

By: Janek, Estes

S.B. No. 1685

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. The heading to Subchapter I, Chapter 431, Health and Safety Code, is amended to read as follows:

SUBCHAPTER I. WHOLESALE ~~[DRUG]~~ DISTRIBUTORS
OF NONPRESCRIPTION DRUGS

SECTION 2. Section 431.201, Health and Safety Code, is amended to read as follows:

Sec. 431.201. DEFINITIONS. In this subchapter:

(1) "Nonprescription drug" means any drug that is not a prescription drug as defined by Section 431.401.

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

(3) "Wholesale distribution" means distribution to a person other than a consumer or patient, and includes distribution by a manufacturer, repackager [repacker], own label distributor, broker, jobber, warehouse, or wholesaler.

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

SECTION 3. Subchapter I, Chapter 431, Health and Safety Code, is amended by adding Section 431.2011 to read as follows:

Sec. 431.2011. APPLICABILITY OF SUBCHAPTER. This

1 subchapter applies only to the wholesale distribution of
2 nonprescription drugs.

3 SECTION 4. Section 431.202, Health and Safety Code, is
4 amended to read as follows:

5 Sec. 431.202. LICENSE [~~STATEMENT~~] REQUIRED. (a) A person
6 may not engage in wholesale distribution of nonprescription drugs
7 in this state unless the person holds a wholesale drug distribution
8 license issued by the department under this subchapter or
9 Subchapter N [~~has filed with the commissioner a signed and verified~~
10 ~~license statement on a form furnished by the commissioner~~].

11 (b) An applicant for a license under this subchapter must
12 submit an application to the department on the form prescribed by
13 the department or electronically on the TexasOnline Internet
14 website [~~The license statement must be filed annually~~].

15 (c) A license issued under this subchapter expires on the
16 second anniversary of the date of issuance.

17 SECTION 5. Section 431.204, Health and Safety Code, is
18 amended to read as follows:

19 Sec. 431.204. FEES. (a) The department [~~board~~] shall
20 collect fees for:

21 (1) a license that is filed or renewed;
22 (2) a license that is amended, including a
23 notification of a change in the location of a licensed place of
24 business required under Section 431.206; and

25 (3) an inspection performed in enforcing this
26 subchapter and rules adopted under this subchapter.

27 (b) The executive commissioner of the Health and Human

1 Services Commission [~~board may charge annual fees.~~

2 [~~(c) The board~~] by rule shall set the fees in amounts that
3 allow the department to recover [~~at least 50 percent of~~] the
4 biennial [~~annual~~] expenditures of state funds by the department in:

- 5 (1) reviewing and acting on a license;
- 6 (2) amending and renewing a license;
- 7 (3) inspecting a licensed facility; and
- 8 (4) implementing and enforcing this subchapter,
9 including a rule or order adopted or a license issued under this
10 subchapter.

11 (c) [~~(d)~~] Fees collected under this section shall be
12 deposited to the credit of the food and drug registration fee
13 account of the general revenue fund and [~~may be~~] appropriated to the
14 department [~~only~~] to carry out the administration and enforcement
15 of this chapter.

16 SECTION 6. Sections 431.206 and 431.207, Health and Safety
17 Code, are amended to read as follows:

18 Sec. 431.206. CHANGE OF LOCATION OF PLACE OF BUSINESS.

19 (a) Not fewer than 30 days in advance of the change, the licensee
20 shall notify the department [~~commissioner or the commissioner's~~
21 ~~designee~~] in writing of the licensee's intent to change the
22 location of a licensed place of business.

23 (b) The notice shall include the address of the new
24 location, and the name and residence address of the individual in
25 charge of the business at the new location.

26 (c) Not more than 10 days after the completion of the change
27 of location, the licensee shall notify the department [~~commissioner~~

1 ~~or the commissioner's designee]~~ in writing to confirm the
2 completion of [~~verify~~] the change of location and provide
3 verification of the information previously provided or correct and
4 confirm any information that has changed since providing the notice
5 of intent[~~, the address of the new location, and the name and~~
6 ~~residence address of the individual in charge of the business at the~~
7 ~~new address~~].

8 (d) The notice and confirmation required by this section are
9 [~~Notice will be~~] deemed adequate if the licensee sends [~~provides~~]
10 the [~~intent and verification~~] notices [~~to the commissioner or the~~
11 ~~commissioner's designee~~] by certified mail, return receipt
12 requested, [~~mailed~~] to the central office of the department or
13 submits them electronically through the TexasOnline Internet
14 website.

15 Sec. 431.207. REFUSAL TO LICENSE; SUSPENSION OR REVOCATION
16 OF LICENSE. (a) The commissioner of state health services may
17 refuse an application for a license or may suspend or revoke a
18 license if the applicant or licensee:

19 (1) has been convicted of a felony or misdemeanor that
20 involves moral turpitude;

21 (2) is an association, partnership, or corporation and
22 the managing officer has been convicted of a felony or misdemeanor
23 that involves moral turpitude;

24 (3) has been convicted in a state or federal court of
25 the illegal use, sale, or transportation of intoxicating liquors,
26 narcotic drugs, barbiturates, amphetamines, desoxyephedrine, their
27 compounds or derivatives, or any other dangerous or habit-forming

1 drugs;

2 (4) is an association, partnership, or corporation and
3 the managing officer has been convicted in a state or federal court
4 of the illegal use, sale, or transportation of intoxicating
5 liquors, narcotic drugs, barbiturates, amphetamines,
6 desoxyephedrine, their compounds or derivatives, or any other
7 dangerous or habit-forming drugs; ~~[or]~~

8 (5) has not complied with this chapter or the ~~[board's]~~
9 rules implementing this chapter;

10 (6) has violated Section 431.021(1)(3), relating to
11 the counterfeiting of a drug or the sale or holding for sale of a
12 counterfeit drug;

13 (7) has violated Chapter 481 (Texas Controlled
14 Substances Act) or 483 (Texas Dangerous Drug Act);

15 (8) has violated the rules of the director of the
16 Department of Public Safety, including being responsible for a
17 significant discrepancy in the records that state law requires the
18 applicant or licensee to maintain; or

19 (9) fails to complete a license application or submits
20 an application that contains false, misleading, or incorrect
21 information or contains information that cannot be verified by the
22 department.

23 (b) The executive commissioner of the Health and Human
24 Services Commission by rule shall establish minimum standards
25 required for the issuance or renewal of a license under this
26 subchapter ~~[may refuse an application for a license or may suspend~~
27 ~~or revoke a license if the commissioner determines from evidence~~

1 ~~presented during a hearing that the applicant or licensee:~~

2 ~~[(1) has violated Section 431.021(1)(3), relating to~~
3 ~~the counterfeiting of a drug or the sale or holding for sale of a~~
4 ~~counterfeit drug;~~

5 ~~[(2) has violated Chapter 481 (Texas Controlled~~
6 ~~Substances Act) or 483 (Dangerous Drugs); or~~

7 ~~[(3) has violated the rules of the director of the~~
8 ~~Department of Public Safety, including being responsible for a~~
9 ~~significant discrepancy in the records that state law requires the~~
10 ~~applicant or licensee to maintain].~~

11 (c) The refusal to license an applicant or the suspension or
12 revocation of a license by the department [~~commissioner~~] and the
13 appeal from that action are governed by [~~the board's formal hearing~~
14 ~~procedures and~~] the procedures for a contested case hearing under
15 Chapter 2001, Government Code.

16 SECTION 7. Chapter 431, Health and Safety Code, is amended
17 by adding Subchapter N to read as follows:

18 SUBCHAPTER N. WHOLESALE DISTRIBUTORS OF PRESCRIPTION DRUGS

19 Sec. 431.401. DEFINITIONS. In this subchapter:

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

24 (2) "Authorized distributor of record" means a
25 distributor with whom a manufacturer has established an ongoing
26 relationship to distribute the manufacturer's products in
27 accordance with Section 431.4011.

1 (3) "Chain pharmacy warehouse" means a location for
2 which a person holds a wholesale drug distribution license under
3 this subchapter, that serves primarily as a central warehouse for
4 drugs or devices, and from which intracompany sales or transfers of
5 drugs or devices are made to a group of pharmacies under common
6 ownership and control.

7 (4) "Logistics provider" means a person that receives
8 prescription drugs only from the original manufacturer, delivers
9 the prescription drugs at the direction of that manufacturer, and
10 does not purchase, sell, trade, or take title to any prescription
11 drug.

12 (5) "Normal distribution chain" means a chain of
13 custody for a drug from a manufacturer to:

14 (A) an authorized distributor of record to a
15 pharmacy to a patient;

16 (B) an authorized distributor of record to one
17 other authorized distributor of record; or

18 (C) an authorized distributor of record to a
19 chain pharmacy warehouse.

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

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

1 (8) "Prescription drug" has the meaning assigned by 21
2 C.F.R. Section 203.3.

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

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

9 (11) "Wholesale distribution" means distribution to a
10 person other than a consumer or patient, and includes distribution
11 by a manufacturer, repackager, own label distributor, broker,
12 jobber, warehouse, retail pharmacy that conducts wholesale
13 distribution, or wholesaler. The term does 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, chain pharmacy warehouse, or
26 charitable institution in accordance with 21 C.F.R. Section 203.23;
27 or

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

4 Sec. 431.4011. ONGOING RELATIONSHIP. In this subchapter,
5 "ongoing relationship" means an association that exists when a
6 manufacturer and distributor enter into a written agreement under
7 which the distributor is authorized to distribute the
8 manufacturer's products for a period of time or for a number of
9 shipments. If the distributor is not authorized to distribute the
10 manufacturer's entire product line, the agreement must identify the
11 specific drug products that the distributor is authorized to
12 distribute.

13 Sec. 431.4012. APPLICABILITY OF SUBCHAPTER. This
14 subchapter applies only to the wholesale distribution of
15 prescription drugs.

16 Sec. 431.402. LICENSE REQUIRED. (a) A person may not
17 engage in wholesale distribution of prescription drugs in this
18 state unless the person holds a wholesale drug distribution license
19 under this subchapter for each place of business.

20 (b) A license issued under this subchapter expires on the
21 second anniversary of the date of issuance.

22 Sec. 431.403. EXEMPTION FROM LICENSING. (a) A person who
23 engages in wholesale distribution of prescription drugs in this
24 state for use in humans is exempt from this subchapter if the person
25 is exempt under:

26 (1) the Prescription Drug Marketing Act of 1987 (21
27 U.S.C. Section 353(c)(3)(B));

1 (2) the regulations adopted by the secretary to
2 administer and enforce that Act; or

3 (3) the interpretations of that Act set out in the
4 compliance policy manual of the United States Food and Drug
5 Administration.

6 (b) An exemption from the licensing requirements under this
7 section does not constitute an exemption from the other provisions
8 of this chapter or the rules adopted under this chapter to
9 administer and enforce the other provisions of this chapter.

10 Sec. 431.4031. EXEMPTION FROM CERTAIN PROVISIONS FOR
11 CERTAIN WHOLESALE DISTRIBUTORS. A wholesale distributor that
12 distributes prescription drugs that are medical gases or a
13 wholesale distributor that is a logistics provider on behalf of a
14 manufacturer is exempt from Sections 431.404(b) and (c), 431.405,
15 431.407, 431.408, 431.412, and 431.413.

16 Sec. 431.404. LICENSE APPLICATION. (a) An applicant for a
17 license under this subchapter must submit an application to the
18 department on the form prescribed by the department. The
19 application must contain:

20 (1) all trade or business names under which the
21 business is conducted;

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

24 (3) the type of business and the name and residence
25 address of:

26 (A) the proprietor, if the business is a
27 proprietorship;

1 (B) all partners, if the business is a
2 partnership; or

3 (C) all principals, if the business is an
4 association;

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

7 (5) the names and business addresses of the
8 individuals in an administrative capacity showing:

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

11 (B) the managing partner, if the business is a
12 partnership;

13 (C) the officers and directors, if the business
14 is a corporation; or

15 (D) the persons in a managerial capacity, if the
16 business is an association;

17 (6) the name, telephone number, and any information
18 necessary to complete a criminal history record check on a
19 designated representative of each place of business;

20 (7) the state of incorporation, if the business is a
21 corporation;

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

25 (9) the name of the manager for each place of business.

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

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

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

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

6 (4) the business name and address of any business,
7 corporation, or other organization in which the person held an
8 office under Subdivision (3) or in which the person conducted an
9 occupation or held a position of employment;

10 (5) a statement of whether during the preceding seven
11 years the person was the subject of a proceeding to revoke a license
12 and the nature and disposition of the proceeding;

13 (6) a statement of whether during the preceding seven
14 years the person has been enjoined, either temporarily or
15 permanently, by a court from violating any federal or state law
16 regulating the possession, control, or distribution of
17 prescription drugs, including the details concerning the event;

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

24 (8) a description of any felony offense for which the
25 person, as an adult, was found guilty, regardless of whether
26 adjudication of guilt was withheld or whether the person pled
27 guilty or nolo contendere;

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

6 (10) a photograph of the person taken not earlier than
7 30 days before the date the application was submitted.

8 (c) The information submitted under Subsection (b) must be
9 attested to under oath.

10 (d) An applicant or license holder shall file with the
11 department a written notice of any change in the information
12 required under this section.

13 Sec. 431.405. QUALIFICATIONS FOR LICENSE. To qualify for
14 the issuance or renewal of a wholesale distributor license under
15 this subchapter, the designated representative of an applicant or
16 license holder must:

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

18 (2) have been employed full-time for at least three
19 years by a pharmacy or a wholesale distributor in a capacity related
20 to the dispensing or distributing of prescription drugs, including
21 recordkeeping for the dispensing or distributing of prescription
22 drugs;

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

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

27 (5) be physically present at the applicant's place of

1 business during regular business hours, except when the absence of
2 the designated representative is authorized, including sick leave
3 and vacation leave;

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

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

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

12 Sec. 431.406. EFFECT OF OPERATION IN OTHER JURISDICTIONS;
13 REPORTS. (a) A person who engages in the wholesale distribution
14 of drugs outside this state may engage in the wholesale
15 distribution of drugs in this state if the person holds a license
16 issued by the department.

17 (b) The department may accept reports from authorities in
18 other jurisdictions to determine the extent of compliance with this
19 subchapter and the minimum standards adopted under this subchapter.

20 (c) The department may issue a license to a person who
21 engages in the wholesale distribution of drugs outside this state
22 to engage in the wholesale distribution of drugs in this state if,
23 after an examination of the reports of the person's compliance
24 history and current compliance record, the department determines
25 that the person is in compliance with this subchapter and the rules
26 adopted under this subchapter.

27 (d) The department shall consider each license application

1 and any related documents or reports filed by or in connection with
2 a person who wishes to engage in wholesale distribution of drugs in
3 this state on an individual basis.

4 Sec. 431.407. CRIMINAL HISTORY RECORD INFORMATION. The
5 department shall submit to the Department of Public Safety the
6 fingerprints provided by a person with an initial or a renewal
7 license application to obtain the person's criminal history record
8 information and may forward the fingerprints to the Federal Bureau
9 of Investigation for a federal criminal history check.

10 Sec. 431.408. BOND. (a) A wholesale distributor applying
11 for or renewing a license shall submit payable to this state a bond
12 or other equivalent security acceptable to the department,
13 including an irrevocable letter of credit or a deposit in a trust
14 account or financial institution, in the amount of \$100,000 payable
15 to this state.

16 (b) The bond or equivalent security submitted under
17 Subsection (a) shall secure payment of any fines or penalties
18 imposed by the department or imposed in connection with an
19 enforcement action by the attorney general, any fees or other
20 enforcement costs, including attorney's fees payable to the
21 attorney general, and any other fees and costs incurred by this
22 state related to that license holder, that are authorized under the
23 laws of this state and that the license holder fails to pay before
24 the 30th day after the date a fine, penalty, fee, or cost is
25 assessed.

26 (c) The department or this state may make a claim against a
27 bond or security submitted under Subsection (a) before the first

1 anniversary of the date a license expires or is revoked under this
2 subchapter.

3 (d) The department shall deposit the bonds and equivalent
4 securities received under this section in a separate account.

5 Sec. 431.409. FEES. (a) The department shall collect fees
6 for:

7 (1) a license that is filed or renewed;

8 (2) a license that is amended, including a
9 notification of a change in the location of a licensed place of
10 business required under Section 431.410; and

11 (3) an inspection performed in enforcing this
12 subchapter and rules adopted under this subchapter.

13 (b) The executive commissioner of the Health and Human
14 Services Commission by rule shall set the fees in amounts that are
15 reasonable and necessary and allow the department to recover the
16 biennial expenditures of state funds by the department in:

17 (1) reviewing and acting on a license;

18 (2) amending and renewing a license;

19 (3) inspecting a licensed facility; and

20 (4) implementing and enforcing this subchapter,
21 including a rule or order adopted or a license issued under this
22 subchapter.

23 (c) Fees collected under this section shall be deposited to
24 the credit of the food and drug registration fee account of the
25 general revenue fund and appropriated to the department to carry
26 out this chapter.

27 Sec. 431.410. CHANGE OF LOCATION OF PLACE OF BUSINESS.

1 (a) Not fewer than 30 days in advance of the change, the license
2 holder shall notify the department in writing of the license
3 holder's intent to change the location of a licensed place of
4 business.

5 (b) The notice shall include the address of the new location
6 and the name and residence address of the individual in charge of
7 the business at the new location.

8 (c) Not more than 10 days after the completion of the change
9 of location, the license holder shall notify the department in
10 writing to confirm the completion of the change of location and
11 provide verification of the information previously provided or
12 correct and confirm any information that has changed since
13 providing the notice of intent.

14 (d) The notice and confirmation required by this section are
15 considered adequate if the license holder sends the notices by
16 certified mail, return receipt requested, to the central office of
17 the department or submits the notices electronically through the
18 TexasOnline Internet website.

19 Sec. 431.411. MINIMUM RESTRICTIONS ON TRANSACTIONS. (a) A
20 wholesale distributor shall receive prescription drug returns or
21 exchanges from a pharmacy or chain pharmacy warehouse in accordance
22 with the terms and conditions of the agreement between the
23 wholesale distributor and the pharmacy or chain pharmacy warehouse.
24 The returns or exchanges received by the wholesale distributor as
25 provided by this subsection are not subject to the pedigree
26 requirement under Section 431.412. Wholesale distributors are
27 responsible for policing the returns process and ensuring the

1 operations are secure and do not allow the entry of an adulterated
2 or counterfeit product into distribution.

3 (b) A manufacturer or wholesale distributor may distribute
4 prescription drugs only to a person licensed by the appropriate
5 state licensing authorities or authorized by federal law to receive
6 the drug. Before furnishing prescription drugs to a person not
7 known to the manufacturer or wholesale distributor, the
8 manufacturer or wholesale distributor must verify that the person
9 is legally authorized by the appropriate state licensing authority
10 to receive the prescription drugs or authorized by federal law to
11 receive the drugs.

12 (c) Except as otherwise provided by this subsection,
13 prescription drugs distributed by a manufacturer or wholesale
14 distributor may be delivered only to the premises listed on the
15 license. A manufacturer or wholesale distributor may distribute
16 prescription drugs to an authorized person or agent of that person
17 at the premises of the manufacturer or wholesale distributor if:

18 (1) the identity and authorization of the recipient is
19 properly established; and

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

22 (d) Prescription drugs may be distributed to a hospital
23 pharmacy receiving area if a pharmacist or an authorized receiving
24 person signs, at the time of delivery, a receipt showing the type
25 and quantity of the prescription drug received. Any discrepancy
26 between the receipt and the type and quantity of the prescription
27 drug actually received shall be reported to the delivering

1 manufacturer or wholesale distributor not later than the next
2 business day after the date of delivery to the pharmacy receiving
3 area.

4 Sec. 431.412. PEDIGREE REQUIRED. (a) A person who is
5 engaged in the wholesale distribution of a prescription drug,
6 including a repackager but excluding the original manufacturer and
7 the original labeler of a prescription drug, shall provide a
8 pedigree for each prescription drug that is not distributed through
9 the normal distribution chain and is sold, traded, or transferred
10 to any other person.

11 (b) A pharmacy that sells a drug to a person other than the
12 final consumer shall provide a pedigree to the person acquiring the
13 prescription drug.

14 (c) The sale, trade, or transfer of a prescription drug
15 between license holders with common ownership or for an emergency
16 is not subject to this section.

17 (d) A person who is engaged in the wholesale distribution of
18 a prescription drug, including a repackager, and who is in
19 possession of a pedigree for a prescription drug must verify before
20 distributing the prescription drug that each transaction listed on
21 the pedigree has occurred.

22 Sec. 431.413. PEDIGREE CONTENTS. (a) A pedigree must
23 include all necessary identifying information concerning each sale
24 in the product's chain of distribution from the manufacturer,
25 through acquisition and sale by a wholesale distributor or
26 repackager, until final sale to a pharmacy or other person
27 dispensing or administering the drug. At a minimum, the chain of

1 distribution information must include:

2 (1) the name, address, telephone number, and, if
3 available, the e-mail address of each person who owns or possesses
4 the prescription drug, except common carriers and logistics
5 providers;

6 (2) the signature of each owner of the prescription
7 drug;

8 (3) the name and address of each location from which
9 the product was shipped, if different from the owner's name and
10 address;

11 (4) the transaction dates; and

12 (5) certification that each recipient has
13 authenticated the pedigree.

14 (b) The pedigree must include, at a minimum, the:

15 (1) name of the prescription drug;

16 (2) dosage form and strength of the prescription drug;

17 (3) size of the container;

18 (4) number of containers;

19 (5) lot number of the prescription drug; and

20 (6) name of the manufacturer of the finished dosage
21 form.

22 (c) Each pedigree statement must be:

23 (1) maintained by the purchaser and the wholesale
24 distributor for at least three years; and

25 (2) available for inspection and photocopying on a
26 request by the department or a peace officer in this state.

27 (d) The executive commissioner of the Health and Human

1 Services Commission shall adopt rules to implement this section.

2 (e) The department shall:

3 (1) conduct a study on the implementation of
4 electronic pedigrees;

5 (2) in conducting the study under Subdivision (1),
6 consult with manufacturers, distributors, and pharmacies
7 responsible for the sale and distribution of prescription drugs in
8 this state; and

9 (3) based on the results of the study, establish an
10 implementation date, which may not be earlier than December 31,
11 2007, for electronic pedigrees.

12 (f) Subsection (e) and this subsection expire January 1,
13 2009.

14 Sec. 431.414. REFUSAL TO LICENSE; SUSPENSION OR REVOCATION
15 OF LICENSE. (a) The commissioner of state health services may
16 refuse an application for a license or may suspend or revoke a
17 license if the applicant or license holder:

18 (1) has been convicted of a felony or misdemeanor that
19 involves moral turpitude;

20 (2) is an association, partnership, or corporation and
21 the managing officer has been convicted of a felony or misdemeanor
22 that involves moral turpitude;

23 (3) has been convicted in a state or federal court of
24 the illegal use, sale, or transportation of intoxicating liquors,
25 narcotic drugs, barbiturates, amphetamines, desoxyephedrine, their
26 compounds or derivatives, or any other dangerous or habit-forming
27 drugs;

1 (4) is an association, partnership, or corporation and
2 the managing officer has been convicted in a state or federal court
3 of the illegal use, sale, or transportation of intoxicating
4 liquors, narcotic drugs, barbiturates, amphetamines,
5 desoxyephedrine, their compounds or derivatives, or any other
6 dangerous or habit-forming drugs;

7 (5) has not complied with this subchapter or the rules
8 implementing this subchapter;

9 (6) has violated Section 431.021(1)(3), relating to
10 the counterfeiting of a drug or the sale or holding for sale of a
11 counterfeit drug;

12 (7) has violated Chapter 481 (Texas Controlled
13 Substances Act) or 483 (Texas Dangerous Drug Act); or

14 (8) has violated the rules of the director of the
15 Department of Public Safety, including being responsible for a
16 significant discrepancy in the records that state law requires the
17 applicant or license holder to maintain.

18 (b) The executive commissioner of the Health and Human
19 Services Commission by rule shall establish minimum standards
20 required for the issuance or renewal of a license under this
21 subchapter.

22 (c) The department shall deny a license application that is
23 incomplete, contains false, misleading, or incorrect information,
24 or contains information that cannot be verified by the department.

25 (d) The refusal to license an applicant or the suspension or
26 revocation of a license by the department and the appeal from that
27 action are governed by the procedures for a contested case hearing

1 under Chapter 2001, Government Code.

2 Sec. 431.415. ORDER TO CEASE DISTRIBUTION. (a) The
3 commissioner of state health services shall issue an order
4 requiring a person, including a manufacturer, distributor, or
5 retailer of a prescription drug, to immediately cease distribution
6 of the drug if the commissioner determines there is a reasonable
7 probability that:

8 (1) a wholesale distributor has:

9 (A) violated this subchapter;

10 (B) falsified a pedigree; or

11 (C) sold, distributed, transferred,
12 manufactured, repackaged, handled, or held a counterfeit
13 prescription drug intended for human use that could cause serious
14 adverse health consequences or death; and

15 (2) other procedures would result in unreasonable
16 delay.

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

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

25 SECTION 8. Section 431.059, Health and Safety Code, is
26 amended by amending Subsection (a) and adding Subsections (a-1) and
27 (a-2) to read as follows:

1 (a) A person commits an offense if the person violates any
2 of the provisions of Section 431.021 relating to unlawful or
3 prohibited acts. A first offense under this subsection is a Class A
4 misdemeanor unless it is shown on the trial of an offense under this
5 subsection that the defendant was previously convicted of an
6 offense under this subsection, in which event the offense is a state
7 jail felony. In a criminal proceeding under this section, it is not
8 necessary to prove intent, knowledge, recklessness, or criminal
9 negligence of the defendant beyond the degree of culpability, if
10 any, stated in Subsection (a-2) or Section 431.021, as applicable,
11 to establish criminal responsibility for the violation.

12 (a-1) A person commits an offense if the person engages in
13 the wholesale distribution of prescription drugs in violation of
14 Subchapter N. An offense under this subsection is punishable by a
15 fine not to exceed \$50,000.

16 (a-2) A person commits an offense if the person knowingly
17 engages in the wholesale distribution of prescription drugs in
18 violation of Subchapter N. An offense under this subsection is
19 punishable by imprisonment for not more than 15 years, a fine not to
20 exceed \$500,000, or both imprisonment and a fine.

21 SECTION 9. Section 431.021, Health and Safety Code, is
22 amended to read as follows:

23 Sec. 431.021. PROHIBITED ACTS. The following acts and the
24 causing of the following acts within this state are unlawful and
25 prohibited:

26 (a) the introduction or delivery for introduction into
27 commerce of any food, drug, device, or cosmetic that is adulterated

1 or misbranded;

2 (b) the adulteration or misbranding of any food, drug,
3 device, or cosmetic in commerce;

4 (c) the receipt in commerce of any food, drug, device,
5 or cosmetic that is adulterated or misbranded, and the delivery or
6 proffered delivery thereof for pay or otherwise;

7 (d) the distribution in commerce of a consumer
8 commodity, if such commodity is contained in a package, or if there
9 is affixed to that commodity a label that does not conform to the
10 provisions of this chapter and of rules adopted under the authority
11 of this chapter; provided, however, that this prohibition shall not
12 apply to persons engaged in business as wholesale or retail
13 distributors of consumer commodities except to the extent that such
14 persons:

15 (1) are engaged in the packaging or labeling of
16 such commodities; or

17 (2) prescribe or specify by any means the manner
18 in which such commodities are packaged or labeled;

19 (e) the introduction or delivery for introduction into
20 commerce of any article in violation of Section 431.084, 431.114,
21 or 431.115;

22 (f) the dissemination of any false advertisement;

23 (g) the refusal to permit entry or inspection, or to
24 permit the taking of a sample or to permit access to or copying of
25 any record as authorized by Sections 431.042-431.044; or the
26 failure to establish or maintain any record or make any report
27 required under Section 512(j), (l), or (m) of the federal Act, or

1 the refusal to permit access to or verification or copying of any
2 such required record;

3 (h) the manufacture within this state of any food,
4 drug, device, or cosmetic that is adulterated or misbranded;

5 (i) the giving of a guaranty or undertaking referred
6 to in Section 431.059, which guaranty or undertaking is false,
7 except by a person who relied on a guaranty or undertaking to the
8 same effect signed by, and containing the name and address of the
9 person residing in this state from whom the person received in good
10 faith the food, drug, device, or cosmetic; or the giving of a
11 guaranty or undertaking referred to in Section 431.059, which
12 guaranty or undertaking is false;

13 (j) the use, removal, or disposal of a detained or
14 embargoed article in violation of Section 431.048;

15 (k) the alteration, mutilation, destruction,
16 obliteration, or removal of the whole or any part of the labeling
17 of, or the doing of any other act with respect to a food, drug,
18 device, or cosmetic, if such act is done while such article is held
19 for sale after shipment in commerce and results in such article
20 being adulterated or misbranded;

21 (l)(1) forging, counterfeiting, simulating, or
22 falsely representing, or without proper authority using any mark,
23 stamp, tag, label, or other identification device authorized or
24 required by rules adopted under this chapter or the regulations
25 promulgated under the provisions of the federal Act;

26 (2) making, selling, disposing of, or keeping in
27 possession, control, or custody, or concealing any punch, die,

1 plate, stone, or other thing designed to print, imprint, or
2 reproduce the trademark, trade name, or other identifying mark,
3 imprint, or device of another or any likeness of any of the
4 foregoing on any drug or container or labeling thereof so as to
5 render such drug a counterfeit drug;

6 (3) the doing of any act that causes a drug to be
7 a counterfeit drug, or the sale or dispensing, or the holding for
8 sale or dispensing, of a counterfeit drug;

9 (m) the using by any person to the person's own
10 advantage, or revealing, other than to the commissioner, an
11 authorized agent, a health authority or to the courts when relevant
12 in any judicial proceeding under this chapter, of any information
13 acquired under the authority of this chapter concerning any method
14 or process that as a trade secret is entitled to protection;

15 (n) the using, on the labeling of any drug or device or
16 in any advertising relating to such drug or device, of any
17 representation or suggestion that approval of an application with
18 respect to such drug or device is in effect under Section 431.114 or
19 Section 505, 515, or 520(g) of the federal Act, as the case may be,
20 or that such drug or device complies with the provisions of such
21 sections;

22 (o) the using, in labeling, advertising or other sales
23 promotion of any reference to any report or analysis furnished in
24 compliance with Sections 431.042-431.044 or Section 704 of the
25 federal Act;

26 (p) in the case of a prescription drug distributed or
27 offered for sale in this state, the failure of the manufacturer,

1 packer, or distributor of the drug to maintain for transmittal, or
2 to transmit, to any practitioner licensed by applicable law to
3 administer such drug who makes written request for information as
4 to such drug, true and correct copies of all printed matter that is
5 required to be included in any package in which that drug is
6 distributed or sold, or such other printed matter as is approved
7 under the federal Act. Nothing in this subsection shall be
8 construed to exempt any person from any labeling requirement
9 imposed by or under other provisions of this chapter;

10 (q)(1) placing or causing to be placed on any drug or
11 device or container of any drug or device, with intent to defraud,
12 the trade name or other identifying mark, or imprint of another or
13 any likeness of any of the foregoing;

14 (2) selling, dispensing, disposing of or causing
15 to be sold, dispensed, or disposed of, or concealing or keeping in
16 possession, control, or custody, with intent to sell, dispense, or
17 dispose of, any drug, device, or any container of any drug or
18 device, with knowledge that the trade name or other identifying
19 mark or imprint of another or any likeness of any of the foregoing
20 has been placed thereon in a manner prohibited by Subdivision (1) of
21 this subsection; or

22 (3) making, selling, disposing of, causing to be
23 made, sold, or disposed of, keeping in possession, control, or
24 custody, or concealing with intent to defraud any punch, die,
25 plate, stone, or other thing designed to print, imprint, or
26 reproduce the trademark, trade name, or other identifying mark,
27 imprint, or device of another or any likeness of any of the

1 foregoing on any drug or container or labeling of any drug or
2 container so as to render such drug a counterfeit drug;

3 (r) dispensing or causing to be dispensed a different
4 drug in place of the drug ordered or prescribed without the express
5 permission in each case of the person ordering or prescribing;

6 (s) the failure to register in accordance with Section
7 510 of the federal Act, the failure to provide any information
8 required by Section 510(j) or (k) of the federal Act, or the failure
9 to provide a notice required by Section 510(j)(2) of the federal
10 Act;

11 (t)(1) the failure or refusal to:

12 (A) comply with any requirement prescribed
13 under Section 518 or 520(g) of the federal Act; or

14 (B) furnish any notification or other
15 material or information required by or under Section 519 or 520(g)
16 of the federal Act;

17 (2) with respect to any device, the submission of
18 any report that is required by or under this chapter that is false
19 or misleading in any material respect;

20 (u) the movement of a device in violation of an order
21 under Section 304(g) of the federal Act or the removal or alteration
22 of any mark or label required by the order to identify the device as
23 detained;

24 (v) the failure to provide the notice required by
25 Section 412(b) or 412(c), the failure to make the reports required
26 by Section 412(d)(1)(B), or the failure to meet the requirements
27 prescribed under Section 412(d)(2) of the federal Act;

1 (w) except as provided under Subchapter M of this
2 chapter and Section 562.1085, Occupations Code, the acceptance by a
3 person of an unused prescription or drug, in whole or in part, for
4 the purpose of resale, after the prescription or drug has been
5 originally dispensed, or sold;

6 (x) engaging in the wholesale distribution of drugs or
7 operating as a distributor or manufacturer of devices in this state
8 without obtaining a license issued by the department under
9 Subchapter I, L, or N [~~filing a licensing statement with the~~
10 ~~commissioner as required by Section 431.202 or having a license as~~
11 ~~required by Section 431.272~~], as applicable;

12 (y) engaging in the manufacture of food in this state
13 or operating as a warehouse operator in this state without having a
14 license as required by Section 431.222 or operating as a food
15 wholesaler in this state without having a license under Section
16 431.222 or being registered under Section 431.2211, as appropriate;

17 (z) unless approved by the United States Food and Drug
18 Administration pursuant to the federal Act, the sale, delivery,
19 holding, or offering for sale of a self-testing kit designed to
20 indicate whether a person has a human immunodeficiency virus
21 infection, acquired immune deficiency syndrome, or a related
22 disorder or condition; [~~or~~]

23 (aa) making a false statement or false representation
24 in an application for a license or in a statement, report, or other
25 instrument to be filed with or requested by the department [~~the~~
26 ~~board, the commissioner, or the department~~] under this chapter;

27 (bb) failing to comply with a requirement or request

1 to provide information or failing to submit an application,
2 statement, report, or other instrument required by the department;

3 (cc) performing, causing the performance of, or aiding
4 and abetting the performance of an act described by Subdivision
5 (x);

6 (dd) purchasing or otherwise receiving a prescription
7 drug from a pharmacy in violation of Section 431.411(a);

8 (ee) selling, distributing, or transferring a
9 prescription drug to a person who is not authorized under state or
10 federal law to receive the prescription drug in violation of
11 Section 431.411(b);

12 (ff) failing to deliver prescription drugs to
13 specified premises as required by Section 431.411(c);

14 (gg) failing to maintain or provide pedigrees as
15 required by Section 431.412 or 431.413; or

16 (hh) failing to obtain, pass, or authenticate a
17 pedigree as required by Section 431.412 or 431.413.

18 SECTION 10. Section 411.110, Government Code, is amended to
19 read as follows:

20 Sec. 411.110. ACCESS TO CRIMINAL HISTORY RECORD
21 INFORMATION: [~~TEXAS~~] DEPARTMENT OF STATE HEALTH SERVICES.

22 (a) The [~~Texas~~] Department of State Health Services is entitled to
23 obtain from the department criminal history record information
24 maintained by the department that relates to:

25 (1) a person who is:

26 (A) [~~(1)~~] an applicant for a license or
27 certificate under the Emergency Medical Services Act (Chapter 773,

1 Health and Safety Code);

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

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

6 (2) an applicant for a license or a license holder
7 under Subchapter N, Chapter 431, Health and Safety Code.

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

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

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

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

25 SECTION 11. Sections 431.2021 and 431.205, Health and
26 Safety Code, are repealed.

27 SECTION 12. Not later than January 1, 2006, the executive

1 commissioner of the Health and Human Services Commission shall
2 adopt the rules necessary to implement the changes in law made by
3 this Act by amending Subchapter I, Chapter 431, Health and Safety
4 Code, and adding Subchapter N, Chapter 431, Health and Safety Code.

5 SECTION 13. Not later than January 1, 2006, the Department
6 of State Health Services shall prescribe the forms required to
7 implement the changes in law made by this Act by the amendment of
8 Subchapter I, Chapter 431, Health and Safety Code, and the addition
9 of Subchapter N, Chapter 431, Health and Safety Code.

10 SECTION 14. The change in law made by this Act applies only
11 to an offense committed on or after March 1, 2006. An offense
12 committed before that date is covered by the law in effect when the
13 offense was committed, and the former law is continued in effect for
14 that purpose. For purposes of this section, an offense was
15 committed before March 1, 2006, if any element of the offense was
16 committed before that date.

17 SECTION 15. (a) Except as provided by Subsection (b) of
18 this section, this Act takes effect September 1, 2005.

19 (b) Sections 1 through 9 of this Act take effect March 1,
20 2006.