

By: Williams, et al.

S.B. No. 1879

Substitute the following for S.B. No. 1879:

By: Delisi

C.S.S.B. No. 1879

A BILL TO BE ENTITLED

AN ACT

relating to the regulation of controlled substances.

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 listed in Schedule II without the written prescription of a

1 practitioner on an official prescription form that meets the
2 requirements of and is completed by the practitioner in accordance
3 with Section 481.075. In an emergency, a person may dispense or
4 administer a controlled substance listed in Schedule II on the oral
5 or telephonically communicated prescription of a practitioner. The
6 person who administers or dispenses the substance shall:

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

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

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

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

27 (1) the quantity of the substance prescribed:

1 (A) numerically, followed by the number written
2 as a word, if the prescription is written; or

3 (B) if the prescription is communicated orally or
4 telephonically, as transcribed by the receiving pharmacist;

5 (2) the date of issue;

6 (3) the name, ~~and~~ address, and date of birth or age
7 of the patient or, if the controlled substance is prescribed for an
8 animal, the species of the animal and the name and address of its
9 owner;

10 (4) the name and strength of the controlled substance
11 prescribed;

12 (5) the directions for use of the controlled
13 substance;

14 (6) the intended use of the substance prescribed
15 unless the practitioner determines the furnishing of this
16 information is not in the best interest of the patient; ~~and~~

17 (7) the legibly printed or stamped name, address,
18 Federal Drug Enforcement Administration registration number, and
19 telephone number of the practitioner at the practitioner's usual
20 place of business;

21 (8) if the prescription is handwritten, the signature
22 of the prescribing practitioner; and

23 (9) if the prescribing practitioner is licensed in
24 this state, the practitioner's department registration number.

25 (q) Each dispensing pharmacist shall send all information
26 required by the director, including any information required to
27 complete the Schedule III through V prescription forms, to the

1 director by electronic transfer or another form approved by the
2 director not later than the 15th day after the last day of the month
3 in which the prescription is completely filled.

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

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

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

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

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

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

24 (B) a pharmacist or practitioner who is a
25 physician, dentist, veterinarian, [~~or~~] podiatrist, or advanced
26 practice nurse or physician assistant described by Section
27 481.002(39)(D) and is inquiring about a [~~the~~] recent Schedule II,

1 III, IV, or V prescription history of a particular patient of the
2 practitioner; or

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

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

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

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

25 (b) The director shall consult with the [~~Texas~~] Department
26 of State Health Services, the Texas State Board of Pharmacy, and the
27 Texas [~~State Board of~~] Medical Board [Examiners] and by rule may:

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

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

11 (c) The director by rule may:

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

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

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

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

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

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

27 (e) In adopting a rule relating to the electronic transfer

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

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

11 SUBCHAPTER H. ADMINISTRATIVE PENALTY

12 Sec. 481.301. IMPOSITION OF PENALTY. The department may
13 impose an administrative penalty on a person who violates Section
14 481.061, 481.066, 481.067, 481.069, 481.073, 481.074, 481.075,
15 481.077, 481.0771, 481.078, 481.080, or 481.081 or a rule or order
16 adopted under any of those sections.

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

23 (b) The amount shall be based on:

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

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

1 (3) the history of previous violations;

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

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

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

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

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

13 (b) The notice must:

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

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

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

19 Sec. 481.304. PENALTY TO BE PAID OR INFORMAL HEARING
20 REQUESTED. (a) Before the 21st day after the date the person
21 receives notice under Section 481.303, the person in writing may:

22 (1) accept the determination and recommended penalty;

23 or

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

27 (b) At the conclusion of an informal hearing requested under

1 Subsection (a), the department may modify the amount of the
2 recommended penalty.

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

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

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

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

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

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

25 (f) If a penalty is proposed under Subsection (e), the
26 administrative law judge shall include in the proposal for a
27 decision a finding setting out costs, fees, expenses, and

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

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

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

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

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

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

19 (1) pay the penalty; or

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

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

26 (1) stay enforcement of the penalty by:

27 (A) paying the penalty to the court for placement

1 in an escrow account; or

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

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

5 (ii) is effective until all judicial review
6 of the order is final; or

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

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

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

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

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

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

26 Sec. 481.310. DECISION BY COURT. (a) If the court
27 sustains the finding that a violation occurred, the court may

1 uphold or reduce the amount of the penalty and order the person to
2 pay the full or reduced amount of the penalty.

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

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

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

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

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

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

25 Sec. 481.313. ADMINISTRATIVE PROCEDURE. A proceeding to
26 impose the penalty is considered to be a contested case under
27 Chapter 2001, Government Code.

1 SECTION 6. (a) An advisory committee is created to advise
2 the Department of Public Safety on the implementation of this Act.

3 (b) The advisory committee is composed of:

4 (1) the public safety director of the Department of
5 Public Safety;

6 (2) a physician appointed by the governor;

7 (3) a pharmacist appointed by the governor;

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

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

10 (6) a physician appointed by the governor from a list
11 of names submitted by the speaker of the house;

12 (7) a pharmacist appointed by the governor from a list
13 of names submitted by the speaker of the house; and

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

15 (A) Texas Medical Board;

16 (B) Texas State Board of Pharmacy;

17 (C) State Board of Dental Examiners; and

18 (D) Board of Nurse Examiners.

19 (c) The public safety director is the presiding officer of
20 the advisory committee. The committee shall meet at the call of the
21 presiding officer or at the request of any three members other than
22 the director.

23 (d) The advisory committee shall:

24 (1) develop recommendations regarding the improvement
25 of the official prescription program established by Section
26 481.075, Health and Safety Code;

27 (2) develop recommendations regarding the

1 implementation of an electronic controlled substance monitoring
2 system that would be used for prescriptions of controlled
3 substances listed in Schedules II through V as established under
4 Subchapter B, Chapter 481, Health and Safety Code;

5 (3) develop recommendations as to which data should be
6 provided to the Department of Public Safety to support a controlled
7 substance monitoring system recommended under Subdivision (2) of
8 this subsection, including provider identification information;

9 (4) monitor and develop recommendations regarding the
10 implementation and enforcement of a controlled substance
11 monitoring system recommended under Subdivision (2) of this
12 subsection;

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

17 (A) the prescription history for a particular
18 patient; or

19 (B) the practitioner's own dispensing or
20 prescribing activity; and

21 (6) develop recommended procedures that should be
22 followed by the Department of Public Safety and the applicable
23 licensing authority of this state, another state, or the United
24 States when:

25 (A) the department shares information related to
26 diversion of controlled substances with a licensing authority for
27 the purpose of licensing enforcement; or

1 (B) a licensing authority shares information
2 related to diversion of controlled substances with the department
3 for the purpose of criminal enforcement.

4 (e) The director shall report the recommendations developed
5 under Subsection (d) of this section to the governor, lieutenant
6 governor, speaker of the house, and appropriate committees of the
7 senate and the house not later than July 1, 2008.

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

10 SECTION 7. (a) The Department of Public Safety, Texas
11 Medical Board, Texas State Board of Pharmacy, State Board of Dental
12 Examiners, and Board of Nurse Examiners shall submit to the
13 presiding officers of the Senate Committee on Health and Human
14 Services and the House Committee on Public Health a report that
15 details the number and type of actions relating to the prosecution
16 of violations of Chapter 481, Health and Safety Code, as amended by
17 this Act.

18 (b) Each agency shall submit its initial report under
19 Subsection (a) of this section not later than November 1, 2007.
20 Each agency shall submit an update of its initial report not later
21 than May 1 and November 1 of each year.

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

23 SECTION 8. The public safety director of the Department of
24 Public Safety shall adopt any rules necessary to administer and
25 enforce Subchapter H, Chapter 481, Health and Safety Code, as added
26 by this Act, not later than September 1, 2007, except that if this
27 section does not take effect before that date, the public safety

1 director shall adopt the rules as soon as practicable after that
2 date.

3 SECTION 9. (a) Except as provided by Subsections (b), (c),
4 and (d) of this section, this Act takes effect September 1, 2007.

5 (b) Section 8 of this Act takes effect immediately if this
6 Act receives a vote of two-thirds of all the members elected to each
7 house, as provided by Section 39, Article III, Texas Constitution.
8 If this Act does not receive the vote necessary for immediate
9 effect, Section 8 of this Act takes effect September 1, 2007.

10 (c) Except as otherwise provided by Subsection (d) of this
11 section, the changes in law made by this Act in amending Subsection
12 (k), Section 481.074, and Section 481.076, Health and Safety Code,
13 and in adding Subsection (q), Section 481.074 of that code, take
14 effect September 1, 2008. The public safety director of the
15 Department of Public Safety shall adopt any rules necessary to
16 administer and enforce the changes in law made by those provisions
17 not later than September 1, 2008.

18 (d) The change in law made by this Act in amending
19 Subsections (b) and (k), Section 481.074, Health and Safety Code,
20 to require the use of registration numbers issued by the Department
21 of Public Safety takes effect only after the department establishes
22 a means by which pharmacies are able to electronically access and
23 verify the accuracy of the registration numbers.