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HOUSE BILL 2006

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By Representatives Van De Wege, Hudgins, Rolfes, Green, Dunshee, Darneille, Tharinger, Finn, Cody, Fitzgibbon, Hasegawa, Roberts, Jinkins, Jacks, Ryu, Kagi, and Dickerson

Read first time 03/03/11. Referred to Committee on Environment.

AN ACT Relating to protecting the health of Washington citizens; amending RCW 82.04.272, 69.41.030, and 18.64.005; and adding a new chapter to Title 70 RCW.

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) "Board" means the board of pharmacy.

(2)(a) "Covered drug" includes all legend and nonlegend drugs from residential sources sold in any form. This includes brand name and generic drugs.

(b) "Covered drug" does not include:

(i) Vitamins or supplement;

(ii) Herbal-based remedies and homeopathic drugs, products, or remedies;

(iii) Cosmetics, shampoos, sunscreens, toothpaste, lip balm, antiperspirants, or other personal care products that are regulated as both cosmetics and nonlegend drugs under the federal food, drug, and cosmetic act;

(iv) Drugs for which producers provide a take-back program as part of a federal food and drug administration managed risk evaluation and mitigation strategy (21 U.S.C. Sec. 355-1);

(v) Drugs that are biological products as defined by 21 C.F.R. 600.3(h) as it exists on the effective date of this section if the producer already provides a take-back program; and

(vi) Pet pesticide products contained in pet collars, powders, shampoos, topical applications, or other forms.

(3) "Drug wholesaler" means a corporation, individual, or other entity which buys drugs or devices for resale and distribution to corporations, individuals, or entities other than consumers.

(4) "Drugs" means:

(a) Articles recognized in the official United States pharmacopoeia, the official national formulary, the official homeopathic pharmacopoeia of the United States, or any supplement of the formulary or those pharmacopoeias;

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

(c) Substances, other than food, intended to affect the structure or any function of the body of humans 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 medical devices or their component parts or accessories.

(5) "Generic drug" means drugs that are chemically identical or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. However, inactive ingredients may vary.

(6) "Legend drug" means any drugs, including controlled substances under chapter 69.50 RCW, that are required by any applicable federal or state law or regulation to be dispensed by prescription only or are restricted to use by practitioners only.

(7) "Nonlegend drug" means any drugs that may be lawfully sold without a prescription.

(8) "Person" means a firm, sole proprietorship, corporation, limited liability company, general partnership, limited partnership, limited liability partnership, association, cooperative, or other entity of any kind or nature.

(9) "Producer" means the person who:

(a) Has legal ownership of the brand, brand name, or cobrand of the covered drug or manufactures a generic covered drug sold in Washington state. "Producer" does not include a retailer who puts its store label on a covered drug or a pharmacist who compounds a prescribed individual drug product for a patient;

(b) Imports a covered drug branded or manufactured by a producer that meets the definition under (a) of this subsection and has no physical presence in the United States; or

(c) Sells at wholesale a covered drug, does not have legal ownership of the brand, and elects to fulfill the responsibilities of the producer for that covered drug.

(10) "Product stewardship program" means a statewide program for the collection, transportation, and disposal of unwanted covered drugs that is managed by the board.

(11) "Residential sources" includes single and multiple-family residences, and locations where household drugs are unused, unwanted, disposed, or abandoned, such as hospice services, boarding homes, schools, foster care, day care, and other locations where either people or their pet animals, or both, reside on a temporary or permanent basis. This does not include waste from hospitals, clinics, pharmacies, airport security, drug seizures by law enforcement, businesses, or other nonresidential or business sources identified by the board of pharmacy.

(12) "Unwanted covered drug" means any covered drug no longer wanted by its owner or that has been abandoned, discarded, or is intended to be discarded by its owner.

NEW SECTION. **Sec. 2.** (1) By January 1, 2013, the board shall create a proposed product stewardship program for review under subsection (2) of this section.

(2)(a) In developing a proposed product stewardship program, the board shall provide opportunities for public comment, including at least one public hearing. Notice of the public hearing must be provided by the board to the department of ecology, the Washington association of sheriffs and police chiefs, covered drug retailers, substance abuse professionals, local governments, solid waste professionals, water quality professionals, and the general public.

(b) The board shall consult with the department of ecology on the proposed product stewardship program including transportation and disposal systems, secure tracking and handling, package recycling, and public education.

(c) The board shall consult with the Washington association of sheriffs and police chiefs on the adequacy of the proposed product stewardship program's security measures for collection, transportation, and disposal of unwanted covered drugs.

(3) After public comment has been received under subsection (2) of this section and by no later than January 1, 2014, the board shall operate a product stewardship program in accordance with this chapter, RCW 82.04.272, 69.41.030, and 18.64.005.

(4)(a) The board shall annually invite comments from health care facilities, health care practitioners, pharmacists, local governments, law enforcement personnel, and citizens on their satisfaction with the services provided by the product stewardship program. This information must be used by the board in developing product stewardship program updates and revisions under (b) of this subsection.

(b) At least every four years, the board shall update its product stewardship program.

NEW SECTION. **Sec. 3.** (1) The product stewardship program created by the board, must, at a minimum, provide for the following:

(a) A collection system for all unwanted covered drugs that is safe, secure, and protects patient information. The collection system must:

(i) Be convenient and adequately serve the needs of residents in both urban and rural areas;

(ii) Provide, at a minimum, one drop-off collection site in all counties in the state and one drop-off collection site in all cities with a population greater than ten thousand, on an ongoing, year-round basis. However, if a drop-off location cannot be arranged in a specific county or city, prepaid mailing envelopes must be provided; and

(iii) Incorporate drop-off collection sites for unwanted covered drugs in existence on the effective date of this section if they meet the requirements of the product stewardship program, and additional collectors to improve convenience and availability of services;

(b) A handling and disposal system, including identification of and contact information for collectors, transporters, and waste disposal facilities to be used by the product stewardship program;

(c) How the board will use existing providers of waste pharmaceutical services to the extent possible;

(d) How covered drugs will be separated from packaging to the extent possible to reduce transportation and disposal costs and how drug packaging will be recycled to the extent feasible;

(e) The policies and procedures to be followed by persons in charge of unwanted covered drugs collected pursuant to the product stewardship program;

(f) How the collected, unwanted covered drugs are tracked through to final disposal and how safety and security is maintained; and

(g) How patient information on drug packaging will be kept secure during collection, transportation, and disposal.

(2) The board may suspend the product stewardship program in whole or in part if the board determines that suspension is necessary to protect the public from imminent danger.

NEW SECTION. **Sec. 4.** This chapter does not require any person to serve as a collector in the product stewardship program. A person may offer to serve as a collector, or may agree to serve as a collector. Collectors may include law enforcement, pharmacies, other relevant public or private locations, such as hospitals, senior centers, community health clinics, fire stations, veterinary clinics, or private sector collectors, and mail-back services, operating in accordance with state and federal laws and regulations for the handling of covered drugs and in compliance with this chapter.

NEW SECTION. **Sec. 5.** (1) The board shall promote the use of the product stewardship program and the safe storage and proper disposal of covered drugs so that collection options are widely understood by customers, pharmacists, retailers of covered drugs, and health care practitioners including doctors and other prescribers.

(2) The board shall establish a toll-free telephone number and web site where collection options will be publicized and prepare educational and outreach materials describing where and how to return

unwanted covered drugs to the product stewardship program. These materials must be provided to pharmacies, health care facilities, and other interested parties for dissemination to residential sources.

(3) The department of ecology and local governments shall promote the use of the product stewardship program and the program's toll-free telephone number and web site through existing educational methods.

(4) The board shall annually evaluate the effectiveness of its outreach and program activities. At least every four years, this evaluation must include the percentage of residents that are aware of the program and to what extent residents find the program convenient.

NEW SECTION. **Sec. 6.** (1) Covered drugs collected under the product stewardship program must be disposed of at a properly permitted hazardous waste disposal facility, or at an in-state solid waste incinerator facility permitted under chapter 173-434 WAC, or at a properly permitted solid waste incinerator facility in a neighboring state or province.

(2) Unwanted covered drugs from residential sources retain all other generator exemptions for household hazardous waste.

(3) The board may petition the department of ecology for approval to use final disposal technologies that provide superior environmental and human health protection than provided by current the disposal technologies in subsection (1) of this section for drugs if and when those technologies are proven and available. The proposed technology must provide equivalent protection in each, and superior protection in one or more, of the following areas:

(a) Monitoring of any emissions or waste;

(b) Worker health and safety;

(c) Air, water, or land emissions contributing to persistent, bioaccumulative, and toxic pollution; and

(d) Overall impact to the environment and human health.

NEW SECTION. **Sec. 7.** (1) The board may adopt rules necessary to implement, administer, and enforce this chapter.

(2) The board, in consultation with the department of ecology, may establish performance standards for the product stewardship program.

(3) By December 31, 2016, the board shall report to the

legislature, consistent with RCW 43.01.036, concerning the status of the product stewardship program and any recommendations for changes to this chapter.

NEW SECTION. **Sec. 8.** The pharmaceutical product stewardship program account is created in the custody of the state treasurer. All receipts to be deposited under RCW 82.04.272(2)(b) must be deposited into the account. Expenditures from the account may be used only for administering this chapter. Only the secretary of the department of health or the secretary's designee may authorize expenditures from the account. The account is subject to allotment procedures under chapter 43.88 RCW, but an appropriation is not required for expenditures.

Sec. 9. RCW 82.04.272 and 2003 c 168 s 401 are each amended to read as follows:

(1) Upon every person engaging within this state in the business of warehousing and reselling drugs for human use pursuant to a prescription; as to such persons, the amount of the tax shall be:

(a) Equal to the gross income of the business multiplied by the rate of 0.138 percent; and

(b) Equal to the gross income of the business multiplied by the rate of 0.346 of which one million two hundred fifty thousand dollars shall be deposited on December 15th of each year into the pharmaceutical product stewardship program account established in section 8 of this act. The remainder shall be deposited into the general fund for transfer to the health care authority for the purposes of maintaining the Washington basic health plan established in chapter 70.47 RCW.

(2) For the purposes of this section:

(a) "Prescription" and "drug" have the same meaning as in RCW 82.08.0281; and

(b) "Warehousing and reselling drugs for human use pursuant to a prescription" means the buying of drugs for human use pursuant to a prescription from a manufacturer or another wholesaler, and reselling of the drugs to persons selling at retail or to hospitals, clinics, health care providers, or other providers of health care services, by a wholesaler or retailer who is registered with the federal drug enforcement administration and licensed by the state board of pharmacy.

Sec. 10. RCW 69.41.030 and 2010 c 83 s 1 are each amended to read as follows:

(1) It shall be unlawful for any person to sell, deliver, or possess any legend drug except upon the order or prescription of a physician under chapter 18.71 RCW, an osteopathic physician and surgeon under chapter 18.57 RCW, an optometrist licensed under chapter 18.53 RCW who is certified by the optometry board under RCW 18.53.010, a dentist under chapter 18.32 RCW, a podiatric physician and surgeon under chapter 18.22 RCW, a veterinarian under chapter 18.92 RCW, a commissioned medical or dental officer in the United States armed forces or public health service in the discharge of his or her official duties, a duly licensed physician or dentist employed by the veterans administration in the discharge of his or her official duties, a registered nurse or advanced registered nurse practitioner under chapter 18.79 RCW when authorized by the nursing care quality assurance commission, an osteopathic physician assistant under chapter 18.57A RCW when authorized by the board of osteopathic medicine and surgery, a physician assistant under chapter 18.71A RCW when authorized by the medical quality assurance commission, or any of the following professionals in any province of Canada that shares a common border with the state of Washington or in any state of the United States: A physician licensed to practice medicine and surgery or a physician licensed to practice osteopathic medicine and surgery, a dentist licensed to practice dentistry, a podiatric physician and surgeon licensed to practice podiatric medicine and surgery, a licensed advanced registered nurse practitioner, or a veterinarian licensed to practice veterinary medicine: PROVIDED, HOWEVER, That the above provisions shall not apply to sale, delivery, or possession by drug wholesalers or drug manufacturers, or their agents or employees, or to any practitioner acting within the scope of his or her license, or to a common or contract carrier or warehouseman, or any employee thereof, whose possession of any legend drug is in the usual course of business or employment: PROVIDED FURTHER, That nothing in this chapter or chapter 18.64 RCW shall prevent a family planning clinic that is under contract with the department of social and health services from selling, delivering, possessing, and dispensing commercially prepackaged oral contraceptives prescribed by authorized, licensed health care practitioners.

(2) The product stewardship program created in chapter 70.--- RCW (the new chapter created in section 14 of this act) may possess and transport drugs provided that the product stewardship program complies with this chapter.

(3)(a) A violation of this section involving the sale, delivery, or possession with intent to sell or deliver is a class B felony punishable according to chapter 9A.20 RCW.

(b) A violation of this section involving possession is a misdemeanor.

Sec. 11. RCW 18.64.005 and 1990 c 83 s 1 are each amended to read as follows:

The board shall:

(1) Regulate the practice of pharmacy and enforce all laws placed under its jurisdiction;

(2) Prepare or determine the nature of, and supervise the grading of, examinations for applicants for pharmacists' licenses;

(3) Establish the qualifications for licensure of pharmacists or pharmacy interns;

(4) Conduct hearings for the revocation or suspension of licenses, permits, registrations, certificates, or any other authority to practice granted by the board, which hearings may also be conducted by an administrative law judge appointed under chapter 34.12 RCW;

(5) Issue subpoenas and administer oaths in connection with any hearing, or disciplinary proceeding held under this chapter or any other chapter assigned to the board;

(6) Assist the regularly constituted enforcement agencies of this state in enforcing all laws pertaining to drugs, controlled substances, and the practice of pharmacy, or any other laws or rules under its jurisdiction;

(7) Promulgate rules for the dispensing, distribution, wholesaling, and manufacturing of drugs and devices and the practice of pharmacy for the protection and promotion of the public health, safety, and welfare. Violation of any such rules shall constitute grounds for refusal, suspension, or revocation of licenses or any other authority to practice issued by the board;

(8) Adopt rules establishing and governing continuing education

requirements for pharmacists and other licensees applying for renewal of licenses under this chapter;

(9) Be immune, collectively and individually, from suit in any action, civil or criminal, based upon any disciplinary proceedings or other official acts performed as members of such board. Such immunity shall apply to employees of the department when acting in the course of disciplinary proceedings;

(10) Suggest strategies for preventing, reducing, and eliminating drug misuse, diversion, and abuse, including professional and public education, and treatment of persons misusing and abusing drugs;

(11) Conduct or encourage educational programs to be conducted to prevent the misuse, diversion, and abuse of drugs for health care practitioners and licensed or certified health care facilities;

(12) Monitor trends of drug misuse, diversion, and abuse and make periodic reports to disciplinary boards of licensed health care practitioners and education, treatment, and appropriate law enforcement agencies regarding these trends;

(13) Enter into written agreements with all other state and federal agencies with any responsibility for controlling drug misuse, diversion, or abuse and with health maintenance organizations, health care service contractors, and health care providers to assist and promote coordination of agencies responsible for ensuring compliance with controlled substances laws and to monitor observance of these laws and cooperation between these agencies. The department of social and health services, the department of labor and industries, and any other state agency including licensure disciplinary boards, shall refer all apparent instances of over-prescribing by practitioners and all apparent instances of legend drug overuse to the department. The department shall also encourage such referral by health maintenance organizations, health service contractors, and health care providers;

(14) Adopt rules to implement, administer, and enforce the laws on the collection, transportation, disposal, and possession of unwanted covered drugs from residential sources through the product stewardship programs under chapter 70.--- RCW (the new chapter created in section 14 of this act).

NEW SECTION. **Sec. 12.** Nothing in this chapter changes or limits the authority of the Washington utilities and transportation commission

to regulate collection of solid waste, including curbside collection of residential recyclable materials, nor does this chapter change or limit the authority of a city or town to provide the service itself or by contract under RCW 81.77.020.

NEW SECTION. **Sec. 13.** Nothing in this chapter applies to hospitals licensed under chapter 70.41 RCW, whose pharmaceutical wastes are disposed of under rules and policies adopted by the department of ecology.

NEW SECTION. **Sec. 14.** Sections 1 through 8, 12, and 13 of this act constitute a new chapter in Title 70 RCW.

NEW SECTION. **Sec. 15.** If any provision of this act or its application to any person or circumstance is held invalid, the remainder of the act or the application of the provision to other persons or circumstances is not affected.

NEW SECTION. **Sec. 16.** This act must be liberally construed to carry out its purposes and objectives.

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