

By: Truitt

H.B. No. 3174

A BILL TO BE ENTITLED

AN ACT

relating to the licensing and regulation of wholesale drug distributors; providing penalties.

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

SECTION 1. Section 431.201, Health and Safety Code, is amended to read as follows:

Sec. 431.201. DEFINITIONS. In this subchapter:

(1) "Authentication" means to affirmatively verify before any distribution of a prescription drug occurs that each transaction listed on the pedigree for the drug has occurred.

(2) "Chain pharmacy warehouse" means a location that serves as a central warehouse for drugs or devices and from which intracompany sales or transfers of drugs or devices are made to a group of pharmacies under common ownership and control.

(3) "Normal distribution chain" means a chain of custody for a drug from a manufacturer to a wholesale distributor to a pharmacy to a patient.

(4) "Pedigree" means a document or electronic file containing information that records each distribution of a prescription drug, from sale by a manufacturer, through acquisition and sale by any wholesale distributor or repackager, until final sale to a pharmacy or other person dispensing or administering the prescription drug.

(5) "Place of business" means each location at which a

1 drug for wholesale distribution is located.

2 (6) "Prescription drug" has the meaning assigned by
3 Section 551.003, Occupations Code.

4 (7) "Repackage" means repackaging or otherwise
5 changing the container, wrapper, or labeling of a drug to further
6 the distribution of a prescription drug. The term does not include
7 repackaging by a pharmacist to dispense a drug to a patient.

8 (8) "Repackager" means a person who engages in
9 repackaging.

10 (9) "Wholesale distribution" means distribution to a
11 person other than a consumer or patient, and includes distribution
12 by a manufacturer, repackager [~~repacker~~], own label distributor,
13 private-label distributor, broker, jobber, warehouse, independent
14 wholesale drug traders, retail pharmacy that conducts wholesale
15 distribution, or wholesaler. The term does not include:

16 (A) intracompany sales of prescription drugs,
17 which means transactions or transfers of prescription drugs between
18 a division, subsidiary, parent, or affiliated or related company
19 that is under common ownership and control of a corporate entity;

20 (B) the sale, purchase, distribution, trade, or
21 transfer of prescription drugs or the offer to sell, purchase,
22 distribute, trade, or transfer a prescription drug for emergency
23 medical reasons;

24 (C) the distribution of prescription drug
25 samples by a representative of a manufacturer;

26 (D) the return of drugs by a hospital, health
27 care entity, retail pharmacy, or charitable institution in

1 accordance with 21 C.F.R. 203.23;

2 (E) the sale of minimal quantities of
3 prescription drugs by retail pharmacies to licensed practitioners
4 for office use; or

5 (F) the delivery by a retail pharmacy of a
6 prescription drug to a patient or a patient's agent under the lawful
7 order of a licensed practitioner.

8 (10) "Wholesale distributor" means a person licensed
9 under this chapter to engage in the wholesale distribution of
10 prescription drugs.

11 ~~[(2) "Place of business" means each location at which~~
12 ~~a drug for wholesale distribution is located.]~~

13 SECTION 2. Sections 431.202 and 431.203, Health and Safety
14 Code, are amended to read as follows:

15 Sec. 431.202. LICENSE [~~STATEMENT~~] REQUIRED. (a) A person
16 may not engage in wholesale distribution of drugs in this state
17 unless the person holds a wholesale drug distribution license under
18 this subchapter for each place of business [~~has filed with the~~
19 ~~commissioner a signed and verified license statement on a form~~
20 ~~furnished by the commissioner)].~~

21 (a-1) A person may not engage in the wholesale distribution
22 of drugs as a chain pharmacy warehouse location unless the person
23 holds a chain pharmacy license under this chapter.

24 (b) A [~~The~~] license issued under this subchapter expires on
25 the first anniversary of the date of issuance [~~statement must be~~
26 ~~filed annually)].~~

27 Sec. 431.203. [~~CONTENTS — OF~~] LICENSE APPLICATION

1 ~~[STATEMENT]~~. (a) An applicant for a license under this subchapter
2 must submit an application to the department on the form prescribed
3 by the department. The application [~~license statement~~] must
4 contain:

5 (1) all trade or business names [~~the name~~] under which
6 the business is conducted;

7 (2) the address and telephone number of each place of
8 business that is licensed;

9 (3) the type of business and the name and residence
10 address of:

11 (A) the proprietor, if the business is a
12 proprietorship;

13 (B) all partners, if the business is a
14 partnership; or

15 (C) all principals, if the business is an
16 association;

17 (4) the date and place of incorporation, if the
18 business is a corporation;

19 (5) the names and residence addresses of the
20 individuals in an administrative capacity showing:

21 (A) the managing proprietor, if the business is a
22 proprietorship;

23 (B) the managing partner, if the business is a
24 partnership;

25 (C) the officers and directors, if the business
26 is a corporation; or

27 (D) the persons in a managerial capacity, if the

1 business is an association; ~~and~~

2 (6) the name, telephone number, and residence address
3 of a designated representative ~~[an individual in charge]~~ of each
4 place of business;

5 (7) the state of incorporation, if the business is a
6 corporation;

7 (8) a list of all licenses and permits issued to the
8 applicant by any other state under which the applicant is permitted
9 to purchase or possess prescription drugs; and

10 (9) the name of:

11 (A) the manager for each place of business; and

12 (B) all affiliated parties for the business.

13 (b) Each person listed in Subsections (a)(6) and (a)(9)
14 shall provide the following to the department:

15 (1) the person's places of residence for the past seven
16 years;

17 (2) the person's date and place of birth;

18 (3) the person's occupations, positions of employment,
19 and offices held during the past seven years;

20 (4) the business name and address of any business,
21 corporation, or other organization in which the person held an
22 office under Subdivision (3) or in which the person conducted an
23 occupation or held a position of employment;

24 (5) a statement of whether during the preceding seven
25 years the person was the subject of a proceeding to revoke a license
26 and the nature and disposition of the proceeding;

27 (6) a statement of whether during the preceding seven

1 years the person has been enjoined, either temporarily or
2 permanently, by a court from violating any federal or state law
3 regulating the possession, control, or distribution of
4 prescription drugs, including the details concerning the event;

5 (7) a written description of any involvement by the
6 person with any business, including any investments, other than the
7 ownership of stock in a publicly traded company or mutual fund
8 during the past seven years, that manufactured, administered,
9 prescribed, distributed, or stored pharmaceutical products and any
10 lawsuits in which the businesses were named as a party;

11 (8) a description of any felony offense for which the
12 person, as an adult, was found guilty, regardless of whether
13 adjudication of guilt was withheld or whether the person pled
14 guilty or nolo contendere;

15 (9) a description of any criminal conviction of the
16 person under appeal, a copy of the notice of appeal for that
17 criminal offense, and a copy of the final written order of an appeal
18 not later than the 15th day after the date of the appeal's
19 disposition; and

20 (10) a photograph of the person taken not earlier than
21 30 days before the date the application was submitted.

22 (c) The information submitted under Subsection (b) must be
23 attested to under oath.

24 (d) An applicant or license holder shall file with the board
25 a written notice of any change in the information required under
26 this section.

27 SECTION 3. Subchapter I, Chapter 431, Health and Safety

1 Code, is amended by adding Section 431.2030 to read as follows:

2 Sec. 431.2030. QUALIFICATIONS FOR LICENSE. (a) To qualify
3 for the issuance or renewal of a wholesale distributor license
4 under this subchapter, the designated representative of an
5 applicant or license holder must:

6 (1) be at least 21 years of age;

7 (2) have been employed full-time for at least three
8 years by a pharmacy or a wholesale distributor in a capacity related
9 to the dispensing and distributing of prescription drugs, including
10 recordkeeping for the dispensing and distributing of prescription
11 drugs;

12 (3) be employed by the applicant full-time in a
13 managerial-level position;

14 (4) be actively involved in and aware of the actual
15 daily operation of the wholesale distributor;

16 (5) be physically present at the applicant's place of
17 business during regular business hours, except when the absence of
18 the designated representative is authorized, including sick leave
19 and vacation leave;

20 (6) serve as a designated representative for only one
21 applicant at any one time;

22 (7) not have been convicted of a violation of any
23 federal, state, or local laws relating to wholesale or retail
24 prescription drug distribution or the distribution of controlled
25 substances; and

26 (8) not have been convicted of a felony under federal,
27 state, or local laws.

1 (b) The department or a nationally recognized accreditation
2 program selected by the department may assess and collect an
3 inspection fee to cover the costs of determining whether an
4 applicant is qualified for a license under this subchapter,
5 including costs to conduct physical inspections, business and
6 criminal background checks, activities related to bonding
7 requirements, and any other necessary activity.

8 SECTION 4. Subchapter I, Chapter 431, Health and Safety
9 Code, is amended by adding Sections 431.2035 and 431.2036 to read as
10 follows:

11 Sec. 431.2035. CRIMINAL HISTORY RECORD INFORMATION. The
12 department shall submit to the Department of Public Safety the
13 fingerprints provided by a person with an initial or a renewal
14 license application to obtain the person's criminal history record
15 information and may forward the fingerprints to the Federal Bureau
16 of Investigation for a federal criminal history check.

17 Sec. 431.2036. BOND. (a) A wholesale distributor applying
18 for or renewing a license shall submit payable to this state a bond
19 or other equivalent security acceptable to the department in the
20 amount of \$100,000, including an irrevocable letter of credit or a
21 deposit in a trust account or financial institution, payable to
22 this state.

23 (b) The bond submitted under Subsection (a) shall secure
24 payment of any fines or penalties imposed by the department and any
25 fees and costs incurred by this state related to that license
26 holder, that are authorized under the laws of this state and that
27 the license holder fails to pay before the 30th day after the date a

1 fine, penalty, or cost is assessed.

2 (c) The department or this state may make a claim against a
3 bond or security submitted under Subsection (a) before the first
4 anniversary of the date a license expires or is revoked under this
5 chapter.

6 (d) The department shall deposit the bonds received under
7 this section in a separate account.

8 SECTION 5. Section 431.204(c), Health and Safety Code, is
9 amended to read as follows:

10 (c) The executive commissioner of the Health and Human
11 Services Commission [~~board~~] by rule shall set the fees in amounts
12 that are reasonable and necessary and allow the department to
13 recover [~~at least 50 percent of~~] the annual expenditures of state
14 funds by the department in:

- 15 (1) reviewing and acting on a license;
- 16 (2) amending and renewing a license;
- 17 (3) inspecting a licensed facility; and
- 18 (4) implementing and enforcing this subchapter,
19 including a rule or order adopted or a license issued under this
20 subchapter.

21 SECTION 6. Subchapter I, Chapter 431, Health and Safety
22 Code, is amended by adding Sections 431.2065-431.2067 to read as
23 follows:

24 Sec. 431.2065. MINIMUM RESTRICTIONS ON TRANSACTIONS. (a)
25 Except as otherwise provided by this subsection, a wholesale
26 distributor may not purchase or otherwise receive a prescription
27 drug from a pharmacy. A wholesale distributor may receive a

1 prescription drug from a pharmacy if the prescription drug was
2 originally purchased by the pharmacy from the wholesale
3 distributor.

4 (b) A wholesale distributor who receives a prescription
5 drug from a pharmacy may not:

6 (1) receive an amount or quantity of a prescription
7 drug greater than the amount or quantity originally sold by the
8 wholesale distributor to the pharmacy; or

9 (2) pay the pharmacy an amount, either in cash or
10 credit, that exceeds the amount the pharmacy originally paid the
11 wholesale distributor for the prescription drug.

12 (c) A manufacturer or wholesale distributor may distribute
13 prescription drugs only to a person licensed by the appropriate
14 state licensing authorities. Before furnishing prescription drugs
15 to a person not known to the manufacturer or wholesale distributor,
16 the manufacturer or wholesale distributor must verify that the
17 person is legally authorized to receive the prescription drugs by
18 contacting the appropriate state licensing authority.

19 (d) Except as otherwise provided by this subsection,
20 prescription drugs distributed by a manufacturer or wholesale
21 distributor may be delivered only to the premises listed on the
22 license. A manufacturer or wholesale distributor may distribute
23 prescription drugs to an authorized person or agent of that person
24 at the premises of the manufacturer or wholesale distributor if:

25 (1) the identity and authorization of the recipient is
26 properly established; and

27 (2) delivery is made only to meet the immediate needs

1 of a particular patient of the authorized person.

2 (e) Prescription drugs may be distributed to a hospital
3 pharmacy receiving area if a pharmacist or an authorized receiving
4 person signs, at the time of delivery, a receipt showing the type
5 and quantity of the prescription drug received. Any discrepancy
6 between the receipt and the type and quantity of the prescription
7 drug actually received shall be reported to the delivering
8 manufacturer or wholesale distributor not later than the next
9 business day after the date of delivery to the pharmacy receiving
10 area.

11 (f) A manufacturer or wholesale distributor may not accept
12 payment for, or allow the use of, a person's credit to establish an
13 account to purchase prescription drugs from any person other than
14 the owner of record, the chief executive officer, or the chief
15 financial officer listed on the license of a person legally
16 authorized to receive prescription drugs. An account established
17 to purchase prescription drugs must bear the name of the license
18 holder.

19 Sec. 431.2066. The Texas Health and Human Services
20 Commission shall:

21 (1) conduct a study on the implementation of
22 electronic pedigrees;

23 (2) in conducting the study under Subdivision (1),
24 consult with manufacturers, distributors, and pharmacies
25 responsible for the sale and distribution of prescription drugs in
26 this state; and

27 (3) based on the results of the study, establish an

1 implementation date, which may not be earlier than December 31,
2 2007, for electronic pedigrees.

3 SECTION 7. Subchapter I, Chapter 431, Health and Safety
4 Code, is amended by adding Sections 431.2075-431.2077 to read as
5 follows:

6 Sec. 431.2075. ORDER TO CEASE DISTRIBUTION. (a) The
7 commissioner of state health services shall issue an order
8 requiring a person, including a manufacturer, distributor, or
9 retailer of a prescription drug, to immediately cease distribution
10 of the drug if the commissioner determines there is a reasonable
11 probability that:

12 (1) a wholesale distributor has:
13 (A) knowingly violated this subchapter;
14 (B) knowingly sold, distributed, transferred,
15 manufactured, repackaged, handled, or held a counterfeit
16 prescription drug intended for human use;

17 (2) the prescription drug could cause serious adverse
18 health consequences or death; and

19 (3) other procedures would result in unreasonable
20 delay.

21 (b) An order under Subsection (a) must provide the person
22 subject to the order with an opportunity for an informal hearing on
23 the actions required by the order to be held not later than the 10th
24 day after the date of issuance of the order.

25 (c) If, after providing an opportunity for a hearing, the
26 commissioner of state health services determines that inadequate
27 grounds exist to support the actions required by the order, the

1 commissioner shall vacate the order.

2 Sec. 431.2076. PROHIBITED ACTS. (a) A person violates this
3 subchapter if the person performs, causes the performance of, or
4 aids and abets the performance of an act listed in Subsection (b).

5 (b) A person violates this subchapter if the person:

6 (1) operates as a wholesale drug distributor under
7 this subchapter without a license;

8 (2) sells, distributes, or transfers a prescription
9 drug to a person who is not authorized under state or federal law to
10 receive the prescription drug in violation of Section 431.2065(c);

11 (4) fails to deliver prescription drugs to specified
12 premises as required by Section 431.2065(d);

13 (5) accepts payment or credit for the sale of
14 prescription drugs in violation of Section 431.2065(f);

15 (6) provides this state or any representative of this
16 state or any federal official with false or fraudulent records or
17 makes false or fraudulent statements regarding any matter related
18 to this subchapter;

19 (7) obtains or attempts to obtain a prescription drug
20 by fraud, deceit, or misrepresentation or engages in
21 misrepresentation or fraud in the distribution of a prescription
22 drug;

23 (9) manufactures, repackages, sells, transfers,
24 delivers, holds, or offers for sale any prescription drug that is
25 adulterated, misbranded, counterfeit, suspected of being
26 counterfeit, or has otherwise been rendered unfit for distribution;

27 (10) adulterates, misbrands, or counterfeits any

1 prescription drug;

2 (11) receives any prescription drug that is
3 adulterated, misbranded, stolen, obtained by fraud or deceit,
4 counterfeit, or suspected of being counterfeit and delivers or
5 proffers delivery of the drug for pay or otherwise; or

6 (12) alters, mutilates, destroys, obliterates, or
7 removes all or any part of the label from a prescription drug or
8 commits any other act related to a prescription drug that results in
9 the prescription drug being misbranded.

10 Sec. 431.2077. CRIMINAL PENALTIES. (a) A person commits an
11 offense if the person engages in the wholesale distribution of
12 prescription drugs in violation of this subchapter. An offense
13 under this subsection is punishable by imprisonment for not more
14 than 15 years, a fine not to exceed \$50,000, or both imprisonment
15 and a fine.

16 (b) A person commits an offense if the person knowingly
17 engages in the wholesale distribution of prescription drugs in
18 violation of this subchapter. An offense under this subsection is
19 punishable by imprisonment, a fine not to exceed \$500,000, or both
20 imprisonment and a fine.

21 SECTION 8. Section 411.110, Government Code, is amended to
22 read as follows:

23 Sec. 411.110. ACCESS TO CRIMINAL HISTORY RECORD
24 INFORMATION: [~~TEXAS~~] DEPARTMENT OF STATE HEALTH SERVICES. (a) The
25 [~~Texas~~] Department of State Health Services is entitled to obtain
26 from the department criminal history record information maintained
27 by the department that relates to:

1 (1) a person who is:

2 (A) [~~(1)~~] an applicant for a license or
3 certificate under the Emergency Medical Services Act (Chapter 773,
4 Health and Safety Code);

5 (B) [~~(2)~~] an owner or manager of an applicant for
6 an emergency medical services provider license under that Act; or

7 (C) [~~(3)~~] the holder of a license or certificate
8 under that Act; or

9 (2) an applicant for a license or a license holder
10 under Subchapter I, Chapter 431, Health and Safety Code.

11 (b) Criminal history record information obtained by the
12 [~~Texas~~] Department of State Health Services under Subsection (a)
13 may not be released or disclosed to any person except on court
14 order, with the written consent of the person or entity that is the
15 subject of the criminal history record information, or as provided
16 by Subsection (e).

17 (c) After an entity is licensed or certified, the [~~Texas~~]
18 Department of State Health Services shall destroy the criminal
19 history record information that relates to that entity.

20 (d) The Department of State Health Services [~~Texas Board of~~
21 ~~Health~~] shall destroy criminal history record information that
22 relates to an applicant that is not certified.

23 (e) The Department of State Health Services [~~Texas Board of~~
24 ~~Health~~] is not prohibited from disclosing criminal history record
25 information obtained under Subsection (a) in a criminal proceeding
26 or in a hearing conducted by the [~~Texas~~] Department of State Health
27 Services.

1 SECTION 9. (a) The executive commissioner of the Health and
2 Human Services Commission shall adopt the rules necessary to
3 implement the changes in law made by this Act to Subchapter I,
4 Chapter 431, Health and Safety Code, not later than January 1, 2006.

5 (b) A wholesale drug manufacturer is not required to comply
6 with and is not subject to penalties for a violation of Subchapter
7 I, Chapter 431, Health and Safety Code, as amended by this Act,
8 before March 1, 2006.

9 SECTION 10. The change in law made by this Act applies only
10 to an offense committed on or after the effective date of this Act.
11 An offense committed before the effective date of this Act is
12 covered by the law in effect when the offense was committed, and the
13 former law is continued in effect for that purpose. For purposes of
14 this section, an offense was committed before the effective date of
15 this Act if any element of the offense was committed before that
16 date.

17 SECTION 11. This Act takes effect September 1, 2005, except
18 that Section 431.2077, Health and Safety Code, as added by this Act,
19 takes effect March 1, 2006.