By: Truitt H.B. No. 1621

Substitute the following for H.B. No. 1621:

By: Kolkhorst C.S.H.B. No. 1621

A BILL TO BE ENTITLED

AN ACT

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

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- 5 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:
- 6 SECTION 1. Subtitle B, Title 4, Health and Safety Code, is
- 7 amended by adding Chapter 260A to read as follows:
- 8 CHAPTER 260A. DIAGNOSTIC IMAGING FACILITIES AND FLUOROSCOPY-GUIDED
- 9 PAIN MANAGEMENT PROCEDURE CENTERS
- 10 SUBCHAPTER A. GENERAL PROVISIONS
- Sec. 260A.001. SHORT TITLE. This chapter may be cited as
- 12 the Texas Diagnostic Imaging Facilities and Fluoroscopy-Guided
- 13 Pain Management Procedure Centers Licensing Act.
- 14 Sec. 260A.002. DEFINITIONS. In this chapter:
- 15 (1) "C-arm fluoroscope" means a fluoroscopic x-ray
- 16 system that connects or coordinates the image receptor and the
- 17 x-ray tube housing assembly to maintain a spatial relationship and
- 18 that allows a change in the direction of the beam axis with respect
- 19 to a patient without moving the patient.
- 20 (2) "Commissioner" means the commissioner of state
- 21 health services.
- 22 (3) "Department" means the Department of State Health
- 23 Services.
- 24 (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-quided pain management procedure facility licensing
- 15 <u>fund and shall be appropriated to the department only to administer</u>
- 16 and enforce this chapter.
- [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 or dental school or an outpatient clinic
- 17 associated with a medical or dental school;
- 18 (5) a health facility, including a hospital,
- 19 maintained or operated by this state or by a hospital district
- 20 created under general or special law;
- 21 (6) a clinic or hospital maintained or operated by the
- 22 United States;
- 23 (7) an office of or clinic owned or operated by:
- 24 (A) a physician licensed under Subtitle B, Title
- 25 3, Occupations Code; or
- 26 (B) a dentist licensed under Subtitle D, Title 3,
- 27 Occupations Code; or

- 1 (8) a diagnostic imaging facility that uses only
- 2 dental diagnostic technology, which may include cone-beam computed
- 3 tomography, to obtain images of the maxillofacial region.
- 4 Sec. 260A.053. EXEMPTIONS FROM FLUOROSCOPY-GUIDED PAIN
- 5 MANAGEMENT PROCEDURE CENTER LICENSING REQUIREMENT. The following
- 6 facilities and offices are not required to hold a
- 7 <u>fluoroscopy-guided pain management procedure center license issued</u>
- 8 under this chapter:
- 9 (1) a pain management clinic that is certified under
- 10 Subtitle B, Title 3, Occupations Code;
- 11 (2) an institution licensed under Chapter 242;
- 12 (3) a hospital licensed under Chapter 241 or Chapter
- 13 577, or an outpatient clinic or facility of a hospital that meets
- 14 the requirements for provider-based status as prescribed by the
- 15 Centers for Medicare and Medicaid Services;
- 16 (4) an ambulatory surgical center licensed under
- 17 Chapter 243;
- 18 (5) a medical or dental school or an outpatient clinic
- 19 associated with a medical or dental school;
- 20 (6) a hospice licensed under Chapter 142 to provide
- 21 hospice services in this state or a hospice as defined by 42 C.F.R.
- 22 Section 418.3;
- 23 <u>(7) a health facility, including a hospital,</u>
- 24 maintained or operated by this state or by a hospital district
- 25 created under general or special law;
- 26 (8) a clinic or hospital maintained or operated by the
- 27 United States;

1 (9) an office of or clinic owned or operated by: 2 (A) a physician licensed under Subtitle B, Title 3 3, Occupations Code; or 4 (B) a dentist licensed under Subtitle D, Title 3, 5 Occupations Code; or 6 (10) a fluoroscopy-guided pain management procedure 7 center that uses only dental diagnostic technology, which may include cone-beam computed tomography, to obtain images of the 8 maxillofacial region. 9 Sec. 260A.054. LICENSE APPLICATION AND ISSUANCE. (a) An 10 applicant for a license under this chapter must submit to the 11 12 department an application on a form prescribed by the department. (b) The application must contain evidence that the facility 13 14 has on staff at least one physician licensed under Subtitle B, Title 15 3, Occupations Code. (c) Each application must be accompanied by a nonrefundable 16 17 license fee in an amount set by the department. (d) The department shall issue a license for a facility 18 under this chapter if, after inspection and investigation of the 19 facility, the department determines the applicant and the facility 20 meet the requirements of this chapter and the rules and standards 21 adopted for that type of facility by the executive commissioner 22 23 under this chapter. 24 Sec. 260A.055. LICENSE RENEWAL. (a) A license issued under this chapter expires on the third anniversary of the date of 25 26 issuance. A person may apply to renew a facility license by:

(1) submitting a renewal application to the department

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on the form prescribed by the department before expiration of the 1 2 license; 3 (2) submitting the renewal fee in the amount required by the department; and 4 5 (3) complying with any other requirements specified by executive commissioner rule. 6 7 (b) The owner or operator of a facility whose license has 8 expired may not continue to operate the facility until the license is renewed. 9 [Sections 260A.056-260A.100 reserved for expansion] 10 SUBCHAPTER C. POWERS AND DUTIES OF DEPARTMENT AND EXECUTIVE 11 12 COMMISSIONER Sec. 260A.101. ADOPTION OF RULES. (a) The executive 13 14 commissioner shall adopt rules necessary to implement this chapter, 15 including rules to address, for each type of facility: 16 (1) requirements for the issuance, renewal, denial, 17 suspension, probation, and revocation of a license to operate a 18 facility; 19 (2) minimum standards for aspects of the operation of the facility that the executive commissioner considers necessary to 20 protect the facility's patients and the public, including minimum 21 22 standards for: 23 (A) the qualifications for the facility's 24 professional staff and other personnel; (B) the equipment, including imaging equipment, 25 26 essential to the health and welfare of the facility's patients; and

(C) the sanitary and hygienic conditions within

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- 1 the premises of the facility;
- 2 (3) minimum design standards for the premises of a
- 3 facility necessary to ensure the health and safety of the
- 4 facility's patients;
- 5 (4) the establishment of a quality assurance program
- 6 for patient care; and
- 7 (5) if the facility is owned wholly or partly by a
- 8 physician or dentist, the provision of a disclosure to the
- 9 facility's patients of the physician's or dentist's ownership
- 10 interest in the facility and, at the option of the facility's
- 11 individual patients, the provision of a list of alternative service
- 12 providers for the services provided by the facility.
- 13 (b) For purposes of regulation of fluoroscopy-guided pain
- 14 management procedure centers, the executive commissioner by rule
- 15 shall adopt standards for determining whether a majority of
- 16 patients at a facility are provided a fluoroscopy-guided pain
- 17 management service by a pain management provider.
- 18 (c) In adopting the rules required under Subsection (a), the
- 19 executive commissioner may adopt different minimum standards and
- 20 requirements to reflect the different services provided and the
- 21 purposes served by each type of facility.
- 22 <u>(d) This section does not authorize the executive</u>
- 23 <u>commissioner to:</u>
- 24 (1) establish the qualifications of a licensed
- 25 practitioner; or
- 26 (2) permit a person to provide health care services
- 27 who is not authorized to provide those services under another state

- 1 law.
- 2 Sec. 260A.102. INSPECTIONS. The department may inspect a
- 3 facility at reasonable times as necessary to assure compliance with
- 4 this chapter and the rules adopted under this chapter.
- 5 Sec. 260A.103. FEES. The department shall set fees imposed
- 6 under this chapter in amounts reasonable and necessary to cover the
- 7 cost of administering and enforcing this chapter.
- 8 [Sections 260A.104-260A.150 reserved for expansion]
- 9 SUBCHAPTER D. GENERAL ENFORCEMENT
- 10 Sec. 260A.151. DENIAL, SUSPENSION, PROBATION, OR
- 11 REVOCATION OF LICENSE. (a) The department may deny, suspend, or
- 12 revoke a license issued under this chapter for a violation of this
- 13 chapter or a rule adopted under this chapter.
- (b) Except as provided by Section 260A.152, the procedures
- 15 by which the department denies, suspends, or revokes a license and
- 16 by which those actions are appealed are governed by the procedures
- 17 for a contested case hearing under Chapter 2001, Government Code.
- 18 (c) If the department finds that a facility is in repeated
- 19 noncompliance with this chapter or rules adopted under this chapter
- 20 but that the noncompliance does not endanger the public health and
- 21 safety, the department may schedule the facility for probation
- 22 rather than suspending or revoking the facility's license. The
- 23 department shall provide notice to the facility of the probation
- 24 and of the items of noncompliance not later than the 10th day before
- 25 the date the probation period begins. The department shall
- 26 designate a period of not less than 30 days during which the
- 27 facility will remain under probation. During the probation period,

- 1 the facility must correct the items that were in noncompliance and
- 2 report the corrections to the department for approval.
- 3 (d) The department may suspend or revoke the license of a
- 4 facility that does not correct items that were in noncompliance or
- 5 that does not comply with this chapter or the rules adopted under
- 6 this chapter within the applicable probation period.
- 7 <u>Sec. 260A.152. EMERGENCY SUSPENSION. (a) The department</u>
- 8 may issue an emergency order to suspend a license issued under this
- 9 chapter if the department has reasonable cause to believe that the
- 10 conduct of a license holder creates an immediate danger to the
- 11 public health and safety. An emergency suspension is effective
- 12 immediately on notice to the license holder.
- 13 (b) On written request of the license holder, the department
- 14 shall conduct a hearing not earlier than the 10th day or later than
- 15 the 30th day after the date the hearing request is received to
- 16 determine if the emergency suspension is to be continued, modified,
- 17 or rescinded.
- 18 (c) The hearing and any appeal are governed by the
- 19 department's rules for a contested case hearing and by Chapter
- 20 2001, Government Code.
- Sec. 260A.153. INJUNCTION. (a) The department may
- 22 petition a district court for a temporary restraining order to
- 23 restrain a continuing violation of this chapter or the rules
- 24 adopted under this chapter if the department finds that the
- 25 violation creates an immediate threat to the health and safety of
- 26 the patients of a facility.
- 27 (b) A district court, on petition of the department and on a

- 1 finding by the court that a person is violating this chapter or the
- 2 rules adopted under this chapter, may by injunction:
- 3 (1) prohibit the person from continuing the violation;
- 4 (2) restrain or prevent the establishment or operation
- 5 of a facility without a license issued under this chapter; or
- 6 (3) grant any other injunctive relief warranted by the
- 7 facts.
- 8 (c) The attorney general shall institute and conduct a suit
- 9 authorized by this section at the request of the department. The
- 10 attorney general and the department may recover reasonable expenses
- 11 incurred in obtaining relief under this section, including court
- 12 costs, reasonable attorney's fees, investigation costs, witness
- 13 fees, and deposition expenses.
- 14 (d) Venue for a suit brought under this section is in the
- 15 county in which the facility is located or in Travis County.
- Sec. 260A.154. CRIMINAL PENALTY. (a) A person commits an
- 17 offense if the person knowingly establishes or operates a facility
- 18 without the appropriate license issued under this chapter.
- 19 (b) An offense under this section is a Class C misdemeanor.
- 20 (c) Each day a violation continues constitutes a separate
- 21 offense.
- Sec. 260A.155. CIVIL PENALTY. (a) A person who violates
- 23 this chapter or who fails to comply with a rule adopted by the
- 24 executive commissioner under this chapter is liable for a civil
- 25 penalty of not less than \$100 or more than \$500 for each violation
- 26 if the department determines the violation threatens the health and
- 27 safety of a patient of the facility.

- 1 (b) Each day a violation continues constitutes a separate
- 2 violation for the purposes of this section.
- 3 (c) The attorney general may sue to collect the penalty.
- 4 The attorney general and the department may recover reasonable
- 5 expenses incurred in obtaining relief under this section, including
- 6 court costs, reasonable attorney's fees, investigation costs,
- 7 witness fees, and deposition expenses.
- 8 <u>(d) All penalties collected under this section shall be</u>
- 9 deposited in the state treasury in the general revenue fund.
- [Sections 260A.156-260A.200 reserved for expansion]
- SUBCHAPTER E. ADMINISTRATIVE PENALTY
- 12 Sec. 260A.201. IMPOSITION OF PENALTY. The commissioner may
- 13 impose an administrative penalty on a person licensed under this
- 14 chapter who violates this chapter or a rule or order adopted under
- 15 <u>this chapter.</u>
- Sec. 260A.202. AMOUNT OF PENALTY. (a) The amount of the
- 17 penalty may not exceed \$1,000 for each violation, and each day a
- 18 violation continues or occurs is a separate violation for purposes
- 19 of imposing a penalty. The total amount of the penalty assessed for
- 20 a violation continuing or occurring on separate days under this
- 21 subsection may not exceed \$5,000.
- 22 (b) The amount shall be based on:
- 23 <u>(1) the seriousness of the violation, including the</u>
- 24 nature, circumstances, extent, and gravity of the violation;
- 25 (2) the threat to health or safety caused by the
- 26 violation;
- 27 (3) the history of previous violations;

C.S.H.B. No. 1621 1 (4) the amount necessary to deter a future violation; 2 (5) whether the violator demonstrated good faith, including when applicable whether the violator made good faith 3 efforts to correct the violation; and 4 5 (6) any other matter that justice may require. 6 Sec. 260A.203. REPORT AND NOTICE OF VIOLATION AND PENALTY. (a) If the department initially determines that a violation 7 8 occurred, the department shall give written notice of the report by certified mail to the person. 9 10 (b) The notice must: (1) include a brief summary of the alleged violation; 11 12 (2) state the amount of the recommended penalty; and (3) inform the person of the person's right to a 13 14 hearing on the occurrence of the violation, the amount of the 15 penalty, or both. Sec. 260A.204. PENALTY TO BE PAID OR HEARING REQUESTED. (a) 16 17 Not later than the 20th day after the date the person receives the notice sent under Section 260A.203, the person in writing may: 18 19 (1) accept the determination and recommended penalty 20 of the department; or 21 (2) make a request for a hearing on the occurrence of

Sec. 260A.205. HEARING. (a) If the person requests a

penalty or if the person fails to respond to the notice, the

commissioner by order shall approve the determination and impose

(b) If the person accepts the determination and recommended

the violation, the amount of the penalty, or both.

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the recommended penalty.

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- 1 hearing, the commissioner shall refer the matter to the State
- 2 Office of Administrative Hearings, which shall promptly set a
- 3 hearing date and give written notice of the time and place of the
- 4 hearing to the person. An administrative law judge of the State
- 5 Office of Administrative Hearings shall conduct the hearing.
- 6 (b) The administrative law judge shall make findings of fact
- 7 and conclusions of law and promptly issue to the commissioner a
- 8 proposal for a decision about the occurrence of the violation and
- 9 the amount of a proposed penalty.
- Sec. 260A.206. DECISION BY COMMISSIONER. (a) Based on the
- 11 findings of fact, conclusions of law, and proposal for a decision,
- 12 the commissioner by order may:
- 13 (1) find that a violation occurred and impose a
- 14 penalty; or
- 15 (2) find that a violation did not occur.
- 16 (b) The notice of the commissioner's order under Subsection
- 17 (a) that is sent to the person in accordance with Chapter 2001,
- 18 Government Code, must include a statement of the right of the person
- 19 to judicial review of the order.
- Sec. 260A.207. OPTIONS FOLLOWING DECISION: PAY OR APPEAL.
- 21 Not later than the 30th day after the date the order of the
- 22 <u>commissioner under Section 260A.206 that imposes an administrative</u>
- 23 penalty becomes final, the person shall:
- 24 (1) pay the penalty; or
- 25 (2) file a petition for judicial review of the
- 26 commissioner's order contesting the occurrence of the violation,
- 27 the amount of the penalty, or both.

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1 Sec. 260A.208. STAY OF ENFORCEMENT OF PENALTY. (a) Within the period prescribed by Section 260A.207, a person who files a 2 petition for judicial review may: 3 4 (1) stay enforcement of the penalty by: 5 (A) paying the penalty to the court for placement in an escrow account; or 6 7 (B) giving the court a supersedeas bond approved 8 by the court that: 9 (i) is for the amount of the penalty; and 10 (ii) is effective until all judicial review of the commissioner's order is final; or 11 12 (2) request the court to stay enforcement of the 13 penalty by: 14 (A) filing with the court a sworn affidavit of 15 the person stating that the person is financially unable to pay the penalty and is financially unable to give the supersedeas bond; and 16 17 (B) sending a copy of the affidavit to the commissioner by certified mail. 18 (b) If the commissioner receives a copy of an affidavit 19 under Subsection (a)(2), the commissioner may file with the court, 20 not later than the fifth day after the date the copy is received, a 21 contest to the affidavit. The court shall hold a hearing on the 22 facts alleged in the affidavit as soon as practicable and shall stay 23 24 the enforcement of the penalty on finding that the alleged facts are true. The person who files an affidavit has the burden of proving 25 26 that the person is financially unable to pay the penalty and to give

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a supersedeas bond.

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- 1 Sec. 260A.209. COLLECTION OF PENALTY. (a) If the person
- 2 does not pay the penalty and the enforcement of the penalty is not
- 3 stayed, the penalty may be collected.
- 4 (b) The attorney general may sue to collect the penalty and
- 5 may recover reasonable expenses, including attorney's fees,
- 6 incurred in recovering the penalty.
- 7 (c) A penalty collected under this subchapter shall be
- 8 deposited in the state treasury in the general revenue fund.
- 9 Sec. 260A.210. DECISION BY COURT. (a) If the court
- 10 sustains the finding that a violation occurred, the court may
- 11 uphold or reduce the amount of the penalty and order the person to
- 12 pay the full or reduced amount of the penalty.
- 13 (b) If the court does not sustain the finding that a
- 14 violation occurred, the court shall order that a penalty is not
- 15 owed.
- Sec. 260A.211. REMITTANCE OF PENALTY AND INTEREST. (a) If
- 17 the person paid the penalty and if the amount of the penalty is
- 18 reduced or the penalty is not upheld by the court, the court shall
- 19 order, when the court's judgment becomes final, that the
- 20 appropriate amount plus accrued interest be remitted to the person
- 21 not later than the 30th day after the date that the judgment of the
- 22 court becomes final.
- 23 (b) The interest accrues at the rate charged on loans to
- 24 depository institutions by the New York Federal Reserve Bank.
- 25 (c) The interest shall be paid for the period beginning on
- 26 the date the penalty is paid and ending on the date the penalty is
- 27 <u>remitted.</u>

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- Sec. 260A.212. RELEASE OF BOND. (a) If the person gave a
- 2 supersedeas bond and the penalty is not upheld by the court, the
- 3 court shall order, when the court's judgment becomes final, the
- 4 release of the bond.
- 5 (b) If the person gave a supersedeas bond and the amount of
- 6 the penalty is reduced, the court shall order the release of the
- 7 bond after the person pays the reduced amount.
- 8 Sec. 260A.213. ADMINISTRATIVE PROCEDURE. A proceeding to
- 9 impose the penalty is considered to be a contested case under
- 10 Chapter 2001, Government Code.
- 11 SECTION 2. (a) Not later than January 1, 2012, the
- 12 executive commissioner of the Health and Human Services Commission
- 13 shall adopt the rules required by Chapter 260A, Health and Safety
- 14 Code, as added by this Act.
- 15 (b) Notwithstanding Section 260A.051, Health and Safety
- 16 Code, as added by this Act, a person is not required to hold a
- 17 diagnostic imaging facility license or a fluoroscopy-guided pain
- 18 management procedure center license until March 1, 2012.
- 19 SECTION 3. (a) Except as provided by Subsection (b) of
- 20 this section, this Act takes effect September 1, 2011.
- 21 (b) Subchapters D and E, Chapter 260A, Health and Safety
- 22 Code, as added by this Act, take effect September 1, 2012.