

HEALTH & SAFETY CODE

CHAPTER 243. AMBULATORY SURGICAL CENTERS

SUBCHAPTER A. GENERAL PROVISIONS; LICENSING AND PENALTIES

Sec. 243.001. SHORT TITLE. This chapter may be cited as the Texas Ambulatory Surgical Center Licensing Act.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 243.002. DEFINITIONS. In this chapter:

(1) "Ambulatory surgical center" means a facility that operates primarily to provide surgical services to patients who do not require overnight hospital care.

(2) "Board" means the Texas Board of Health.

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

(4) "Person" means an individual, firm, partnership, corporation, or association.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 243.003. LICENSE REQUIRED. (a) Except as provided by Section 243.004, a person may not establish or operate an ambulatory surgical center in this state without a license issued under this chapter.

(b) Each ambulatory surgical center must have a separate license.

(c) A license is not transferable or assignable.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 243.004. EXEMPTIONS FROM LICENSING REQUIREMENT. The following facilities need not be licensed under this chapter:

(1) an office or clinic of a licensed physician, dentist, or podiatrist;

(2) a licensed nursing home; or

(3) a licensed hospital.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 243.005. LICENSE APPLICATION AND ISSUANCE. (a) An applicant for an ambulatory surgical center license must submit an application to the department on a form prescribed by the department.

(b) Each application must be accompanied by a nonrefundable license fee in an amount set by the board.

(c) The application must contain evidence that there is at least one physician, dentist, or podiatrist on the staff of the center who is licensed by the appropriate state licensing board.

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

(e) The license fee must be paid annually on renewal of the license.

(f) The department shall issue a renewal license to a center certified under Title XVIII of the Social Security Act (42 U.S.C. Section 1395 et seq.) when the center:

(1) remits any annual license fee; and

(2) submits the inspection results or the inspection results report from the certification body.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 243.006. INSPECTIONS. (a) The department may inspect an ambulatory surgical center at reasonable times as necessary to assure compliance with this chapter.

(b) An ambulatory surgical center licensed by the department and certified under Title XVIII of the Social Security Act (42 U.S.C. Section 1395 et seq.) is subject to an on-site licensing inspection under this chapter once every three years while the center maintains the certification.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1999, 76th Leg., ch. 1546, Sec. 1, eff. Sept. 1, 1999.

Sec. 243.007. FEES. The board shall set fees imposed by this chapter in amounts reasonable and necessary to defray the cost of administering this chapter.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 243.008. AMBULATORY SURGICAL CENTER LICENSING FUND. All fees collected under this chapter shall be deposited in the state treasury to the credit of the ambulatory surgical center licensing fund and may be appropriated to the department only to administer and enforce this chapter.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 243.009. ADOPTION OF RULES. The board shall adopt rules necessary to implement this chapter, including requirements for the issuance, renewal, denial, suspension, and revocation of a

license to operate an ambulatory surgical center.
Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 243.010. MINIMUM STANDARDS. (a) The rules must contain minimum standards applicable to an ambulatory surgical center and for:

(1) the construction and design, including plumbing, heating, lighting, ventilation, and other design standards necessary to ensure the health and safety of patients;

(2) the qualifications of the professional staff and other personnel;

(3) the equipment essential to the health and welfare of the patients;

(4) the sanitary and hygienic conditions within the center and its surroundings; and

(5) a quality assurance program for patient care.

(b) Standards set under this section may not exceed the minimum standards for certification of ambulatory surgical centers under Title XVIII of the Social Security Act (42 U.S.C. Section 1395 et seq.).

(c) This section does not authorize the board to:

(1) establish the qualifications of a licensed practitioner; or

(2) permit a person to provide health care services who is not authorized to provide those services under another state law.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 243.011. DENIAL, SUSPENSION, PROBATION, OR REVOCATION OF LICENSE. (a) The department may deny, suspend, or revoke a license 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 ambulatory surgical center 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 center for probation rather than suspending or revoking the center's license. The department shall provide notice to the center 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 center will remain under probation. During the probation period, the center 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 ambulatory surgical center 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.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1995, 74th Leg., ch. 76, Sec. 5.95(49), eff. Sept. 1, 1995; Acts 2003, 78th Leg., ch. 802, Sec. 3, 4, eff. June 20, 2003.

Sec. 243.0115. 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 1999, 76th Leg., ch. 1546, Sec. 2, eff. Sept. 1, 1999.

Sec. 243.012. INJUNCTION. (a) The department may petition a district court for a temporary restraining order to restrain a continuing violation of the standards or licensing requirements provided under this chapter if the department finds that the violation creates an immediate threat to the health and safety of the patients of an ambulatory surgical center.

(b) A district court, on petition of the department and on a finding by the court that a person is violating the standards or

licensing requirements provided under this chapter, may by injunction:

(1) prohibit a person from continuing a violation of the standards or licensing requirements provided under this chapter;

(2) restrain or prevent the establishment or operation of an ambulatory surgical center without a license issued under this chapter; or

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

(c) The attorney general shall 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 ambulatory surgical center is located or in Travis County.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 243.013. CRIMINAL PENALTY. (a) A person commits an offense if the person violates Section 243.003(a).

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

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

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 243.014. CIVIL PENALTY. (a) A person who violates this chapter or who fails to comply with a rule adopted under this chapter is liable for a civil penalty of not less than \$100 or more than \$500 for each violation if the department determines the violation threatens the health and safety of a patient.

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

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 243.015. IMPOSITION OF ADMINISTRATIVE PENALTY. (a) The department may impose an administrative penalty on a person licensed under this chapter who violates this chapter or a rule or order adopted under this chapter. A penalty collected under this section or Section 243.016 shall be deposited in the state treasury in the general revenue fund.

(b) A proceeding to impose the penalty is considered to be a contested case under Chapter 2001, Government Code.

(c) The amount of the penalty may not exceed \$1,000 for each violation, and each day a violation continues or occurs is a separate violation for purposes of imposing a penalty. The total amount of the penalty assessed for a violation continuing or occurring on separate days under this subsection may not exceed \$5,000.

(d) The amount shall be based on:

(1) the seriousness of the violation, including the nature, circumstances, extent, and gravity of the violation;

(2) the threat to health or safety caused by the violation;

(3) the history of previous violations;

(4) the amount necessary to deter a future violation;

(5) whether the violator demonstrated good faith, including when applicable whether the violator made good faith efforts to correct the violation; and

(6) any other matter that justice may require.

(e) If the department initially determines that a violation occurred, the department shall give written notice of the report by certified mail to the person.

(f) The notice under Subsection (e) must:

(1) include a brief summary of the alleged violation;

(2) state the amount of the recommended penalty; and

(3) inform the person of the person's right to a hearing on the occurrence of the violation, the amount of the penalty, or both.

(g) Within 20 days after the date the person receives the notice under Subsection (e), the person in writing may:

(1) accept the determination and recommended penalty of the department; or

(2) make a request for a hearing on the occurrence of the violation, the amount of the penalty, or both.

(h) If the person accepts the determination and recommended penalty or if the person fails to respond to the notice, the commissioner of public health by order shall approve the determination and impose the recommended penalty.

(i) If the person requests a hearing, the commissioner of

public health shall refer the matter to the State Office of Administrative Hearings, which shall promptly set a hearing date and give written notice of the time and place of the hearing to the person. An administrative law judge of the State Office of Administrative Hearings shall conduct the hearing.

(j) The administrative law judge shall make findings of fact and conclusions of law and promptly issue to the commissioner of public health a proposal for a decision about the occurrence of the violation and the amount of a proposed penalty.

(k) Based on the findings of fact, conclusions of law, and proposal for a decision, the commissioner of public health by order may:

(1) find that a violation occurred and impose a penalty; or

(2) find that a violation did not occur.

(1) The notice of the commissioner's order under Subsection (k) that is sent to the person in accordance with Chapter 2001, Government Code, must include a statement of the right of the person to judicial review of the order.

Added by Acts 1999, 76th Leg., ch. 1411, Sec. 3.01, eff. Sept. 1, 1999.

Sec. 243.016. PAYMENT AND COLLECTION OF ADMINISTRATIVE PENALTY; JUDICIAL REVIEW. (a) Within 30 days after the date an order of the commissioner of public health under Section 243.015(k) that imposes an administrative penalty becomes final, the person shall:

(1) pay the penalty; or

(2) file a petition for judicial review of the commissioner's order contesting the occurrence of the violation, the amount of the penalty, or both.

(b) Within the 30-day period prescribed by Subsection (a), a person who files a petition for judicial review may:

(1) stay enforcement of the penalty by:

(A) paying the penalty to the court for placement in an escrow account; or

(B) giving the court a supersedeas bond approved by the court that:

(i) is for the amount of the penalty; and

(ii) is effective until all judicial review of the commissioner'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 penalty and is financially unable to give the supersedeas bond; and

(B) sending a copy of the affidavit to the commissioner of public health by certified mail.

(c) If the commissioner of public health receives a copy of an affidavit under Subsection (b)(2), the commissioner 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 penalty or to give a supersedeas bond.

(d) If the person does not pay the penalty and the enforcement of the penalty is not stayed, the penalty may be collected. The attorney general may sue to collect the penalty.

(e) If the court sustains the finding that a violation occurred, 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.

(f) If the court does not sustain the finding that a violation occurred, the court shall order that a penalty is not owed.

(g) If the person paid the penalty and if the amount of the penalty is reduced or the penalty is not upheld by the court, the court shall order, when the court's judgment becomes final, that the appropriate amount plus accrued interest be remitted to the person within 30 days after the date that the judgment of the court becomes final. The interest accrues at the rate charged on loans to depository institutions by the New York Federal Reserve Bank. The interest shall be paid for the period beginning on the date the penalty is paid and ending on the date the penalty is remitted.

(h) If the person gave a supersedeas bond and the penalty is not upheld by the court, the court shall order, when the court's judgment becomes final, the release of the bond. If the person gave a supersedeas bond and the amount of the penalty is reduced, the court shall order the release of the bond after the person pays the reduced amount.

Added by Acts 1999, 76th Leg., ch. 1411, Sec. 3.01, eff. Sept. 1, 1999.

SUBCHAPTER B. PATIENT SAFETY PROGRAM

Sec. 243.051. DUTIES OF DEPARTMENT. The department shall develop a patient safety program for ambulatory surgical centers. The program must:

(1) be administered by the ambulatory surgical center licensing program within the department; and

(2) serve as an information clearinghouse for ambulatory surgical centers concerning best practices and quality improvement strategies.

Added by Acts 2003, 78th Leg., ch. 569, Sec. 4, eff. June 20, 2003.

Sec. 243.052. ANNUAL REPORT. (a) On renewal of a license under this chapter, an ambulatory surgical center shall submit to the department an annual report that lists the number of occurrences at the center or at an outpatient facility owned or operated by the center of each of the following events during the preceding year:

(1) a medication error resulting in a patient's unanticipated death or major permanent loss of bodily function in circumstances unrelated to the natural course of the illness or underlying condition of the patient;

(2) the suicide of a patient;

(3) the sexual assault of a patient during treatment or while the patient was on the premises of the center or facility;

(4) a hemolytic transfusion reaction in a patient resulting from the administration of blood or blood products with major blood group incompatibilities;

(5) a surgical procedure on the wrong patient or on the wrong body part of a patient;

(6) a foreign object accidentally left in a patient during a procedure; and

(7) a patient death or serious disability associated with the use or function of a device designed for patient care that is used or functions other than as intended.

(b) The department may not require the annual report to include any information other than the number of occurrences of each event listed in Subsection (a).

Added by Acts 2003, 78th Leg., ch. 569, Sec. 4, eff. June 20, 2003.

Sec. 243.053. ROOT CAUSE ANALYSIS AND ACTION PLAN. (a) In this section, "root cause analysis" means the process that identifies basic or causal factors underlying a variation in performance leading to an event listed in Section 243.052 and that:

(1) focuses primarily on systems and processes;

(2) progresses from special causes in clinical processes to common causes in organizational processes; and

(3) identifies potential improvements in processes or systems.

(b) Not later than the 45th day after an ambulatory surgical center becomes aware of the occurrence of an event listed in Section 243.052, the center shall:

(1) conduct a root cause analysis of the event; and

(2) develop an action plan that identifies strategies to reduce the risk of a similar event occurring in the future.

(c) The department may review a root cause analysis or action plan related to an event listed in Section 243.052 during a survey, inspection, or investigation of an ambulatory surgical center.

(d) The department may not require a root cause analysis or action plan to be submitted to the department.

(e) The department or an employee or agent of the department may not in any form, format, or manner remove, copy, reproduce, redact, or dictate from any part of a root cause analysis or action plan.

Added by Acts 2003, 78th Leg., ch. 569, Sec. 4, eff. June 20, 2003.

Sec. 243.054. CONFIDENTIALITY; ABSOLUTE PRIVILEGE. (a) Except as provided by Sections 243.055 and 243.056, all information and materials obtained or compiled by the department under this subchapter or compiled by an ambulatory surgical center under this

subchapter, including the root cause analysis, annual report of an ambulatory surgical center, action plan, best practices report, department summary, and all related information and materials, are confidential and:

(1) are not subject to disclosure under Chapter 552, Government Code, or discovery, subpoena, or other means of legal compulsion for release to any person, subject to Section 243.053(c); and

(2) may not be admitted as evidence or otherwise disclosed in any civil, criminal, or administrative proceeding.

(b) The confidentiality protections under Subsection (a) apply without regard to whether the information or materials are obtained from or compiled by an ambulatory surgical center or an entity that has an ownership or management interest in an ambulatory surgical center.

(c) The transfer of information or materials under this subchapter is not a waiver of a privilege or protection granted under law.

(d) Information reported by an ambulatory surgical center under this subchapter and analyses, plans, records, and reports obtained, prepared, or compiled by the center under this subchapter and all related information and materials are subject to an absolute privilege and may not be used in any form against the center or the center's agents, employees, partners, assignees, or independent contractors in any civil, criminal, or administrative proceeding, regardless of the means by which a person came into possession of the information, analysis, plan, record, report, or related information or material. A court shall enforce this privilege for all matters covered by this subsection.

(e) The provisions of this section regarding the confidentiality of information or materials compiled or reported by an ambulatory surgical center in compliance with or as authorized under this subchapter do not restrict access, to the extent authorized by law, by the patient or the patient's legally authorized representative to records of the patient's medical diagnosis or treatment or to other primary health records.

Added by Acts 2003, 78th Leg., ch. 569, Sec. 4, eff. June 20, 2003.

Sec. 243.055. ANNUAL DEPARTMENT SUMMARY. The department annually shall compile and make available to the public a summary of the events reported by ambulatory surgical centers as required by Section 243.052. The summary may contain only aggregated information and may not directly or indirectly identify:

(1) a specific ambulatory surgical center or group of centers;

(2) an individual; or

(3) a specific reported event or the circumstances or individuals surrounding the event.

Added by Acts 2003, 78th Leg., ch. 569, Sec. 4, eff. June 20, 2003.

Sec. 243.056. BEST PRACTICES REPORT AND DEPARTMENT SUMMARY. (a) An ambulatory surgical center shall provide to the department at least one report of best practices and safety measures related to a reported event.

(b) An ambulatory surgical center may provide to the department a report of other best practices and the safety measures, such as marking a surgical site and involving the patient in the marking process, that are effective in improving patient safety.

(c) The department by rule may prescribe the form and format of a best practices report. The department may not require a best practices report to exceed one page in length. The department shall accept, in lieu of a report in the form and format prescribed by the department, a copy of a report submitted by an ambulatory surgical center to a patient safety organization.

(d) The department periodically shall:

(1) review the best practices reports;

(2) compile a summary of the best practices reports determined by the department to be effective and recommended as best practices; and

(3) make the summary available to the public.

(e) The summary may not directly or indirectly identify:

(1) a specific ambulatory surgical center or group of centers;

(2) an individual; or

(3) a specific reported event or the circumstances or individuals surrounding the event.

Added by Acts 2003, 78th Leg., ch. 569, Sec. 4, eff. June 20, 2003.

Sec. 243.057. PROHIBITION. The annual report of an ambulatory surgical center, the department summary, or the best practices report may not distinguish between an event that occurred at an outpatient facility owned or operated by the center and an event that occurred at a center facility.

Added by Acts 2003, 78th Leg., ch. 569, Sec. 4, eff. June 20, 2003.

Sec. 243.058. REPORT TO LEGISLATURE. (a) Not later than December 1, 2006, the commissioner of public health shall:

(1) evaluate the patient safety program established under this subchapter; and

(2) report the results of the evaluation and make recommendations to the legislature.

(b) The commissioner of public health shall conduct the evaluation in consultation with ambulatory surgical centers.

(c) The evaluation must address:

(1) the degree to which the department was able to detect statewide trends in errors based on the types and numbers of events reported;

(2) the degree to which the statewide summaries of events compiled by the department were accessed by the public;

(3) the effectiveness of the department's best practices summary in improving patient care; and

(4) the impact of national studies on the effectiveness of state or federal systems of reporting medical errors.

Added by Acts 2003, 78th Leg., ch. 569, Sec. 4, eff. June 20, 2003.

Sec. 243.059. GIFTS, GRANTS, AND DONATIONS. The department may accept and administer a gift, grant, or donation from any source to carry out the purposes of this subchapter.

Added by Acts 2003, 78th Leg., ch. 569, Sec. 4, eff. June 20, 2003.

Sec. 243.060. EXPIRATION. Unless continued in existence, this subchapter expires September 1, 2007.

Added by Acts 2003, 78th Leg., ch. 569, Sec. 4, eff. June 20, 2003.