

By: Williams, Van de Putte

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.

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 practitioner on an official prescription form that meets the requirements of and is completed by the practitioner in accordance with Section 481.075. In an emergency, a person may dispense or

1 administer a controlled substance listed in Schedule II on the oral  
2 or telephonically communicated prescription of a practitioner. The  
3 person who administers or dispenses the substance shall:

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

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

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

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

24 (1) the quantity of the substance prescribed:

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

27 (B) if the prescription is communicated orally or

1 telephonically, as transcribed by the receiving pharmacist;

2 (2) the date of issue;

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

7 (4) the name and strength of the controlled substance  
8 prescribed;

9 (5) the directions for use of the controlled  
10 substance;

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

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

18 (8) if the prescription is handwritten, the signature  
19 of the prescribing practitioner.

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

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

1 (a) The director may not permit any person to have access to  
2 information submitted to the director under Section 481.074(g) or  
3 481.075 except:

4 (1) an investigator for the Texas [~~State Board of~~  
5 Medical Board [~~Examiners~~], the Texas State Board of Podiatric  
6 Medical Examiners, the State Board of Dental Examiners, the State  
7 Board of Veterinary Medical Examiners, or the Texas State Board of  
8 Pharmacy;

9 (2) an authorized officer or member of the department  
10 engaged in the administration, investigation, or enforcement of  
11 this chapter or another law governing illicit drugs in this state or  
12 another state; or

13 (3) if the director finds that proper need has been  
14 shown to the director:

15 (A) a law enforcement or prosecutorial official  
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;

19 (B) a pharmacist or practitioner who is a  
20 physician, dentist, veterinarian, or podiatrist and is inquiring  
21 about the recent Schedule II prescription history of a particular  
22 patient of the practitioner; or

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

25 (c) The director by rule shall design and implement a system  
26 for submission of information to the director by electronic or  
27 other means and for retrieval of information submitted to the

1 director under this section and Sections 481.074 and ~~[Section]~~  
2 481.075. The director shall use automated information security  
3 techniques and devices to preclude improper access to the  
4 information. The director shall submit the system design to the  
5 Texas State Board of Pharmacy and the Texas ~~[State Board of]~~ Medical  
6 Board ~~[Examiners]~~ for review and approval or comment a reasonable  
7 time before implementation of the system and shall comply with the  
8 comments of those agencies unless it is unreasonable to do so.

9 SECTION 4. Subsections (a), (b), (c), and (e), Section  
10 481.0761, Health and Safety Code, are amended to read as follows:

11 (a) The director shall consult with the Texas State Board of  
12 Pharmacy and by rule establish and revise as necessary a  
13 standardized database format that may be used by a pharmacy to  
14 transmit the information required by Sections 481.074(q) and  
15 ~~[Section]~~ 481.075(i) to the director electronically or to deliver  
16 the information on storage media, including disks, tapes, and  
17 cassettes.

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

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

26 (2) return a substance previously removed from  
27 Schedules ~~[Schedule]~~ II through V to the official prescription

1 program, if the director determines that the risk of diversion  
2 substantially outweighs the burden imposed by the program on the  
3 particular controlled substance.

4 (c) The director by rule may:

5 (1) permit more than one prescription to be  
6 administered or dispensed and recorded on one [~~official~~]  
7 prescription form for a Schedule III through V controlled  
8 substance;

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

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

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

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

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

20 (e) In adopting a rule relating to the electronic transfer  
21 of information under this subchapter, the director shall consider  
22 the economic impact of the rule on practitioners and pharmacists  
23 and, to the extent permitted by law, act to minimize any negative  
24 economic impact, including the imposition of costs related to  
25 computer hardware or software or to the transfer of information.  
26 The director may not adopt a rule relating to the electronic  
27 transfer of information under this subchapter that imposes a fee in

1 addition to the fees [~~fee~~] authorized by Section 481.064.

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

4 SUBCHAPTER H. ADMINISTRATIVE PENALTY

5 Sec. 481.301. IMPOSITION OF PENALTY. The department may  
6 impose an administrative penalty on a person who violates Section  
7 481.061, 481.066, 481.067, 481.069-481.075, 481.077, 481.0771,  
8 481.078, 481.080, or 481.081 or a rule or order adopted under any of  
9 those sections.

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

16 (b) The amount shall be based on:

17 (1) the seriousness of the violation, including the  
18 nature, circumstances, extent, and gravity of the violation;

19 (2) the threat to health or safety caused by the  
20 violation;

21 (3) the history of previous violations;

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

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

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

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

1 (a) If the department initially determines that a violation  
2 occurred, the department shall give written notice of the report to  
3 the person by certified mail, registered mail, personal delivery,  
4 or another manner of delivery that records the person's receipt of  
5 the notice.

6 (b) The notice must:

7 (1) include a brief summary of the alleged violation;  
8 (2) state the amount of the recommended penalty; and  
9 (3) inform the person of the person's right to a  
10 hearing on the occurrence of the violation, the amount of the  
11 penalty, or both.

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

15 (1) accept the determination and recommended penalty;  
16 or

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

20 (b) At the conclusion of an informal hearing requested under  
21 Subsection (a), the department may modify the amount of the  
22 recommended penalty.

23 (c) If the person accepts the determination and recommended  
24 penalty, including any modification of the amount, or if the person  
25 fails to timely respond to the notice, the director by order shall  
26 approve the determination and impose the recommended penalty.

27 Sec. 481.305. FORMAL HEARING. (a) The person may request



1 a formal hearing only after participating in an informal hearing.

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

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

8 (d) If the person timely requests a formal hearing, the  
9 director shall refer the matter to the State Office of  
10 Administrative Hearings, which shall promptly set a hearing date  
11 and give written notice of the time and place of the hearing to the  
12 director and to the person. An administrative law judge of the  
13 State Office of Administrative Hearings shall conduct the hearing.

14 (e) The administrative law judge shall make findings of fact  
15 and conclusions of law and promptly issue to the director a proposal  
16 for a decision about the occurrence of the violation and the amount  
17 of any proposed penalty.

18 (f) If a penalty is proposed under Subsection (e), the  
19 administrative law judge shall include in the proposal for a  
20 decision a finding setting out costs, fees, expenses, and  
21 reasonable and necessary attorney's fees incurred by the state in  
22 bringing the proceeding. The director may adopt the finding and  
23 impose the costs, fees, and expenses on the person as part of the  
24 final order entered in the proceeding.

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

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

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

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

8           Sec. 481.307. OPTIONS FOLLOWING DECISION: PAY OR APPEAL.

9 Before the 31st day after the date the order under Section 481.306  
10 that imposes an administrative penalty becomes final, the person  
11 shall:

12           (1) pay the penalty; or

13           (2) file a petition for judicial review of the order  
14 contesting the occurrence of the violation, the amount of the  
15 penalty, or both.

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

19           (1) stay enforcement of the penalty by:

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

22                   (B) giving the court a supersedeas bond approved  
23 by the court that:

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

25                           (ii) is effective until all judicial review  
26 of the order is final; or

27           (2) request the court to stay enforcement of the

1 penalty by:

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

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

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

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

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

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

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

26 Sec. 481.311. REMITTANCE OF PENALTY AND INTEREST. (a) If  
27 the person paid the penalty and if the amount of the penalty is

1 reduced or the penalty is not upheld by the court, the court shall  
2 order, when the court's judgment becomes final, that the  
3 appropriate amount plus accrued interest be remitted to the person  
4 before the 31st day after the date that the judgment of the court  
5 becomes final.

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

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

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

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

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

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

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

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

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

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