

By: Hamilton

H.B. No. 3684

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. Section 481.064(a), 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, shall establish the period after  
17 the date on which the prescription is issued that a person may [not]  
18 fill a prescription for a controlled substance listed in Schedule  
19 II [~~after the end of the seventh day after the date on which the~~  
20 ~~prescription is issued~~]. A person may not refill a prescription for  
21 a substance listed in Schedule II.

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

23 (1) the quantity of the substance prescribed:

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

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

- 1           (2) the date of issue;
- 2           (3) the name, ~~and~~ address, and date of birth or age  
3 of the patient or, if the controlled substance is prescribed for an  
4 animal, the species of the animal and the name and address of its  
5 owner;
- 6           (4) the name and strength of the controlled substance  
7 prescribed;
- 8           (5) the directions for use of the controlled  
9 substance;
- 10          (6) the intended use of the substance prescribed  
11 unless the practitioner determines the furnishing of this  
12 information is not in the best interest of the patient; ~~and~~
- 13          (7) the legibly printed or stamped name, address,  
14 Federal Drug Enforcement Administration registration number,  
15 department registration number, and telephone number of the  
16 practitioner at the practitioner's usual place of business; and
- 17          (8) the signatures of the prescribing practitioner and  
18 the dispensing pharmacist.
- 19          (g) Each dispensing pharmacist shall send all information  
20 required by the director, including any information required to  
21 complete the Schedules III through V prescription forms, to the  
22 director by electronic transfer or another form approved by the  
23 director not later than the 15th day after the last day of the month  
24 in which the prescription is completely filled.

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

- 27           (a) The director may not permit any person to have access to

1 information submitted to the director under Section 481.074(g) or  
2 481.075 except:

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

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

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

14 (A) a law enforcement or prosecutorial official  
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;

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

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

24 (c) The director by rule shall design and implement a system  
25 for submission of information to the director by electronic or  
26 other means and for retrieval of information submitted to the  
27 director under this section and Sections 481.074 and [~~Section~~]

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

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

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

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

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

25 (2) return a substance previously removed from  
26 Schedules [~~Schedule~~] II through V to the official prescription  
27 program, if the director determines that the risk of diversion

1 substantially outweighs the burden imposed by the program on the  
2 particular controlled substance.

3 (c) The director by rule may:

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

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

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

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

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

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

19 (e) In adopting a rule relating to the electronic transfer  
20 of information under this subchapter, the director shall consider  
21 the economic impact of the rule on practitioners and pharmacists  
22 and, to the extent permitted by law, act to minimize any negative  
23 economic impact, including the imposition of costs related to  
24 computer hardware or software or to the transfer of information.  
25 The director may not adopt a rule relating to the electronic  
26 transfer of information under this subchapter that imposes a fee in  
27 addition to the fees ~~[fee]~~ authorized by Section 481.064.

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

3 SUBCHAPTER H. ADMINISTRATIVE PENALTY

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

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

15 (b) The amount shall be based on:

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

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

20 (3) the history of previous violations;

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

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

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

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

27 (a) If the department initially determines that a violation

1 occurred, the department shall give written notice of the report to  
2 the person by certified mail, registered mail, personal delivery,  
3 or another manner of delivery that records the person's receipt of  
4 the notice.

5 (b) The notice must:

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

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

8 (3) inform the person of the person's right to a  
9 hearing on the occurrence of the violation, the amount of the  
10 penalty, or both.

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

14 (1) accept the determination and recommended penalty;

15 or

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

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

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

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



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

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

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

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

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

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

27       (1) find that a violation occurred and impose a

1 penalty; or

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

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

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

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

11 (1) pay the penalty; or

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

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

18 (1) stay enforcement of the penalty by:

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

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

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

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

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

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

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

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

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

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

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

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

25           Sec. 481.311. REMITTANCE OF PENALTY AND INTEREST. (a) If  
26 the person paid the penalty and if the amount of the penalty is  
27 reduced or the penalty is not upheld by the court, the court shall

1 order, when the court's judgment becomes final, that the  
2 appropriate amount plus accrued interest be remitted to the person  
3 before the 31st day after the date that the judgment of the court  
4 becomes final.

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

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

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

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

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

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

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

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

6           (c) The changes in law made by this Act in amending Sections  
7 481.074(k) and 481.076, Health and Safety Code, and in adding  
8 Section 481.074(q) of that code take effect September 1, 2008. The  
9 director of the Department of Public Safety shall adopt any rules  
10 necessary to administer and enforce the changes in law made by those  
11 provisions not later than September 1, 2008.