

AN ACT

relating to the regulation of controlled substances; providing an administrative penalty.

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

SECTION 1. Subsection (a), Section 481.064, Health and Safety Code, is amended to read as follows:

(a) The director may charge a nonrefundable fee of not more than \$25 before processing an application for annual registration and may charge a late fee of not more than \$50 for each application for renewal the department receives after the date the registration expires. The director by rule shall set the amounts [~~amount~~] of the fees [~~fee~~] at the amounts [~~amount~~] that are [~~is~~] necessary to cover the cost of administering and enforcing this subchapter. Except as provided by Subsection (b), registrants shall pay the fees to the director. Not later than 60 days before the date the registration expires, the director shall send a renewal notice to the registrant at the last known address of the registrant according to department records.

SECTION 2. Section 481.074, Health and Safety Code, is amended by amending Subsections (b), (d), and (k) and adding Subsection (q) to read as follows:

(b) Except in an emergency as defined by rule of the director or as provided by Subsection (o) or Section 481.075(j) or (m), a person may not dispense or administer a controlled substance

1 listed in Schedule II without the written prescription of a
2 practitioner on an official prescription form that meets the
3 requirements of and is completed by the practitioner in accordance
4 with Section 481.075. In an emergency, a person may dispense or
5 administer a controlled substance listed in Schedule II on the oral
6 or telephonically communicated prescription of a practitioner. The
7 person who administers or dispenses the substance shall:

8 (1) if the person is a prescribing practitioner or a
9 pharmacist, promptly comply with Subsection (c); or

10 (2) if the person is not a prescribing practitioner or
11 a pharmacist, promptly write the oral or telephonically
12 communicated prescription and include in the written record of the
13 prescription the name, address, department registration number,
14 and Federal Drug Enforcement Administration number of the
15 prescribing practitioner, all information required to be provided
16 by a practitioner under Section 481.075(e)(1), and all information
17 required to be provided by a dispensing pharmacist under Section
18 481.075(e)(2).

19 (d) Except as specified in Subsections (e) and (f) [~~of this~~
20 ~~section~~], the director, by rule and in consultation with the Texas
21 Medical Board and the Texas State Board of Pharmacy, shall
22 establish the period after the date on which the prescription is
23 issued that a person may [not] fill a prescription for a controlled
24 substance listed in Schedule II [after the end of the seventh day
25 after the date on which the prescription is issued]. A person may
26 not refill a prescription for a substance listed in Schedule II.

27 (k) A prescription for a controlled substance must show:

- 1 (1) the quantity of the substance prescribed:
2 (A) numerically, followed by the number written
3 as a word, if the prescription is written; or
4 (B) if the prescription is communicated orally or
5 telephonically, as transcribed by the receiving pharmacist;
6 (2) the date of issue;
7 (3) the name, ~~and~~ address, and date of birth or age
8 of the patient or, if the controlled substance is prescribed for an
9 animal, the species of the animal and the name and address of its
10 owner;
11 (4) the name and strength of the controlled substance
12 prescribed;
13 (5) the directions for use of the controlled
14 substance;
15 (6) the intended use of the substance prescribed
16 unless the practitioner determines the furnishing of this
17 information is not in the best interest of the patient; ~~and~~
18 (7) the legibly printed or stamped name, address,
19 Federal Drug Enforcement Administration registration number, and
20 telephone number of the practitioner at the practitioner's usual
21 place of business;
22 (8) if the prescription is handwritten, the signature
23 of the prescribing practitioner; and
24 (9) if the prescribing practitioner is licensed in
25 this state, the practitioner's department registration number.
26 (q) Each dispensing pharmacist shall send all information
27 required by the director, including any information required to

1 complete the Schedule III through V prescription forms, to the
2 director by electronic transfer or another form approved by the
3 director not later than the 15th day after the last day of the month
4 in which the prescription is completely filled.

5 SECTION 3. Subsections (a) and (c), Section 481.076, Health
6 and Safety Code, are amended to read as follows:

7 (a) The director may not permit any person to have access to
8 information submitted to the director under Section 481.074(q) or
9 481.075 except:

10 (1) an investigator for the Texas [~~State Board of~~
11 Medical Board [~~Examiners~~], the Texas State Board of Podiatric
12 Medical Examiners, the State Board of Dental Examiners, the State
13 Board of Veterinary Medical Examiners, or the Texas State Board of
14 Pharmacy;

15 (2) an authorized officer or member of the department
16 engaged in the administration, investigation, or enforcement of
17 this chapter or another law governing illicit drugs in this state or
18 another state; or

19 (3) if the director finds that proper need has been
20 shown to the director:

21 (A) a law enforcement or prosecutorial official
22 engaged in the administration, investigation, or enforcement of
23 this chapter or another law governing illicit drugs in this state or
24 another state;

25 (B) a pharmacist or practitioner who is a
26 physician, dentist, veterinarian, [~~or~~] podiatrist, or advanced
27 practice nurse or physician assistant described by Section

1 481.002(39)(D) and is inquiring about a ~~[the]~~ recent Schedule II,
2 III, IV, or V prescription history of a particular patient of the
3 practitioner; or

4 (C) a pharmacist or practitioner who is inquiring
5 about the person's own dispensing or prescribing activity.

6 (c) The director by rule shall design and implement a system
7 for submission of information to the director by electronic or
8 other means and for retrieval of information submitted to the
9 director under this section and Sections 481.074 and [Section]
10 481.075. The director shall use automated information security
11 techniques and devices to preclude improper access to the
12 information. The director shall submit the system design to the
13 Texas State Board of Pharmacy and the Texas ~~[State Board of]~~ Medical
14 Board [Examiners] for review and approval or comment a reasonable
15 time before implementation of the system and shall comply with the
16 comments of those agencies unless it is unreasonable to do so.

17 SECTION 4. Subsections (a), (b), (c), and (e), Section
18 481.0761, Health and Safety Code, are amended to read as follows:

19 (a) The director shall consult with the Texas State Board of
20 Pharmacy and by rule establish and revise as necessary a
21 standardized database format that may be used by a pharmacy to
22 transmit the information required by Sections 481.074(q) and
23 ~~[Section]~~ 481.075(i) to the director electronically or to deliver
24 the information on storage media, including disks, tapes, and
25 cassettes.

26 (b) The director shall consult with the ~~[Texas]~~ Department
27 of State Health Services, the Texas State Board of Pharmacy, and the

1 Texas [~~State Board of~~] Medical Board [~~Examiners~~] and by rule may:

2 (1) remove a controlled substance listed in Schedules
3 [~~Schedule~~] II through V from the official prescription program, if
4 the director determines that the burden imposed by the program
5 substantially outweighs the risk of diversion of the particular
6 controlled substance; or

7 (2) return a substance previously removed from
8 Schedules [~~Schedule~~] II through V to the official prescription
9 program, if the director determines that the risk of diversion
10 substantially outweighs the burden imposed by the program on the
11 particular controlled substance.

12 (c) The director by rule may:

13 (1) permit more than one prescription to be
14 administered or dispensed and recorded on one [~~official~~]
15 prescription form for a Schedule III through V controlled
16 substance;

17 (2) remove from or return to the official prescription
18 program any aspect of a practitioner's or pharmacist's hospital
19 practice, including administering or dispensing;

20 (3) waive or delay any requirement relating to the
21 time or manner of reporting;

22 (4) establish compatibility protocols for electronic
23 data transfer hardware, software, or format;

24 (5) establish a procedure to control the release of
25 information under Sections 481.074, 481.075, and 481.076; and

26 (6) establish a minimum level of prescription activity
27 below which a reporting activity may be modified or deleted.

1 (e) In adopting a rule relating to the electronic transfer
2 of information under this subchapter, the director shall consider
3 the economic impact of the rule on practitioners and pharmacists
4 and, to the extent permitted by law, act to minimize any negative
5 economic impact, including the imposition of costs related to
6 computer hardware or software or to the transfer of information.
7 The director may not adopt a rule relating to the electronic
8 transfer of information under this subchapter that imposes a fee in
9 addition to the fees [~~fee~~] authorized by Section 481.064.

10 SECTION 5. Chapter 481, Health and Safety Code, is amended
11 by adding Subchapter H to read as follows:

12 SUBCHAPTER H. ADMINISTRATIVE PENALTY

13 Sec. 481.301. IMPOSITION OF PENALTY. The department may
14 impose an administrative penalty on a person who violates Section
15 481.061, 481.066, 481.067, 481.069, 481.074, 481.075, 481.077,
16 481.0771, 481.078, 481.080, or 481.081 or a rule or order adopted
17 under any of those sections.

18 Sec. 481.302. AMOUNT OF PENALTY. (a) The amount of the
19 penalty may not exceed \$1,000 for each violation, and each day a
20 violation continues or occurs is a separate violation for purposes
21 of imposing a penalty. The total amount of the penalty assessed for
22 a violation continuing or occurring on separate days under this
23 subsection may not exceed \$20,000.

24 (b) The amount shall be based on:

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

27 (2) the threat to health or safety caused by the

1 violation;

2 (3) the history of previous violations;

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

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

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

8 Sec. 481.303. REPORT AND NOTICE OF VIOLATION AND PENALTY.

9 (a) If the department initially determines that a violation
10 occurred, the department shall give written notice of the report to
11 the person by certified mail, registered mail, personal delivery,
12 or another manner of delivery that records the person's receipt of
13 the notice.

14 (b) The notice must:

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

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

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

20 Sec. 481.304. PENALTY TO BE PAID OR INFORMAL HEARING
21 REQUESTED. (a) Before the 21st day after the date the person

22 receives notice under Section 481.303, the person in writing may:

23 (1) accept the determination and recommended penalty;

24 or

25 (2) make a request for an informal hearing held by the
26 department on the occurrence of the violation, the amount of the
27 penalty, or both.

1 (b) At the conclusion of an informal hearing requested under
2 Subsection (a), the department may modify the amount of the
3 recommended penalty.

4 (c) If the person accepts the determination and recommended
5 penalty, including any modification of the amount, or if the person
6 fails to timely respond to the notice, the director by order shall
7 approve the determination and impose the recommended penalty.

8 Sec. 481.305. FORMAL HEARING. (a) The person may request
9 a formal hearing only after participating in an informal hearing.

10 (b) The request must be submitted in writing and received by
11 the department before the 21st day after the date the person is
12 notified of the decision from the informal hearing.

13 (c) If a timely request for a formal hearing is not
14 received, the director by order shall approve the determination
15 from the informal hearing and impose the recommended penalty.

16 (d) If the person timely requests a formal hearing, the
17 director shall refer the matter to the State Office of
18 Administrative Hearings, which shall promptly set a hearing date
19 and give written notice of the time and place of the hearing to the
20 director and to the person. An administrative law judge of the
21 State Office of Administrative Hearings shall conduct the hearing.

22 (e) The administrative law judge shall make findings of fact
23 and conclusions of law and promptly issue to the director a proposal
24 for a decision about the occurrence of the violation and the amount
25 of any proposed penalty.

26 (f) If a penalty is proposed under Subsection (e), the
27 administrative law judge shall include in the proposal for a

1 decision a finding setting out costs, fees, expenses, and
2 reasonable and necessary attorney's fees incurred by the state in
3 bringing the proceeding. The director may adopt the finding and
4 impose the costs, fees, and expenses on the person as part of the
5 final order entered in the proceeding.

6 Sec. 481.306. DECISION. (a) Based on the findings of
7 fact, conclusions of law, and proposal for a decision, the director
8 by order may:

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

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

12 (b) The notice of the director's order under Subsection (a)
13 that is sent to the person in the manner provided by Chapter 2001,
14 Government Code, must include a statement of the right of the person
15 to judicial review of the order.

16 Sec. 481.307. OPTIONS FOLLOWING DECISION: PAY OR APPEAL.
17 Before the 31st day after the date the order under Section 481.306
18 that imposes an administrative penalty becomes final, the person
19 shall:

20 (1) pay the penalty; or

21 (2) file a petition for judicial review of the order
22 contesting the occurrence of the violation, the amount of the
23 penalty, or both.

24 Sec. 481.308. STAY OF ENFORCEMENT OF PENALTY. (a) Within
25 the period prescribed by Section 481.307, a person who files a
26 petition for judicial review may:

27 (1) stay enforcement of the penalty by:

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

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

5 (i) is for the amount of the penalty; and
6 (ii) is effective until all judicial review
7 of the order is final; or

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

10 (A) filing with the court a sworn affidavit of
11 the person stating that the person is financially unable to pay the
12 penalty and is financially unable to give the supersedeas bond; and

13 (B) sending a copy of the affidavit to the
14 director by certified mail.

15 (b) Following receipt of a copy of an affidavit under
16 Subsection (a)(2), the director may file with the court, before the
17 sixth day after the date of receipt, a contest to the affidavit.
18 The court shall hold a hearing on the facts alleged in the affidavit
19 as soon as practicable and shall stay the enforcement of the penalty
20 on finding that the alleged facts are true. The person who files an
21 affidavit has the burden of proving that the person is financially
22 unable to pay the penalty or to give a supersedeas bond.

23 Sec. 481.309. COLLECTION OF PENALTY. (a) If the person
24 does not pay the penalty and the enforcement of the penalty is not
25 stayed, the penalty may be collected.

26 (b) The attorney general may sue to collect the penalty.

27 Sec. 481.310. DECISION BY COURT. (a) If the court

1 sustains the finding that a violation occurred, the court may
2 uphold or reduce the amount of the penalty and order the person to
3 pay the full or reduced amount of the penalty.

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

7 Sec. 481.311. REMITTANCE OF PENALTY AND INTEREST. (a) If
8 the person paid the penalty and if the amount of the penalty is
9 reduced or the penalty is not upheld by the court, the court shall
10 order, when the court's judgment becomes final, that the
11 appropriate amount plus accrued interest be remitted to the person
12 before the 31st day after the date that the judgment of the court
13 becomes final.

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

16 (c) The interest shall be paid for the period beginning on
17 the date the penalty is paid and ending on the date the penalty is
18 remitted.

19 Sec. 481.312. RELEASE OF BOND. (a) If the person gave a
20 supersedeas bond and the penalty is not upheld by the court, the
21 court shall order, when the court's judgment becomes final, the
22 release of the bond.

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

26 Sec. 481.313. ADMINISTRATIVE PROCEDURE. A proceeding to
27 impose the penalty is considered to be a contested case under

1 Chapter 2001, Government Code.

2 Sec. 481.314. DISPOSITION OF PENALTY. The department shall
3 send any amount collected as a penalty under this subchapter to the
4 comptroller for deposit to the credit of the general revenue fund.

5 SECTION 6. Chapter 107, Occupations Code, is amended by
6 adding Subchapter E to read as follows:

7 SUBCHAPTER E. PAIN TREATMENT REVIEW COMMITTEE

8 Sec. 107.201. PAIN TREATMENT REVIEW COMMITTEE. (a) The
9 following individuals shall be appointed as a review committee on
10 pain treatment:

11 (1) the attorney general or the attorney general's
12 designee;

13 (2) a physician who practices at a public hospital in
14 this state;

15 (3) a physician who practices at a private hospital in
16 this state;

17 (4) a physician who practices in this state as a
18 psychiatrist specializing in the treatment of addictive diseases;

19 (5) a probate court judge licensed to practice law in
20 this state;

21 (6) a member of the governing board of the American
22 Cancer Society, Texas Division, or the member's designee;

23 (7) a member of the governing board of the Texas
24 Medical Association or the member's designee;

25 (8) a member of the governing board of the Texas Nurses
26 Association or the member's designee;

27 (9) an officer of a public hospital in this state who

1 is a member of the governing board of the Texas Hospital Association
2 or the member's designee;

3 (10) an officer of a private hospital in this state who
4 is a member of the governing board of the Texas Hospital Association
5 or the member's designee; and

6 (11) a public member who is a resident of this state.

7 (b) The lieutenant governor and the speaker of the house of
8 representatives shall each appoint five of the members described by
9 Subsections (a)(2) through (11).

10 (c) The following individuals serve on the committee as
11 nonvoting resource members and are appointed by the executive
12 director of the agency the member represents:

13 (1) a pharmacist member of the Texas State Board of
14 Pharmacy;

15 (2) a physician member of the Texas Medical Board;

16 (3) a nurse member of the Board of Nurse Examiners;

17 (4) a representative of the Department of Aging and
18 Disability Services; and

19 (5) a representative of the narcotics regulatory
20 programs of the Department of Public Safety.

21 (d) The committee shall study the relevant provisions in the
22 laws of this state that relate to the administration of
23 prescription medication, controlled substances, and the needs of
24 patients for effective pain control and management. The committee
25 shall examine how the following statutes affect public health
26 needs, the professional medical community, and persons affected by
27 acute, chronic, or end-of-life pain:

1 (1) this chapter;

2 (2) Subtitles B, E, I, and J of this title; and

3 (3) Chapter 481, Health and Safety Code.

4 (e) The committee shall meet at least once every three
5 months.

6 (f) Not later than September 1, 2008, the committee shall
7 report any changes recommended to the statutes examined under
8 Subsection (d) to the lieutenant governor, the speaker of the house
9 of representatives, and the appropriate standing committees in the
10 senate and the house of representatives that have jurisdiction over
11 the issues studied by the committee.

12 (g) This section expires July 1, 2009.

13 SECTION 7. (a) An advisory committee is created to advise
14 the Department of Public Safety of the State of Texas on the
15 implementation of this Act.

16 (b) The advisory committee is composed of:

17 (1) the public safety director of the Department of
18 Public Safety of the State of Texas or the director's designee;

19 (2) a physician appointed by the governor;

20 (3) a pharmacist appointed by the governor;

21 (4) a physician appointed by the lieutenant governor;

22 (5) a pharmacist appointed by the lieutenant governor;

23 (6) a physician appointed by the governor from a list
24 of names submitted by the speaker of the house of representatives;

25 (7) a pharmacist appointed by the governor from a list
26 of names submitted by the speaker of the house of representatives;

27 and

1 (8) one member from each of the following boards:

2 (A) Texas Medical Board;

3 (B) Texas State Board of Pharmacy;

4 (C) State Board of Dental Examiners; and

5 (D) Board of Nurse Examiners.

6 (c) The public safety director or the director's designee is
7 the presiding officer of the advisory committee. The committee
8 shall meet at the call of the presiding officer or at the request of
9 any three members other than the presiding officer.

10 (d) The advisory committee shall:

11 (1) develop recommendations regarding the improvement
12 of the official prescription program established by Section
13 481.075, Health and Safety Code;

14 (2) develop recommendations regarding the
15 implementation of an electronic controlled substance monitoring
16 system that would be used for prescriptions of controlled
17 substances listed in Schedules II through V as established under
18 Subchapter B, Chapter 481, Health and Safety Code;

19 (3) develop recommendations as to which data should be
20 provided to the Department of Public Safety of the State of Texas to
21 support a controlled substance monitoring system recommended under
22 Subdivision (2) of this subsection, including provider
23 identification information;

24 (4) monitor and develop recommendations regarding the
25 implementation and enforcement of a controlled substance
26 monitoring system recommended under Subdivision (2) of this
27 subsection;

1 (5) develop recommended procedures necessary for
2 real-time point-of-service access for a practitioner authorized to
3 prescribe or dispense controlled substances listed in Schedules II
4 through V so that the practitioner may obtain:

5 (A) the prescription history for a particular
6 patient; or

7 (B) the practitioner's own dispensing or
8 prescribing activity; and

9 (6) develop recommended procedures that should be
10 followed by the Department of Public Safety of the State of Texas
11 and the applicable licensing authority of this state, another
12 state, or the United States when:

13 (A) the department shares information related to
14 diversion of controlled substances with a licensing authority for
15 the purpose of licensing enforcement; or

16 (B) a licensing authority shares information
17 related to diversion of controlled substances with the department
18 for the purpose of criminal enforcement.

19 (e) The public safety director shall report the
20 recommendations developed under Subsection (d) of this section to
21 the governor, lieutenant governor, speaker of the house of
22 representatives, and appropriate committees of the senate and the
23 house not later than July 1, 2008.

24 (f) This section expires and the advisory committee is
25 abolished on September 1, 2009.

26 SECTION 8. (a) The Department of Public Safety of the
27 State of Texas, Texas Medical Board, Texas State Board of Pharmacy,

1 State Board of Dental Examiners, and Board of Nurse Examiners shall
2 submit to the presiding officers of the Senate Committee on Health
3 and Human Services and the House Committee on Public Health a report
4 that details the number and type of actions relating to the
5 prosecution of violations of Chapter 481, Health and Safety Code,
6 as amended by this Act.

7 (b) Each agency shall submit its initial report under
8 Subsection (a) of this section not later than November 1, 2007.
9 Each agency shall submit an update of its initial report not later
10 than May 1 and November 1 of each year.

11 (c) This section expires November 1, 2011.

12 SECTION 9. The public safety director of the Department of
13 Public Safety of the State of Texas shall adopt any rules necessary
14 to administer and enforce Subchapter H, Chapter 481, Health and
15 Safety Code, as added by this Act, not later than September 1, 2007,
16 except that if this section does not take effect before that date,
17 the public safety director shall adopt the rules as soon as
18 practicable after that date.

19 SECTION 10. (a) Except as provided by Subsections (b),
20 (c), and (d) of this section, this Act takes effect September 1,
21 2007.

22 (b) Section 9 of this Act takes effect immediately if this
23 Act receives a vote of two-thirds of all the members elected to each
24 house, as provided by Section 39, Article III, Texas Constitution.
25 If this Act does not receive the vote necessary for immediate
26 effect, Section 9 of this Act takes effect September 1, 2007.

27 (c) Except as otherwise provided by Subsection (d) of this

1 section, the changes in law made by this Act in amending Subsection
2 (k), Section 481.074, and Section 481.076, Health and Safety Code,
3 and in adding Subsection (q), Section 481.074 of that code, take
4 effect September 1, 2008. The public safety director of the
5 Department of Public Safety of the State of Texas shall adopt any
6 rules necessary to administer and enforce the changes in law made by
7 those provisions not later than September 1, 2008.

8 (d) The change in law made by this Act in amending
9 Subsections (b) and (k), Section 481.074, Health and Safety Code,
10 to require the use of registration numbers issued by the Department
11 of Public Safety of the State of Texas takes effect only after the
12 department establishes a means by which pharmacies are able to
13 electronically access and verify the accuracy of the registration
14 numbers.

President of the Senate

Speaker of the House

I hereby certify that S.B. No. 1879 passed the Senate on April 25, 2007, by the following vote: Yeas 28, Nays 1; May 24, 2007, Senate refused to concur in House amendments and requested appointment of Conference Committee; May 26, 2007, House granted request of the Senate; May 26, 2007, Senate adopted Conference Committee Report by the following vote: Yeas 30, Nays 0.

Secretary of the Senate

I hereby certify that S.B. No. 1879 passed the House, with amendments, on May 23, 2007, by the following vote: Yeas 139, Nays 0, one present not voting; May 26, 2007, House granted request of the Senate for appointment of Conference Committee; May 27, 2007, House adopted Conference Committee Report by the following vote: Yeas 143, Nays 1, two present not voting.

Chief Clerk of the House

Approved:

Date

Governor