S-0797.1

SENATE BILL 5631

State of Washington 60th Legislature 2007 Regular Session

By Senators Keiser and Pflug

Read first time 01/26/2007. Referred to Committee on Health & Long-Term Care.

AN ACT Relating to the wholesale distribution of prescription drugs; adding a new chapter to Title 19 RCW; and prescribing penalties.

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

NEW SECTION. **Sec. 1.** The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

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

(2) "Authorized distributor of record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. An ongoing relationship is deemed to exist between such a wholesale distributor and a manufacturer when the wholesale distributor, including any affiliated group of the wholesale distributor, as defined in section 1504 of the internal revenue code, complies with any one of the following: (a) The wholesale distributor has a written agreement currently in effect with the manufacturer evidencing such an ongoing relationship; and (b) the wholesale distributor is listed on the

manufacturer's current list of authorized distributors of record, which is updated by the manufacturer on no less than a monthly basis.

(3) "Drop shipment" means the sale of a prescription drug to a wholesale distributor by the manufacturer of the prescription drug, or that manufacturer's colicensed product partner, that manufacturer's third-party logistics provider, or that manufacturer's exclusive distributor, whereby the wholesale distributor or chain pharmacy warehouse takes title but not physical possession of such a prescription drug and the wholesale distributor invoices the pharmacy or chain pharmacy warehouse, or other person authorized by law to dispense or administer such a drug to a patient, and the pharmacy or chain pharmacy warehouse or other authorized person receives delivery of the prescription drug directly from the manufacturer, that manufacturer's third-party logistics provider, or that manufacturer's exclusive distributor.

(4) "Chain pharmacy warehouse" means a physical location for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of the drugs to a group of chain pharmacies that have the same common ownership and control.

(5) "Colicensed product" means a prescription drug in which two or more parties have the right to engage in the manufacturing or marketing of such a drug.

(6) "Facility" means a facility of a wholesale distributor where prescription drugs are stored, handled, repackaged, or offered for sale.

(7) "Manufacturer" means a person licensed or approved by the federal food and drug administration to engage in the manufacture of drugs or devices.

(8) "Manufacturer's exclusive distributor" means anyone who contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer and who takes title to that manufacturer's prescription drug, but who does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug. A manufacturer's exclusive distributor must be licensed as a wholesale distributor under this chapter, and to be considered part of the normal distribution channel must also be an authorized distributor of record.

(9) "Normal distribution channel" means a chain of custody for a prescription drug that goes from a manufacturer of the prescription drug, from that manufacturer to that manufacturer's colicensed partner, from that manufacturer to that manufacturer's third-party logistics provider, or from that manufacturer to that manufacturer's exclusive distributor to:

(a) A pharmacy to a patient or other designated person authorized by law to dispense or administer the drug to a patient;

(b) A wholesale distributor to a pharmacy to a patient or other designated person authorized by law to dispense or administer the drug to a patient;

(c) A wholesale distributor to a chain pharmacy warehouse to that chain pharmacy warehouse's intracompany pharmacy to a patient or other designated person authorized by law to dispense or administer the drug to a patient; or

(d) A chain pharmacy warehouse to the chain pharmacy warehouse's intracompany pharmacy to a patient or other designated person authorized by law to dispense or administer the drug to a patient.

(10) "Pedigree" means a document or electronic file containing information that records each distribution of any given prescription drug.

(11) "Prescription drug" means any drug (including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices) required by federal law or federal regulation to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to section 503(b) of the federal food, drug, and cosmetic act.

(12) "Repackage" means repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of a prescription drug excluding that completed by the pharmacists responsible for dispensing the product to the patient.

(13) "Repackager" means a person who repackages.

(14) "Third-party logistics provider" means anyone who contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer, but does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition. The third-party logistics provider must be licensed as a

wholesale distributor under this chapter, and to be considered part of the normal distribution channel must also be an authorized distributor of record.

(15) "Wholesale distributor" means anyone engaged in the wholesale distribution of prescription drugs, including, but not limited to: Manufacturers; repackagers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses; manufacturer's exclusive distributors; authorized distributors of record; drug wholesalers or distributors; independent wholesale drug traders; specialty wholesale distributors; third-party logistics providers; retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution. To be considered part of the normal distribution channel the wholesale distributor must also be an authorized distributor of record.

(16) "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(a) Intracompany sales of prescription drugs, meaning any transaction or transfer between any division, subsidiary, parent, or affiliated or related company under common ownership and control of a corporate entity, or any transaction or transfer between colicensees of a colicensed product;

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

(c) The distribution of prescription drug samples by manufacturers' representatives;

(d) Drug returns, when conducted by a hospital, health care entity, or charitable institution in accordance with 21 C.F.R. Sec. 203.23;

(e) The sale of minimal quantities of prescription drugs by retail pharmacies to licensed practitioners 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 pursuant to a prescription;

(g) The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy or pharmacies from or with another pharmacy

or pharmacies, 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 when the manufacturer has stated in writing to the receiving authorized distributor of record that the manufacturer is unable to supply the prescription drug and the supplying authorized distributor of record 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, and the common carrier does not store, warehouse, or take legal ownership of the prescription drug;

(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.

NEW SECTION. **Sec. 2.** (1) Every wholesale distributor who engages in the wholesale distribution of prescription drugs must be licensed by the department of licensing, and every nonresident wholesale distributor must be licensed by the department of licensing if it ships prescription drugs into this state, in accordance with this chapter before engaging in wholesale distributions of wholesale prescription drugs. The department of licensing shall exempt manufacturers distributing their own United States food and drug administration-approved drugs and devices from any licensing and other requirements of this section, to the extent not required by federal law or regulation, unless particular requirements are deemed necessary and appropriate by rule.

(2) The department of licensing shall require the following minimum information from each wholesale distributor applying to get a license under subsection (1) of this section:

(a) The name, full business address, and telephone number of the licensee;

(b) All trade or business names used by the licensee;

(c) Addresses, telephone numbers, and the names of contact persons

for all facilities used by the licensee for the storage, handling, and distribution of prescription drugs;

(d) The type of ownership or operation;

(e) The name or names of the owner or operator of the licensee, including:

(i) If a person, the name of the person;

(ii) If a partnership, the name of each partner, and the name of the partnership;

(iii) If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation; and

(iv) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity;

(f) A list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to purchase or possess prescription drugs;

(g) The name of the applicant's designated representative for the facility, together with the personal information statement and fingerprints required under (h) of this subsection for the person;

(h) Each person required by (g) of this subsection to provide a personal information statement and fingerprints must provide the following information to the department of licensing:

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

(ii) The person's date and place of birth;

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

(iv) The principal business and address of any business, corporation, or other organization in which each office of the person was held or in which each occupation or position of employment was carried on;

(v) Whether during the past seven years the person has been the subject of any proceeding for the revocation of any license or any criminal violation and, if so, the nature of the proceeding and the disposition of the proceeding;

(vi) Whether during the past seven years the person has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any federal or state law regulating the

possession, control, or distribution of prescription drugs or criminal violations, together with details concerning such an event;

(vii) A description of any involvement by the person 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 such businesses were named as a party;

(viii) A description of any misdemeanor or felony criminal offense of 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. If the person indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of that criminal offense, the applicant must, within fifteen days after the disposition of the appeal, submit to the department of licensing a copy of the final written order of disposition; and

(ix) A photograph of the person taken in the previous thirty days.

(3) The information required under subsection (2) of this section must be provided under oath.

(4) The department of licensing shall not issue a wholesale distributor license to an applicant unless the department of licensing:

(a) Conducts a physical inspection of the facility at the address provided by the applicant as required in subsection (2)(a) of this section; and

(b) Determines that the designated representative meets the following qualifications:

(i) Is at least twenty-one years of age;

(ii) Has been employed full time for at least three years in a pharmacy or with a wholesale distributor in a capacity related to the dispensing and distribution of, and recordkeeping relating to, prescription drugs;

(iii) Is employed by the applicant full time in a managerial level position;

(iv) Is actively involved in and aware of the actual daily operation of the wholesale distributor;

(v) Is physically present at the facility of the applicant during regular business hours, except when the absence of the designated

representative is authorized, including but not limited to, sick leave and vacation leave;

(vi) Is serving in the capacity of a designated representative for only one applicant at a time, except where more than one licensed wholesale distributor is colocated in the same facility and the wholesale distributors are members of an affiliated group, as defined in section 1504 of the internal revenue code;

(vii) Does not have any convictions under any federal, state, or local laws relating to wholesale or retail prescription drug distribution or distribution of controlled substances; and

(viii) Does not have any felony convictions under federal, state, or local laws.

(5) The department of licensing shall submit the fingerprints provided by a person with a license application for a statewide criminal record check and for forwarding to the federal bureau of investigation for a national criminal record check of the person.

(6) The department of licensing shall require every wholesale distributor applying for a license to submit a bond of at least one hundred thousand dollars, or other equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to a fund established by the department of licensing under subsection (7) of this section. Chain pharmacy warehouses that are engaged only in intracompany transfers are exempt from the bond requirement. The purpose of the bond is to secure payment of any fines or penalties imposed by the department of licensing and any fees and costs incurred by the department of licensing regarding that license, which are authorized under state law and which the licensee fails to pay thirty days after the fines, penalties, or costs become final. The department of licensing may make a claim against such a bond or security until one year after the licensee's license ceases to be valid. A single bond may suffice to cover all facilities operated by the applicant in the state.

(7) The department of licensing shall establish a fund, separate from its other accounts, in which to deposit the wholesale distributor bonds.

(8) If a wholesale distributor distributes prescription drugs from

more than one facility, the wholesale distributor shall obtain a license for each facility.

(9) In accordance with each licensure renewal, the department of licensing shall send to each wholesale distributor licensed under this section a form setting forth the information that the wholesale distributor provided under subsection (2) of this section. Within thirty days of receiving such a form, the wholesale distributor must identify and state under oath to the department of licensing all changes or corrections to the information that was provided under subsection (2) of this section. Changes in, or corrections to, any information in subsection (2) of this section must be submitted to the department of licensing as required by the department. The department of licensing may suspend or revoke the license of a wholesale distributor if the department determines that the wholesale distributor no longer qualifies for the license issued under this section.

(10) The designated representative identified under subsection (2)(g) of this section must receive and complete continuing training in applicable federal and state laws governing wholesale distribution of prescription drugs.

(11) Information provided under this section may not be disclosed to any person or entity other than the department of licensing.

NEW SECTION. **Sec. 3.** (1) A wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy or chain pharmacy warehouse pursuant to the terms and conditions of the agreement between the wholesale distributor and the pharmacy or chain pharmacy warehouse, including the returns of expired, damaged, and recalled pharmaceutical product to either the original manufacturer or a third-party returns processor, and such returns or exchanges are not subject to the pedigree requirement of section 4 of this act, as long as they are exempt from pedigree under the United States food and drug administration's currently applicable prescription drug marketing act guidance. Wholesale distributors and pharmacies shall be held accountable for administering their returns process and ensuring that the aspects of this operation are secure and do not permit the entry of adulterated and counterfeit product.

(2) A manufacturer or wholesale distributor shall furnish prescription drugs only to a person licensed by the department of

licensing. Before furnishing prescription drugs to a person not known to the manufacturer or wholesale distributor, the manufacturer or wholesale distributor shall affirmatively verify that the person is legally authorized to receive the prescription drugs by contacting the department of licensing.

(3) Prescription drugs furnished by a manufacturer or wholesale distributor must be delivered only to the premises listed on the license. However, the manufacturer or wholesale distributor may furnish prescription drugs to an authorized person or agent of that person at the premises of the manufacturer or wholesale distributor if:

(a) The identity and authorization of the recipient is properly established; and

(b) This method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person.

(4) Prescription drugs may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the prescription drug so received. Any discrepancy between receipt and the type and quantity of the prescription drug actually received must be reported to the delivering manufacturer or wholesale distributor by the next business day after the delivery to the pharmacy receiving area.

(5) A manufacturer or wholesale distributor may not accept payment for, or allow the use of, a person or entity'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 or entity legally authorized to receive prescription drugs. Any account established for the purchase of prescription drugs must bear the name of the licensee.

NEW SECTION. **Sec. 4.** (1) Each person who is engaged in wholesale distribution of prescription drugs, including repackagers, but excluding the original manufacturer of the finished form of the prescription drug, that leaves, or has ever left, the normal distribution channel shall before each wholesale distribution of the drug provide a pedigree to the person who receives the drug.

(a) A retail pharmacy or chain pharmacy warehouse must comply with

the requirements of this section only if the pharmacy or chain pharmacy warehouse engages in wholesale distribution of prescription drugs.

(b) The board of pharmacy created under RCW 18.64.001 shall determine by July 1, 2009, a targeted implementation date for electronic track and trace pedigree technology. Such a determination must be based on consultation with manufacturers, distributors, and pharmacies responsible for the sale and distribution of prescription drug products in the state. After consultation with interested stakeholders and prior to implementation of the electronic pedigree, the board of pharmacy shall deem that the technology is universally available across the entire prescription pharmaceutical supply chain. The implementation date for the mandated electronic track and trace pedigree technology may be no sooner than July 1, 2010, and may be extended by the board of pharmacy in one-year increments if it appears the technology is not universally available across the entire prescription pharmaceutical supply chain.

(2) Each person who is engaged in the wholesale distribution of a prescription drug, including repackagers, but excluding the original manufacturer of the finished form of the prescription drug, who is provided a pedigree for a prescription drug and attempts to further distribute that prescription drug, shall affirmatively verify before any distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred.

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

(i) The name, address, telephone number, and if available, the electronic mail address, of each owner of the prescription drug, and each wholesale distributor of the prescription drug;

(ii) The name and address of each location from which the product was shipped, if different from the owner's name and address;

(iii) Transaction dates; and

(iv) Certification that each recipient has authenticated the pedigree.

(b) At minimum, the pedigree must also include the:

(i) Name of the prescription drug;

(ii) Dosage form and strength of the prescription drug;

(iii) Size of the container;

(iv) Number of containers;

(v) Lot number of the prescription drug; and

(vi) Name of the manufacturer of the finished dosage form.

(4) Each pedigree or electronic file must be:

(a) Maintained by the purchaser and the wholesale distributor for three years from the date of sale or transfer; and

(b) Available for inspection or use within five business days upon a request of an authorized peace officer.

(5) The department of licensing shall adopt rules and a form relating to the requirements of this section no later than ninety days after the effective date of this section.

NEW SECTION. **Sec. 5.** (1)(a) If the department of licensing finds that there is a reasonable probability that a wholesale distributor, other than a manufacturer, has:

(i) Violated a provision in this chapter; or

(ii) Falsified a pedigree, or sold, distributed, transferred, manufactured, repackaged, handled, or held a counterfeit prescription drug intended for human use; and

(b)(i) The prescription drug at issue as a result of a violation in (a) of this subsection could cause serious, adverse health consequences or death; and

(ii) Other procedures would result in unreasonable delay;

the department of licensing shall issue an order requiring the appropriate person, including the distributors or retailers of the drug, to immediately cease distribution of the drug within that state.

(2) An order under subsection (1) of this section shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than ten days after the date of the issuance of the order, on the actions required by the order. If, after providing an opportunity for such a hearing, the department of

licensing determines that inadequate grounds exist to support the actions required by the order, the department of licensing shall vacate the order.

NEW SECTION. **Sec. 6.** (1) It is unlawful for a person to perform or cause the performance of or aid and abet any of the following acts:

(a) Failure to obtain a license in accordance with this chapter, or operating without a valid license when a license is required by this chapter;

(b) If the requirements of section 3(1) of this act are applicable and are not met, the purchasing or otherwise receiving a prescription drug from a pharmacy;

(c) If a license is required under section 3(2) of this act, the sale, distribution, or transfer of a prescription drug to a person that is not authorized under the law of the jurisdiction in which the person receives the prescription drug to receive the prescription drug;

(d) Failure to deliver prescription drugs to specified premises, as required by section 3(3) of this act;

(e) Accepting payment or credit for the sale of prescription drugs in violation of section 3(5) of this act;

(f) Failure to maintain or provide pedigrees as required by this chapter;

(g) Failure to obtain, pass, or authenticate a pedigree, as required by this chapter;

(h) Providing the department of licensing or any of its representatives or any federal official with false or fraudulent records or making false or fraudulent statements regarding any matter within the provisions of this chapter;

(i) Obtaining or attempting to obtain a prescription drug by fraud, deceit, or misrepresentation or engaging in misrepresentation or fraud in the distribution of a prescription drug;

(j) Except for the wholesale distribution by manufacturers 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, holding, or offering for sale of any prescription drug that is adulterated, misbranded, counterfeit, suspected of being counterfeit, or has otherwise been rendered unfit for distribution;

(k) Except for the wholesale distribution by manufacturers 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;

(l) The receipt of any 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 pay or otherwise; and

(m) 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.

(2) The prohibited acts listed under subsection (1) of this section do not include a prescription drug manufacturer, or agent of a prescription drug manufacturer, obtaining or attempting to obtain a prescription drug for the sole purpose of testing the prescription drug for authenticity.

NEW SECTION. **Sec. 7.** (1) If a person engages in the wholesale distribution of prescription drugs in violation of this chapter, the person may be either imprisoned for not more than fifteen years or fined not more than fifty thousand dollars, or both.

(2) If a person knowingly engages in wholesale distribution of prescription drugs in violation of this chapter, the person shall be either imprisoned for any term of years or fined not more than five hundred thousand dollars, or both.

NEW SECTION. **Sec. 8.** Sections 1 through 7 of this act constitute a new chapter in Title 19 RCW.

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