By: Janek S.B. No. 943

(In the Senate - Filed February 27, 2007; March 7, 2007, read first time and referred to Committee on Health and Human Services; April 2, 2007, reported adversely, with favorable Committee Substitute by the following vote: Yeas 9, Nays 0; April 2, 2007, sent to printer.)

COMMITTEE SUBSTITUTE FOR S.B. No. 943 By: Janek

A BILL TO BE ENTITLED
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 (5) and (11) and adding Subdivisions (3-a), (3-b), (4-a), (4-b), (10-a), and (12) to read as follows:

(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, in which:

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

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

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

(4-a) "Manufacturer" means a person licensed or approved by the United States Food and Drug Administration to engage in the manufacture of drugs or devices, consistent with the federal agency's definition of "manufacturer" under the agency's regulations and guidances implementing the Prescription Drug Marketing Act of 1987 (Pub. L. No. 100-293).

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

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

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

(i) a patient; or

(ii) another designated person authorized

by law to dispense or administer the drug [~~practitioner~~] to a patient;

(B) a wholesale distributor to:

(i) a pharmacy to a patient; or

(ii) another designated person authorized by law to dispense or administer the drug [~~a manufacturer to an authorized distributor of record to one other authorized distributor of record to a pharmacy or practitioner~~] to a patient; [~~or~~]

(C) a wholesale distributor [~~a manufacturer to an authorized distributor of record~~] to a chain pharmacy warehouse to the chain pharmacy warehouse's intracompany pharmacy or other designated person authorized by law to dispense or administer the drug [~~a pharmacy or practitioner~~] to a patient; or

(D) an authorized prescriber of a drug that, by law, may be administered only under the supervision of the prescriber.

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

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

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

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

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

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

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

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

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

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

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

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

(I) the delivery of, or offer to deliver, a

prescription drug by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs, if the common carrier does not store, warehouse, or take legal ownership of the prescription drug; or

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

(12) "Wholesale distributor" means a person engaged in the wholesale distribution of prescription drugs, including a manufacturer, repackager, own-label distributor, private-label distributor, jobber, broker, manufacturer warehouse, distributor warehouse, or other warehouse, manufacturer's exclusive distributor, authorized distributor of record, drug wholesaler or distributor, independent wholesale drug trader, specialty wholesale distributor, third-party logistics provider, retail pharmacy that conducts wholesale distribution, and chain pharmacy warehouse that conducts wholesale distribution. A wholesale distributor must be an authorized distributor of record to be considered part of the normal distribution channel.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[~~(6)~~] the name and[~~,~~] telephone number of, and any

information necessary to complete a criminal history record check on, a designated representative of each place of business; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) be at least 21 years of age;

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

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

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

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

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

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

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

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

(a-1) A chain pharmacy warehouse that engages only in intracompany transfers is exempt from the bond requirement under Subsection (a).

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

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

Sec. 431.4095. RENEWAL NOTIFICATION; CHANGE OR RENEWAL. (a) Before the expiration of a license issued under this subchapter, the department shall send to each licensed wholesale distributor a form containing a copy of the information the distributor provided to the department under Section 431.404.

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

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

Sec. 431.4101. CONTINUING EDUCATION. Designated representatives identified in Section 431.404(a)(5) shall successfully complete continuing education training regarding applicable federal and state laws governing the wholesale distribution of prescription drugs as required by department rule.

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

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

(a) A wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy or chain pharmacy warehouse in accordance with the terms and conditions of the agreement between the wholesale distributor and the pharmacy or chain pharmacy warehouse. An expired, damaged, recalled, or otherwise nonsalable prescription drug that is returned to the wholesale distributor may be distributed by the wholesale distributor only to either the original manufacturer or a third-party returns processor. The returns or exchanges, salable or otherwise, received by the wholesale distributor as provided by this subsection, including any redistribution of returns or exchanges by the wholesale distributor, are not subject to the pedigree requirement under

Section 431.412 if the returns or exchanges are exempt from pedigree under:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(c) Each pedigree statement must be:

(1) maintained by the purchaser and the wholesale

distributor for at least three years; and

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

(e) The department shall:

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

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

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

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

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

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

SECTION 13. Section 431.415, Health and Safety Code, is amended by amending Subsection (a) and adding Subsection (a-1) to read as follows:

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

(1) a wholesale distributor has:

(A) violated this subchapter;

(B) falsified a pedigree; or

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

(2) other procedures would result in unreasonable delay.

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

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

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

(1) the failure to obtain a license in accordance with this subchapter;

(2) operating without a valid license when a license is required by this subchapter;

(3) the purchase or receipt of a prescription drug from a pharmacy in violation of Section 431.411(a) or (a-1);

(4) if a license is required under Section 431.411(b), the sale, distribution, or transfer of a prescription drug to a person who is not authorized under the laws of the jurisdiction in which the person receives the prescription drug to receive the prescription drug;

(5) the failure to deliver a prescription drug to a specified premise, as required by Section 431.411(c);

(6) accepting payment or credit for the sale of a prescription drug in violation of Section 431.411(e);

(7) the failure to maintain or provide a pedigree as required by this subchapter;

(8) the failure to obtain, pass, or authenticate a pedigree as required by this subchapter;

(9) providing this state or a representative of this state or a federal official with a false or fraudulent record regarding any matter covered under this subchapter;

(10) making a false or fraudulent statement regarding any matter covered under this subchapter;

(11) obtaining or attempting to obtain a prescription drug by fraud, deceit, or misrepresentation;

(12) engaging in misrepresentation or fraud in the distribution of a prescription drug;

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

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

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

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

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

Sec. 431.417. CRIMINAL PENALTIES. (a) A person commits an offense if the person engages in the wholesale distribution of prescription drugs in violation of this subchapter.

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

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

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

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

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

SECTION 17. The change in law made by this Act applies only to an offense committed on or after the effective date of this Act. An offense committed before the effective date of this Act is covered by the law in effect when the offense was committed, and the former law is continued in effect for that purpose. For purposes of

this section, an offense was committed before the effective date of this Act if any element of the offense was committed before that date.

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

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