~

~~(1) introduction to dialytic therapies to include history and major issues as follows:~~

~~(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 which may result in inadequate treatment;~~

~~(D) observing and reporting patient reactions to treatment;~~

~~(E) glucose monitoring and hemoglobin/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 control, and continuous quality improvement;~~

~~(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 Standard, Water Treatment Equipment for Hemodialysis Applications, August 2001 Edition, published by the American Association for the Advancement of Medical Instrumentation (AAMI), 1110 North Glebe Road, Suite 220, Arlington, Virginia 22201;~~

~~(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, quality control, universal precautions, and water treatment; and~~

~~(C) standards for reuse as described in the American National Standard, Reuse of Hemodialyzers, 1993 Edition, published by the AAMI;~~

~~(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) quality assurance and continuous quality improvement (QA/CQI) to include:~~

~~(A) role of the technician in quality assurance activities;~~

~~(B) principles of QA/CQI; and~~

~~(C) the importance of ongoing quality control activities in assuring safe dialysis treatments are provided to patients.~~

~~(e) Additional responsibilities:~~

~~(1) If a dialysis technician is to assist with training or treatment of peritoneal dialysis patients, the following content must 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 must 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 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 complications; and~~
- ~~(v) information to report and record; and~~

~~(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) Roster. A roster of attendance for each training class shall be maintained by the instructor.~~

~~(e) Trainee evaluation. Each trainee shall be evaluated on a weekly basis during the training program to ascertain the trainee's progress.~~

~~(f) Written examination. The dialysis technician trainee shall complete a written examination. The examination shall encompass the content required in subsection (b) of this section. If the dialysis technician trainee will cannulate access and administer medications, the examination shall encompass the content described in subsection (c) of this section. A score of 80% is required on the written examination(s) 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) Instructors. 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) Preceptors. 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) Length of training. For persons with no previous experience in direct patient care, a minimum of 80 clock hours of classroom education and 200 clock hours of directly 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.~~

~~§117.63. Competency Evaluation.~~

~~(a) Each facility shall appoint a training review committee to consist of at least the medical director, supervising nurse, technical supervisor, and administrator. This committee shall review the training records of each trainee, including tests and skills checklists, hear comments from the training instructor(s) and preceptor(s), and validate that the trainee has successfully completed the training program.~~

~~(b) An individual who completed the facility's orientation program and was determined by the facility to be qualified to deliver dialysis patient care before September 1, 1996, may qualify as a dialysis technician by passing the written examination described in §117.62(f) of this title (relating to Training Curricula and Instructors) and demonstrating competency by completion of the skills checklist described in subsection (c) of this section. Current certification as a dialysis technician by a nationally recognized testing organization may be substituted for the written examination.~~

~~(c) The supervising nurse or a registered nurse who qualifies as an instructor under §117.62(e)(2) of this title 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 predialysis 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) obtaining 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;~~

~~(6) performing a transfer tubing change; and~~

~~(7) setting up and operating continuous cycling peritoneal dialysis equipment.~~

~~(e) For dialysis technician trainees who will be cannulating dialysis access and administering heparin and normal saline, 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; and~~
- ~~(H) securing needles;~~

~~(2) administration of heparin 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; and~~

~~(4) administration of lidocaine to include:~~

- ~~(A) checking the patient's prescription;~~

~~(B) identifying the correct vial of medication;~~

~~(C) preparing the dose;~~

~~(D) administering the dose; and~~

~~(E) observing for complications.~~

~~(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 other than an LVN is to cannulate a dialysis access, administer normal saline, heparin, lidocaine 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 the Medical Practice Act, Article 4495b, §3.06(d).~~

~~§117.64. Documentation of Competency.~~

~~(a) A training program is required to provide a document to the trainee on the 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 §117.63(c), (d), and (e) of this title (relating to Competency Evaluation) within two weeks of hire.~~

~~§117.65. Prohibited Acts.~~

~~(a) Performance of the following acts by any dialysis technician who is not a licensed vocational nurse qualified to function in the charge role is prohibited:~~

~~(1) initiation of patient education; or~~

~~(2) alteration of ordered treatment, including shortening of the treatment time.~~

~~(b) Performance of the following acts by a dialysis technician who is not a licensed vocational nurse is prohibited:~~

~~(1) initiation or discontinuation of dialysis via a central catheter, manipulation of a central catheter, or dressing changes for a central catheter;~~

~~(2) administration of medications other than normal saline, heparin, lidocaine, or oxygen, which may only be administered in the course of a routine dialysis treatment;~~

~~(3) administration of blood or blood products;~~

~~(4) performance of non-access site arterial puncture;~~

~~(5) acceptance of physician orders;~~

~~(6) provision of hemodialysis treatment to pediatric patients under 35 kilograms;~~

~~(7) alteration of the level of electrolytes in dialysate through the use of additive(s) ("spiking"); or~~

~~(8) initiation or discontinuation of dialysis via an implantable port.~~

~~§117.81. Corrective Action Plan.~~

~~(a) Medical review board. The medical review board (MRB) may assist the Texas Department of Health (department) 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.~~

~~(1) At the conclusion of an on-site inspection, the department may refer a facility to the MRB if the results of the inspection present concerns related to patient outcomes.~~

~~(2) The MRB will review data from facilities' annual reports and identify to the department facilities with potential quality issues. 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) Corrective action plan. A corrective action plan may be used in accordance with §251.061 of the statute. This subsection is consistent with §251.061 of the statute.~~

~~(1) The department may use a corrective action plan as an alternative to enforcement action under the statute.~~

~~(2) Before taking enforcement action, the department 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 a 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.~~

~~(3) The department may use a level one, level two, or level three corrective action plan, as determined by the department in accordance with this subsection, after inspection of the facility.~~

~~(A) If deficiencies are identified after an inspection, the surveyor may request a corrective action plan. The surveyor shall identify the level of corrective action plan required.~~

~~(B) The facility shall develop and implement a corrective action plan approved by the department. The facility shall provide the corrective action plan within the time frames specified by the department. A corrective action plan shall identify dates by which compliance will be accomplished. The dates by which compliance will be accomplished on a corrective action plan shall not exceed 45 days from the date the deficiency is cited.~~

~~(C) The department shall review and approve the corrective action plan. If the corrective action plan is not acceptable, the department shall notify the facility of changes needed in order for the department to approve the plan.~~

~~(D) The facility shall come into compliance within the time frames set out in the corrective action plan.~~

~~(E) The department shall verify the correction of deficiencies by mail or on-site inspection.~~

~~(F) Acceptance of a corrective action plan does not preclude the department from taking other enforcement action as appropriate under this subchapter.~~

~~(4) A level one corrective action plan is appropriate if the department finds that the facility is not in compliance with the statute or this chapter, but the circumstances are not serious or life threatening. The department or a monitor may supervise the implementation of the plan.~~

~~(5) A level two corrective action plan is appropriate if the department 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 the department finds that the facility failed to implement or comply with a level one corrective action plan. The department 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.~~

~~(6) A level three corrective action plan is appropriate if the department finds that the facility is not in compliance with the statute or this chapter and the circumstances are serious or life threatening or if the department finds that the facility failed to comply with a level two corrective action plan or to cooperate with the department in connection with that plan. The department 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 §117.82 of this title (relating to Voluntary Appointment of a Temporary Manager). Involuntary appointment of a temporary manager shall be in accordance with §117.83 of this title (relating to Involuntary Appointment of a Temporary Manager).~~

~~(7) A corrective action plan is not confidential. Information contained in the plan may be excepted from required disclosure under the Government Code, Chapter 552 or other applicable law.~~

~~(8) The department 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 MRB.~~

~~(A) The monitor may not be or include individuals who are current or former employees of the facility that is the subject of the corrective action plan or of an affiliated facility.~~

~~(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.~~

~~(C) The facility shall pay the cost of the monitor.~~

~~§117.82. Voluntary Appointment of a Temporary Manager.~~

~~(a) A person holding a controlling interest in a facility may, at any time, request the department to assume the management of the facility through the appointment of a temporary manager in accordance with §251.091 of the statute.~~

~~(b) After receiving the request, the department 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 the department 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.~~

~~§117.83. Involuntary Appointment of a Temporary Manager.~~

~~(a) Under §251.092 of the statute, the department 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) the department 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 the department determines that an imminent or reasonably foreseeable threat to the health and safety of a patient of the facility exists;~~

~~(4) the department 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) the department determines a level three corrective action plan under §117.81(b)(6) of this title (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 facilities or similar facilities.~~

~~(3) 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 §251.093 of the statute.~~

~~(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.~~

~~§117.84. Disciplinary Action.~~

~~(a) The department may deny, suspend, or revoke a license if the applicant or facility:~~

~~(1) fails to comply with any provision of the statute;~~

~~(2) fails to comply with any provision of this chapter;~~

~~(3) commits fraud, misrepresentation, or concealment of a material fact on any documents required to be submitted to the department or required to be maintained by the facility pursuant to this chapter;~~

~~(4) aids, abets, or permits the commission of an illegal act;~~

~~(5) fails to comply with an order of the commissioner of health or another enforcement procedure under the statute; or~~

~~(6) fails to comply with applicable requirements within a designated probation period.~~

~~(b) The department may deny a license if the applicant or licensee fails to provide the required license fee, application or renewal information.~~

~~(c) The department 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, the department 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 Texas 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 the department 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 or parole, or revocation of mandatory supervision, the license shall be revoked.~~

~~(d) If the department proposes to deny, suspend, or revoke a license, the department 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 tenth calendar day after the notice is mailed to the last address known to the department 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 Director, Health Facility Licensing and Compliance Division, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756-3199.~~

~~(3) A hearing shall be conducted pursuant to the Administrative Procedure Act, Texas Government Code, Chapter 2001, and the department's formal hearing procedures in Chapter 1 of this title (relating to Texas Board of Health).~~

~~(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 the department suspends a license, the suspension shall remain in effect until the department determines that the reason for suspension no longer exists. An authorized representative of the department shall investigate prior to making a determination.~~

~~(1) During the time of suspension, the suspended license holder shall return the license to the department.~~

~~(2) If a suspension overlaps a renewal date, the suspended license holder shall comply with the renewal procedures in this chapter; however, the department may not renew the license until the department determines that the reason for suspension no longer exists.~~

~~(f) If the department 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. The department 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 the department.~~

~~(h) The department may issue an emergency order to suspend a license issued under this chapter if the department 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, the department shall conduct a hearing not earlier than the 10th day or later than the 30th day after 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 the department's rules for a contested case hearing and Government Code, Chapter 2001.~~

~~(i) The department may schedule the facility for a probation period of not less than 30 days if the facility is found in repeated non-compliance, and the facility's non-compliance does not endanger the health and safety of the public.~~

~~§117.85. Administrative Penalties.~~

~~(a) Under §§251.066-251.070 of the statute, the department 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, the department 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, Government Code, Chapter 2001.~~

~~(e) If after investigation of a possible violation and the facts surrounding that possible violation the department determines that a violation has occurred, the department shall give written notice of the violation to the person alleged to have committed the violation. The notice shall include:~~

- ~~(1) a brief summary of the alleged violation;~~
- ~~(2) a statement of the amount of the proposed penalty, based on the factors listed in subsection (c)(2) of this section. This statement shall be mailed to the facility no later than 90 working days after the investigation is completed (exit date); 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 the department 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 the department, 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. The hearings examiner 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 board's order is final; or~~

~~(B) request the court to stay enforcement of the penalty by:~~

~~(i) filing with the court a sworn 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 the department by certified mail.~~

~~(k) If the department receives a copy of an affidavit under subsection (j)(3)(B) of this section, the department may file with the court, within five calendar days after the date the copy is received, a contest to the affidavit.~~

~~§117.86. Recovery of Costs.~~

~~(a) The department may assess reasonable expenses and costs against a person in a 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 a board order requiring the payment of expenses and costs is final.~~

~~(c) The department 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 §251.063 or §251.065 of the statute 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 the department, reasonable expenses and costs.~~

~~(e) For purposes of this section, "reasonable expenses and costs" include expenses incurred by the department and the attorney general in the investigation, initiation, or prosecution of an action, including reasonable investigative costs, court costs, attorney's fees, witness fees, and deposition expenses.~~