Chapter 980

S.B. No. 943

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

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

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

(f) the dissemination of any false advertisement;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

federal Act;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(jj) 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; or

(kk) 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.

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

Sec. 431.0211. EXCEPTION. Any provision of Section 431.021 that relates to a prescription drug 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.

SECTION 3. 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, in which:

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

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

(C) the pharmacy, 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). The term does not include a pharmacist engaged in compounding that is done within the practice of pharmacy and pursuant to a prescription drug order or

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

(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 [~~or practitioner~~] to:

(i) a patient; or

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

(B) an authorized distributor of record to:

(i) a pharmacy to a patient; or

(ii) another designated person authorized

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

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

[~~or~~]

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

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

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

(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, or any transaction or transfer between co-license holders of a co-licensed product [~~of a corporate entity~~];

(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, or trade of a drug, or the offer to sell, purchase, or trade a drug, for emergency medical reasons, including a transfer of a prescription drug by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

(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 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 pharmacy warehouse that conducts wholesale distribution.

SECTION 4. 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(2), 431.405, 431.407, and 431.408[~~, 431.412, and 431.413~~].

SECTION 5. 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 180 [~~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 6. 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 or determines that an inspection is unnecessary after thoroughly evaluating the information in the application, the compliance history of the applicant and the applicant's principals, and the risk of counterfeiting in the applicant's product; and

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

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

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

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

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

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

(b) In addition to meeting the minimum federal requirements as provided by Subsection (a), to [~~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, as the department determines reasonable, 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 8. Section 431.408, Health and Safety Code, is amended by adding Subsections (a-1) and (c-1) to read as follows:

(a-1) A pharmacy warehouse that is not engaged in wholesale distribution 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 9. 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 10. Section 431.411, Health and Safety Code, is amended by amending Subsection (a) and adding Subsections (a-1) and (a-2) 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 guide 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.

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

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

SECTION 11. 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 for human consumption 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 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 12. 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, 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 second 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 a targeted implementation date for electronic track and trace pedigree technology. After the department has established a targeted implementation date, the department may revise the date. The targeted implementation date may not be earlier than July 1, 2010.

SECTION 13. 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 14. Subsections (a-1) and (a-2), Section 431.059, and Subsections (b) and (c), Section 431.412, Health and Safety

Code, are repealed.

SECTION 15. 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 May 1, 2008.

SECTION 16. 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 17. This Act takes effect September 1, 2007.

David Dewhurst
President of the Senate

Tom Craddick
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.

Patsy Spaw
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.

Robert Haney
Chief Clerk of the House

Approved:

15 JUN 07
Date

Rick Perry
Governor

FILED IN THE OFFICE OF THE
SECRETARY OF STATE
6:00 PM O'CLOCK
JUN 15 2007
Roger Williams
Secretary of State