

HEALTH & SAFETY CODE
CHAPTER 251. END STAGE RENAL DISEASE FACILITIES
SUBCHAPTER A. GENERAL PROVISIONS

Sec. 251.001. DEFINITIONS. In this chapter:

(1) "Board" means the Texas Board of Health.
(2) "Commissioner" means the commissioner of public health.

(3) "Department" means the Texas Department of Health.

(4) "Dialysis" means a process by which dissolved substances are removed from a patient's body by diffusion from one fluid compartment to another across a semipermeable membrane.

(5) "Dialysis technician" means an individual who is not a registered nurse or physician and who provides dialysis care under the supervision of a registered nurse or physician.

(6) "End stage renal disease" means that stage of renal impairment that appears irreversible and permanent and that requires a regular course of dialysis or kidney transplantation to maintain life.

(7) "End stage renal disease facility" means a facility that provides dialysis treatment or dialysis training to individuals with end stage renal disease.

(8) "Medical review board" means a medical review board that:

(A) is appointed by a renal disease network organization which includes this state; and

(B) has a contract with the Health Care Financing Administration of the United States Department of Health and Human Services under Section 1881, Title XVIII, Social Security Act (42 U.S.C. Section 1395rr).

(9) "Physician" means an individual who is licensed to practice medicine under Subtitle B, Title 3, Occupations Code. Added by Acts 1995, 74th Leg., ch. 608, Sec. 1, eff. Sept. 1, 1995. Amended by Acts 2001, 77th Leg., ch. 1420, Sec. 14.790, eff. Sept. 1, 2001.

Sec. 251.002. FEES. (a) The board shall set fees imposed by this chapter in amounts reasonable and necessary to defray the cost of administering this chapter.

(b) In setting fees under this section, the board shall consider setting a range of license and renewal fees based on the number of dialysis stations at each end stage renal disease facility and the patient census.

(c) An end stage renal disease facility owned or operated by a state agency is not required to pay fees imposed under this chapter.

Added by Acts 1995, 74th Leg., ch. 608, Sec. 1, eff. Sept. 1, 1995.

Sec. 251.003. ADOPTION OF RULES. The board shall adopt rules to implement this chapter, including requirements for the issuance, renewal, denial, suspension, and revocation of a license to operate an end stage renal disease facility.

Added by Acts 1995, 74th Leg., ch. 608, Sec. 1, eff. Sept. 1, 1995.

SUBCHAPTER B. LICENSING OF END STAGE RENAL DISEASE FACILITIES

Sec. 251.011. LICENSE REQUIRED. Except as provided by Section 251.012, a person may not operate an end stage renal disease facility without a license issued under this chapter.

Added by Acts 1995, 74th Leg., ch. 608, Sec. 1, eff. Sept. 1, 1996.

Sec. 251.012. EXEMPTIONS FROM LICENSING REQUIREMENT. The following facilities are not required to be licensed under this chapter:

(1) a home and community support services agency licensed under Chapter 142 with a home dialysis designation;

(2) a hospital licensed under Chapter 241 that provides dialysis only to individuals receiving inpatient services from the hospital; or

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

Added by Acts 1995, 74th Leg., ch. 608, Sec. 1, eff. Sept. 1, 1995.

Sec. 251.013. ISSUANCE AND RENEWAL OF LICENSE. (a) An applicant for a license under this chapter must submit an application to the department on a form prescribed by the board.

(b) Each application must be accompanied by a nonrefundable license fee.

(c) Each application must contain evidence that there is at least one qualified physician on the staff of the facility and that each dialysis technician on staff has completed the training program required by this chapter.

(d) The department may grant a temporary initial license to an applicant. The temporary initial license expires on the earlier of:

(1) the date the department issues or denies the license; or

(2) the date six months after the date the temporary initial license was issued.

(e) The department shall issue a license if, after inspection and investigation, it finds the applicant meets the requirements of this chapter and the standards adopted under this chapter.

(f) The license is renewable annually after submission of:

(1) the renewal application and fee; and

(2) an annual report on a form prescribed by the board.

(g) The annual report required under Subsection (f) must include information related to the quality of care at the end stage renal disease facility. The report must be in the form and documented by evidence as required by board rule.

Added by Acts 1995, 74th Leg., ch. 608, Sec. 1, eff. Sept. 1, 1995.

Sec. 251.014. MINIMUM STANDARDS. (a) The rules adopted under Section 251.003 must contain minimum standards to protect the health and safety of a patient of an end stage renal disease facility, including standards for:

(1) the qualifications and supervision of the professional staff, including physicians, and other personnel;

(2) the equipment used by the facility is compatible with the health and safety of the patients;

(3) the sanitary and hygienic conditions in the facility;

(4) quality assurance for patient care;

(5) the provision and coordination of treatment and services by the facility;

(6) clinical records maintained by the facility;

(7) design and space requirements for the facility for safe access by patients and personnel and for ensuring patient privacy;

(8) indicators of the quality of care provided by the facility; and

(9) water treatment and reuse by the facility.

(b) The standards described in Subsection (a)(7) of this section shall apply only:

(1) to a facility which initiates the provision of end stage renal disease services on or after September 1, 1996; or

(2) to the area of a facility affected by design and space modifications or renovations completed after September 1, 1996.

Added by Acts 1995, 74th Leg., ch. 608, Sec. 1, eff. Sept. 1, 1995.

Sec. 251.015. MEDICAL REVIEW BOARD. (a) A medical review board shall advise the board on minimum standards and rules to be adopted under this chapter.

(b) The medical review board shall review the information on quality of care provided in the annual report filed under Section 251.013(f) and other appropriate information provided to or compiled by the department with respect to an end stage renal disease facility. Based on the review, the medical review board may advise the department about the quality of care provided by a facility and recommend an appropriate corrective action plan under Section 251.061 or other enforcement proceedings against the facility.

(c) Information concerning quality of care provided to or compiled by the department or medical review board and a recommendation of the medical review board are confidential. The information or recommendation may not be made available for public inspection, is not subject to disclosure under Chapter 552, Government Code, and is not subject to discovery, subpoena, or other compulsory legal process.

(d) The department, in its discretion, may release to a facility information relating to that facility that is made confidential under Subsection (c). Release of information to a facility under this subsection does not waive the confidentiality of that information or the privilege from compulsory legal process.

Added by Acts 1995, 74th Leg., ch. 608, Sec. 1, eff. Sept. 1, 1995.

SUBCHAPTER C. DIALYSIS TECHNICIANS

Sec. 251.031. TRAINING REQUIRED. An individual may not act as a dialysis technician employed by or working in an end stage

renal disease facility unless that individual is trained and competent under this subchapter.

Added by Acts 1995, 74th Leg., ch. 608, Sec. 1, eff. Sept. 1, 1996.

Sec. 251.032. MINIMUM REQUIREMENTS; TRAINING. The rules adopted by the board under Section 251.003 shall establish:

(1) minimum standards for the curricula and instructors used to train individuals to act as dialysis technicians;

(2) minimum standards for the determination of the competency of individuals who have been trained as dialysis technicians;

(3) minimum requirements for documentation that an individual has been trained and determined to be competent as a dialysis technician and the acceptance of that documentation by another end stage renal disease facility that may later employ the individual; and

(4) the acts and practices that are allowed or prohibited for dialysis technicians.

Added by Acts 1995, 74th Leg., ch. 608, Sec. 1, eff. Sept. 1, 1995.

SUBCHAPTER D. INSPECTIONS

Sec. 251.051. INSPECTIONS. (a) The department may conduct an inspection of an end stage renal disease facility to verify compliance with this chapter, rules adopted under this chapter, or a corrective action plan under Section 251.061.

(b) An inspection conducted under this section may be unannounced.

Added by Acts 1995, 74th Leg., ch. 608, Sec. 1, eff. Sept. 1, 1995.

Sec. 251.052. DISCLOSURE OF UNANNOUNCED INSPECTION; CRIMINAL PENALTY. (a) A person commits an offense if the person intentionally, knowingly, or recklessly discloses to an unauthorized person the date or time of or any other fact about an unannounced inspection of an end stage renal disease facility before the inspection occurs.

(b) In this section, "unauthorized person" does not include:

(1) the department;

(2) the office of the attorney general; or

(3) any other person authorized by law to make an inspection or to accompany an inspector.

(c) An offense under this section is a Class B misdemeanor.

(d) A person convicted under this section is not eligible for state employment.

Added by Acts 1995, 74th Leg., ch. 608, Sec. 1, eff. Sept. 1, 1995.

SUBCHAPTER E. ENFORCEMENT

Sec. 251.061. CORRECTIVE ACTION PLAN. (a) The department may use a corrective action plan as an alternative to enforcement action under this subchapter.

(b) Before taking enforcement action under this subchapter, the department shall consider whether the use of a corrective action plan under this section is appropriate. In determining whether to use a corrective action plan, the department shall consider whether:

(1) the end stage renal disease facility has violated this chapter or a rule adopted under this chapter and the violation has resulted in an adverse patient result;

(2) the facility has a previous history of lack of compliance with this chapter, rules adopted under this chapter, or a corrective action plan; or

(3) the facility fails to agree to a corrective action plan.

(c) The department may use a level one, level two, or level three corrective action plan, as determined by the department in accordance with this section, after inspection of the end stage renal disease facility.

(d) A level one corrective action plan is appropriate if the department finds that the end stage renal disease facility is not in compliance with this chapter or rules adopted under this chapter, but the circumstances are not serious or life-threatening. Under a level one corrective action plan, the department shall require the facility to develop and implement a corrective action plan approved by the department. The department or a monitor may supervise the implementation of the plan.

(e) A level two corrective action plan is appropriate if the department finds that the end stage renal disease facility is not in compliance with this chapter or rules adopted under 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. Under a level two corrective action plan, the department shall require the facility to develop and implement a corrective action plan approved by the department. 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.

(f) A level three corrective action plan is appropriate if the department finds that the end stage renal disease facility is not in compliance with this chapter or rules adopted under 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. Under a level three corrective action plan, the department shall require the facility to develop and implement a corrective action plan approved by the department. In connection with requiring a level three corrective action plan, the department may seek the appointment of a temporary manager under Subchapter F.

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

(h) The department shall select the monitor for a corrective action plan. The monitor shall be an individual or team of individuals and may include a professional with end stage renal disease experience or a member of the medical review board. 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. 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. The facility shall pay the cost of the monitor.

Added by Acts 1995, 74th Leg., ch. 608, Sec. 1, eff. Sept. 1, 1996.

Sec. 251.062. DENIAL, SUSPENSION, PROBATION, OR REVOCATION OF LICENSE. (a) The department may deny, suspend, or revoke a license issued under this chapter for a violation of this chapter or a rule adopted under this chapter.

(b) The denial, suspension, or revocation of a license by the department and the appeal from that action are governed by the procedures for a contested case hearing under Chapter 2001, Government Code.

(c) If the department finds that an end stage renal disease facility is in repeated noncompliance with this chapter or rules adopted under this chapter but that the noncompliance does not endanger public health and safety, the department may schedule the facility for probation rather than suspending or revoking the facility's license. The department shall provide notice to the facility of the probation and of the items of noncompliance not later than the 10th day before the date the probation period begins. The department shall designate a period of not less than 30 days during which the facility will remain under probation. During the probation period, the facility must correct the items that were in noncompliance and report the corrections to the department for approval.

(d) The department may suspend or revoke the license of an end stage renal disease facility that does not correct items that were in noncompliance or that does not comply with this chapter or the rules adopted under this chapter within the applicable probation period.

Added by Acts 1995, 74th Leg., ch. 608, Sec. 1, eff. Sept. 1, 1996. Amended by Acts 2003, 78th Leg., ch. 802, Sec. 11, 12, eff. June 20, 2003.

Sec. 251.0621. EMERGENCY SUSPENSION. 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. An emergency suspension is effective immediately without a hearing on notice to the license holder. 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 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 Chapter 2001, Government Code.

Added by Acts 2003, 78th Leg., ch. 802, Sec. 13, eff. June 20, 2003.

Sec. 251.063. INJUNCTION. (a) The department may petition a district court for a temporary restraining order to restrain a continuing violation of this chapter or a rule adopted under this chapter if the department finds that the violation creates an immediate threat to the health and safety of patients of an end stage renal disease facility.

(b) A district court, on petition of the department and on a finding that a person is violating this chapter or a rule adopted under this chapter, may by injunction:

(1) prohibit a person from continuing the violation;
(2) restrain or prevent the operation of an end stage renal disease facility without a license issued under this chapter; or

(3) grant other injunctive relief warranted by the facts.

(c) The attorney general may institute and conduct a suit authorized by this section at the request of the department.

(d) Venue for a suit brought under this section is in the county in which the end stage renal disease facility is located or in Travis County.

Added by Acts 1995, 74th Leg., ch. 608, Sec. 1, eff. Sept. 1, 1996.

Sec. 251.064. CRIMINAL PENALTY. (a) A person commits an offense if the person violates Section 251.011 or 251.031.

(b) An offense under this section is a Class C misdemeanor.

(c) Each day of a continuing violation constitutes a separate offense.

Added by Acts 1995, 74th Leg., ch. 608, Sec. 1, eff. Sept. 1, 1996.

Sec. 251.065. CIVIL PENALTY. (a) A person who knowingly violates this chapter or who knowingly fails to comply with a rule adopted under this chapter is liable for a civil penalty of not more than \$1,000 for each violation if the department finds that the violation threatens the health and safety of a patient of an end stage renal disease facility.

(b) Each day of a continuing violation constitutes a separate ground for recovery.

Added by Acts 1995, 74th Leg., ch. 608, Sec. 1, eff. Sept. 1, 1996.

Sec. 251.066. ADMINISTRATIVE PENALTY. (a) The department may assess an administrative penalty against a person who violates this chapter or a rule adopted under 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 under this chapter are subject to Chapter 2001, Government Code.

Added by Acts 1995, 74th Leg., ch. 608, Sec. 1, eff. Sept. 1, 1996.

Sec. 251.067. REPORT RECOMMENDING ADMINISTRATIVE PENALTY. (a) 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 Section 251.066(c); 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.

(b) Not later than the 20th 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.

(c) If the person notified of the violation accepts the determination of the department, the commissioner or the

commissioner's designee shall issue an order approving the determination and ordering that the person pay the recommended penalty.

Added by Acts 1995, 74th Leg., ch. 608, Sec. 1, eff. Sept. 1, 1996.

Sec. 251.068. HEARING; ORDER. (a) If the person notified fails to respond in a timely manner to the notice under Section 251.067(b) or if the person requests a hearing, the commissioner or 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.

(b) 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.

(c) Based on the findings of fact and conclusions of law and the recommendations 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.

Added by Acts 1995, 74th Leg., ch. 608, Sec. 1, eff. Sept. 1, 1996.

Sec. 251.069. NOTICE AND PAYMENT OF ADMINISTRATIVE PENALTY; JUDICIAL REVIEW; REFUND. (a) The commissioner or the commissioner's designee shall give notice of the commissioner's order under Section 251.068(c) to the person notified. The notice must 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.

(b) Not later than the 30th day after the date the decision is final as provided by Chapter 2001, Government Code, 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.

(c) Within the 30-day period, a person who acts under Subsection (b)(3) may:

- (1) stay enforcement of the penalty by:
 - (A) paying the amount of the penalty to the court for placement in an escrow account; or
 - (B) 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

(2) request the court to stay enforcement of the penalty by:

(A) 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

(B) giving a copy of the affidavit to the department by certified mail.

(d) If the department receives a copy of an affidavit under Subsection (c)(2), the department may file with the court, within five days after the date the copy is received, a contest to the affidavit. The court shall hold a hearing on the facts alleged in the affidavit as soon as practicable and shall stay the enforcement of the penalty on finding that the alleged facts are true. The person who files an affidavit has the burden of proving that the person is financially unable to pay the amount of the penalty and to give a supersedeas bond.

(e) If the person does not pay the amount of the penalty and the enforcement of the penalty is not stayed, the department may refer the matter to the attorney general for collection of the amount of the penalty.

(f) Judicial review of the order of the board:
(1) is instituted by filing a petition as provided by Subchapter G, Chapter 2001, Government Code; and
(2) is under the substantial evidence rule.

(g) If the court sustains the occurrence of the violation, the court may uphold or reduce the amount of the penalty and order the person to pay the full or reduced amount of the penalty. If the court does not sustain the occurrence of the violation, the court shall order that no penalty is owed.

(h) When the judgment of the court becomes final, the court shall proceed under this subsection. If the person paid the amount of the penalty and if that amount is reduced or is not upheld by the court, the court shall order that the appropriate amount plus accrued interest be remitted to the person. The rate of the interest is the rate charged on loans to depository institutions by the New York Federal Reserve Bank, and the interest shall be paid for the period beginning on the date the penalty was paid and ending on the date the penalty is remitted. If the person gave a supersedeas bond and if the amount of the penalty is not upheld by the court, the court shall order the release of the bond. If the person gave a supersedeas bond and if the amount of the penalty is reduced, the court shall order the release of the bond after the person pays the amount.

Added by Acts 1995, 74th Leg., ch. 608, Sec. 1, eff. Sept. 1, 1996.

Sec. 251.070. PENALTY DEPOSITED TO STATE TREASURY. A civil or administrative penalty collected under this chapter shall be deposited in the state treasury to the credit of the general revenue fund.

Added by Acts 1995, 74th Leg., ch. 608, Sec. 1, eff. Sept. 1, 1996.

Sec. 251.071. 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. The person shall pay expenses and costs assessed under this subsection not later than the 30th day after the date of a board order requiring the payment of expenses and costs is final. The department may refer the matter to the attorney general for collection of the expenses and costs.

(b) If the attorney general brings an action against a person under Section 251.063 or 251.065 or to enforce an administrative penalty assessed under Section 251.066, 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.

(c) 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.

Added by Acts 1995, 74th Leg., ch. 608, Sec. 1, eff. Sept. 1, 1996.

SUBCHAPTER F. TEMPORARY MANAGER

Sec. 251.091. APPOINTMENT BY AGREEMENT. (a) A person holding a controlling interest in an end stage renal disease facility may, at any time, request the department to assume the management of the facility through the appointment of a temporary manager under this subchapter.

(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 must:

(1) specify all terms and conditions of the temporary manager's appointment and authority; and

(2) preserve all rights of the 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.

Added by Acts 1995, 74th Leg., ch. 608, Sec. 1, eff. Sept. 1, 1995.

Sec. 251.092. INVOLUNTARY APPOINTMENT. (a) 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 an end stage renal disease 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) 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 Section 251.061 that includes appointment of a 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.

(c) 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 this chapter and rules adopted under this chapter, or closure of the facility.

(d) If possible, the court shall appoint as temporary manager an individual whose background includes administration of end stage renal disease facilities or similar facilities.

(e) Venue for an action under this section is in Travis County.

Added by Acts 1995, 74th Leg., ch. 608, Sec. 1, eff. Sept. 1, 1995.

Sec. 251.093. FEE; RELEASE OF FUNDS. (a) A temporary manager appointed under Section 251.092 is entitled to a reasonable fee as determined by the court. The fee shall be paid by the facility.

(b) 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.

(c) Withheld payments that may be released under Subsection (b) may include payments withheld by a governmental agency or other entity before or during the appointment of the temporary manager, including:

- (1) Medicaid, Medicare, or insurance payments; or
- (2) payments from another third party.

Added by Acts 1995, 74th Leg., ch. 608, Sec. 1, eff. Sept. 1, 1995.