

By: Janek

S.B. No. 943

A BILL TO BE ENTITLED

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

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

(3-a) "Co-licensed product partner" means one of two or more parties that have the right to engage in the manufacturing or marketing of a prescription drug consistent with the United States Food and Drug Administration's regulations and guidances implementing the Prescription Drug Marketing Act of 1987 (Pub. L. No. 100-293).

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

1 in which:

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

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

7 (C) the pharmacy, pharmacy warehouse, or other
8 authorized person receives delivery of the prescription drug
9 directly from the manufacturer or the manufacturer's third-party
10 logistics provider or exclusive distributor.

11 (4-a) "Manufacturer" means a person licensed or
12 approved by the United States Food and Drug Administration to
13 engage in the manufacture of drugs or devices, consistent with the
14 federal agency's definition of "manufacturer" under the agency's
15 regulations and guidances implementing the Prescription Drug
16 Marketing Act of 1987 (Pub. L. No. 100-293). The term does not
17 include a pharmacist engaged in compounding that is done within the
18 practice of pharmacy and pursuant to a prescription drug order or
19 initiative from a practitioner for a patient or prepackaging that
20 is done in accordance with Section 562.154, Occupations Code.

21 (4-b) "Manufacturer's exclusive distributor" means a
22 person who holds a wholesale distributor license under this
23 subchapter, who contracts with a manufacturer to provide or
24 coordinate warehousing, distribution, or other services on behalf
25 of the manufacturer, and who takes title to, but does not have
26 general responsibility to direct the sale or disposition of, the
27 manufacturer's prescription drug. A manufacturer's exclusive

1 distributor must be an authorized distributor of record to be
2 considered part of the normal distribution channel.

3 (5) "Normal distribution channel [~~chain~~]" means a
4 chain of custody for a prescription drug, either directly or by drop
5 shipment, from the manufacturer of the prescription drug, the
6 manufacturer to the manufacturer's co-licensed product partner,
7 the manufacturer to the manufacturer's third-party logistics
8 provider, or the manufacturer to the manufacturer's exclusive
9 distributor, to:

10 (A) [~~a manufacturer to an authorized distributor~~
11 ~~of record or to a wholesale distributor licensed under this~~
12 ~~subchapter to]~~ a pharmacy [~~or practitioner~~] to:

- 13 (i) a patient; or
14 (ii) another designated person authorized
15 by law to dispense or administer the drug to a patient;

16 (B) an authorized distributor of record to:
17 (i) a pharmacy to a patient; or
18 (ii) another designated person authorized
19 by law to dispense or administer the drug to a patient;

20 (C) [~~a manufacturer to]~~ an authorized
21 distributor of record to a pharmacy warehouse to the pharmacy
22 warehouse's intracompany pharmacy or another designated person
23 authorized by law to dispense or administer the drug [~~one other~~
24 ~~authorized distributor of record to a pharmacy or practitioner]~~ to
25 a patient; [~~or~~]

26 (D) [~~(C) a manufacturer to an authorized~~
27 ~~distributor of record to]~~ a [~~chain~~] pharmacy warehouse to the

1 pharmacy warehouse's intracompany pharmacy or another designated
2 person authorized by law to dispense or administer the drug [a
3 pharmacy or practitioner] to a patient; or

4 (E) a person authorized by law to prescribe a
5 prescription drug that by law may be administered only under the
6 supervision of the prescriber.

7 (10-a) "Third-party logistics provider" means a
8 person who holds a wholesale distributor license under this
9 subchapter, who contracts with a prescription drug manufacturer to
10 provide or coordinate warehousing, distribution, or other services
11 on behalf of the manufacturer, and who does not take title to the
12 prescription drug or have general responsibility to direct the
13 prescription drug's sale or disposition. A third-party logistics
14 provider must be an authorized distributor of record to be
15 considered part of the normal distribution channel.

16 (11) "Wholesale distribution" means distribution of
17 prescription drugs to a person other than a consumer or patient[
18 and includes distribution by a manufacturer, repackager, own label
19 distributor, broker, jobber, warehouse, retail pharmacy that
20 conducts wholesale distribution, or wholesaler]. The term does not
21 include:

22 (A) intracompany sales of prescription drugs,
23 which means transactions or transfers of prescription drugs between
24 a division, subsidiary, parent, or affiliated or related company
25 that is under common ownership and control, or any transaction or
26 transfer between co-license holders of a co-licensed product [of a
27 corporate entity];

1 (B) the sale, purchase, distribution, trade, or
2 transfer of prescription drugs or the offer to sell, purchase,
3 distribute, trade, or transfer a prescription drug for emergency
4 medical reasons;

5 (C) the distribution of prescription drug
6 samples by a representative of a manufacturer;

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

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

15 (F) the sale, purchase, or trade of a drug, an
16 offer to sell, purchase, or trade a drug, or the dispensing of a
17 drug under a prescription;

18 (G) the sale, transfer, merger, or consolidation
19 of all or part of the business of a pharmacy from or with another
20 pharmacy, whether accomplished as a purchase and sale of stock or
21 business assets;

22 (H) the sale, purchase, distribution, trade, or
23 transfer of a prescription drug from one authorized distributor of
24 record to one additional authorized distributor of record if:

25 (i) the manufacturer states in writing to
26 the receiving distributor that the manufacturer is unable to supply
27 the prescription drug; and

1 (ii) the supplying distributor states in
2 writing that the prescription drug being supplied had until that
3 time been exclusively in the normal distribution channel;

4 (I) the delivery of, or offer to deliver, a
5 prescription drug by a common carrier solely in the common
6 carrier's usual course of business of transporting prescription
7 drugs, if the common carrier does not store, warehouse, or take
8 legal ownership of the prescription drug; or

9 (J) the sale or transfer from a retail pharmacy
10 or pharmacy warehouse of expired, damaged, returned, or recalled
11 prescription drugs to the original manufacturer or to a third-party
12 returns processor.

13 (12) "Wholesale distributor" means a person engaged in
14 the wholesale distribution of prescription drugs, including a
15 manufacturer, repackager, own-label distributor, private-label
16 distributor, jobber, broker, manufacturer warehouse, distributor
17 warehouse, or other warehouse, manufacturer's exclusive
18 distributor, authorized distributor of record, drug wholesaler or
19 distributor, independent wholesale drug trader, specialty
20 wholesale distributor, third-party logistics provider, retail
21 pharmacy that conducts wholesale distribution, and pharmacy
22 warehouse that conducts wholesale distribution.

23 SECTION 2. Section 431.4031, Health and Safety Code, is
24 amended to read as follows:

25 Sec. 431.4031. EXEMPTION FROM CERTAIN PROVISIONS FOR
26 CERTAIN WHOLESAL DISTRIBUTORS. A wholesale distributor that
27 distributes prescription drugs that are medical gases or a

1 wholesale distributor that is a manufacturer or a third-party
2 logistics provider on behalf of a manufacturer is exempt from
3 Sections 431.404(a)(5) and (6), (b), [431.404(b)] and (c),
4 431.4045, 431.405, 431.407, and 431.408 [~~431.412, and 431.413~~].

5 SECTION 3. Subsections (a), (b), and (d), Section 431.404,
6 Health and Safety Code, are amended to read as follows:

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

10 (1) the name, full business address, and telephone
11 number of the applicant;

12 (2) all trade or business names under which the
13 business is conducted;

14 (3) [~~(2)~~] the address, [and] telephone number, and
15 name of a contact person for each of the applicant's places of
16 business [~~of each place of business that is licensed~~];

17 (4) [~~(3)~~] the type of business entity and:

18 (A) if the business is a sole proprietorship, the
19 name of the proprietor;

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

22 (C) if the business is a corporation, the name of
23 the corporation, the place of incorporation, and the name and title
24 of each corporate officer and director [~~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~~
10 ~~a 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 and~~[7]~~ telephone number of, and any
18 information necessary to complete a criminal history record check
19 on a designated representative of each place of business; and

20 (6) ~~[(7) the state of incorporation, if the business~~
21 ~~is a 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~~
26 ~~business].~~

27 (b) Each person listed in Subsection (a)(5) ~~[Subsections~~

1 ~~(a)(6) and (a)(9)]~~ shall provide the following to the department:

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

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

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

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

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

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

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

27 (8) a description of any misdemeanor or felony offense

1 for which the person, as an adult, was found guilty, regardless of
2 whether adjudication of guilt was withheld or whether the person
3 pled guilty or nolo contendere;

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

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

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

15 SECTION 4. Subchapter N, Chapter 431, Health and Safety
16 Code, is amended by adding Section 431.4045 to read as follows:

17 Sec. 431.4045. INSPECTION REQUIRED. The department may not
18 issue a wholesale distributor license to an applicant under this
19 subchapter unless the department:

20 (1) conducts a physical inspection of the place of
21 business at the address provided by the applicant under Section
22 431.404; and

23 (2) determines that the designated representative of
24 the place of business meets the qualifications required by Section
25 431.405.

26 SECTION 5. Section 431.405, Health and Safety Code, is
27 amended to read as follows:

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

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

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

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

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

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

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

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

1 substances; and

2 (8) not have been convicted of a felony under a
3 federal, state, or local law.

4 SECTION 6. Section 431.408, Health and Safety Code, is
5 amended by adding Subsections (a-1) and (c-1) to read as follows:

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

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

11 SECTION 7. Subchapter N, Chapter 431, Health and Safety
12 Code, is amended by adding Section 431.4095 to read as follows:

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

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

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

22 SECTION 8. Subchapter N, Chapter 431, Health and Safety
23 Code, is amended by adding Sections 431.4101 and 431.4102 to read as
24 follows:

25 Sec. 431.4101. CONTINUING TRAINING. Designated
26 representatives identified in Section 431.404(a)(5) shall
27 successfully complete continuing training regarding applicable

1 federal and state laws governing the wholesale distribution of
2 prescription drugs as required by department rule.

3 Sec. 431.4102. CONFIDENTIALITY. Information provided
4 under Section 431.404 may not be disclosed to any person other than
5 the department for licensing or monitoring purposes.

6 SECTION 9. Section 431.411, Health and Safety Code, is
7 amended by amending Subsection (a) and adding Subsections (a-1),
8 (a-2), and (e) to read as follows:

9 (a) A wholesale distributor shall receive prescription drug
10 returns or exchanges from a pharmacy or [~~chain~~] pharmacy warehouse
11 in accordance with the terms and conditions of the agreement
12 between the wholesale distributor and the pharmacy or [~~chain~~]
13 pharmacy warehouse. An expired, damaged, recalled, or otherwise
14 nonsalable prescription drug that is returned to the wholesale
15 distributor may be distributed by the wholesale distributor only to
16 either the original manufacturer or a third-party returns
17 processor. The returns or exchanges, salable or otherwise,
18 received by the wholesale distributor as provided by this
19 subsection, including any redistribution of returns or exchanges by
20 the wholesale distributor, are not subject to the pedigree
21 requirement under Section 431.412 if the returns or exchanges are
22 exempt from pedigree under:

23 (1) Section 503, Prescription Drug Marketing Act of
24 1987 (21 U.S.C. Section 353(c)(3)(B));

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

27 (3) the interpretations of that Act set out in the

1 compliance policy guide of the United States Food and Drug
2 Administration.

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

9 (a-2) Notwithstanding any provision of state or federal law
10 to the contrary, a person that has not otherwise been required to
11 obtain a wholesale license under this subchapter and that is a
12 pharmacy engaging in the sale or transfer of expired, damaged,
13 returned, or recalled prescription drugs to the originating
14 wholesale distributor or manufacturer and pursuant to federal
15 statute, rules, and regulations, including the United States Food
16 and Drug Administration's applicable guidances implementing the
17 Prescription Drug Marketing Act of 1987 (Pub. L. No. 100-293), is
18 exempt from wholesale licensure requirements under this
19 subchapter.

20 (e) A manufacturer or wholesale distributor may not accept
21 payment for, or allow the use of a person's credit to establish an
22 account for the purchase of, prescription drugs from any person
23 other than the owner of record, the chief executive officer, or the
24 chief financial officer listed on the license of a person legally
25 authorized to receive prescription drugs. Any account for the
26 purchase of prescription drugs must be established in the name of
27 the license holder or the license holder's professional entity, as

1 that term is defined by Section 301.003, Business Organizations
2 Code. This subsection does not prohibit a pharmacy or pharmacy
3 warehouse from receiving prescription drugs where the payment for
4 the prescription drugs is processed through the pharmacy's or
5 pharmacy warehouse's contractual wholesale distributor.

6 SECTION 10. Section 431.412, Health and Safety Code, is
7 amended by amending Subsections (a) and (d) and adding Subsection
8 (b-1) to read as follows:

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

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

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

25 SECTION 11. Section 431.413, Health and Safety Code, is
26 amended by amending Subsections (a), (c), and (e) and adding
27 Subsection (e-1) to read as follows:

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

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

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

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

19 (3) [~~(4)~~] the transaction dates; and

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

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 not
26 later than the fifth business day after the date [~~on~~] a request is
27 submitted by the department or a peace officer in this state.

1 (e) The department shall:

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

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

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

11 (e-1) If, after consulting with manufacturers,
12 distributors, and pharmacies responsible for the sale and
13 distribution of prescription drugs in this state, the department
14 determines that electronic track and trace pedigree technology is
15 universally available across the entire prescription
16 pharmaceutical supply chain, the department shall establish a
17 targeted implementation date for electronic track and trace
18 pedigree technology. After the department has established a
19 targeted implementation date, the department may revise the date.
20 The targeted implementation date may not be earlier than July 1,
21 2010.

22 SECTION 12. Section 431.414, Health and Safety Code, is
23 amended by adding Subsection (a-1) to read as follows:

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

27 SECTION 13. Section 431.415, Health and Safety Code, is

1 amended by amending Subsection (a) and adding Subsection (a-1) to
2 read as follows:

3 (a) Except as provided by Subsection (a-1), the [The]
4 commissioner of state health services shall issue an order
5 requiring a person, including a [~~manufacturer,~~] distributor[~~,~~] or
6 retailer of a prescription drug, to immediately cease distribution
7 of the drug if the commissioner determines there is a reasonable
8 probability that:

9 (1) a wholesale distributor has:

10 (A) violated this subchapter;

11 (B) falsified a pedigree; or

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

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

18 (a-1) This section does not authorize the commissioner of
19 state health services to issue a cease and desist order against a
20 manufacturer.

21 SECTION 14. Subchapter N, Chapter 431, Health and Safety
22 Code, is amended by adding Sections 431.416 and 431.417 to read as
23 follows:

24 Sec. 431.416. PROHIBITED ACTS. (a) The following acts and
25 the causing of or aiding or abetting of the following acts within
26 this state are unlawful and prohibited:

27 (1) the failure to obtain a license in accordance with

- 1 this subchapter;
- 2 (2) operating without a valid license when a license
3 is required by this subchapter;
- 4 (3) the purchase or receipt of a prescription drug
5 from a pharmacy in violation of Section 431.411(a) or (a-1);
- 6 (4) if a license is required under Section 431.411(b),
7 the sale, distribution, or transfer of a prescription drug to a
8 person who is not authorized under the laws of the jurisdiction in
9 which the person receives the prescription drug to receive the
10 prescription drug;
- 11 (5) the failure to deliver a prescription drug to a
12 specified premise, as required by Section 431.411(c);
- 13 (6) accepting payment or credit for the sale of a
14 prescription drug in violation of Section 431.411(e);
- 15 (7) the failure to maintain or provide a pedigree as
16 required by this subchapter;
- 17 (8) the failure to obtain, pass, or authenticate a
18 pedigree as required by this subchapter;
- 19 (9) providing this state or a representative of this
20 state or a federal official with a false or fraudulent record
21 regarding any matter covered under this subchapter;
- 22 (10) making a false or fraudulent statement regarding
23 any matter covered under this subchapter;
- 24 (11) obtaining or attempting to obtain a prescription
25 drug by fraud, deceit, or misrepresentation;
- 26 (12) engaging in misrepresentation or fraud in the
27 distribution of a prescription drug;

1 (13) except for a manufacturer's wholesale
2 distribution of a prescription drug that has been delivered into
3 commerce pursuant to an application approved under federal law by
4 the United States Food and Drug Administration, the manufacture,
5 repacking, sale, transfer, delivery, or holding of, or offering for
6 sale, any prescription drug that is adulterated, misbranded,
7 counterfeit, or suspected of being counterfeit or has otherwise
8 been rendered unfit for distribution;

9 (14) except for a manufacturer's wholesale
10 distribution of a prescription drug that has been delivered into
11 commerce pursuant to an application approved under federal law by
12 the United States Food and Drug Administration, the adulteration,
13 misbranding, or counterfeiting of any prescription drug;

14 (15) the receipt of a prescription drug that is
15 adulterated, misbranded, stolen, obtained by fraud or deceit,
16 counterfeit, or suspected of being counterfeit, and the delivery or
17 proffered delivery of such a drug for payment or otherwise; and

18 (16) the alteration, mutilation, destruction,
19 obliteration, or removal of all or any part of the labeling of a
20 prescription drug or the commission of any other act with respect to
21 a prescription drug that results in the prescription drug being
22 misbranded.

23 (b) Subsection (a) does not apply to a prescription drug
24 manufacturer, or an agent of a prescription drug manufacturer, who
25 is obtaining or attempting to obtain a prescription drug for the
26 sole purpose of testing the prescription drug for authenticity.

27 Sec. 431.417. CRIMINAL PENALTIES. (a) A person commits an

1 offense if the person knowingly or with criminal negligence engages
2 in the wholesale distribution of prescription drugs in violation of
3 this subchapter.

4 (b) Except as otherwise provided by this section, an offense
5 under this section is a felony punishable by imprisonment for a term
6 not to exceed 15 years, a fine not to exceed \$50,000, or both
7 imprisonment and a fine.

8 (c) If it is shown on the trial of an offense under this
9 section that the person knowingly engaged in the wholesale
10 distribution of prescription drugs in violation of this subchapter,
11 the offense is a felony punishable by imprisonment for a term of not
12 more than 99 years or less than 15 years, a fine not to exceed
13 \$500,000, or both imprisonment and a fine.

14 (d) If conduct constituting an offense under this section
15 also constitutes an offense under any other law, the actor may be
16 prosecuted under this section, the other law, or both.

17 SECTION 15. Subsections (a-1) and (a-2), Section 431.059,
18 and Subsections (b) and (c), Section 431.412, Health and Safety
19 Code, are repealed.

20 SECTION 16. The executive commissioner of the Health and
21 Human Services Commission shall adopt the rules necessary to
22 implement the changes in law made by this Act not later than
23 December 1, 2007.

24 SECTION 17. The change in law made by this Act applies only
25 to an offense committed on or after the effective date of this Act.
26 An offense committed before the effective date of this Act is
27 covered by the law in effect when the offense was committed, and the

1 former law is continued in effect for that purpose. For purposes of
2 this section, an offense was committed before the effective date of
3 this Act if any element of the offense was committed before that
4 date.

5 SECTION 18. This Act takes effect September 1, 2007.