

1-1 By: Williams S.B. No. 1879
1-2 (In the Senate - Filed March 9, 2007; March 22, 2007, read
1-3 first time and referred to Committee on Health and Human Services;
1-4 April 19, 2007, reported adversely, with favorable Committee
1-5 Substitute by the following vote: Yeas 9, Nays 0; April 19, 2007,
1-6 sent to printer.)

1-7 COMMITTEE SUBSTITUTE FOR S.B. No. 1879 By: Deuell

1-8 A BILL TO BE ENTITLED
1-9 AN ACT

1-10 relating to the regulation of controlled substances.

1-11 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

1-12 SECTION 1. Subsection (a), Section 481.064, Health and
1-13 Safety Code, is amended to read as follows:

1-14 (a) The director may charge a nonrefundable fee of not more
1-15 than \$25 before processing an application for annual registration
1-16 and may charge a late fee of not more than \$50 for each application
1-17 for renewal the department receives after the date the registration
1-18 expires. The director by rule shall set the amounts [~~amount~~]
1-19 fees [~~fee~~] at the amounts [~~amount~~] that are [~~is~~]
1-20 the cost of administering and enforcing this subchapter. Except as
1-21 provided by Subsection (b), registrants shall pay the fees to the
1-22 director.

1-23 SECTION 2. Section 481.074, Health and Safety Code, is
1-24 amended by amending Subsections (b), (d), and (k) and adding
1-25 Subsection (q) to read as follows:

1-26 (b) Except in an emergency as defined by rule of the
1-27 director or as provided by Subsection (o) or Section 481.075(j) or
1-28 (m), a person may not dispense or administer a controlled substance
1-29 listed in Schedule II without the written prescription of a
1-30 practitioner on an official prescription form that meets the
1-31 requirements of and is completed by the practitioner in accordance
1-32 with Section 481.075. In an emergency, a person may dispense or
1-33 administer a controlled substance listed in Schedule II on the oral
1-34 or telephonically communicated prescription of a practitioner. The
1-35 person who administers or dispenses the substance shall:

1-36 (1) if the person is a prescribing practitioner or a
1-37 pharmacist, promptly comply with Subsection (c); or

1-38 (2) if the person is not a prescribing practitioner or
1-39 a pharmacist, promptly write the oral or telephonically
1-40 communicated prescription and include in the written record of the
1-41 prescription the name, address, department registration number,
1-42 and Federal Drug Enforcement Administration number of the
1-43 prescribing practitioner, all information required to be provided
1-44 by a practitioner under Section 481.075(e)(1), and all information
1-45 required to be provided by a dispensing pharmacist under Section
1-46 481.075(e)(2).

1-47 (d) Except as specified in Subsections (e) and (f) [~~of this~~
1-48 ~~section~~], the director, by rule and in consultation with the Texas
1-49 Medical Board and the Texas State Board of Pharmacy, shall
1-50 establish the period after the date on which the prescription is
1-51 issued that a person may [~~not~~] fill a prescription for a controlled
1-52 substance listed in Schedule II [~~after the end of the seventh day~~
1-53 ~~after the date on which the prescription is issued~~]. A person may
1-54 not refill a prescription for a substance listed in Schedule II.

1-55 (k) A prescription for a controlled substance must show:

1-56 (1) the quantity of the substance prescribed:

1-57 (A) numerically, followed by the number written
1-58 as a word, if the prescription is written; or

1-59 (B) if the prescription is communicated orally or
1-60 telephonically, as transcribed by the receiving pharmacist;

1-61 (2) the date of issue;

1-62 (3) the name, [~~and~~] address, and date of birth or age
1-63 of the patient or, if the controlled substance is prescribed for an

2-1 animal, the species of the animal and the name and address of its
2-2 owner;

2-3 (4) the name and strength of the controlled substance
2-4 prescribed;

2-5 (5) the directions for use of the controlled
2-6 substance;

2-7 (6) the intended use of the substance prescribed
2-8 unless the practitioner determines the furnishing of this
2-9 information is not in the best interest of the patient; ~~and~~

2-10 (7) the legibly printed or stamped name, address,
2-11 Federal Drug Enforcement Administration registration number,
2-12 department registration number, and telephone number of the
2-13 practitioner at the practitioner's usual place of business; and

2-14 (8) if the prescription is handwritten, the signature
2-15 of the prescribing practitioner.

2-16 (g) Each dispensing pharmacist shall send all information
2-17 required by the director, including any information required to
2-18 complete the Schedule III through V prescription forms, to the
2-19 director by electronic transfer or another form approved by the
2-20 director not later than the 15th day after the last day of the month
2-21 in which the prescription is completely filled.

2-22 SECTION 3. Subsections (a) and (c), Section 481.076, Health
2-23 and Safety Code, are amended to read as follows:

2-24 (a) The director may not permit any person to have access to
2-25 information submitted to the director under Section 481.074(q) or
2-26 481.075 except:

2-27 (1) an investigator for the Texas [~~State Board of~~]
2-28 Medical Board [Examiners], the Texas State Board of Podiatric
2-29 Medical Examiners, the State Board of Dental Examiners, the State
2-30 Board of Veterinary Medical Examiners, or the Texas State Board of
2-31 Pharmacy;

2-32 (2) an authorized officer or member of the department
2-33 engaged in the administration, investigation, or enforcement of
2-34 this chapter or another law governing illicit drugs in this state or
2-35 another state; or

2-36 (3) if the director finds that proper need has been
2-37 shown to the director:

2-38 (A) a law enforcement or prosecutorial official
2-39 engaged in the administration, investigation, or enforcement of
2-40 this chapter or another law governing illicit drugs in this state or
2-41 another state;

2-42 (B) a pharmacist or practitioner who is a
2-43 physician, dentist, veterinarian, or podiatrist and is inquiring
2-44 about the recent Schedule II prescription history of a particular
2-45 patient of the practitioner; or

2-46 (C) a pharmacist or practitioner who is inquiring
2-47 about the person's own dispensing or prescribing activity.

2-48 (c) The director by rule shall design and implement a system
2-49 for submission of information to the director by electronic or
2-50 other means and for retrieval of information submitted to the
2-51 director under this section and Sections 481.074 and [Section]
2-52 481.075. The director shall use automated information security
2-53 techniques and devices to preclude improper access to the
2-54 information. The director shall submit the system design to the
2-55 Texas State Board of Pharmacy and the Texas [~~State Board of~~]
2-56 Board [Examiners] for review and approval or comment a reasonable
2-57 time before implementation of the system and shall comply with the
2-58 comments of those agencies unless it is unreasonable to do so.

2-59 SECTION 4. Subsections (a), (b), (c), and (e), Section
2-60 481.0761, Health and Safety Code, are amended to read as follows:

2-61 (a) The director shall consult with the Texas State Board of
2-62 Pharmacy and by rule establish and revise as necessary a
2-63 standardized database format that may be used by a pharmacy to
2-64 transmit the information required by Sections 481.074(q) and
2-65 [Section] 481.075(i) to the director electronically or to deliver
2-66 the information on storage media, including disks, tapes, and
2-67 cassettes.

2-68 (b) The director shall consult with the [~~Texas~~]
2-69 of State Health Services, the Texas State Board of Pharmacy, and the

3-1 Texas [~~State Board of~~] Medical Board [~~Examiners~~] and by rule may:

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

3-7 (2) return a substance previously removed from
3-8 Schedules [Schedule] II through V to the official prescription
3-9 program, if the director determines that the risk of diversion
3-10 substantially outweighs the burden imposed by the program on the
3-11 particular controlled substance.

3-12 (c) The director by rule may:

3-13 (1) permit more than one prescription to be
3-14 administered or dispensed and recorded on one [~~official~~]
3-15 prescription form for a Schedule III through V controlled
3-16 substance;

3-17 (2) remove from or return to the official prescription
3-18 program any aspect of a practitioner's or pharmacist's hospital
3-19 practice, including administering or dispensing;

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

3-22 (4) establish compatibility protocols for electronic
3-23 data transfer hardware, software, or format;

3-24 (5) establish a procedure to control the release of
3-25 information under Sections 481.074, 481.075, and 481.076; and

3-26 (6) establish a minimum level of prescription activity
3-27 below which a reporting activity may be modified or deleted.

3-28 (e) In adopting a rule relating to the electronic transfer
3-29 of information under this subchapter, the director shall consider
3-30 the economic impact of the rule on practitioners and pharmacists
3-31 and, to the extent permitted by law, act to minimize any negative
3-32 economic impact, including the imposition of costs related to
3-33 computer hardware or software or to the transfer of information.
3-34 The director may not adopt a rule relating to the electronic
3-35 transfer of information under this subchapter that imposes a fee in
3-36 addition to the fees [fee] authorized by Section 481.064.

3-37 SECTION 5. Chapter 481, Health and Safety Code, is amended
3-38 by adding Subchapter H to read as follows:

3-39 SUBCHAPTER H. ADMINISTRATIVE PENALTY

3-40 Sec. 481.301. IMPOSITION OF PENALTY. The department may
3-41 impose an administrative penalty on a person who violates Section
3-42 481.061, 481.066, 481.067, 481.069-481.075, 481.077, 481.0771,
3-43 481.078, 481.080, or 481.081 or a rule or order adopted under any of
3-44 those sections.

3-45 Sec. 481.302. AMOUNT OF PENALTY. (a) The amount of the
3-46 penalty may not exceed \$1,000 for each violation, and each day a
3-47 violation continues or occurs is a separate violation for purposes
3-48 of imposing a penalty. The total amount of the penalty assessed for
3-49 a violation continuing or occurring on separate days under this
3-50 subsection may not exceed \$20,000.

3-51 (b) The amount shall be based on:

3-52 (1) the seriousness of the violation, including the
3-53 nature, circumstances, extent, and gravity of the violation;

3-54 (2) the threat to health or safety caused by the
3-55 violation;

3-56 (3) the history of previous violations;

3-57 (4) the amount necessary to deter a future violation;

3-58 (5) whether the violator demonstrated good faith,
3-59 including when applicable whether the violator made good faith
3-60 efforts to correct the violation; and

3-61 (6) any other matter that justice may require.

3-62 Sec. 481.303. REPORT AND NOTICE OF VIOLATION AND PENALTY.

3-63 (a) If the department initially determines that a violation
3-64 occurred, the department shall give written notice of the report to
3-65 the person by certified mail, registered mail, personal delivery,
3-66 or another manner of delivery that records the person's receipt of
3-67 the notice.

3-68 (b) The notice must:

3-69 (1) include a brief summary of the alleged violation;

4-1 (2) state the amount of the recommended penalty; and
4-2 (3) inform the person of the person's right to a
4-3 hearing on the occurrence of the violation, the amount of the
4-4 penalty, or both.

4-5 Sec. 481.304. PENALTY TO BE PAID OR INFORMAL HEARING
4-6 REQUESTED. (a) Before the 21st day after the date the person
4-7 receives notice under Section 481.303, the person in writing may:

4-8 (1) accept the determination and recommended penalty;
4-9 or

4-10 (2) make a request for an informal hearing held by the
4-11 department on the occurrence of the violation, the amount of the
4-12 penalty, or both.

4-13 (b) At the conclusion of an informal hearing requested under
4-14 Subsection (a), the department may modify the amount of the
4-15 recommended penalty.

4-16 (c) If the person accepts the determination and recommended
4-17 penalty, including any modification of the amount, or if the person
4-18 fails to timely respond to the notice, the director by order shall
4-19 approve the determination and impose the recommended penalty.

4-20 Sec. 481.305. FORMAL HEARING. (a) The person may request
4-21 a formal hearing only after participating in an informal hearing.

4-22 (b) The request must be submitted in writing and received by
4-23 the department before the 21st day after the date the person is
4-24 notified of the decision from the informal hearing.

4-25 (c) If a timely request for a formal hearing is not
4-26 received, the director by order shall approve the determination
4-27 from the informal hearing and impose the recommended penalty.

4-28 (d) If the person timely requests a formal hearing, the
4-29 director shall refer the matter to the State Office of
4-30 Administrative Hearings, which shall promptly set a hearing date
4-31 and give written notice of the time and place of the hearing to the
4-32 director and to the person. An administrative law judge of the
4-33 State Office of Administrative Hearings shall conduct the hearing.

4-34 (e) The administrative law judge shall make findings of fact
4-35 and conclusions of law and promptly issue to the director a proposal
4-36 for a decision about the occurrence of the violation and the amount
4-37 of any proposed penalty.

4-38 (f) If a penalty is proposed under Subsection (e), the
4-39 administrative law judge shall include in the proposal for a
4-40 decision a finding setting out costs, fees, expenses, and
4-41 reasonable and necessary attorney's fees incurred by the state in
4-42 bringing the proceeding. The director may adopt the finding and
4-43 impose the costs, fees, and expenses on the person as part of the
4-44 final order entered in the proceeding.

4-45 Sec. 481.306. DECISION. (a) Based on the findings of
4-46 fact, conclusions of law, and proposal for a decision, the director
4-47 by order may:

4-48 (1) find that a violation occurred and impose a
4-49 penalty; or

4-50 (2) find that a violation did not occur.

4-51 (b) The notice of the director's order under Subsection (a)
4-52 that is sent to the person in the manner provided by Chapter 2001,
4-53 Government Code, must include a statement of the right of the person
4-54 to judicial review of the order.

4-55 Sec. 481.307. OPTIONS FOLLOWING DECISION: PAY OR APPEAL.
4-56 Before the 31st day after the date the order under Section 481.306
4-57 that imposes an administrative penalty becomes final, the person
4-58 shall:

4-59 (1) pay the penalty; or

4-60 (2) file a petition for judicial review of the order
4-61 contesting the occurrence of the violation, the amount of the
4-62 penalty, or both.

4-63 Sec. 481.308. STAY OF ENFORCEMENT OF PENALTY. (a) Within
4-64 the period prescribed by Section 481.307, a person who files a
4-65 petition for judicial review may:

4-66 (1) stay enforcement of the penalty by:

4-67 (A) paying the penalty to the court for placement
4-68 in an escrow account; or

4-69 (B) giving the court a supersedeas bond approved

by the court that:

- (i) is for the amount of the penalty; and
- (ii) is effective until all judicial review

of the order is final; or

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

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

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

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

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

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

Sec. 481.310. DECISION BY COURT. (a) If the court sustains the finding that a violation occurred, the court may uphold or reduce the amount of the penalty and order the person to pay the full or reduced amount of the penalty.

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

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

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

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

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

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

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

SECTION 6. The public safety director of the Department of Public Safety of the State of Texas shall adopt any rules necessary to administer and enforce Subchapter H, Chapter 481, Health and Safety Code, as added by this Act, not later than September 1, 2007, except that if this section does not take effect before that date, the public safety director shall adopt the rules as soon as possible after that date.

SECTION 7. (a) Except as provided by Subsections (b), (c), and (d) of this section, this Act takes effect September 1, 2007.

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

(c) Except as otherwise provided by Subsection (d) of this section, the changes in law made by this Act in amending Subsection (k), Section 481.074, and Section 481.076, Health and Safety Code,

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

6-6 (d) The change in law made by this Act in amending
6-7 Subsections (b) and (k), Section 481.074, Health and Safety Code,
6-8 to require the use of registration numbers issued by the Department
6-9 of Public Safety of the State of Texas takes effect only after the
6-10 department establishes a means by which pharmacies are able to
6-11 electronically access and verify the accuracy of the registration
6-12 numbers.

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