

AN ACT

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

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

SECTION 1. Section 431.021, Health and Safety Code, is amended to read as follows:

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

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

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

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

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

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

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

5 (e) the introduction or delivery for introduction into
6 commerce of any article in violation of Section 431.084, 431.114,
7 or 431.115;

8 (f) the dissemination of any false advertisement;

9 (g) the refusal to permit entry or inspection, or to permit
10 the taking of a sample or to permit access to or copying of any
11 record as authorized by Sections 431.042-431.044; or the failure
12 to establish or maintain any record or make any report required
13 under Section 512(j), (l), or (m) of the federal Act, or the refusal
14 to permit access to or verification or copying of any such required
15 record;

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

18 (i) the giving of a guaranty or undertaking referred to in
19 Section 431.059, which guaranty or undertaking is false, except by
20 a person who relied on a guaranty or undertaking to the same effect
21 signed by, and containing the name and address of the person
22 residing in this state from whom the person received in good faith
23 the food, drug, device, or cosmetic; or the giving of a guaranty or
24 undertaking referred to in Section 431.059, which guaranty or
25 undertaking is false;

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

1 (k) the alteration, mutilation, destruction, obliteration,
2 or removal of the whole or any part of the labeling of, or the doing
3 of any other act with respect to a food, drug, device, or cosmetic,
4 if such act is done while such article is held for sale after
5 shipment in commerce and results in such article being adulterated
6 or misbranded;

7 (1)(1) forging, counterfeiting, simulating, or falsely
8 representing, or without proper authority using any mark, stamp,
9 tag, label, or other identification device authorized or required
10 by rules adopted under this chapter or the regulations promulgated
11 under the provisions of the federal Act;

12 (2) making, selling, disposing of, or keeping in
13 possession, control, or custody, or concealing any punch, die,
14 plate, stone, or other thing designed to print, imprint, or
15 reproduce the trademark, trade name, or other identifying mark,
16 imprint, or device of another or any likeness of any of the
17 foregoing on any drug or container or labeling thereof so as to
18 render such drug a counterfeit drug;

19 (3) the doing of any act that causes a drug to be a
20 counterfeit drug, or the sale or dispensing, or the holding for sale
21 or dispensing, of a counterfeit drug;

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

1 (n) the using, on the labeling of any drug or device or in
2 any advertising relating to such drug or device, of any
3 representation or suggestion that approval of an application with
4 respect to such drug or device is in effect under Section 431.114 or
5 Section 505, 515, or 520(g) of the federal Act, as the case may be,
6 or that such drug or device complies with the provisions of such
7 sections;

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

12 (p) in the case of a prescription drug distributed or
13 offered for sale in this state, the failure of the manufacturer,
14 packer, or distributor of the drug to maintain for transmittal, or
15 to transmit, to any practitioner licensed by applicable law to
16 administer such drug who makes written request for information as
17 to such drug, true and correct copies of all printed matter that is
18 required to be included in any package in which that drug is
19 distributed or sold, or such other printed matter as is approved
20 under the federal Act. Nothing in this subsection shall be
21 construed to exempt any person from any labeling requirement
22 imposed by or under other provisions of this chapter;

23 (q)(1) placing or causing to be placed on any drug or device
24 or container of any drug or device, with intent to defraud, the
25 trade name or other identifying mark, or imprint of another or any
26 likeness of any of the foregoing;

27 (2) selling, dispensing, disposing of or causing to be

1 sold, dispensed, or disposed of, or concealing or keeping in
2 possession, control, or custody, with intent to sell, dispense, or
3 dispose of, any drug, device, or any container of any drug or
4 device, with knowledge that the trade name or other identifying
5 mark or imprint of another or any likeness of any of the foregoing
6 has been placed thereon in a manner prohibited by Subdivision (1) of
7 this subsection; or

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

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

19 (s) the failure to register in accordance with Section 510
20 of the federal Act, the failure to provide any information required
21 by Section 510(j) or (k) of the federal Act, or the failure to
22 provide a notice required by Section 510(j)(2) of the federal Act;

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

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

26 (B) furnish any notification or other material or
27 information required by or under Section 519 or 520(g) of the

1 federal Act;

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

5 (u) the movement of a device in violation of an order under
6 Section 304(g) of the federal Act or the removal or alteration of
7 any mark or label required by the order to identify the device as
8 detained;

9 (v) the failure to provide the notice required by Section
10 412(b) or 412(c), the failure to make the reports required by
11 Section 412(d)(1)(B), or the failure to meet the requirements
12 prescribed under Section 412(d)(2) of the federal Act;

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

18 (x) engaging in the wholesale distribution of drugs or
19 operating as a distributor or manufacturer of devices in this state
20 without obtaining a license issued by the department under
21 Subchapter I, L, or N, as applicable;

22 (y) engaging in the manufacture of food in this state or
23 operating as a warehouse operator in this state without having a
24 license as required by Section 431.222 or operating as a food
25 wholesaler in this state without having a license under Section
26 431.222 or being registered under Section 431.2211, as appropriate;

27 (z) unless approved by the United States Food and Drug

1 Administration pursuant to the federal Act, the sale, delivery,
2 holding, or offering for sale of a self-testing kit designed to
3 indicate whether a person has a human immunodeficiency virus
4 infection, acquired immune deficiency syndrome, or a related
5 disorder or condition;

6 (aa) making a false statement or false representation in an
7 application for a license or in a statement, report, or other
8 instrument to be filed with or requested by the department under
9 this chapter;

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

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

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

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

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

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

24 (hh) failing to obtain, pass, or authenticate a pedigree as
25 required by Section 431.412 or 431.413; [~~or~~]

26 (ii) the introduction or delivery for introduction into
27 commerce of a drug or prescription device at a flea market;

1 (jj) the receipt of a prescription drug that is adulterated,
2 misbranded, stolen, obtained by fraud or deceit, counterfeit, or
3 suspected of being counterfeit, and the delivery or proffered
4 delivery of such a drug for payment or otherwise; or

5 (kk) the alteration, mutilation, destruction,
6 obliteration, or removal of all or any part of the labeling of a
7 prescription drug or the commission of any other act with respect to
8 a prescription drug that results in the prescription drug being
9 misbranded.

10 SECTION 2. Subchapter B, Chapter 431, Health and Safety
11 Code, is amended by adding Section 431.0211 to read as follows:

12 Sec. 431.0211. EXCEPTION. Any provision of Section 431.021
13 that relates to a prescription drug does not apply to a prescription
14 drug manufacturer, or an agent of a prescription drug manufacturer,
15 who is obtaining or attempting to obtain a prescription drug for the
16 sole purpose of testing the prescription drug for authenticity.

17 SECTION 3. Section 431.401, Health and Safety Code, is
18 amended by amending Subdivisions (3), (5), and (11) and adding
19 Subdivisions (3-a), (3-b), (4-a), (4-b), (10-a), and (12) to read
20 as follows:

21 (3) "Pharmacy [~~Chain pharmacy~~] warehouse" means a
22 location for which a person holds a wholesale drug distribution
23 license under this subchapter, that serves [~~primarily~~] as a central
24 warehouse for drugs or devices, and from which intracompany sales
25 or transfers of drugs or devices are made to a group of pharmacies
26 under common ownership and control.

27 (3-a) "Co-licensed product partner" means one of two

1 or more parties that have the right to engage in the manufacturing
2 or marketing of a prescription drug consistent with the United
3 States Food and Drug Administration's regulations and guidances
4 implementing the Prescription Drug Marketing Act of 1987 (Pub. L.
5 No. 100-293).

6 (3-b) "Drop shipment" means the sale of a prescription
7 drug to a wholesale distributor by the manufacturer of the
8 prescription drug, or by the manufacturer's co-licensed product
9 partner, third-party logistics provider, or exclusive distributor,
10 in which:

11 (A) the wholesale distributor takes title but not
12 physical possession of the prescription drug;

13 (B) the wholesale distributor invoices the
14 pharmacy, pharmacy warehouse, or other person authorized by law to
15 dispense or administer the drug to a patient; and

16 (C) the pharmacy, pharmacy warehouse, or other
17 authorized person receives delivery of the prescription drug
18 directly from the manufacturer or the manufacturer's third-party
19 logistics provider or exclusive distributor.

20 (4-a) "Manufacturer" means a person licensed or
21 approved by the United States Food and Drug Administration to
22 engage in the manufacture of drugs or devices, consistent with the
23 federal agency's definition of "manufacturer" under the agency's
24 regulations and guidances implementing the Prescription Drug
25 Marketing Act of 1987 (Pub. L. No. 100-293). The term does not
26 include a pharmacist engaged in compounding that is done within the
27 practice of pharmacy and pursuant to a prescription drug order or

1 initiative from a practitioner for a patient or prepackaging that
2 is done in accordance with Section 562.154, Occupations Code.

3 (4-b) "Manufacturer's exclusive distributor" means a
4 person who holds a wholesale distributor license under this
5 subchapter, who contracts with a manufacturer to provide or
6 coordinate warehousing, distribution, or other services on behalf
7 of the manufacturer, and who takes title to, but does not have
8 general responsibility to direct the sale or disposition of, the
9 manufacturer's prescription drug. A manufacturer's exclusive
10 distributor must be an authorized distributor of record to be
11 considered part of the normal distribution channel.

12 (5) "Normal distribution channel [~~chain~~]" means a
13 chain of custody for a prescription drug, either directly or by drop
14 shipment, from the manufacturer of the prescription drug, the
15 manufacturer to the manufacturer's co-licensed product partner,
16 the manufacturer to the manufacturer's third-party logistics
17 provider, or the manufacturer to the manufacturer's exclusive
18 distributor, to:

19 (A) [~~a manufacturer to an authorized distributor~~
20 ~~of record or to a wholesale distributor licensed under this~~
21 ~~subchapter to] a pharmacy [~~or practitioner~~] to:~~

22 (i) a patient; or
23 (ii) another designated person authorized
24 by law to dispense or administer the drug to a patient;

25 (B) an authorized distributor of record to:

26 (i) a pharmacy to a patient; or
27 (ii) another designated person authorized

1 by law to dispense or administer the drug to a patient;

2 (C) [a manufacturer to] an authorized
3 distributor of record to a pharmacy warehouse to the pharmacy
4 warehouse's intracompany pharmacy [one other authorized
5 distributor of record to a pharmacy or practitioner to a patient];
6 [or]

7 (D) [(C) a manufacturer to an authorized
8 distributor of record to] a [chain] pharmacy warehouse to the
9 pharmacy warehouse's intracompany pharmacy or another designated
10 person authorized by law to dispense or administer the drug [a
11 pharmacy or practitioner] to a patient;

12 (E) a person authorized by law to prescribe a
13 prescription drug that by law may be administered only under the
14 supervision of the prescriber; or

15 (F) an authorized distributor of record to one
16 other authorized distributor of record to a licensed practitioner
17 for office use.

18 (10-a) "Third-party logistics provider" means a
19 person who holds a wholesale distributor license under this
20 subchapter, who contracts with a prescription drug manufacturer to
21 provide or coordinate warehousing, distribution, or other services
22 on behalf of the manufacturer, and who does not take title to the
23 prescription drug or have general responsibility to direct the
24 prescription drug's sale or disposition. A third-party logistics
25 provider must be an authorized distributor of record to be
26 considered part of the normal distribution channel.

27 (11) "Wholesale distribution" means distribution of

1 prescription drugs to a person other than a consumer or patient[~~7~~
2 ~~and includes distribution by a manufacturer, repackager, own label~~
3 ~~distributor, broker, jobber, warehouse, retail pharmacy that~~
4 ~~conducts wholesale distribution, or wholesaler]. The term does not
5 include:~~

6 (A) intracompany sales of prescription drugs,
7 which means transactions or transfers of prescription drugs between
8 a division, subsidiary, parent, or affiliated or related company
9 that is under common ownership and control, or any transaction or
10 transfer between co-license holders of a co-licensed product [~~of a~~
11 ~~corporate entity~~];

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

16 (C) the distribution of prescription drug
17 samples by a representative of a manufacturer;

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

22 (E) the sale of reasonable quantities [~~delivery~~]
23 by a retail pharmacy of a prescription drug to [~~a patient or a~~
24 ~~patient's agent under the lawful order of~~] a licensed practitioner
25 for office use;

26 (F) the sale, purchase, or trade of a drug, an
27 offer to sell, purchase, or trade a drug, or the dispensing of a

1 drug under a prescription;

2 (G) the sale, transfer, merger, or consolidation
3 of all or part of the business of a pharmacy from or with another
4 pharmacy, whether accomplished as a purchase and sale of stock or
5 business assets;

6 (H) the sale, purchase, or trade of a drug, or the
7 offer to sell, purchase, or trade a drug, for emergency medical
8 reasons, including a transfer of a prescription drug by a retail
9 pharmacy to another retail pharmacy to alleviate a temporary
10 shortage;

11 (I) the delivery of, or offer to deliver, a
12 prescription drug by a common carrier solely in the common
13 carrier's usual course of business of transporting prescription
14 drugs, if the common carrier does not store, warehouse, or take
15 legal ownership of the prescription drug; or

16 (J) the sale or transfer from a retail pharmacy
17 or pharmacy warehouse of expired, damaged, returned, or recalled
18 prescription drugs to the original manufacturer or to a third-party
19 returns processor.

20 (12) "Wholesale distributor" means a person engaged in
21 the wholesale distribution of prescription drugs, including a
22 manufacturer, repackager, own-label distributor, private-label
23 distributor, jobber, broker, manufacturer warehouse, distributor
24 warehouse, or other warehouse, manufacturer's exclusive
25 distributor, authorized distributor of record, drug wholesaler or
26 distributor, independent wholesale drug trader, specialty
27 wholesale distributor, third-party logistics provider, retail

1 pharmacy that conducts wholesale distribution, and pharmacy
2 warehouse that conducts wholesale distribution.

3 SECTION 4. Section 431.4031, Health and Safety Code, is
4 amended to read as follows:

5 Sec. 431.4031. EXEMPTION FROM CERTAIN PROVISIONS FOR
6 CERTAIN WHOLESALE DISTRIBUTORS. A wholesale distributor that
7 distributes prescription drugs that are medical gases or a
8 wholesale distributor that is a manufacturer or a third-party
9 logistics provider on behalf of a manufacturer is exempt from
10 Sections 431.404(a)(5) and (6), (b), [~~431.404(b)~~] and (c),
11 431.4045(2), 431.405, 431.407, and 431.408[, ~~431.412, and~~
12 ~~431.413~~].

13 SECTION 5. Subsections (a), (b), and (d), Section 431.404,
14 Health and Safety Code, are amended to read as follows:

15 (a) An applicant for a license under this subchapter must
16 submit an application to the department on the form prescribed by
17 the department. The application must contain:

18 (1) the name, full business address, and telephone
19 number of the applicant;

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

22 (3) [~~(2)~~] the address, [and] telephone number, and
23 name of a contact person for each of the applicant's places of
24 business [~~of each place of business that is licensed~~];

25 (4) [~~(3)~~] the type of business entity and:

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

1 (B) if the business is a partnership, the name of
2 the partnership and each of the partners; or

3 (C) if the business is a corporation, the name of
4 the corporation, the place of incorporation, and the name and title
5 of each corporate officer and director [~~the name and residence~~
6 ~~address of:~~

7 [~~(A) the proprietor, if the business is a~~
8 ~~proprietorship;~~

9 [~~(B) all partners, if the business is a~~
10 ~~partnership; or~~

11 [~~(C) all principals, if the business is an~~
12 ~~association];~~

13 [~~(4) the date and place of incorporation, if the~~
14 ~~business is a corporation;]~~

15 (5) [~~the names and business addresses of the~~
16 ~~individuals in an administrative capacity showing:~~

17 [~~(A) the managing proprietor, if the business is~~
18 ~~a proprietorship;~~

19 [~~(B) the managing partner, if the business is a~~
20 ~~partnership;~~

21 [~~(C) the officers and directors, if the business~~
22 ~~is a corporation; or~~

23 [~~(D) the persons in a managerial capacity, if the~~
24 ~~business is an association;~~

25 [~~(6)~~] the name and[~~7~~] telephone number of, and any
26 information necessary to complete a criminal history record check
27 on a designated representative of each place of business; and

1 (6) [~~(7)~~ the state of incorporation, if the business
2 is a corporation,

3 [~~(8)~~] a list of all licenses and permits issued to the
4 applicant by any other state under which the applicant is permitted
5 to purchase or possess prescription drugs[, and

6 [~~(9)~~ the name of the manager for each place of
7 business].

8 (b) Each person listed in Subsection (a)(5) [~~Subsections~~
9 ~~(a)(6) and (a)(9)~~] shall provide the following to the department:

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

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

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

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

19 (5) a statement of whether during the preceding seven
20 years the person was the subject of a proceeding to revoke a license
21 or a criminal proceeding and the nature and disposition of the
22 proceeding;

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

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

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

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

17 (10) a photograph of the person taken not earlier than
18 180 [~~30~~] days before the date the application was submitted.

19 (d) An applicant or license holder shall submit to [~~file~~
20 ~~with~~] the department [~~a written notice of~~] any change in or
21 correction to the information required under this section in the
22 form and manner prescribed by the department.

23 SECTION 6. Subchapter N, Chapter 431, Health and Safety
24 Code, is amended by adding Section 431.4045 to read as follows:

25 Sec. 431.4045. INSPECTION REQUIRED. The department may not
26 issue a wholesale distributor license to an applicant under this
27 subchapter unless the department:

1 (1) conducts a physical inspection of the place of
2 business at the address provided by the applicant under Section
3 431.404 or determines that an inspection is unnecessary after
4 thoroughly evaluating the information in the application, the
5 compliance history of the applicant and the applicant's principals,
6 and the risk of counterfeiting in the applicant's product; and

7 (2) determines that the designated representative of
8 the place of business meets the qualifications required by Section
9 431.405.

10 SECTION 7. Section 431.405, Health and Safety Code, is
11 amended to read as follows:

12 Sec. 431.405. QUALIFICATIONS FOR LICENSE. (a) The
13 department may not issue a wholesale distributor license to an
14 applicant without considering the minimum federal information and
15 related qualification requirements published in federal
16 regulations at 21 C.F.R. Part 205, including:

17 (1) factors in reviewing the qualifications of persons
18 who engage in wholesale distribution, 21 C.F.R. Section 205.6;

19 (2) appropriate education and experience for
20 personnel employed in wholesale distribution, 21 C.F.R. Section
21 205.7; and

22 (3) the storage and handling of prescription drugs and
23 the establishment and maintenance of prescription drug
24 distribution records, 21 C.F.R. Section 205.50.

25 (b) In addition to meeting the minimum federal requirements
26 as provided by Subsection (a), to [~~T~~] qualify for the issuance or
27 renewal of a wholesale distributor license under this subchapter,

1 the designated representative of an applicant or license holder
2 must:

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

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

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

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

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

17 (6) serve as a designated representative for only one
18 applicant at any one time, except in a circumstance, as the
19 department determines reasonable, in which more than one licensed
20 wholesale distributor is colocated in the same place of business
21 and the wholesale distributors are members of an affiliated group,
22 as defined by Section 1504, Internal Revenue Code of 1986;

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

27 (8) not have been convicted of a felony under a

1 federal, state, or local law.

2 SECTION 8. Section 431.408, Health and Safety Code, is
3 amended by adding Subsections (a-1) and (c-1) to read as follows:

4 (a-1) A pharmacy warehouse that is not engaged in wholesale
5 distribution is exempt from the bond requirement under Subsection
6 (a).

7 (c-1) A single bond is sufficient to cover all places of
8 business operated by a wholesale distributor in this state.

9 SECTION 9. Subchapter N, Chapter 431, Health and Safety
10 Code, is amended by adding Section 431.4095 to read as follows:

11 Sec. 431.4095. RENEWAL NOTIFICATION; CHANGE OR RENEWAL.

12 (a) Before the expiration of a license issued under this
13 subchapter, the department shall send to each licensed wholesale
14 distributor a form containing a copy of the information the
15 distributor provided to the department under Section 431.404.

16 (b) Not later than the 30th day after the date the wholesale
17 distributor receives the form under Subsection (a), the wholesale
18 distributor shall identify and state under oath to the department
19 any change in or correction to the information.

20 SECTION 10. Section 431.411, Health and Safety Code, is
21 amended by amending Subsection (a) and adding Subsections (a-1) and
22 (a-2) to read as follows:

23 (a) A wholesale distributor shall receive prescription drug
24 returns or exchanges from a pharmacy or [~~chain~~] pharmacy warehouse
25 in accordance with the terms and conditions of the agreement
26 between the wholesale distributor and the pharmacy or [~~chain~~]
27 pharmacy warehouse. An expired, damaged, recalled, or otherwise

1 nonsalable prescription drug that is returned to the wholesale
2 distributor may be distributed by the wholesale distributor only to
3 either the original manufacturer or a third-party returns
4 processor. The returns or exchanges, salable or otherwise,
5 received by the wholesale distributor as provided by this
6 subsection, including any redistribution of returns or exchanges by
7 the wholesale distributor, are not subject to the pedigree
8 requirement under Section 431.412 if the returns or exchanges are
9 exempt from pedigree under:

10 (1) Section 503, Prescription Drug Marketing Act of
11 1987 (21 U.S.C. Section 353(c)(3)(B));

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

14 (3) the interpretations of that Act set out in the
15 compliance policy guide of the United States Food and Drug
16 Administration.

17 (a-1) Each [In connection with the returned goods process,
18 a] wholesale distributor and pharmacy shall administer the process
19 of drug returns and exchanges to ensure that the process is secure
20 and does not permit [should establish appropriate business
21 practices and exercise due diligence designed to prevent] the entry
22 of adulterated or counterfeit drugs into the distribution channel.

23 (a-2) Notwithstanding any provision of state or federal law
24 to the contrary, a person that has not otherwise been required to
25 obtain a wholesale license under this subchapter and that is a
26 pharmacy engaging in the sale or transfer of expired, damaged,
27 returned, or recalled prescription drugs to the originating

1 wholesale distributor or manufacturer and pursuant to federal
2 statute, rules, and regulations, including the United States Food
3 and Drug Administration's applicable guidances implementing the
4 Prescription Drug Marketing Act of 1987 (Pub. L. No. 100-293), is
5 exempt from wholesale licensure requirements under this
6 subchapter.

7 SECTION 11. Section 431.412, Health and Safety Code, is
8 amended by amending Subsections (a) and (d) and adding Subsection
9 (b-1) to read as follows:

10 (a) A person who is engaged in the wholesale distribution of
11 a prescription drug, including a repackager but excluding the
12 original manufacturer [~~and the original labeler of a prescription~~
13 ~~drug~~], shall provide a pedigree for each prescription drug for
14 human consumption that leaves or at any time has left [~~is not~~
15 ~~distributed through~~] the normal distribution channel [~~chain~~] and is
16 sold, traded, or transferred to any other person.

17 (b-1) A retail pharmacy or pharmacy warehouse is required to
18 comply with this section only if the pharmacy or warehouse engages
19 in the wholesale distribution of a prescription drug.

20 (d) A person who is engaged in the wholesale distribution of
21 a prescription drug, including a repackager, but excluding the
22 original manufacturer of the finished form of a prescription drug,
23 and who is in possession of a pedigree for a prescription drug must
24 verify before distributing the prescription drug that each
25 transaction listed on the pedigree has occurred.

26 SECTION 12. Section 431.413, Health and Safety Code, is
27 amended by amending Subsections (a), (c), and (e) and adding

1 Subsection (e-1) to read as follows:

2 (a) A pedigree must include all necessary identifying
3 information concerning each sale in the product's chain of
4 distribution from the manufacturer, through acquisition and sale by
5 a wholesale distributor or repackager, until final sale to a
6 pharmacy or other person dispensing or administering the drug. At a
7 minimum, the chain of distribution information must include:

8 (1) the name, address, telephone number, and, if
9 available, the e-mail address of each person who owns [~~or~~
10 ~~possesses~~] the prescription drug and each wholesale distributor of
11 the prescription drug[~~, except common carriers and logistics~~
12 ~~providers~~];

13 (2) [~~the signature of each owner of the prescription~~
14 ~~drug~~;

15 [~~(3)~~] the name and address of each location from which
16 the product was shipped, if different from the owner's name and
17 address;

18 (3) [~~(4)~~] the transaction dates; and

19 (4) [~~(5)~~] certification that each recipient has
20 authenticated the pedigree.

21 (c) Each pedigree statement must be:

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

24 (2) available for inspection and photocopying not
25 later than the second business day after the date [~~on~~] a request is
26 submitted by the department or a peace officer in this state.

27 (e) The department shall:

1 (1) conduct a study on the implementation of
2 electronic pedigrees; and

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

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

10 (e-1) If, after consulting with manufacturers,
11 distributors, and pharmacies responsible for the sale and
12 distribution of prescription drugs in this state, the department
13 determines that electronic track and trace pedigree technology is
14 universally available across the entire prescription
15 pharmaceutical supply chain, the department shall establish a
16 targeted implementation date for electronic track and trace
17 pedigree technology. After the department has established a
18 targeted implementation date, the department may revise the date.
19 The targeted implementation date may not be earlier than July 1,
20 2010.

21 SECTION 13. Section 431.414, Health and Safety Code, is
22 amended by adding Subsection (a-1) to read as follows:

23 (a-1) The commissioner of state health services may suspend
24 or revoke a license if the license holder no longer meets the
25 qualifications for obtaining a license under Section 431.405.

26 SECTION 14. Subsections (a-1) and (a-2), Section 431.059,
27 and Subsections (b) and (c), Section 431.412, Health and Safety

1 Code, are repealed.

2 SECTION 15. The executive commissioner of the Health and
3 Human Services Commission shall adopt the rules necessary to
4 implement the changes in law made by this Act not later than May 1,
5 2008.

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

14 SECTION 17. This Act takes effect September 1, 2007.

President of the Senate

Speaker of the House

I hereby certify that S.B. No. 943 passed the Senate on April 17, 2007, by the following vote: Yeas 30, Nays 0; and that the Senate concurred in House amendments on May 21, 2007, by the following vote: Yeas 30, Nays 0.

Secretary of the Senate

I hereby certify that S.B. No. 943 passed the House, with amendments, on May 17, 2007, by the following vote: Yeas 141, Nays 3, two present not voting.

Chief Clerk of the House

Approved:

Date

Governor