
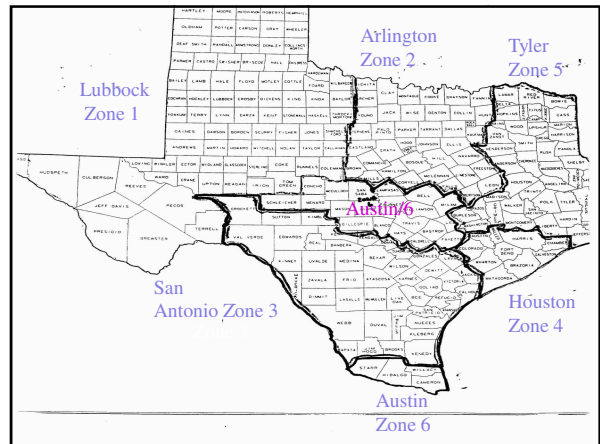


ESRD Licensing Rules: What Has Changed?



Or some of the many changes which might interest the interested parties here today.

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OBJECTIVES

- 1. List three major changes in the revised Texas regulations for ESRD.
- 2. Describe areas of difference between the Texas regulations and the Medicare regulations.
- 3. Discuss proactive steps to meet the new regulations.

ESRD New Rules

- 25 Texas Administrative Code
- Chapter 117
- 8
- 20
- 78
- 149
- 54,320

117.18 (c) Inspection

- Entrance conference
- Evaluation of compliance
- Exit conference
- Written notice of findings
- 117.18(d) Process for an ESRD facility to register a complaint against a Department of State Health Services surveyor.

Subchapter C: 117.31, 117.32, and 117.33

- 117.31 Equipment
- 117.32 Water Treatment, Dialysate Concentrates, and Reuse
- 117.33 Sanitary Conditions and Hygienic Practices

117.31 Equipment

(a) All equipment used by the facility shall be FDA approved, operated in accordance with the manufacturer's direction for use (DFU), and maintained free of defects. (Please have the DFU for each piece of equipment, follow the DFU, and have the DFU be readily available for all staff and the surveyor to review.)

- Ensure compliance with 117.31 (a)(5) in the event a patient is injured or dies while dialyzing.
- Maintain documentation on the facility's equipment or system repair log 117.31(a)(6).

117.32 Water Treatment, Dialysate Concentrates and Reuse

- 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.
- 117.32(b)(3) ...always be flow in a piping system...
- 117.32(b)(3)(C) This rule shall not apply to facilities providing only home training and support services utilizing single patient devices.
- 117.32(b)(4) RD52:2004 Edition of AAMI

117.322(a)(8)(C) (iv)

- Remember 54,320? Austin we have a problem. During the rule process there were many keystrokes. Sometimes things happen. This one sentence of probably many. It should read Water from the sample following the first bed shall be tested for chlorine/chloramine levels at the beginning of each treatment day prior to patients initiating treatment...
- We seek forgiveness.

117.32(b)(19) Microbiological testing of product water

- Routine testing shall be conducted monthly.
- For a newly installed system, or when 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 levels are within allowed limits. (Components which are designed to be replaced on a routine schedule do not require a period of more frequent testing.)
- <200 CFU/ml, endotoxin <2EU/ml
Action limits 50 CFU/ml and 1 EU/ml.

117.33 Sanitary Conditions and Hygienic Practices

- In accordance with 29 Code of Federal Regulations, and the Health and Safety Code Chapter 85;
- Implement the Recommended Infection Control Practices for Hemodialysis Units at a Glance 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 18-22, developed by the CDC.

117.33(b) Physical Environment

- Develop, implement and enforce policies and procedures to provide and ACTIVELY monitor a safe, functional, comfortable, and sanitary environment. (This includes patient treatment area and the water treatment area. Record in the facility's safety report or maintenance log records. No casual access to the water treatment area.)
- Specific procedures for equipment and dialysis machines. (This includes all items at the dialysis station. The chair, individual personal television, and the dialysis machine. (Please clean any devices attached to the dialysis machine, intravenous pole, hand sanitizer, prime buckets, sharps containers.) and items hanging from the pole.)

117.33(d) Hepatitis B

- Staff vaccination records maintained
- Prevention requirements for patients. With a physician's order, make the vaccine available to patients, provided that the patient has coverage or is willing to pay for the vaccination.
- Serologic screening of patients before admission. (Refer to 117.33(d)(2)(C)(ix) for direction if status unknown before admission to the facility.)

117.33(d)(2)(C) Isolation procedures ...

- If a facility is licensed after the effective date of February 9, 2009, the facility must have a separate isolation room unless the facility has obtained a waiver from CMS to this requirement. (Refer to 117.12 (a)(3) for information related to this process.)
- Follow the procedures regarding separate dedicated supplies, which are labeled "isolation".
- Ensure that there is a "buffer zone". Staff who provide care to the Hepatitis B positive patients shall only provide care to patients who are antibody positive.
- Ensure that the staff who provide care to Hepatitis B positive patients are antibody positive.

Subchapter D. Minimum Standards for Patient Care and Treatment

117.41 Governing Body

- 117.41 Governing Body
- 117.42 Patient Rights
- 117.43 Quality Assessment and Performance Improvement
- 117.44 Indicators of Quality of Care
- 117.45 Provision and Coordination of Treatment and Services
- 117.46 Qualifications of Staff
- 117.47 Clinical Records
- 117.48 Incident Reports

- The governing body is responsible for the organization, management, control, and operation of the facility.
- Appointment of a qualified medical director who is board certified in internal medicine, nephrology or pediatric nephrology, with at least 12 months of experience providing care to patients who receive dialysis.
- Regarding a waiver request for the medical director this shall be made through the Texas Department of State Health Services for transmission to CMS.

117.41(f) Governing Body....

- Ensure qualified staff.
- Develop, implement, and enforce policies and procedures relating to the facility's disaster preparedness plan, to meet the requirements of 117.45(b)(5).
- 117.41(l) Develop, implement, and enforce policies and procedures regarding disruptive patients or family members to ensure the health and safety of patients, facility personnel, and the public.
- 117.41(m) Ensure that personnel are assigned to assist the social worker when the patient load is greater than 100 patients (all modalities).

Elements of Quality Management

- Monthly meetings
- Includes the core staff members as identified in the definition section.
- Data-driven
- All services which the facility provides
- Measure, analyze and track the quality indicators listed on a monthly basis.
- Continuously monitor take actions that result in performance improvement, and track performance to ensure that improvements are sustained over time.

117.45 Provision and Coordination of Treatment and Services

- 117.45 (a)(1) The plan of care is based on an interdisciplinary assessment.
- 117.45(a)(6) The 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, and annually thereafter.
- 117.45(a)(7) The facility shall monitor the plan of care at least monthly to recognize and address any deviations from the plan of care.

117.45 Provision and Coordination of Treatment and Services...

- 117.45 (b) Emergency preparedness, transfer agreements, and written disaster preparedness plan.
- The facility must incorporate the use of and participate in the ESRD Network of Texas disaster preparedness activities.
- Make contact annually with the local disaster management representative (EOC).

117.45 (d) Nursing Services

- One supervising nurse per facility, and shall not be a contracted employee.
- Registered nurse in the facility when patients are PRESENT in the facility.
- The charge nurse is a qualified registered nurse.
- Staffing level shall not exceed 4 patients per licensed nurse or patient care technician per patient shift. Table 1 includes the staff to patient ratios.
- All patients shall be in full view of staff during dialysis treatments, especially nocturnal.

117.45 (d) Pediatric Staff

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

117.45 (g) and (h)

- Nutrition Services The maximum patient load is 125 patients.
- Social Services The facility must have specifically assigned personnel to assist the social worker when the patient load exceeds 100 patient, including all modalities. The maximum patient load with assigned personnel assistance is 125 patients.
- Initial contact must be made with the patient by the RDLD and the LMSW within 2 weeks or 7 treatments from the patient's admission, and a completed assessment within 30 days or 13 treatments of the patient's admission, whichever occurs later.

117.45...

- 117.45(i) Medical Services
Shall be seen by a physician on the medical staff every 2 weeks during the patient's dialysis treatment.
- 117.45(l)(3) Physician Extenders
 - (i) Evidence of communication with physician
 - (v) Shall meet the requirements by the Texas Board of Nursing or the Texas Board of Medical Examiners.
 - (vi) The physician and the physician extender shall develop and sign protocols or other written authorization which are followed, and will be reviewed and re-signed at least annually. These will be made available to the department to review.

117.45 (j) Home Dialysis

- Staffing level for home dialysis patients 1-20.
- Training by a qualified registered nurse, 12 months clinical experience and 6 months experience in the specific modality.
- An initial monitoring visit of the patient's home by facility personnel.
- AAMI analysis of the product water every 6 months. **
- Bacteriological and endotoxin testing of water used for dialysate and also dialysate monthly until results do not exceed ...for 3 consecutive months, then quarterly thereafter.

Chart for Home Dialysis Machines (Conventional and Integrated)

- AAMI 2 times a year
- Culture and endotoxin of water monthly for 3 months until no growth then quarterly
- Culture and endotoxin of dialysate for 3 months until no growth then quarterly
- Chlorine/chloramines levels checked on conventional machines prior to each treatment
- Chlorine/chloramines levels checked on integrated machines prior to using the prepared dialysate. (This test is performed after the preparation of each dialysate sack. The surveyor will look to see that the results were documented by the patient on their dialysis treatment sheet. Therefore, some of the dialysis treatment sheets will not have the chlorine/chloramines results.)

Chart for Home Dialysis Machines (Closed systems, and Peritoneal)

- **NO** labs for water and dialysate, in that the fluid is sterile. (This includes the System One for the NxStage.)
- **PD NO** labs to be drawn

117.46 Qualifications

- If facility policies and equipment are similar then the facility may share staff, and this allows for a shortened orientation time.
- For a PCT there must be documentation of competency and medical director's delegation at the facility.
- Ensure only qualified staff in the water area.
- Delegated duties by the Medical Director upon completion of the technical program related to their level of responsibility. (Initial written test and skills test)
- Written test and skills test annually related to the employees level of responsibility.

Training for Technical Staff

- The training curriculum must include the requirements at 117.33(f)(3)(B)(ii).
- Must have objectives and be approved by the medical director.

REQUIRE EVIDENCE OF TECHNICAL TRAINING FOR ALL TECHNICAL STAFF, INCLUDING NURSES AND PCT'S IF THEY ARE RESPONSIBLE FOR WATER TESTING/OPENING OR CLOSING PROCEDURES , ETC.

117.47 Clinical Records

- Establish and maintain an accurate record system, centralized, safe, separate storage, confidential, no signature stamps, may be electronic.
- Protection from casual access.
- Alterations to the documents must include an explanation of the alteration, electronic or hand-written.
- History and physical shall be completed within 30 days of a patient's admission.

117.48 Incident Reports

- Death of a patient
- Hospital transfers from the facility
- Conversion of staff or patient to Hepatitis B
- Involuntary transfer or discharge of a patient
- Fire in the facility
- Form available at the Network site, and DSHS site, which shall be completed by the facility's supervising nurse, and sent in for review by the zone office.

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

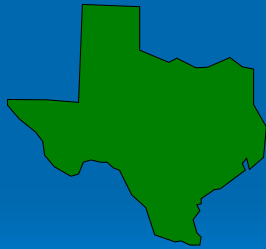
Subchapter G Fire Prevention and Safety Requirements

- 117.91 Fire Prevention, Protection, and Emergency Contingency Plan
- 117.91(h)(1) or (2) or (3) Requirements for a facility related to emergency contingency plan
- 117.92 General Safety
- 117.93 Handling and Storage of Gases and Flammable Liquids.

Subchapter H Physical Plant and Construction Requirements

- 117.101 Construction Requirement for an Existing End Stage Renal Disease Facility
- 117.102 Construction Requirements for a New End Stage Renal Disease Facility
- 117.103 Elevators, Escalators, and Conveyors
- 117.104 Preparation, Submittal, Review and Approval of Plans and Retention of Records.

Survey Process for Texas



- Entrance conference;
- Tour of the facility ;
- Tour of the water room and the reuse room;
- Patient interviews;
- Review of the daily logs, machine maintenance, etc;
- Review of the Governing Body meetings;
- Review of the facility's contracts;
- Staff interviews;
- Chart review;
- Review of QAPI;
- Credentials for all staff;
- Exit conference.

REVIEW OF THE OBJECTIVES

1. List three major changes in the revised Texas regulations for ESRD.

- ❖ No water loop required for a facility who will only offer the services of peritoneal dialysis or home hemodialysis.
- ❖ Facilities must adopt the Recommended Infection Control Practices for Hemodialysis Units at a Glance.
- ❖ QAPI must be data-driven, measure, analyze, and track, and review implementations to ensure
- ❖ Interdisciplinary comprehensive assessment and plan of care must be monitored on a monthly basis to ensure that the patient's plan of care is revised and updated.
- ❖ Must contact and report monthly status of the facility to the Network.
- ❖ Registered nurse present when patients are present in the facility.
- ❖ Home hemodialysis services expanded.
- ❖ Qualifications of all staff.
- ❖ Ensures completion of all incident reports, which are measured, analyzed, and tracked in QAPI.

2. Describe areas of difference between the Texas regulations and the Medicare regulations.

- ❖ Texas requires the nurse, the social worker, the dietitian the physician to complete the interdisciplinary assessment and the plan of care within 30 days or 13 treatments of a patient's admission to the facility. (H & P, etc., even if the patient is transferred)
- ❖ Texas requires that a facility will monitor the patient's plan of care on a monthly basis. (by way of reviewing progress notes and physician's orders, and dialysis treatment sheets, etc.).
- ❖ Texas regulations include rules related to home hemodialysis which Medicare has as interpretive guidance.
- ❖ Texas requires all deaths, hospital transfers, and other incidents to be reported to the state.

3. Discuss proactive steps to meet the new regulations.

- ❖ Review policies and procedures to ensure compliance with the regulations.
- ❖ Ensure facility staff adhere to infection control practices adopted by the facility.
- ❖ Ensure that the facility is safe, functional, comfortable, and sanitary.
- ❖ Ensure that the QAPI program complies with the regulations.

3. Discuss proactive steps to meet the new regulations.

- ❖ Develop tools to ensure that all assessments and plans of care are completed.
- ❖ Ensure that a patient's plan of care will be monitored to recognize and address any deviations from the plan of care.
- ❖ Review dialysis treatment sheets to ensure that the patient received the dialysis care according to complete physician's orders.
- ❖ Develop a tool to ensure that all staff are qualified to perform the assigned duties.

Thank you for coming and for
discussing the 54,320 words

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