

By: Truitt

H.B. No. 3174

Substitute the following for H.B. No. 3174:

By: McReynolds

C.S.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) "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.

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

(3) "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.

(4) "Place of business" means each location at which a drug for wholesale distribution is located.

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

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

5 (7) "Repackager" means a person who engages in
6 repackaging.

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

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

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

22 (C) the distribution of prescription drug
23 samples by a representative of a manufacturer;

24 (D) the return of drugs by a hospital, health
25 care entity, retail pharmacy, or charitable institution in
26 accordance with 21 C.F.R. Section 203.23;

27 (E) the sale of minimal quantities of

1 prescription drugs by retail pharmacies to licensed practitioners
2 for office use; or

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

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

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

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

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

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

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

25 Sec. 431.203. [~~CONTENTS OF~~] LICENSE APPLICATION
26 [~~STATEMENT~~]. (a) An applicant for a license under this subchapter
27 must submit an application to the department on the form prescribed

1 by the department. The application [~~license statement~~] must
2 contain:

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

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

7 (3) the type of business and the name and residence
8 address of:

9 (A) the proprietor, if the business is a
10 proprietorship;

11 (B) all partners, if the business is a
12 partnership; or

13 (C) all principals, if the business is an
14 association;

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

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

19 (A) the managing proprietor, if the business is a
20 proprietorship;

21 (B) the managing partner, if the business is a
22 partnership;

23 (C) the officers and directors, if the business
24 is a corporation; or

25 (D) the persons in a managerial capacity, if the
26 business is an association; [~~and~~]

27 (6) the name, telephone number, and residence address

1 of a designated representative [~~an individual in charge~~] of each
2 place of business;

3 (7) the state of incorporation, if the business is a
4 corporation;

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

8 (9) the name of:

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

10 (B) all affiliated parties for the business.

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

13 (1) the person's places of residence for the past seven
14 years;

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

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

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

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

25 (6) a statement of whether during the preceding seven
26 years the person has been enjoined, either temporarily or
27 permanently, by a court from violating any federal or state law

1 regulating the possession, control, or distribution of
2 prescription drugs, including the details concerning the event;

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

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

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

18 (10) a photograph of the person taken not earlier than
19 30 days before the date the application was submitted.

20 (c) The information submitted under Subsection (b) must be
21 attested to under oath.

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

25 SECTION 3. Subchapter I, Chapter 431, Health and Safety
26 Code, is amended by adding Section 431.2030 to read as follows:

27 Sec. 431.2030. QUALIFICATIONS FOR LICENSE. (a) To qualify

1 for the issuance or renewal of a wholesale distributor license
2 under this subchapter, the designated representative of an
3 applicant or license holder must:

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

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

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

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

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

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

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

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

26 (b) The department or a nationally recognized accreditation
27 program selected by the department may assess and collect an

1 inspection fee to cover the costs of determining whether an
2 applicant is qualified for a license under this subchapter,
3 including costs to conduct physical inspections, business and
4 criminal background checks, activities related to bonding
5 requirements, and any other necessary activity.

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

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

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

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

27 (c) The department or this state may make a claim against a

1 bond or security submitted under Subsection (a) before the first
2 anniversary of the date a license expires or is revoked under this
3 chapter.

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

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

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

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

19 SECTION 6. Subchapter I, Chapter 431, Health and Safety
20 Code, is amended by adding Sections 431.2065 and 431.2066 to read as
21 follows:

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

1 distributor.

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

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

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

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

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

23 (1) the identity and authorization of the recipient is
24 properly established; and

25 (2) delivery is made only to meet the immediate needs
26 of a particular patient of the authorized person.

27 (e) Prescription drugs may be distributed to a hospital

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

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

17 Sec. 431.2066. ELECTRONIC PEDIGREES: STUDY; RULES. (a)
18 The department shall:

19 (1) conduct a study on electronic pedigrees and the
20 implementation of a program to require persons engaged in the
21 wholesale distribution of prescription drugs to provide a pedigree
22 on distribution of certain prescription drugs;

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 requiring electronic pedigrees on distribution of certain
3 prescription drugs under this subchapter as necessary to protect
4 public health and safety.

5 (b) The executive commissioner of the Health and Human
6 Services Commission may adopt the rules necessary to implement the
7 electronic pedigree program based on the results of the study
8 conducted under Subsection (a).

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

12 Sec. 431.2075. ORDER TO CEASE DISTRIBUTION. (a) The
13 commissioner of state health services shall issue an order
14 requiring a person, including a manufacturer, distributor, or
15 retailer of a prescription drug, to immediately cease distribution
16 of the drug if the commissioner determines there is a reasonable
17 probability that:

18 (1) a wholesale distributor has:

19 (A) knowingly violated this subchapter; or

20 (B) knowingly sold, distributed, transferred,
21 manufactured, repackaged, handled, or held a counterfeit
22 prescription drug intended for human use;

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

25 (3) other procedures would result in unreasonable
26 delay.

27 (b) An order under Subsection (a) must provide the person

1 subject to the order with an opportunity for an informal hearing on
2 the actions required by the order to be held not later than the 10th
3 day after the date of issuance of the order.

4 (c) If, after providing an opportunity for a hearing, the
5 commissioner of state health services determines that inadequate
6 grounds exist to support the actions required by the order, the
7 commissioner shall vacate the order.

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

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

12 (1) operates as a wholesale drug distributor under
13 this subchapter without a license;

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

17 (3) fails to deliver prescription drugs to specified
18 premises as required by Section 431.2065(d);

19 (4) accepts payment or credit for the sale of
20 prescription drugs in violation of Section 431.2065(f);

21 (5) provides this state or any representative of this
22 state or any federal official with false or fraudulent records or
23 makes false or fraudulent statements regarding any matter related
24 to this subchapter;

25 (6) obtains or attempts to obtain a prescription drug
26 by fraud, deceit, or misrepresentation or engages in
27 misrepresentation or fraud in the distribution of a prescription

1 drug;

2 (7) manufactures, repackages, sells, transfers,
3 delivers, holds, or offers for sale any prescription drug that is
4 adulterated, misbranded, counterfeit, or suspected of being
5 counterfeit or has otherwise been rendered unfit for distribution;

6 (8) adulterates, misbrands, or counterfeits any
7 prescription drug;

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

12 (10) alters, mutilates, destroys, obliterates, or
13 removes all or any part of the label from a prescription drug or
14 commits any other act related to a prescription drug that results in
15 the prescription drug being misbranded.

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

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

27 SECTION 8. Section 411.110, Government Code, is amended to

1 read as follows:

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

7 (1) a person who is:

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

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

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

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

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

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

26 (d) The Department of State Health Services [~~Texas Board of~~
27 ~~Health~~] shall destroy criminal history record information that

1 relates to an applicant that is not certified.

2 (e) The Department of State Health Services [~~Texas Board of~~
3 ~~Health~~] is not prohibited from disclosing criminal history record
4 information obtained under Subsection (a) in a criminal proceeding
5 or in a hearing conducted by the [~~Texas~~] Department of State Health
6 Services.

7 SECTION 9. (a) Except as provided by Section 431.2066,
8 Health and Safety Code, as added by this Act, the executive
9 commissioner of the Health and Human Services Commission shall
10 adopt the rules necessary to implement the changes in law made by
11 this Act to Subchapter I, Chapter 431, Health and Safety Code, not
12 later than January 1, 2006.

13 (b) A wholesale drug manufacturer is not required to comply
14 with and is not subject to penalties for a violation of Subchapter
15 I, Chapter 431, Health and Safety Code, as amended by this Act,
16 before March 1, 2006. To the extent that the manufacturer engages
17 in the wholesale distribution of drugs in this state before that
18 date, the manufacturer remains subject to Subchapter I as it
19 existed immediately before the effective date of this Act.

20 SECTION 10. The change in law made by this Act applies only
21 to an offense committed on or after March 1, 2006. An offense
22 committed before March 1, 2006, is covered by the law in effect when
23 the offense was committed, and the former law is continued in effect
24 for that purpose. For purposes of this section, an offense was
25 committed before March 1, 2006, if any element of the offense was
26 committed before that date.

27 SECTION 11. This Act takes effect September 1, 2005, except

C.S.H.B. No. 3174

1 that Section 431.2077, Health and Safety Code, as added by this Act,
2 takes effect March 1, 2006.