

1-1 By: Janek, Estes S.B. No. 1685
1-2 (In the Senate - Filed March 11, 2005; March 30, 2005, read
1-3 first time and referred to Committee on Health and Human Services;
1-4 May 5, 2005, reported adversely, with favorable Committee
1-5 Substitute by the following vote: Yeas 8, Nays 0; May 5, 2005, sent
1-6 to printer.)

1-7 COMMITTEE SUBSTITUTE FOR S.B. No. 1685 By: Janek

1-8 A BILL TO BE ENTITLED
1-9 AN ACT

1-10 relating to the licensing and regulation of wholesale drug
1-11 distributors; providing penalties.

1-12 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

1-13 SECTION 1. The heading to Subchapter I, Chapter 431, Health
1-14 and Safety Code, is amended to read as follows:

1-15 SUBCHAPTER I. WHOLESALE ~~[DRUG]~~ DISTRIBUTORS
1-16 OF NONPRESCRIPTION DRUGS

1-17 SECTION 2. Section 431.201, Health and Safety Code, is
1-18 amended to read as follows:

1-19 Sec. 431.201. DEFINITIONS. In this subchapter:

1-20 (1) "Nonprescription drug" means any drug that is not
1-21 a prescription drug as defined by Section 431.401.

1-22 (2) "Place of business" means each location at which a
1-23 drug for wholesale distribution is located.

1-24 (3) "Wholesale distribution" means distribution to a
1-25 person other than a consumer or patient, and includes distribution
1-26 by a manufacturer, repackager ~~[repacker]~~, own label distributor,
1-27 broker, jobber, warehouse, or wholesaler.

1-28 ~~[(2) "Place of business" means each location at which~~
1-29 ~~a drug for wholesale distribution is located.]~~

1-30 SECTION 3. Subchapter I, Chapter 431, Health and Safety
1-31 Code, is amended by adding Section 431.2011 to read as follows:

1-32 Sec. 431.2011. APPLICABILITY OF SUBCHAPTER. This
1-33 subchapter applies only to the wholesale distribution of
1-34 nonprescription drugs.

1-35 SECTION 4. Section 431.202, Health and Safety Code, is
1-36 amended to read as follows:

1-37 Sec. 431.202. LICENSE ~~[STATEMENT]~~ REQUIRED. (a) A person
1-38 may not engage in wholesale distribution of nonprescription drugs
1-39 in this state unless the person holds a wholesale drug distribution
1-40 license issued by the department under this subchapter or
1-41 Subchapter N ~~[has filed with the commissioner a signed and verified~~
1-42 license statement on a form furnished by the commissioner].

1-43 (b) An applicant for a license under this subchapter must
1-44 submit an application to the department on the form prescribed by
1-45 the department or electronically on the TexasOnline Internet
1-46 website ~~[The license statement must be filed annually].~~

1-47 (c) A license issued under this subchapter expires on the
1-48 second anniversary of the date of issuance.

1-49 SECTION 5. Section 431.204, Health and Safety Code, is
1-50 amended to read as follows:

1-51 Sec. 431.204. FEES. (a) The department ~~[board]~~ shall
1-52 collect fees for:

1-53 (1) a license that is filed or renewed;

1-54 (2) a license that is amended, including a
1-55 notification of a change in the location of a licensed place of
1-56 business required under Section 431.206; and

1-57 (3) an inspection performed in enforcing this
1-58 subchapter and rules adopted under this subchapter.

1-59 (b) The executive commissioner of the Health and Human
1-60 Services Commission ~~[board may charge annual fees.~~

1-61 ~~[(c) The board]~~ by rule shall set the fees in amounts that
1-62 allow the department to recover ~~[at least 50 percent of]~~ the
1-63 biennial ~~[annual]~~ expenditures of state funds by the department in:

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

2-7 (c) ~~[(d)]~~ Fees collected under this section shall be
 2-8 deposited to the credit of the food and drug registration fee
 2-9 account of the general revenue fund and ~~[may be]~~ appropriated to the
 2-10 department ~~[only]~~ to carry out the administration and enforcement
 2-11 of this chapter.

2-12 SECTION 6. Sections 431.206 and 431.207, Health and Safety
 2-13 Code, are amended to read as follows:

2-14 Sec. 431.206. CHANGE OF LOCATION OF PLACE OF BUSINESS.

2-15 (a) Not fewer than 30 days in advance of the change, the licensee
 2-16 shall notify the department ~~[commissioner or the commissioner's~~
 2-17 ~~designee]~~ in writing of the licensee's intent to change the
 2-18 location of a licensed place of business.

2-19 (b) The notice shall include the address of the new
 2-20 location, and the name and residence address of the individual in
 2-21 charge of the business at the new location.

2-22 (c) Not more than 10 days after the completion of the change
 2-23 of location, the licensee shall notify the department ~~[commissioner~~
 2-24 ~~or the commissioner's designee]~~ in writing to confirm the
 2-25 completion of [verify] the change of location and provide
 2-26 verification of the information previously provided or correct and
 2-27 confirm any information that has changed since providing the notice
 2-28 of intent~~[, the address of the new location, and the name and~~
 2-29 ~~residence address of the individual in charge of the business at the~~
 2-30 ~~new address].~~

2-31 (d) The notice and confirmation required by this section are
 2-32 [Notice will be] deemed adequate if the licensee sends [provides]
 2-33 the [intent and verification] notices [to the commissioner or the
 2-34 commissioner's designee] by certified mail, return receipt
 2-35 requested, [mailed] to the central office of the department or
 2-36 submits them electronically through the TexasOnline Internet
 2-37 website.

2-38 Sec. 431.207. REFUSAL TO LICENSE; SUSPENSION OR REVOCATION
 2-39 OF LICENSE. (a) The commissioner of state health services may
 2-40 refuse an application for a license or may suspend or revoke a
 2-41 license if the applicant or licensee:

2-42 (1) has been convicted of a felony or misdemeanor that
 2-43 involves moral turpitude;

2-44 (2) is an association, partnership, or corporation and
 2-45 the managing officer has been convicted of a felony or misdemeanor
 2-46 that involves moral turpitude;

2-47 (3) has been convicted in a state or federal court of
 2-48 the illegal use, sale, or transportation of intoxicating liquors,
 2-49 narcotic drugs, barbiturates, amphetamines, desoxyephedrine, their
 2-50 compounds or derivatives, or any other dangerous or habit-forming
 2-51 drugs;

2-52 (4) is an association, partnership, or corporation and
 2-53 the managing officer has been convicted in a state or federal court
 2-54 of the illegal use, sale, or transportation of intoxicating
 2-55 liquors, narcotic drugs, barbiturates, amphetamines,
 2-56 desoxyephedrine, their compounds or derivatives, or any other
 2-57 dangerous or habit-forming drugs; ~~[or]~~

2-58 (5) has not complied with this chapter or the ~~[board's]~~
 2-59 rules implementing this chapter;

2-60 (6) has violated Section 431.021(1)(3), relating to
 2-61 the counterfeiting of a drug or the sale or holding for sale of a
 2-62 counterfeit drug;

2-63 (7) has violated Chapter 481 (Texas Controlled
 2-64 Substances Act) or 483 (Texas Dangerous Drug Act);

2-65 (8) has violated the rules of the director of the
 2-66 Department of Public Safety, including being responsible for a
 2-67 significant discrepancy in the records that state law requires the
 2-68 applicant or licensee to maintain; or

2-69 (9) fails to complete a license application or submits

3-1 an application that contains false, misleading, or incorrect
 3-2 information or contains information that cannot be verified by the
 3-3 department.

3-4 (b) The executive commissioner of the Health and Human
 3-5 Services Commission by rule shall establish minimum standards
 3-6 required for the issuance or renewal of a license under this
 3-7 subchapter [may refuse an application for a license or may suspend
 3-8 or revoke a license if the commissioner determines from evidence
 3-9 presented during a hearing that the applicant or licensee:

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

3-13 [~~(2) has violated Chapter 481 (Texas Controlled~~
 3-14 ~~Substances Act) or 483 (Dangerous Drugs); or~~

3-15 [~~(3) has violated the rules of the director of the~~
 3-16 ~~Department of Public Safety, including being responsible for a~~
 3-17 ~~significant discrepancy in the records that state law requires the~~
 3-18 ~~applicant or licensee to maintain].~~

3-19 (c) The refusal to license an applicant or the suspension or
 3-20 revocation of a license by the department [commissioner] and the
 3-21 appeal from that action are governed by [the board's formal hearing
 3-22 procedures and] the procedures for a contested case hearing under
 3-23 Chapter 2001, Government Code.

3-24 SECTION 7. Chapter 431, Health and Safety Code, is amended
 3-25 by adding Subchapter N to read as follows:

3-26 SUBCHAPTER N. WHOLESALE DISTRIBUTORS OF PRESCRIPTION DRUGS

3-27 Sec. 431.401. DEFINITIONS. In this subchapter:

3-28 (1) "Authentication" means to affirmatively verify
 3-29 before any wholesale distribution of a prescription drug occurs
 3-30 that each transaction listed on the pedigree for the drug has
 3-31 occurred.

3-32 (2) "Authorized distributor of record" means a
 3-33 distributor with whom a manufacturer has established an ongoing
 3-34 relationship to distribute the manufacturer's products in
 3-35 accordance with Section 431.4011.

3-36 (3) "Chain pharmacy warehouse" means a location for
 3-37 which a person holds a wholesale drug distribution license under
 3-38 this subchapter, that serves primarily as a central warehouse for
 3-39 drugs or devices, and from which intracompany sales or transfers of
 3-40 drugs or devices are made to a group of pharmacies under common
 3-41 ownership and control.

3-42 (4) "Logistics provider" means a person that receives
 3-43 prescription drugs only from the original manufacturer, delivers
 3-44 the prescription drugs at the direction of that manufacturer, and
 3-45 does not purchase, sell, trade, or take title to any prescription
 3-46 drug.

3-47 (5) "Normal distribution chain" means a chain of
 3-48 custody for a drug from a manufacturer to:

3-49 (A) an authorized distributor of record to a
 3-50 pharmacy to a patient;

3-51 (B) an authorized distributor of record to one
 3-52 other authorized distributor of record; or

3-53 (C) an authorized distributor of record to a
 3-54 chain pharmacy warehouse.

3-55 (6) "Pedigree" means a document or electronic file
 3-56 containing information that records each wholesale distribution of
 3-57 a prescription drug, from sale by a manufacturer, through
 3-58 acquisition and sale by any wholesale distributor or repackager,
 3-59 until final sale to a pharmacy or other person dispensing or
 3-60 administering the prescription drug.

3-61 (7) "Place of business" means each location at which a
 3-62 drug for wholesale distribution is located.

3-63 (8) "Prescription drug" has the meaning assigned by 21
 3-64 C.F.R. Section 203.3.

3-65 (9) "Repackage" means repackaging or otherwise
 3-66 changing the container, wrapper, or labeling of a drug to further
 3-67 the distribution of a prescription drug. The term does not include
 3-68 repackaging by a pharmacist to dispense a drug to a patient.

3-69 (10) "Repackager" means a person who engages in

4-1 repackaging.

4-2 (11) "Wholesale distribution" means distribution to a
 4-3 person other than a consumer or patient, and includes distribution
 4-4 by a manufacturer, repackager, own label distributor, broker,
 4-5 jobber, warehouse, retail pharmacy that conducts wholesale
 4-6 distribution, or wholesaler. The term does not include:

4-7 (A) intracompany sales of prescription drugs,
 4-8 which means transactions or transfers of prescription drugs between
 4-9 a division, subsidiary, parent, or affiliated or related company
 4-10 that is under common ownership and control of a corporate entity;

4-11 (B) the sale, purchase, distribution, trade, or
 4-12 transfer of prescription drugs or the offer to sell, purchase,
 4-13 distribute, trade, or transfer a prescription drug for emergency
 4-14 medical reasons;

4-15 (C) the distribution of prescription drug
 4-16 samples by a representative of a manufacturer;

4-17 (D) the return of drugs by a hospital, health
 4-18 care entity, retail pharmacy, chain pharmacy warehouse, or
 4-19 charitable institution in accordance with 21 C.F.R. Section 203.23;
 4-20 or

4-21 (E) the delivery by a retail pharmacy of a
 4-22 prescription drug to a patient or a patient's agent under the lawful
 4-23 order of a licensed practitioner.

4-24 Sec. 431.4011. ONGOING RELATIONSHIP. In this subchapter,
 4-25 "ongoing relationship" means an association that exists when a
 4-26 manufacturer and distributor enter into a written agreement under
 4-27 which the distributor is authorized to distribute the
 4-28 manufacturer's products for a period of time or for a number of
 4-29 shipments. If the distributor is not authorized to distribute the
 4-30 manufacturer's entire product line, the agreement must identify the
 4-31 specific drug products that the distributor is authorized to
 4-32 distribute.

4-33 Sec. 431.4012. APPLICABILITY OF SUBCHAPTER. This
 4-34 subchapter applies only to the wholesale distribution of
 4-35 prescription drugs.

4-36 Sec. 431.402. LICENSE REQUIRED. (a) A person may not
 4-37 engage in wholesale distribution of prescription drugs in this
 4-38 state unless the person holds a wholesale drug distribution license
 4-39 under this subchapter for each place of business.

4-40 (b) A license issued under this subchapter expires on the
 4-41 second anniversary of the date of issuance.

4-42 Sec. 431.403. EXEMPTION FROM LICENSING. (a) A person who
 4-43 engages in wholesale distribution of prescription drugs in this
 4-44 state for use in humans is exempt from this subchapter if the person
 4-45 is exempt under:

4-46 (1) the Prescription Drug Marketing Act of 1987 (21
 4-47 U.S.C. Section 353(c)(3)(B));

4-48 (2) the regulations adopted by the secretary to
 4-49 administer and enforce that Act; or

4-50 (3) the interpretations of that Act set out in the
 4-51 compliance policy manual of the United States Food and Drug
 4-52 Administration.

4-53 (b) An exemption from the licensing requirements under this
 4-54 section does not constitute an exemption from the other provisions
 4-55 of this chapter or the rules adopted under this chapter to
 4-56 administer and enforce the other provisions of this chapter.

4-57 Sec. 431.4031. EXEMPTION FROM CERTAIN PROVISIONS FOR
 4-58 CERTAIN WHOLESAL DISTRIBUTORS. A wholesale distributor that
 4-59 distributes prescription drugs that are medical gases or a
 4-60 wholesale distributor that is a logistics provider on behalf of a
 4-61 manufacturer is exempt from Sections 431.404(b) and (c), 431.405,
 4-62 431.407, 431.408, 431.412, and 431.413.

4-63 Sec. 431.404. LICENSE APPLICATION. (a) An applicant for a
 4-64 license under this subchapter must submit an application to the
 4-65 department on the form prescribed by the department. The
 4-66 application must contain:

4-67 (1) all trade or business names under which the
 4-68 business is conducted;

4-69 (2) the address and telephone number of each place of

5-1 business that is licensed;
 5-2 (3) the type of business and the name and residence
 5-3 address of:
 5-4 (A) the proprietor, if the business is a
 5-5 proprietorship;
 5-6 (B) all partners, if the business is a
 5-7 partnership; or
 5-8 (C) all principals, if the business is an
 5-9 association;
 5-10 (4) the date and place of incorporation, if the
 5-11 business is a corporation;
 5-12 (5) the names and business addresses of the
 5-13 individuals in an administrative capacity showing:
 5-14 (A) the managing proprietor, if the business is a
 5-15 proprietorship;
 5-16 (B) the managing partner, if the business is a
 5-17 partnership;
 5-18 (C) the officers and directors, if the business
 5-19 is a corporation; or
 5-20 (D) the persons in a managerial capacity, if the
 5-21 business is an association;
 5-22 (6) the name, telephone number, and any information
 5-23 necessary to complete a criminal history record check on a
 5-24 designated representative of each place of business;
 5-25 (7) the state of incorporation, if the business is a
 5-26 corporation;
 5-27 (8) a list of all licenses and permits issued to the
 5-28 applicant by any other state under which the applicant is permitted
 5-29 to purchase or possess prescription drugs; and
 5-30 (9) the name of the manager for each place of business.
 5-31 (b) Each person listed in Subsections (a)(6) and (a)(9)
 5-32 shall provide the following to the department:
 5-33 (1) the person's places of residence for the past seven
 5-34 years;
 5-35 (2) the person's date and place of birth;
 5-36 (3) the person's occupations, positions of employment,
 5-37 and offices held during the past seven years;
 5-38 (4) the business name and address of any business,
 5-39 corporation, or other organization in which the person held an
 5-40 office under Subdivision (3) or in which the person conducted an
 5-41 occupation or held a position of employment;
 5-42 (5) a statement of whether during the preceding seven
 5-43 years the person was the subject of a proceeding to revoke a license
 5-44 and the nature and disposition of the proceeding;
 5-45 (6) a statement of whether during the preceding seven
 5-46 years the person has been enjoined, either temporarily or
 5-47 permanently, by a court from violating any federal or state law
 5-48 regulating the possession, control, or distribution of
 5-49 prescription drugs, including the details concerning the event;
 5-50 (7) a written description of any involvement by the
 5-51 person with any business, including any investments, other than the
 5-52 ownership of stock in a publicly traded company or mutual fund
 5-53 during the past seven years, that manufactured, administered,
 5-54 prescribed, distributed, or stored pharmaceutical products and any
 5-55 lawsuits in which the businesses were named as a party;
 5-56 (8) a description of any felony offense for which the
 5-57 person, as an adult, was found guilty, regardless of whether
 5-58 adjudication of guilt was withheld or whether the person pled
 5-59 guilty or nolo contendere;
 5-60 (9) a description of any criminal conviction of the
 5-61 person under appeal, a copy of the notice of appeal for that
 5-62 criminal offense, and a copy of the final written order of an appeal
 5-63 not later than the 15th day after the date of the appeal's
 5-64 disposition; and
 5-65 (10) a photograph of the person taken not earlier than
 5-66 30 days before the date the application was submitted.
 5-67 (c) The information submitted under Subsection (b) must be
 5-68 attested to under oath.
 5-69 (d) An applicant or license holder shall file with the

6-1 department a written notice of any change in the information
6-2 required under this section.

6-3 Sec. 431.405. QUALIFICATIONS FOR LICENSE. To qualify for
6-4 the issuance or renewal of a wholesale distributor license under
6-5 this subchapter, the designated representative of an applicant or
6-6 license holder must:

6-7 (1) be at least 21 years of age;

6-8 (2) have been employed full-time for at least three
6-9 years by a pharmacy or a wholesale distributor in a capacity related
6-10 to the dispensing or distributing of prescription drugs, including
6-11 recordkeeping for the dispensing or distributing of prescription
6-12 drugs;

6-13 (3) be employed by the applicant full-time in a
6-14 managerial-level position;

6-15 (4) be actively involved in and aware of the actual
6-16 daily operation of the wholesale distributor;

6-17 (5) be physically present at the applicant's place of
6-18 business during regular business hours, except when the absence of
6-19 the designated representative is authorized, including sick leave
6-20 and vacation leave;

6-21 (6) serve as a designated representative for only one
6-22 applicant at any one time;

6-23 (7) not have been convicted of a violation of any
6-24 federal, state, or local laws relating to wholesale or retail
6-25 prescription drug distribution or the distribution of controlled
6-26 substances; and

6-27 (8) not have been convicted of a felony under federal,
6-28 state, or local laws.

6-29 Sec. 431.406. EFFECT OF OPERATION IN OTHER JURISDICTIONS;
6-30 REPORTS. (a) A person who engages in the wholesale distribution
6-31 of drugs outside this state may engage in the wholesale
6-32 distribution of drugs in this state if the person holds a license
6-33 issued by the department.

6-34 (b) The department may accept reports from authorities in
6-35 other jurisdictions to determine the extent of compliance with this
6-36 subchapter and the minimum standards adopted under this subchapter.

6-37 (c) The department may issue a license to a person who
6-38 engages in the wholesale distribution of drugs outside this state
6-39 to engage in the wholesale distribution of drugs in this state if,
6-40 after an examination of the reports of the person's compliance
6-41 history and current compliance record, the department determines
6-42 that the person is in compliance with this subchapter and the rules
6-43 adopted under this subchapter.

6-44 (d) The department shall consider each license application
6-45 and any related documents or reports filed by or in connection with
6-46 a person who wishes to engage in wholesale distribution of drugs in
6-47 this state on an individual basis.

6-48 Sec. 431.407. CRIMINAL HISTORY RECORD INFORMATION. The
6-49 department shall submit to the Department of Public Safety the
6-50 fingerprints provided by a person with an initial or a renewal
6-51 license application to obtain the person's criminal history record
6-52 information and may forward the fingerprints to the Federal Bureau
6-53 of Investigation for a federal criminal history check.

6-54 Sec. 431.408. BOND. (a) A wholesale distributor applying
6-55 for or renewing a license shall submit payable to this state a bond
6-56 or other equivalent security acceptable to the department,
6-57 including an irrevocable letter of credit or a deposit in a trust
6-58 account or financial institution, in the amount of \$100,000 payable
6-59 to this state.

6-60 (b) The bond or equivalent security submitted under
6-61 subsection (a) shall secure payment of any fines or penalties
6-62 imposed by the department or imposed in connection with an
6-63 enforcement action by the attorney general, any fees or other
6-64 enforcement costs, including attorney's fees payable to the
6-65 attorney general, and any other fees and costs incurred by this
6-66 state related to that license holder, that are authorized under the
6-67 laws of this state and that the license holder fails to pay before
6-68 the 30th day after the date a fine, penalty, fee, or cost is
6-69 assessed.

7-1 (c) The department or this state may make a claim against a
 7-2 bond or security submitted under Subsection (a) before the first
 7-3 anniversary of the date a license expires or is revoked under this
 7-4 subchapter.

7-5 (d) The department shall deposit the bonds and equivalent
 7-6 securities received under this section in a separate account.

7-7 Sec. 431.409. FEES. (a) The department shall collect fees
 7-8 for:

7-9 (1) a license that is filed or renewed;

7-10 (2) a license that is amended, including a
 7-11 notification of a change in the location of a licensed place of
 7-12 business required under Section 431.410; and

7-13 (3) an inspection performed in enforcing this
 7-14 subchapter and rules adopted under this subchapter.

7-15 (b) The executive commissioner of the Health and Human
 7-16 Services Commission by rule shall set the fees in amounts that are
 7-17 reasonable and necessary and allow the department to recover the
 7-18 biennial expenditures of state funds by the department in:

7-19 (1) reviewing and acting on a license;

7-20 (2) amending and renewing a license;

7-21 (3) inspecting a licensed facility; and

7-22 (4) implementing and enforcing this subchapter,
 7-23 including a rule or order adopted or a license issued under this
 7-24 subchapter.

7-25 (c) Fees collected under this section shall be deposited to
 7-26 the credit of the food and drug registration fee account of the
 7-27 general revenue fund and appropriated to the department to carry
 7-28 out this chapter.

7-29 Sec. 431.410. CHANGE OF LOCATION OF PLACE OF BUSINESS.

7-30 (a) Not fewer than 30 days in advance of the change, the license
 7-31 holder shall notify the department in writing of the license
 7-32 holder's intent to change the location of a licensed place of
 7-33 business.

7-34 (b) The notice shall include the address of the new location
 7-35 and the name and residence address of the individual in charge of
 7-36 the business at the new location.

7-37 (c) Not more than 10 days after the completion of the change
 7-38 of location, the license holder shall notify the department in
 7-39 writing to confirm the completion of the change of location and
 7-40 provide verification of the information previously provided or
 7-41 correct and confirm any information that has changed since
 7-42 providing the notice of intent.

7-43 (d) The notice and confirmation required by this section are
 7-44 considered adequate if the license holder sends the notices by
 7-45 certified mail, return receipt requested, to the central office of
 7-46 the department or submits the notices electronically through the
 7-47 TexasOnline Internet website.

7-48 Sec. 431.411. MINIMUM RESTRICTIONS ON TRANSACTIONS. (a) A
 7-49 wholesale distributor shall receive prescription drug returns or
 7-50 exchanges from a pharmacy or chain pharmacy warehouse in accordance
 7-51 with the terms and conditions of the agreement between the
 7-52 wholesale distributor and the pharmacy or chain pharmacy warehouse.
 7-53 The returns or exchanges received by the wholesale distributor as
 7-54 provided by this subsection are not subject to the pedigree
 7-55 requirement under Section 431.412. Wholesale distributors are
 7-56 responsible for policing the returns process and ensuring the
 7-57 operations are secure and do not allow the entry of an adulterated
 7-58 or counterfeit product into distribution.

7-59 (b) A manufacturer or wholesale distributor may distribute
 7-60 prescription drugs only to a person licensed by the appropriate
 7-61 state licensing authorities or authorized by federal law to receive
 7-62 the drug. Before furnishing prescription drugs to a person not
 7-63 known to the manufacturer or wholesale distributor, the
 7-64 manufacturer or wholesale distributor must verify that the person
 7-65 is legally authorized by the appropriate state licensing authority
 7-66 to receive the prescription drugs or authorized by federal law to
 7-67 receive the drugs.

7-68 (c) Except as otherwise provided by this subsection,
 7-69 prescription drugs distributed by a manufacturer or wholesale

8-1 distributor may be delivered only to the premises listed on the
 8-2 license. A manufacturer or wholesale distributor may distribute
 8-3 prescription drugs to an authorized person or agent of that person
 8-4 at the premises of the manufacturer or wholesale distributor if:

8-5 (1) the identity and authorization of the recipient is
 8-6 properly established; and

8-7 (2) delivery is made only to meet the immediate needs
 8-8 of a particular patient of the authorized person.

8-9 (d) Prescription drugs may be distributed to a hospital
 8-10 pharmacy receiving area if a pharmacist or an authorized receiving
 8-11 person signs, at the time of delivery, a receipt showing the type
 8-12 and quantity of the prescription drug received. Any discrepancy
 8-13 between the receipt and the type and quantity of the prescription
 8-14 drug actually received shall be reported to the delivering
 8-15 manufacturer or wholesale distributor not later than the next
 8-16 business day after the date of delivery to the pharmacy receiving
 8-17 area.

8-18 Sec. 431.412. PEDIGREE REQUIRED. (a) A person who is
 8-19 engaged in the wholesale distribution of a prescription drug,
 8-20 including a repackager but excluding the original manufacturer and
 8-21 the original labeler of a prescription drug, shall provide a
 8-22 pedigree for each prescription drug that is not distributed through
 8-23 the normal distribution chain and is sold, traded, or transferred
 8-24 to any other person.

8-25 (b) A pharmacy that sells a drug to a person other than the
 8-26 final consumer shall provide a pedigree to the person acquiring the
 8-27 prescription drug.

8-28 (c) The sale, trade, or transfer of a prescription drug
 8-29 between license holders with common ownership or for an emergency
 8-30 is not subject to this section.

8-31 (d) A person who is engaged in the wholesale distribution of
 8-32 a prescription drug, including a repackager, and who is in
 8-33 possession of a pedigree for a prescription drug must verify before
 8-34 distributing the prescription drug that each transaction listed on
 8-35 the pedigree has occurred.

8-36 Sec. 431.413. PEDIGREE CONTENTS. (a) A pedigree must
 8-37 include all necessary identifying information concerning each sale
 8-38 in the product's chain of distribution from the manufacturer,
 8-39 through acquisition and sale by a wholesale distributor or
 8-40 repackager, until final sale to a pharmacy or other person
 8-41 dispensing or administering the drug. At a minimum, the chain of
 8-42 distribution information must include:

8-43 (1) the name, address, telephone number, and, if
 8-44 available, the e-mail address of each person who owns or possesses
 8-45 the prescription drug, except common carriers and logistics
 8-46 providers;

8-47 (2) the signature of each owner of the prescription
 8-48 drug;

8-49 (3) the name and address of each location from which
 8-50 the product was shipped, if different from the owner's name and
 8-51 address;

8-52 (4) the transaction dates; and

8-53 (5) certification that each recipient has
 8-54 authenticated the pedigree.

8-55 (b) The pedigree must include, at a minimum, the:

8-56 (1) name of the prescription drug;

8-57 (2) dosage form and strength of the prescription drug;

8-58 (3) size of the container;

8-59 (4) number of containers;

8-60 (5) lot number of the prescription drug; and

8-61 (6) name of the manufacturer of the finished dosage
 8-62 form.

8-63 (c) Each pedigree statement must be:

8-64 (1) maintained by the purchaser and the wholesale
 8-65 distributor for at least three years; and

8-66 (2) available for inspection and photocopying on a
 8-67 request by the department or a peace officer in this state.

8-68 (d) The executive commissioner of the Health and Human
 8-69 Services Commission shall adopt rules to implement this section.

9-1 (e) The department shall:

9-2 (1) conduct a study on the implementation of
9-3 electronic pedigrees;

9-4 (2) in conducting the study under Subdivision (1),
9-5 consult with manufacturers, distributors, and pharmacies
9-6 responsible for the sale and distribution of prescription drugs in
9-7 this state; and

9-8 (3) based on the results of the study, establish an
9-9 implementation date, which may not be earlier than December 31,
9-10 2007, for electronic pedigrees.

9-11 (f) Subsection (e) and this subsection expire January 1,
9-12 2009.

9-13 Sec. 431.414. REFUSAL TO LICENSE; SUSPENSION OR REVOCATION
9-14 OF LICENSE. (a) The commissioner of state health services may
9-15 refuse an application for a license or may suspend or revoke a
9-16 license if the applicant or license holder:

9-17 (1) has been convicted of a felony or misdemeanor that
9-18 involves moral turpitude;

9-19 (2) is an association, partnership, or corporation and
9-20 the managing officer has been convicted of a felony or misdemeanor
9-21 that involves moral turpitude;

9-22 (3) has been convicted in a state or federal court of
9-23 the illegal use, sale, or transportation of intoxicating liquors,
9-24 narcotic drugs, barbiturates, amphetamines, desoxyephedrine, their
9-25 compounds or derivatives, or any other dangerous or habit-forming
9-26 drugs;

9-27 (4) is an association, partnership, or corporation and
9-28 the managing officer has been convicted in a state or federal court
9-29 of the illegal use, sale, or transportation of intoxicating
9-30 liquors, narcotic drugs, barbiturates, amphetamines,
9-31 desoxyephedrine, their compounds or derivatives, or any other
9-32 dangerous or habit-forming drugs;

9-33 (5) has not complied with this subchapter or the rules
9-34 implementing this subchapter;

9-35 (6) has violated Section 431.021(1)(3), relating to
9-36 the counterfeiting of a drug or the sale or holding for sale of a
9-37 counterfeit drug;

9-38 (7) has violated Chapter 481 (Texas Controlled
9-39 Substances Act) or 483 (Texas Dangerous Drug Act); or

9-40 (8) has violated the rules of the director of the
9-41 Department of Public Safety, including being responsible for a
9-42 significant discrepancy in the records that state law requires the
9-43 applicant or license holder to maintain.

9-44 (b) The executive commissioner of the Health and Human
9-45 Services Commission by rule shall establish minimum standards
9-46 required for the issuance or renewal of a license under this
9-47 subchapter.

9-48 (c) The department shall deny a license application that is
9-49 incomplete, contains false, misleading, or incorrect information,
9-50 or contains information that cannot be verified by the department.

9-51 (d) The refusal to license an applicant or the suspension or
9-52 revocation of a license by the department and the appeal from that
9-53 action are governed by the procedures for a contested case hearing
9-54 under Chapter 2001, Government Code.

9-55 Sec. 431.415. ORDER TO CEASE DISTRIBUTION. (a) The
9-56 commissioner of state health services shall issue an order
9-57 requiring a person, including a manufacturer, distributor, or
9-58 retailer of a prescription drug, to immediately cease distribution
9-59 of the drug if the commissioner determines there is a reasonable
9-60 probability that:

9-61 (1) a wholesale distributor has:

9-62 (A) violated this subchapter;

9-63 (B) falsified a pedigree; or

9-64 (C) sold, distributed, transferred,
9-65 manufactured, repackaged, handled, or held a counterfeit
9-66 prescription drug intended for human use that could cause serious
9-67 adverse health consequences or death; and

9-68 (2) other procedures would result in unreasonable
9-69 delay.

10-1 (b) An order under Subsection (a) must provide the person
10-2 subject to the order with an opportunity for an informal hearing on
10-3 the actions required by the order to be held not later than the 10th
10-4 day after the date of issuance of the order.

10-5 (c) If, after providing an opportunity for a hearing, the
10-6 commissioner of state health services determines that inadequate
10-7 grounds exist to support the actions required by the order, the
10-8 commissioner shall vacate the order.

10-9 SECTION 8. Section 431.059, Health and Safety Code, is
10-10 amended by amending Subsection (a) and adding Subsections (a-1) and
10-11 (a-2) to read as follows:

10-12 (a) A person commits an offense if the person violates any
10-13 of the provisions of Section 431.021 relating to unlawful or
10-14 prohibited acts. A first offense under this subsection is a Class A
10-15 misdemeanor unless it is shown on the trial of an offense under this
10-16 subsection that the defendant was previously convicted of an
10-17 offense under this subsection, in which event the offense is a state
10-18 jail felony. In a criminal proceeding under this section, it is not
10-19 necessary to prove intent, knowledge, recklessness, or criminal
10-20 negligence of the defendant beyond the degree of culpability, if
10-21 any, stated in Subsection (a-2) or Section 431.021, as applicable,
10-22 to establish criminal responsibility for the violation.

10-23 (a-1) A person commits an offense if the person engages in
10-24 the wholesale distribution of prescription drugs in violation of
10-25 Subchapter N. An offense under this subsection is punishable by a
10-26 fine not to exceed \$50,000.

10-27 (a-2) A person commits an offense if the person knowingly
10-28 engages in the wholesale distribution of prescription drugs in
10-29 violation of Subchapter N. An offense under this subsection is
10-30 punishable by imprisonment for not more than 15 years, a fine not to
10-31 exceed \$500,000, or both imprisonment and a fine.

10-32 SECTION 9. Section 431.021, Health and Safety Code, is
10-33 amended to read as follows:

10-34 Sec. 431.021. PROHIBITED ACTS. The following acts and the
10-35 causing of the following acts within this state are unlawful and
10-36 prohibited:

10-37 (a) the introduction or delivery for introduction into
10-38 commerce of any food, drug, device, or cosmetic that is adulterated
10-39 or misbranded;

10-40 (b) the adulteration or misbranding of any food, drug,
10-41 device, or cosmetic in commerce;

10-42 (c) the receipt in commerce of any food, drug, device,
10-43 or cosmetic that is adulterated or misbranded, and the delivery or
10-44 proffered delivery thereof for pay or otherwise;

10-45 (d) the distribution in commerce of a consumer
10-46 commodity, if such commodity is contained in a package, or if there
10-47 is affixed to that commodity a label that does not conform to the
10-48 provisions of this chapter and of rules adopted under the authority
10-49 of this chapter; provided, however, that this prohibition shall not
10-50 apply to persons engaged in business as wholesale or retail
10-51 distributors of consumer commodities except to the extent that such
10-52 persons:

10-53 (1) are engaged in the packaging or labeling of
10-54 such commodities; or

10-55 (2) prescribe or specify by any means the manner
10-56 in which such commodities are packaged or labeled;

10-57 (e) the introduction or delivery for introduction into
10-58 commerce of any article in violation of Section 431.084, 431.114,
10-59 or 431.115;

10-60 (f) the dissemination of any false advertisement;

10-61 (g) the refusal to permit entry or inspection, or to
10-62 permit the taking of a sample or to permit access to or copying of
10-63 any record as authorized by Sections 431.042-431.044; or the
10-64 failure to establish or maintain any record or make any report
10-65 required under Section 512(j), (l), or (m) of the federal Act, or
10-66 the refusal to permit access to or verification or copying of any
10-67 such required record;

10-68 (h) the manufacture within this state of any food,
10-69 drug, device, or cosmetic that is adulterated or misbranded;

11-1 (i) the giving of a guaranty or undertaking referred
 11-2 to in Section 431.059, which guaranty or undertaking is false,
 11-3 except by a person who relied on a guaranty or undertaking to the
 11-4 same effect signed by, and containing the name and address of the
 11-5 person residing in this state from whom the person received in good
 11-6 faith the food, drug, device, or cosmetic; or the giving of a
 11-7 guaranty or undertaking referred to in Section 431.059, which
 11-8 guaranty or undertaking is false;

11-9 (j) the use, removal, or disposal of a detained or
 11-10 embargoed article in violation of Section 431.048;

11-11 (k) the alteration, mutilation, destruction,
 11-12 obliteration, or removal of the whole or any part of the labeling
 11-13 of, or the doing of any other act with respect to a food, drug,
 11-14 device, or cosmetic, if such act is done while such article is held
 11-15 for sale after shipment in commerce and results in such article
 11-16 being adulterated or misbranded;

11-17 (l)(1) forging, counterfeiting, simulating, or
 11-18 falsely representing, or without proper authority using any mark,
 11-19 stamp, tag, label, or other identification device authorized or
 11-20 required by rules adopted under this chapter or the regulations
 11-21 promulgated under the provisions of the federal Act;

11-22 (2) making, selling, disposing of, or keeping in
 11-23 possession, control, or custody, or concealing any punch, die,
 11-24 plate, stone, or other thing designed to print, imprint, or
 11-25 reproduce the trademark, trade name, or other identifying mark,
 11-26 imprint, or device of another or any likeness of any of the
 11-27 foregoing on any drug or container or labeling thereof so as to
 11-28 render such drug a counterfeit drug;

11-29 (3) the doing of any act that causes a drug to be
 11-30 a counterfeit drug, or the sale or dispensing, or the holding for
 11-31 sale or dispensing, of a counterfeit drug;

11-32 (m) the using by any person to the person's own
 11-33 advantage, or revealing, other than to the commissioner, an
 11-34 authorized agent, a health authority or to the courts when relevant
 11-35 in any judicial proceeding under this chapter, of any information
 11-36 acquired under the authority of this chapter concerning any method
 11-37 or process that as a trade secret is entitled to protection;

11-38 (n) the using, on the labeling of any drug or device or
 11-39 in any advertising relating to such drug or device, of any
 11-40 representation or suggestion that approval of an application with
 11-41 respect to such drug or device is in effect under Section 431.114 or
 11-42 Section 505, 515, or 520(g) of the federal Act, as the case may be,
 11-43 or that such drug or device complies with the provisions of such
 11-44 sections;

11-45 (o) the using, in labeling, advertising or other sales
 11-46 promotion of any reference to any report or analysis furnished in
 11-47 compliance with Sections 431.042-431.044 or Section 704 of the
 11-48 federal Act;

11-49 (p) in the case of a prescription drug distributed or
 11-50 offered for sale in this state, the failure of the manufacturer,
 11-51 packer, or distributor of the drug to maintain for transmittal, or
 11-52 to transmit, to any practitioner licensed by applicable law to
 11-53 administer such drug who makes written request for information as
 11-54 to such drug, true and correct copies of all printed matter that is
 11-55 required to be included in any package in which that drug is
 11-56 distributed or sold, or such other printed matter as is approved
 11-57 under the federal Act. Nothing in this subsection shall be
 11-58 construed to exempt any person from any labeling requirement
 11-59 imposed by or under other provisions of this chapter;

11-60 (q)(1) placing or causing to be placed on any drug or
 11-61 device or container of any drug or device, with intent to defraud,
 11-62 the trade name or other identifying mark, or imprint of another or
 11-63 any likeness of any of the foregoing;

11-64 (2) selling, dispensing, disposing of or causing
 11-65 to be sold, dispensed, or disposed of, or concealing or keeping in
 11-66 possession, control, or custody, with intent to sell, dispense, or
 11-67 dispose of, any drug, device, or any container of any drug or
 11-68 device, with knowledge that the trade name or other identifying
 11-69 mark or imprint of another or any likeness of any of the foregoing

12-1 has been placed thereon in a manner prohibited by Subdivision (1) of
 12-2 this subsection; or

12-3 (3) making, selling, disposing of, causing to be
 12-4 made, sold, or disposed of, keeping in possession, control, or
 12-5 custody, or concealing with intent to defraud any punch, die,
 12-6 plate, stone, or other thing designed to print, imprint, or
 12-7 reproduce the trademark, trade name, or other identifying mark,
 12-8 imprint, or device of another or any likeness of any of the
 12-9 foregoing on any drug or container or labeling of any drug or
 12-10 container so as to render such drug a counterfeit drug;

12-11 (r) dispensing or causing to be dispensed a different
 12-12 drug in place of the drug ordered or prescribed without the express
 12-13 permission in each case of the person ordering or prescribing;

12-14 (s) the failure to register in accordance with Section
 12-15 510 of the federal Act, the failure to provide any information
 12-16 required by Section 510(j) or (k) of the federal Act, or the failure
 12-17 to provide a notice required by Section 510(j)(2) of the federal
 12-18 Act;

12-19 (t)(1) the failure or refusal to:

12-20 (A) comply with any requirement prescribed
 12-21 under Section 518 or 520(g) of the federal Act; or

12-22 (B) furnish any notification or other
 12-23 material or information required by or under Section 519 or 520(g)
 12-24 of the federal Act;

12-25 (2) with respect to any device, the submission of
 12-26 any report that is required by or under this chapter that is false
 12-27 or misleading in any material respect;

12-28 (u) the movement of a device in violation of an order
 12-29 under Section 304(g) of the federal Act or the removal or alteration
 12-30 of any mark or label required by the order to identify the device as
 12-31 detained;

12-32 (v) the failure to provide the notice required by
 12-33 Section 412(b) or 412(c), the failure to make the reports required
 12-34 by Section 412(d)(1)(B), or the failure to meet the requirements
 12-35 prescribed under Section 412(d)(2) of the federal Act;

12-36 (w) except as provided under Subchapter M of this
 12-37 chapter and Section 562.1085, Occupations Code, the acceptance by a
 12-38 person of an unused prescription or drug, in whole or in part, for
 12-39 the purpose of resale, after the prescription or drug has been
 12-40 originally dispensed, or sold;

12-41 (x) engaging in the wholesale distribution of drugs or
 12-42 operating as a distributor or manufacturer of devices in this state
 12-43 without obtaining a license issued by the department under
 12-44 Subchapter I, L, or N [filing a licensing statement with the
 12-45 commissioner as required by Section 431.202 or having a license as
 12-46 required by Section 431.272], as applicable;

12-47 (y) engaging in the manufacture of food in this state
 12-48 or operating as a warehouse operator in this state without having a
 12-49 license as required by Section 431.222 or operating as a food
 12-50 wholesaler in this state without having a license under Section
 12-51 431.222 or being registered under Section 431.2211, as appropriate;

12-52 (z) unless approved by the United States Food and Drug
 12-53 Administration pursuant to the federal Act, the sale, delivery,
 12-54 holding, or offering for sale of a self-testing kit designed to
 12-55 indicate whether a person has a human immunodeficiency virus
 12-56 infection, acquired immune deficiency syndrome, or a related
 12-57 disorder or condition; ~~[or]~~

12-58 (aa) making a false statement or false representation
 12-59 in an application for a license or in a statement, report, or other
 12-60 instrument to be filed with or requested by the department [the
 12-61 board, the commissioner, or the department] under this chapter;

12-62 (bb) failing to comply with a requirement or request
 12-63 to provide information or failing to submit an application,
 12-64 statement, report, or other instrument required by the department;

12-65 (cc) performing, causing the performance of, or aiding
 12-66 and abetting the performance of an act described by Subdivision
 12-67 (x);

12-68 (dd) purchasing or otherwise receiving a prescription
 12-69 drug from a pharmacy in violation of Section 431.411(a);

- 13-1 (ee) selling, distributing, or transferring a
- 13-2 prescription drug to a person who is not authorized under state or
- 13-3 federal law to receive the prescription drug in violation of
- 13-4 Section 431.411(b);
- 13-5 (ff) failing to deliver prescription drugs to
- 13-6 specified premises as required by Section 431.411(c);
- 13-7 (gg) failing to maintain or provide pedigrees as
- 13-8 required by Section 431.412 or 431.413; or
- 13-9 (hh) failing to obtain, pass, or authenticate a
- 13-10 pedigree as required by Section 431.412 or 431.413.

13-11 SECTION 10. Section 411.110, Government Code, is amended to
13-12 read as follows:

13-13 Sec. 411.110. ACCESS TO CRIMINAL HISTORY RECORD
13-14 INFORMATION: [~~TEXAS~~] DEPARTMENT OF STATE HEALTH SERVICES.

13-15 (a) The [~~Texas~~] Department of State Health Services is entitled to
13-16 obtain from the department criminal history record information
13-17 maintained by the department that relates to:

13-18 (1) a person who is:
13-19 (A) [~~(1)~~] an applicant for a license or
13-20 certificate under the Emergency Medical Services Act (Chapter 773,
13-21 Health and Safety Code);

13-22 (B) [~~(2)~~] an owner or manager of an applicant for
13-23 an emergency medical services provider license under that Act; or

13-24 (C) [~~(3)~~] the holder of a license or certificate
13-25 under that Act; or

13-26 (2) an applicant for a license or a license holder
13-27 under Subchapter N, Chapter 431, Health and Safety Code.

13-28 (b) Criminal history record information obtained by the
13-29 [~~Texas~~] Department of State Health Services under Subsection (a)
13-30 may not be released or disclosed to any person except on court
13-31 order, with the written consent of the person or entity that is the
13-32 subject of the criminal history record information, or as provided
13-33 by Subsection (e).

13-34 (c) After an entity is licensed or certified, the [~~Texas~~]
13-35 Department of State Health Services shall destroy the criminal
13-36 history record information that relates to that entity.

13-37 (d) The Department of State Health Services [~~Texas Board of~~
13-38 ~~Health~~] shall destroy criminal history record information that
13-39 relates to an applicant that is not certified.

13-40 (e) The Department of State Health Services [~~Texas Board of~~
13-41 ~~Health~~] is not prohibited from disclosing criminal history record
13-42 information obtained under Subsection (a) in a criminal proceeding
13-43 or in a hearing conducted by the [~~Texas~~] Department of State Health
13-44 Services.

13-45 SECTION 11. Sections 431.2021 and 431.205, Health and
13-46 Safety Code, are repealed.

13-47 SECTION 12. Not later than January 1, 2006, the executive
13-48 commissioner of the Health and Human Services Commission shall
13-49 adopt the rules necessary to implement the changes in law made by
13-50 this Act by amending Subchapter I, Chapter 431, Health and Safety
13-51 Code, and adding Subchapter N, Chapter 431, Health and Safety Code.

13-52 SECTION 13. Not later than January 1, 2006, the Department
13-53 of State Health Services shall prescribe the forms required to
13-54 implement the changes in law made by this Act by the amendment of
13-55 Subchapter I, Chapter 431, Health and Safety Code, and the addition
13-56 of Subchapter N, Chapter 431, Health and Safety Code.

13-57 SECTION 14. The change in law made by this Act applies only
13-58 to an offense committed on or after March 1, 2006. An offense
13-59 committed before that date is covered by the law in effect when the
13-60 offense was committed, and the former law is continued in effect for
13-61 that purpose. For purposes of this section, an offense was
13-62 committed before March 1, 2006, if any element of the offense was
13-63 committed before that date.

13-64 SECTION 15. (a) Except as provided by Subsection (b) of
13-65 this section, this Act takes effect September 1, 2005.

13-66 (b) Sections 1 through 9 of this Act take effect March 1,
13-67 2006.

13-68 * * * * *