

By: Shapiro

S.B. No. 401

A BILL TO BE ENTITLED

AN ACT

relating to the licensing and regulation of diagnostic imaging facilities and fluoroscopy-guided pain management procedure centers; providing penalties.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Subtitle B, Title 4, Health and Safety Code, is amended by adding Chapter 260A to read as follows:

CHAPTER 260A. DIAGNOSTIC IMAGING FACILITIES AND FLUOROSCOPY-GUIDED PAIN MANAGEMENT PROCEDURE CENTERS

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 260A.001. SHORT TITLE. This chapter may be cited as the Texas Diagnostic Imaging Facilities and Fluoroscopy-Guided Pain Management Procedure Centers Licensing Act.

Sec. 260A.002. DEFINITIONS. In this chapter:

(1) "C-arm fluoroscope" means a fluoroscopic x-ray system that connects or coordinates the image receptor and the x-ray tube housing assembly to maintain a spatial relationship and that allows a change in the direction of the beam axis with respect to a patient without moving the patient.

(2) "Commissioner" means the commissioner of state health services.

(3) "Department" means the Department of State Health Services.

(4) "Diagnostic imaging facility" means a facility at

1 which a diagnostic imaging service is provided to a patient by a
2 diagnostic imaging provider.

3 (5) "Diagnostic imaging provider" means any person
4 that provides a diagnostic imaging service to a patient for a fee.

5 (6) "Diagnostic imaging service" means magnetic
6 resonance imaging, computed tomography, positron emission
7 tomography, or any hybrid technology that combines any of those
8 imaging modalities.

9 (7) "Executive commissioner" means the executive
10 commissioner of the Health and Human Services Commission.

11 (8) "Facility" means a diagnostic imaging facility or
12 fluoroscopy-guided pain management procedure center.

13 (9) "Fluoroscope" means a radiologic instrument
14 equipped with a fluorescent screen on which opaque internal
15 structures can be viewed as moving shadow images formed by the
16 differential transmission of x-rays throughout the body or a
17 similar radiologic or other instrument, as defined by executive
18 commissioner rule.

19 (10) "Fluoroscopy-guided pain management procedure
20 center" means a facility at which a majority of patients at the
21 facility are provided a fluoroscopy-guided pain management service
22 by a pain management provider.

23 (11) "Fluoroscopy-guided pain management service"
24 means the diagnosis and treatment of chronic pain through the use of
25 a fluoroscope or C-arm fluoroscope and interventional techniques,
26 including:

27 (A) ablation of targeted nerves; and

1 (B) percutaneous precision needle placement
2 within the spinal column with placement of drugs such as local
3 anesthetics, steroids, or analgesics in targeted areas of the
4 spinal column.

5 (12) "Pain management provider" means any person that
6 provides a fluoroscopy-guided pain management service to a patient
7 for a fee.

8 (13) "Person" means an individual, firm, partnership,
9 corporation, or association.

10 Sec. 260A.003. DIAGNOSTIC IMAGING AND FLUOROSCOPY-GUIDED
11 PAIN MANAGEMENT PROCEDURE FACILITY LICENSING FUND. All licensing
12 fees collected under this chapter shall be deposited in the state
13 treasury to the credit of the diagnostic imaging and
14 fluoroscopy-guided pain management procedure facility licensing
15 fund and shall be appropriated to the department only to administer
16 and enforce this chapter.

17 [Sections 260A.004-260A.050 reserved for expansion]

18 SUBCHAPTER B. FACILITY LICENSING AND REGULATION

19 Sec. 260A.051. LICENSE REQUIRED. (a) Except as provided by
20 Section 260A.052, a person may not establish or operate a
21 diagnostic imaging facility in this state unless the person holds a
22 diagnostic imaging facility license issued under this chapter.

23 (b) Except as provided by Section 260A.053, a person may not
24 establish or operate a fluoroscopy-guided pain management
25 procedure center in this state unless the person holds a
26 fluoroscopy-guided pain management procedure center license issued
27 under this chapter.

1 (c) Each separate facility location must have a separate
2 license.

3 (d) A license issued under this chapter is not transferable
4 or assignable.

5 Sec. 260A.052. EXEMPTIONS FROM DIAGNOSTIC IMAGING FACILITY
6 LICENSING REQUIREMENT. The following facilities and offices are
7 not required to hold a diagnostic imaging facility license issued
8 under this chapter:

9 (1) an institution licensed under Chapter 242;

10 (2) a hospital licensed under Chapter 241 or Chapter
11 577, or an outpatient clinic or facility of a hospital that meets
12 the requirements for provider-based status as prescribed by the
13 Centers for Medicare and Medicaid Services;

14 (3) an ambulatory surgical center licensed under
15 Chapter 243;

16 (4) a medical school or an outpatient clinic
17 associated with a medical school;

18 (5) a health facility, including a hospital,
19 maintained or operated by this state;

20 (6) a clinic or hospital maintained or operated by the
21 United States; or

22 (7) an office of or clinic owned or operated by a
23 physician licensed under Subtitle B, Title 3, Occupations Code.

24 Sec. 260A.053. EXEMPTIONS FROM FLUOROSCOPY-GUIDED PAIN
25 MANAGEMENT PROCEDURE CENTER LICENSING REQUIREMENT. The following
26 facilities and offices are not required to hold a
27 fluoroscopy-guided pain management procedure center license issued

1 under this chapter:

2 (1) a pain management clinic that is certified under
3 Subtitle B, Title 3, Occupations Code;

4 (2) an institution licensed under Chapter 242;

5 (3) a hospital licensed under Chapter 241 or Chapter
6 577, or an outpatient clinic or facility of a hospital that meets
7 the requirements for provider-based status as prescribed by the
8 Centers for Medicare and Medicaid Services;

9 (4) an ambulatory surgical center licensed under
10 Chapter 243;

11 (5) a medical school or an outpatient clinic
12 associated with a medical school;

13 (6) a hospice licensed under Chapter 142 to provide
14 hospice services in this state or a hospice as defined by 42 C.F.R.
15 Section 418.3;

16 (7) a health facility, including a hospital,
17 maintained or operated by this state;

18 (8) a clinic or hospital maintained or operated by the
19 United States; or

20 (9) an office of or clinic owned or operated by a
21 physician licensed under Subtitle B, Title 3, Occupations Code.

22 Sec. 260A.054. LICENSE APPLICATION AND ISSUANCE. (a) An
23 applicant for a license under this chapter must submit to the
24 department an application on a form prescribed by the department.

25 (b) The application must contain evidence that the facility
26 has on staff at least one physician licensed under Subtitle B, Title
27 3, Occupations Code.

1 (c) Each application must be accompanied by a nonrefundable
2 license fee in an amount set by the department.

3 (d) The department shall issue a license for a facility
4 under this chapter if, after inspection and investigation of the
5 facility, the department determines the applicant and the facility
6 meet the requirements of this chapter and the rules and standards
7 adopted for that type of facility by the executive commissioner
8 under this chapter.

9 Sec. 260A.055. LICENSE RENEWAL. (a) A license issued under
10 this chapter expires on the third anniversary of the date of
11 issuance. A person may apply to renew a facility license by:

12 (1) submitting a renewal application to the department
13 on the form prescribed by the department before expiration of the
14 license;

15 (2) submitting the renewal fee in the amount required
16 by the department; and

17 (3) complying with any other requirements specified by
18 executive commissioner rule.

19 (b) The owner or operator of a facility whose license has
20 expired may not continue to operate the facility until the license
21 is renewed.

22 [Sections 260A.056-260A.100 reserved for expansion]

23 SUBCHAPTER C. POWERS AND DUTIES OF DEPARTMENT AND EXECUTIVE
24 COMMISSIONER

25 Sec. 260A.101. ADOPTION OF RULES. (a) The executive
26 commissioner shall adopt rules necessary to implement this chapter,
27 including rules to address, for each type of facility:

1 (1) requirements for the issuance, renewal, denial,
2 suspension, probation, and revocation of a license to operate a
3 facility;

4 (2) minimum standards for aspects of the operation of
5 the facility that the executive commissioner considers necessary to
6 protect the facility's patients and the public, including minimum
7 standards for:

8 (A) the qualifications for the facility's
9 professional staff and other personnel;

10 (B) the equipment, including imaging equipment,
11 essential to the health and welfare of the facility's patients; and

12 (C) the sanitary and hygienic conditions within
13 the premises of the facility;

14 (3) minimum design standards for the premises of a
15 facility necessary to ensure the health and safety of the
16 facility's patients;

17 (4) the establishment of a quality assurance program
18 for patient care; and

19 (5) if the facility is owned wholly or partly by a
20 physician, the provision of a disclosure to the facility's patients
21 of the physician's ownership interest in the facility and, at the
22 option of the facility's individual patients, the provision of a
23 list of alternative service providers for the services provided by
24 the facility.

25 (b) For purposes of regulation of fluoroscopy-guided pain
26 management procedure centers, the executive commissioner by rule
27 shall adopt standards for determining whether a majority of

1 patients at a facility are provided a fluoroscopy-guided pain
2 management service by a pain management provider.

3 (c) In adopting the rules required under Subsection (a), the
4 executive commissioner may adopt different minimum standards and
5 requirements to reflect the different services provided and the
6 purposes served by each type of facility.

7 (d) This section does not authorize the executive
8 commissioner to:

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

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

14 Sec. 260A.102. INSPECTIONS. The department may inspect a
15 facility at reasonable times as necessary to assure compliance with
16 this chapter and the rules adopted under this chapter.

17 Sec. 260A.103. FEES. The department shall set fees imposed
18 under this chapter in amounts reasonable and necessary to cover the
19 cost of administering and enforcing this chapter.

20 [Sections 260A.104-260A.150 reserved for expansion]

21 SUBCHAPTER D. GENERAL ENFORCEMENT

22 Sec. 260A.151. DENIAL, SUSPENSION, PROBATION, OR
23 REVOCAION OF LICENSE. (a) The department may deny, suspend, or
24 revoke a license issued under this chapter for a violation of this
25 chapter or a rule adopted under this chapter.

26 (b) Except as provided by Section 260A.152, the procedures
27 by which the department denies, suspends, or revokes a license and

1 by which those actions are appealed are governed by the procedures
2 for a contested case hearing under Chapter 2001, Government Code.

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

15 (d) The department may suspend or revoke the license of a
16 facility that does not correct items that were in noncompliance or
17 that does not comply with this chapter or the rules adopted under
18 this chapter within the applicable probation period.

19 Sec. 260A.152. EMERGENCY SUSPENSION. (a) The department
20 may issue an emergency order to suspend a license issued under this
21 chapter if the department has reasonable cause to believe that the
22 conduct of a license holder creates an immediate danger to the
23 public health and safety. An emergency suspension is effective
24 immediately on notice to the license holder.

25 (b) On written request of the license holder, the department
26 shall conduct a hearing not earlier than the 10th day or later than
27 the 30th day after the date the hearing request is received to

1 determine if the emergency suspension is to be continued, modified,
2 or rescinded.

3 (c) The hearing and any appeal are governed by the
4 department's rules for a contested case hearing and by Chapter
5 2001, Government Code.

6 Sec. 260A.153. INJUNCTION. (a) The department may
7 petition a district court for a temporary restraining order to
8 restrain a continuing violation of this chapter or the rules
9 adopted under this chapter if the department finds that the
10 violation creates an immediate threat to the health and safety of
11 the patients of a facility.

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

15 (1) prohibit the person from continuing the violation;

16 (2) restrain or prevent the establishment or operation
17 of a facility without a license issued under this chapter; or

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

20 (c) The attorney general shall institute and conduct a suit
21 authorized by this section at the request of the department. The
22 attorney general and the department may recover reasonable expenses
23 incurred in obtaining relief under this section, including court
24 costs, reasonable attorney's fees, investigation costs, witness
25 fees, and deposition expenses.

26 (d) Venue for a suit brought under this section is in the
27 county in which the facility is located or in Travis County.

1 Sec. 260A.154. CRIMINAL PENALTY. (a) A person commits an
2 offense if the person knowingly establishes or operates a facility
3 without the appropriate license issued under this chapter.

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

5 (c) Each day a violation continues constitutes a separate
6 offense.

7 Sec. 260A.155. CIVIL PENALTY. (a) A person who violates
8 this chapter or who fails to comply with a rule adopted by the
9 executive commissioner under this chapter is liable for a civil
10 penalty of not less than \$100 or more than \$500 for each violation
11 if the department determines the violation threatens the health and
12 safety of a patient of the facility.

13 (b) Each day a violation continues constitutes a separate
14 violation for the purposes of this section.

15 (c) The attorney general may sue to collect the penalty.
16 The attorney general and the department may recover reasonable
17 expenses incurred in obtaining relief under this section, including
18 court costs, reasonable attorney's fees, investigation costs,
19 witness fees, and deposition expenses.

20 (d) All penalties collected under this section shall be
21 deposited in the state treasury in the general revenue fund.

22 [Sections 260A.156-260A.200 reserved for expansion]

23 SUBCHAPTER E. ADMINISTRATIVE PENALTY

24 Sec. 260A.201. IMPOSITION OF PENALTY. The commissioner may
25 impose an administrative penalty on a person licensed under this
26 chapter who violates this chapter or a rule or order adopted under
27 this chapter.

1 Sec. 260A.202. AMOUNT OF PENALTY. (a) The amount of the
2 penalty may not exceed \$1,000 for each violation, and each day a
3 violation continues or occurs is a separate violation for purposes
4 of imposing a penalty. The total amount of the penalty assessed for
5 a violation continuing or occurring on separate days under this
6 subsection may not exceed \$5,000.

7 (b) The amount shall be based on:

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

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

12 (3) the history of previous violations;

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

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

17 (6) any other matter that justice may require.

18 Sec. 260A.203. REPORT AND NOTICE OF VIOLATION AND PENALTY.

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

22 (b) The notice must:

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

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

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

1 Sec. 260A.204. PENALTY TO BE PAID OR HEARING REQUESTED. (a)

2 Not later than the 20th day after the date the person receives the
3 notice sent under Section 260A.203, the person in writing may:

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

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

8 (b) If the person accepts the determination and recommended
9 penalty or if the person fails to respond to the notice, the
10 commissioner by order shall approve the determination and impose
11 the recommended penalty.

12 Sec. 260A.205. HEARING. (a) If the person requests a
13 hearing, the commissioner shall refer the matter to the State
14 Office of Administrative Hearings, which shall promptly set a
15 hearing date and give written notice of the time and place of the
16 hearing to the person. An administrative law judge of the State
17 Office of Administrative Hearings shall conduct the hearing.

18 (b) The administrative law judge shall make findings of fact
19 and conclusions of law and promptly issue to the commissioner a
20 proposal for a decision about the occurrence of the violation and
21 the amount of a proposed penalty.

22 Sec. 260A.206. DECISION BY COMMISSIONER. (a) Based on the
23 findings of fact, conclusions of law, and proposal for a decision,
24 the commissioner by order may:

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

27 (2) find that a violation did not occur.

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

5 Sec. 260A.207. OPTIONS FOLLOWING DECISION: PAY OR APPEAL.
6 Not later than the 30th day after the date the order of the
7 commissioner under Section 260A.206 that imposes an administrative
8 penalty becomes final, the person shall:

- 9 (1) pay the penalty; or
10 (2) file a petition for judicial review of the
11 commissioner's order contesting the occurrence of the violation,
12 the amount of the penalty, or both.

13 Sec. 260A.208. STAY OF ENFORCEMENT OF PENALTY. (a) Within
14 the period prescribed by Section 260A.207, a person who files a
15 petition for judicial review may:

- 16 (1) stay enforcement of the penalty by:
17 (A) paying the penalty to the court for placement
18 in an escrow account; or
19 (B) giving the court a supersedeas bond approved
20 by the court that:

- 21 (i) is for the amount of the penalty; and
22 (ii) is effective until all judicial review
23 of the commissioner's order is final; or

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

- 26 (A) filing with the court a sworn affidavit of
27 the person stating that the person is financially unable to pay the

1 penalty and is financially unable to give the supersedeas bond; and

2 (B) sending a copy of the affidavit to the
3 commissioner by certified mail.

4 (b) If the commissioner receives a copy of an affidavit
5 under Subsection (a)(2), the commissioner may file with the court,
6 not later than the fifth day after the date the copy is received, a
7 contest to the affidavit. The court shall hold a hearing on the
8 facts alleged in the affidavit as soon as practicable and shall stay
9 the enforcement of the penalty on finding that the alleged facts are
10 true. The person who files an affidavit has the burden of proving
11 that the person is financially unable to pay the penalty and to give
12 a supersedeas bond.

13 Sec. 260A.209. COLLECTION OF PENALTY. (a) If the person
14 does not pay the penalty and the enforcement of the penalty is not
15 stayed, the penalty may be collected.

16 (b) The attorney general may sue to collect the penalty and
17 may recover reasonable expenses, including attorney's fees,
18 incurred in recovering the penalty.

19 (c) A penalty collected under this subchapter shall be
20 deposited in the state treasury in the general revenue fund.

21 Sec. 260A.210. DECISION BY COURT. (a) If the court
22 sustains the finding that a violation occurred, the court may
23 uphold or reduce the amount of the penalty and order the person to
24 pay the full or reduced amount of the penalty.

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

1 Sec. 260A.211. REMITTANCE OF PENALTY AND INTEREST. (a) If
2 the person paid the penalty and if the amount of the penalty is
3 reduced or the penalty is not upheld by the court, the court shall
4 order, when the court's judgment becomes final, that the
5 appropriate amount plus accrued interest be remitted to the person
6 not later than the 30th day after the date that the judgment of the
7 court becomes final.

8 (b) The interest accrues at the rate charged on loans to
9 depository institutions by the New York Federal Reserve Bank.

10 (c) The interest shall be paid for the period beginning on
11 the date the penalty is paid and ending on the date the penalty is
12 remitted.

13 Sec. 260A.212. RELEASE OF BOND. (a) If the person gave a
14 supersedeas bond and the penalty is not upheld by the court, the
15 court shall order, when the court's judgment becomes final, the
16 release of the bond.

17 (b) If the person gave a supersedeas bond and the amount of
18 the penalty is reduced, the court shall order the release of the
19 bond after the person pays the reduced amount.

20 Sec. 260A.213. ADMINISTRATIVE PROCEDURE. A proceeding to
21 impose the penalty is considered to be a contested case under
22 Chapter 2001, Government Code.

23 SECTION 2. (a) Not later than January 1, 2012, the
24 executive commissioner of the Health and Human Services Commission
25 shall adopt the rules required by Chapter 260A, Health and Safety
26 Code, as added by this Act.

27 (b) Notwithstanding Section 260A.051, Health and Safety

1 Code, as added by this Act, a person is not required to hold a
2 diagnostic imaging facility license or a fluoroscopy-guided pain
3 management procedure center license until March 1, 2012.

4 SECTION 3. (a) Except as provided by Subsection (b) of
5 this section, this Act takes effect September 1, 2011.

6 (b) Subchapters D and E, Chapter 260A, Health and Safety
7 Code, as added by this Act, take effect September 1, 2012.