S-3924.2

SENATE BILL 6591

State of Washington 59th Legislature 2006 Regular Session

By Senators Keiser and Deccio

Read first time 01/16/2006. Referred to Committee on Health & Long-Term Care.

AN ACT Relating to the distribution of dangerous drugs; amending RCW 18.64.011 and 18.64.046; creating a new section; prescribing penalties; and declaring an emergency.

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

NEW SECTION. **Sec. 1.** (1) The legislature finds that the public assumes the prescription drugs they obtain at their local pharmacy will be safe and effective. However, the legislature also finds that there is increasing evidence of efforts by certain entities to profit from the production or distribution of dangerous or counterfeit prescription drugs. These practices may result in patients not receiving therapies that alleviate suffering and save lives.

(2) The legislature intends to minimize the public's risk of exposure to dangerous prescription drugs by enhancing the current regulatory framework, in an effort to prevent the introduction of dangerous drugs and biologics into the drug distribution chain without imposing unnecessary costs on the drug distribution system.

Sec. 2. RCW 18.64.011 and 1997 c 129 s 1 are each amended to read as follows:

Unless the context clearly requires otherwise, definitions of terms shall be as indicated when used in this chapter.

(1) "Person" means an individual, corporation, government, governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.

(2) "Board" means the Washington state board of pharmacy.

(3) "Drugs" means:

(a) Articles recognized in the official United States pharmacopoeia or the official homeopathic pharmacopoeia of the United States;

(b) Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;

(c) Substances (other than food) intended to affect the structure or any function of the body of man or other animals; or

(d) Substances intended for use as a component of any substances specified in (a), (b), or (c) of this subsection, but not including devices or their component parts or accessories.

(4) "Device" means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (a) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, or (b) to affect the structure or any function of the body of man or other animals.

(5) "Nonlegend" or "nonprescription" drugs means any drugs which may be lawfully sold without a prescription.

(6) "Legend drugs" means any drugs which are required by any applicable federal or state law or regulation to be dispensed on prescription only or are restricted to use by practitioners only.

(7) "Controlled substance" means a drug or substance, or an immediate precursor of such drug or substance, so designated under or pursuant to the provisions of chapter 69.50 RCW.

(8) "Prescription" means an order for drugs or devices issued by a practitioner duly authorized by law or rule in the state of Washington to prescribe drugs or devices in the course of his or her professional practice for a legitimate medical purpose.

(9) "Practitioner" means a physician, dentist, veterinarian, nurse, or other person duly authorized by law or rule in the state of Washington to prescribe drugs.

(10) "Pharmacist" means a person duly licensed by the Washington state board of pharmacy to engage in the practice of pharmacy.

(11) "Practice of pharmacy" includes the practice of and responsibility for: Interpreting prescription orders; the compounding, dispensing, labeling, administering, and distributing of drugs and devices; the monitoring of drug therapy and use; the initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs; the participating in drug utilization reviews and drug product selection; the proper and safe storing and distributing of drugs and devices and maintenance of proper records thereof; the providing of information on legend drugs which may include, but is not limited to, the advising of therapeutic values, hazards, and the uses of drugs and devices.

(12) "Pharmacy" means every place properly licensed by the board of pharmacy where the practice of pharmacy is conducted.

(13) The words "drug" and "devices" shall not include surgical or dental instruments or laboratory materials, gas and oxygen, therapy equipment, X-ray apparatus or therapeutic equipment, their component parts or accessories, or equipment, instruments, apparatus, or contrivances used to render such articles effective in medical, surgical, or dental treatment, or for use or consumption in or for mechanical, industrial, manufacturing, or scientific applications or purposes, nor shall the word "drug" include any article or mixture covered by the Washington pesticide control act (chapter 15.58 RCW), as enacted or hereafter amended, nor medicated feed intended for and used exclusively as a feed for animals other than man.

(14) The word "poison" shall not include any article or mixture covered by the Washington pesticide control act (chapter 15.58 RCW), as enacted or hereafter amended.

(15) "Deliver" or "delivery" means the actual, constructive, or attempted transfer from one person to another of a drug or device, whether or not there is an agency relationship.

(16) "Dispense" means the interpretation of a prescription or order for a drug, biological, or device and, pursuant to that prescription or order, the proper selection, measuring, compounding, labeling, or packaging necessary to prepare that prescription or order for delivery.

(17) "Distribute" means the delivery of a drug or device other than by administering or dispensing.

(18) "Compounding" shall be the act of combining two or more ingredients in the preparation of a prescription.

(19) "Wholesaler" shall mean a corporation, individual, or other entity which buys drugs or devices for resale and distribution to corporations, individuals, or entities other than consumers.

(20) "Manufacture" means the production, preparation, propagation, compounding, or processing of a drug or other substance or device or the packaging or repackaging of such substance or device, or the labeling or relabeling of the commercial container of such substance or device, but does not include the activities of a practitioner who, as an incident to his or her administration or dispensing such substance or device in the course of his or her professional practice, prepares, compounds, packages, or labels such substance or device.

(21) "Manufacturer" shall mean a person, corporation, or other entity engaged in the manufacture of drugs or devices.

(22) "Labeling" shall mean the process of preparing and affixing a label to any drug or device container. The label must include all information required by current federal and state law and pharmacy rules.

(23) "Administer" means the direct application of a drug or device, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject.

(24) "Master license system" means the mechanism established by chapter 19.02 RCW by which master licenses, endorsed for individual state-issued licenses, are issued and renewed utilizing a master application and a master license expiration date common to each renewable license endorsement.

(25) "Department" means the department of health.

(26) "Secretary" means the secretary of health or the secretary's designee.

(27) "Health care entity" means an organization that provides health care services in a setting that is not otherwise licensed by the state. Health care entity includes a free-standing outpatient surgery center or a free-standing cardiac care center. It does not include an individual practitioner's office or a multipractitioner clinic.

(28) "Chain drug warehouse" means a permanent physical location for drugs and/or devices that acts as a central warehouse and performs intracompany sales, and sales and transfers of drugs or devices to

chain pharmacies, which are members of the same affiliated group under common ownership and control. Chain drug warehouses must be licensed as wholesale distributors.

(29) "Designated representative" means an individual designated by the wholesale distributor who is actively involved in and aware of the actual daily operations of the wholesale distributor.

(30) "Normal distribution channel" means the route that the legend drug travels:

(a) From a manufacturer to a wholesale drug distributor, to a pharmacy, and to a patient or patient's agent;

(b) From a manufacturer to a wholesale drug distributor, to a chain drug warehouse, to a pharmacy affiliated with the chain drug warehouse, and to a patient or patient's agent;

(c) From a manufacturer to a chain drug warehouse, to a pharmacy affiliated with the chain drug warehouse, and to a patient or patient's agent;

(d) From a manufacturer to a third party logistics provider, to a wholesale drug distributor, to a pharmacy, and to a patient or patient's agent;

(e) From a manufacturer to a third party logistics provider, to a wholesale drug distributor, to a chain drug warehouse, to a pharmacy affiliated with the chain drug warehouse, and to a patient or patient's agent;

(f) From a manufacturer to a third party logistics provider, to a chain drug warehouse, to a pharmacy affiliated with the chain drug warehouse, and to a patient or patient's agent; or

(g) As prescribed by rules adopted by the board.

(31) "Pedigree" means a statement or record in a written or electronic form that is approved by the board, that records each distribution of a legend drug from the sale by the manufacturer through acquisition and sale by each wholesale drug distributor through the normal distribution channel, and includes information designated by the board through rules for each transaction. Effective December 31, 2007, pedigrees shall electronically record, for all prescription drugs, each distribution starting with the sale by a manufacturer through acquisition or sale by a wholesale distributor or third party logistics provider, until final sale to a pharmacy or other authorized person administering or dispensing the prescription drug.

(32) "Third party logistics provider" means an entity that:

(a) Provides or coordinates warehousing, distribution, or other services on behalf of a manufacturer, but does not take title to the legend drug or have general responsibility to direct the legend drug's sale or disposition; and

(b) Is licensed under this section.

Sec. 3. RCW 18.64.046 and 2005 c 388 s 6 are each amended to read as follows:

(1) The owner of each place of business which sells legend drugs and nonprescription drugs, or nonprescription drugs at wholesale shall pay a license fee to be determined by the secretary, and thereafter, on or before a date to be determined by the secretary as provided in RCW 43.70.250 and 43.70.280, a like fee to be determined by the secretary, for which the owner shall receive a license of location from the department, which shall entitle such owner to either sell legend drugs and nonprescription drugs or nonprescription drugs at wholesale at the location specified for the period ending on a date to be determined by the secretary, and each such owner shall at the time of payment of such fee file with the department, on a blank therefor provided, a declaration of ownership and location, which declaration of ownership and location so filed as aforesaid shall be deemed presumptive evidence of the ownership of such place of business mentioned therein. It shall be the duty of the owner to notify immediately the department of any change of location and ownership and to keep the license of location or the renewal thereof properly exhibited in such place of business.

(2) Entities engaged in wholesale distribution shall not be located in a place of residence.

(3) Every wholesaler, wherever located, who engages in wholesale distribution into, out of, or within this state must be licensed by the board in accordance with the laws and rules of this state before engaging in wholesale distribution.

(4) Failure to conform with this section is a misdemeanor, and each day that the failure continues is a separate offense.

((~~(3)~~)) (5) In event the license fee remains unpaid on the date due, no renewal or new license shall be issued except upon compliance with administrative procedures, administrative requirements, and fees determined as provided in RCW 43.70.250 and 43.70.280.

((~~(4)~~)) (6)(a) The board requires the following from each wholesale drug distributor as part of the initial licensing procedure and as part of any renewal of such license:

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

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

(iii) The addresses, telephone numbers, and names of contact persons for the facility used by the licensee for the storage, handling, and distribution of prescription drugs;

(iv) The type of ownership or operation (i.e. partnership, corporation, or sole proprietorship);

(v) If a partnership, corporation, or sole proprietorship, the name of the partnership, corporation, or sole proprietorship, name of any parent company, and state of registration of partnership, corporation, or sole proprietorship; and

(vi) The names, social security numbers, and criminal and financial background check information of the owners and/or operators, principal owners, or officers, including those of:

(A) Designated representatives;

(B) If a partnership, those of each partner;

(C) If a corporation, those of each corporate officer and director;

(D) If a sole proprietorship, that of the sole proprietor.

(b) Applicants for a new or renewal license as a wholesale drug distributor shall submit to the board proof of a bond or other equivalent means of security acceptable to the board, which shall be for the purpose of securing payment of any fines or other penalties imposed by the board and any fees or costs incurred by the board relating to such applicant as authorized under rules adopted under this section and which remain unpaid by the applicant within thirty days after such fines, penalties, and costs become final. The board may make a claim against such bond or security until one year after the expiration of the license issued to the applicant under this section.

(7) The board shall adopt rules for the establishment of a pedigree or electronic file to be used by wholesalers, chain pharmacy warehouses, and repackagers for the purpose of ensuring the integrity of drugs owned, purchased, distributed, returned, transferred, and sold when the products leave the normal distribution channel.

(8) Each facility that engages in wholesale distribution must undergo an inspection by the board or third party working on behalf of the board for the purpose of inspecting the wholesale distribution operations before the initial licensure and periodically thereafter in accordance with a schedule to be determined by the board not less than once every three years.

(9) The board shall be authorized to use an outside agency, such as the national association of boards of pharmacy or the verified accredited wholesale distributors, to accredit wholesale distributors and repackagers.

(10) Before the initial purchase or sale of prescription drugs to or from any wholesale distributor, or to any wholesale distribution to a wholesale distributor by a manufacturer, a wholesale distributor or manufacturer shall adhere to the due diligence standards and requirements set by the board. The board may waive the due diligence requirements if the information has been verified by a third party working on behalf of the board.

(11) The board may exempt, by rule, wholesalers accredited by the verified accredited wholesale distributors from some of the provisions of subsection (6) of this section.

(12) In adopting the rules, the board shall seek input from manufacturers, wholesale distributors, chain pharmacy warehouses, and repackagers.

(13) A wholesaler's license may be denied, refused renewal, suspended, limited or revoked if the applicant or licensee has violated any rules adopted by the board of pharmacy under this section.

(a) A person is guilty of a class C felony if he or she:

(i) With intent to defraud or deceive, performs the act of adulteration, misbranding, or counterfeiting of any drug or device;

(ii) With intent to defraud or deceive, fails to deliver or acquire, alters, destroys, conceals, forges, counterfeits, or otherwise fails to maintain a complete and accurate pedigree, when required;

(iii) Knowingly purchases, receives, sells, acquires, or transfers a drug or device from a person not legally authorized to distribute the drug or device;

(iv) Knowingly counterfeits, or falsely creates any label for a drug or device, or falsely represents any factual matter contained in any label of a drug or device; or

(v) Knowingly manufactures, purchases, sells, delivers, or brings into the state, or is in actual or constructive possession of any amount of drug or device prohibited by law.

(b) A person is guilty of a class A felony if he or she:

(i) Knowingly manufactures, purchases, sells, delivers, or brings into the state, or is in actual or constructive possession of any amount of drug or device prohibited by law; and

(ii) Due to his or her acts, result in the death of a person.

(c) A person found guilty of any offense under this section, shall be ordered to forfeit to the state any real or personal property:

(i) Used or intended to be used to commit, facilitate, or promote the commission of the offense; and

(ii) Constituting, derived from, or traceable to the gross proceeds that he or she obtained directly or indirectly as a result of the offense. Any property subject to forfeiture under this section may be seized pursuant to a warrant obtained in the same manner as a search warrant or as otherwise permitted by law, and held until the case against a defendant is adjudicated. Moneys ordered forfeited, or proceeds from the sale of other property ordered forfeited, shall be equitably divided between the board and other agencies involved in the investigation and prosecution that lead to the conviction.

(14) No wholesaler may sell any quantity of drug products containing ephedrine, pseudoephedrine, phenylpropanolamine, or their salts, isomers, or salts of isomers, if the total monthly sales of these products to persons within the state of Washington exceed five percent of the wholesaler's total prior monthly sales of nonprescription drugs to persons within the state in March through October. In November through February, no wholesaler may sell any quantity of drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers if the total monthly sales of these products to persons within the state of Washington exceed ten percent of the wholesaler's total prior monthly sales of nonprescription drugs to persons within the state. For purposes of this section, monthly sales means total dollars paid by buyers. The board may suspend or revoke the license of any wholesaler that violates this section.

((~~(5)~~)) (15) The board may exempt a wholesaler from the limitations of subsection ((~~(4)~~)) (14) of this section if it finds that the

wholesaler distributes nonprescription drugs only through transactions between divisions, subsidiaries, or related companies when the wholesaler and the retailer are related by common ownership, and that neither the wholesaler nor the retailer has a history of suspicious transactions in precursor drugs as defined in RCW 69.43.035.

((~~(6)~~)) (16) The requirements for a license apply to all persons, in Washington and outside of Washington, who sell both legend drugs and nonprescription drugs and to those who sell only nonprescription drugs, at wholesale to pharmacies, practitioners, and shopkeepers in Washington.

((~~(7)~~)) (17)(a) No wholesaler may sell any product containing any detectable quantity of ephedrine, pseudoephedrine, phenylpropanolamine, or their salts, isomers, or salts of isomers, to any person in Washington other than a pharmacy licensed under this chapter, a shopkeeper or itinerant vendor registered under this chapter, a practitioner as defined in RCW 18.64.011, or a traditional Chinese herbal practitioner as defined in RCW 69.43.105.

(b) A violation of this subsection is punishable as a class C felony according to chapter 9A.20 RCW, and each sale in violation of this subsection constitutes a separate offense.

NEW SECTION. **Sec. 4.** This act is necessary for the immediate preservation of the public peace, health, or safety, or support of the state government and its existing public institutions, and takes effect immediately.

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