S-4341.1

SUBSTITUTE SENATE BILL 5279

State of Washington 61st Legislature 2010 Regular Session

By Senate Health & Long-Term Care (originally sponsored by Senators Kline, Ranker, Rockefeller, Pridemore, Oemig, Regala, Franklin, Murray, Kauffman, Fairley, Kohl-Welles, Haugen, McAuliffe, Pflug, Shin, and McDermott)

READ FIRST TIME 01/29/10.

AN ACT Relating to providing safe collection and disposal of unwanted drugs from residential sources through a producer provided and funded product stewardship program; amending RCW 18.64.005; reenacting and amending RCW 69.41.030; adding a new section to chapter 18.64 RCW; adding a new chapter to Title 70 RCW; creating a new section; and prescribing penalties.

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

NEW SECTION. **Sec. 1.** The citizens of Washington state have long benefited from prescription and nonprescription medicines. These medicines allow us to live longer, healthier, and more productive lives. After they have served their intended use, expired or left-over drugs need to be handled safely and disposed of properly to prevent harm to people and our environment. The legislature finds that a convenient, safe, secure, and environmentally sound product stewardship program for the collection, transportation, and disposal of unwanted drugs from residential sources may help to avoid accidental poisonings, decrease illegitimate access to drugs that can lead to abuse, and protect our surface and groundwater. The legislature further finds

that producers of those drugs are the best entity to provide and finance the product stewardship program.

NEW SECTION. **Sec. 2.** The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

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

(2) "Covered product" means all legend and nonlegend drugs, including both brand name and generic drugs.

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

(4) "Drug wholesalers" means businesses that sell or distribute for resale drugs to any entity other than the consumer.

(5) "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.

(6) "Entity" means a person other than a natural person.

(7) "Generic drug" means a drug that is 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.

(8) "Legend" or "prescription" drugs 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 on prescription only or are restricted to use by practitioners only.

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

(10) "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.

(11) "Plan" means a product stewardship plan required under this chapter that describes the manner in which a product stewardship program will be provided.

(12) "Producer" means the person who:

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

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

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

(13) "Product stewardship program" means a program for the collection, transportation, and either recycling or disposal, or both, of unwanted products that is financed as well as managed or provided by the producers of those products.

(14) "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 airport security, drug seizures by law enforcement, pharmacy waste, business waste, or any other source identified by the board as a nonresidential or business source.

(15) "Stewardship organization" means a person designated by a group of producers to act as an agent on behalf of each producer to operate a product stewardship program.

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

NEW SECTION. **Sec. 3.** (1) Beginning January 1, 2013, every producer of covered products sold in or into Washington state must participate in a product stewardship program for unwanted products from residential sources.

(2) Every producer must:

(a) Operate, either individually or jointly with other producers, a product stewardship program; or

(b) Enter into an agreement with a stewardship organization to operate, on the producer's behalf, a product stewardship program.

(3) A product stewardship program must be licensed by the board prior to collecting unwanted covered products from residential sources.

(4) A producer, group of producers, or stewardship organization must pay all administrative and operational costs associated with their product stewardship program, including the cost of the collection, transportation, and disposal of the unwanted products that are collected from residential sources and the recycling or disposal, or both, of its related packaging that is collected with the unwanted product.

(5) A product stewardship program must be provided without charging any fee at the time of sale of the covered product or at the time the unwanted products from residential sources are delivered or collected for disposal.

(6) Unless otherwise approved by the board, each product stewardship program must accept all unwanted products regardless of who produces the unwanted product.

(7) A producer, group of producers, or stewardship organization operating or intending to operate a product stewardship program must submit a product stewardship plan to the board prior to engaging in the collection of unwanted covered products.

NEW SECTION. **Sec. 4.** A product stewardship plan must contain the following:

(1) Contact information, including:

(a) The individual and the entity submitting the plan; and

(b) A list of all producers participating in the product stewardship program and their contact information;

(2) A description of the proposed collection system. The proposed collection system must be safe, secure, and protect patient information. The proposed collection system must provide service in all counties in the state and in all cities with a population greater than ten thousand, and must include a description of collection methods. Prepaid mailing envelopes must be provided unless other

collection methods are utilized. The collection system must be convenient and adequately serve the needs of residents in both urban and rural areas;

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

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

(5) A description of how the collected, unwanted products are tracked through to final disposal and how safety and security is maintained;

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

(7) A description of the public education effort and communications strategy as required in section 8 of this act.

NEW SECTION. **Sec. 5.** (1) Product stewardship plans must be submitted to the board for approval. The initial plans must be submitted by January 1, 2012. The department of ecology shall consult with the board on any element of the plan including transportation and disposal systems, secure tracking and handling, package recycling, hazardous waste permitting, and public education.

(2) Within ninety days after receipt of a plan, the board shall approve or reject the plan. If it approves a plan, the board shall notify the applicant of its approval. If it rejects a plan, the board shall notify the applicant of its decision and its reasons for rejecting the plan. An applicant whose plan has been rejected may:

(a) Submit a revised plan within sixty days after receiving notice of the rejection; or

(b) Appeal the board's decision under the administrative procedure act, chapter 34.05 RCW.

(3) At least every four years, a producer, group of producers, or stewardship organization operating a product stewardship program must update its product stewardship plan and submit the updated plan to the board for review.

(4) After January 1, 2012, each new producer and each producer new to Washington state shall obtain a letter of approval from the board for a new plan or join an approved plan upon initiating sales in or into this state.

NEW SECTION. **Sec. 6.** (1) Any proposed change to a product stewardship plan must have prior approval of the board.

(2) The product stewardship program must inform the board of changes in collection locations and producer participation in a product stewardship program fifteen days prior to the changes occurring.

NEW SECTION. **Sec. 7.** (1) On or before June 30, 2013, and in each subsequent year, every producer, group of producers, or stewardship organization operating a product stewardship program must prepare and submit an annual report to the board describing the program's activities during the previous reporting period. The report must include the following:

(a) A list of producers participating in the product stewardship program;

(b) The amount, by weight, of unwanted products collected from residential sources, including the amount by weight from each collection method used;

(c) A list of collection sites, if applicable, locations where mailers are provided, if applicable, transporters used, and the disposal facility or facilities used;

(d) Whether any safety or security problems occurred during collection, transportation, or disposal of unwanted products during the reporting period, and, if so, what changes have or will be made to policies, procedures, or tracking mechanisms to alleviate the problem and to improve safety and security in the future; and

(e) A description of the public education and outreach activities in compliance with section 8 of this act implemented during the reporting period.

(2) The board must make annual reports available to the public.

(3) For the purposes of this section, "reporting period" means the period commencing January 1st and ending December 31st of the same calendar year.

NEW SECTION. **Sec. 8.** (1) A product stewardship program must promote the use of the program and the proper disposal of drugs so that collection options are widely understood by customers, pharmacists, retailers of covered products, and health care practitioners including doctors and other prescribers.

(2) A product stewardship program must 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 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) A product stewardship program must annually evaluate the effectiveness of its outreach and program activities. 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. 9.** (1) Each product stewardship program must dispose of all unwanted products from residential sources at a hazardous waste facility. However, unwanted products from residential sources otherwise retain all other generator exemptions for household hazardous waste. The hazardous waste facility must be:

(a) Permitted with interim or final status under the Washington dangerous waste rules;

(b) Authorized to manage hazardous waste by another state with a hazardous waste program approved by the United States environmental protection agency; or

(c) Authorized under interim status or permitted by the United States environmental protection agency.

(2) Product stewardship programs 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 hazardous waste disposal technologies 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.

(3) Each product stewardship program is encouraged to recycle drug packaging if feasible.

NEW SECTION. **Sec. 10.** (1) The board may refuse, suspend or revoke the license of a product stewardship program as provided in RCW 18.64.200.

(2) If the board determines that it is necessary to protect the public from imminent danger, it may immediately amend, suspend, or cancel approval of a product stewardship plan without giving the person operating the product stewardship program an opportunity to be heard. However, the board shall give the person operating the product stewardship program an opportunity to be heard through proceedings consistent with RCW 18.64.200 and the administrative procedure act, chapter 34.05 RCW.

NEW SECTION. **Sec. 11.** (1) The board shall send a written warning and a copy of this chapter and any rules adopted to implement this chapter to a producer who is not participating in a product stewardship program approved by the board and whose covered product is being sold in or into the state.

(2) A producer not participating in a product stewardship program licensed by the board whose covered product continues to be sold in or into the state sixty days after receiving a written warning from the board must be assessed a penalty of ten thousand dollars for each calendar day that the violation continues.

(3) If an approved plan is not fully implemented within thirty days of the planned start date, the board shall assess a penalty of five thousand dollars along with notification to each producer associated with the product stewardship program. If, after an additional thirty days, an approved plan is not fully implemented, the board shall assess a penalty of ten thousand dollars to each producer associated with the product stewardship program. Subsequent violations occur each thirty days that the approved plan is not fully implemented.

(4) When a product stewardship program is found to be out of compliance with: (a) The requirement to update its plan under section

5 of this act; (b) reporting requirements under section 7 of this act; or (c) notification requirements under section 6 of this act, each producer in the product stewardship program must first receive a written warning including a copy of the requirements under this chapter and must be give thirty days to correct the noncompliance. After thirty days, each producer in the product stewardship program must be assessed a penalty of five thousand dollars for the first violation and ten thousand dollars for the second and each subsequent violation. A subsequent violation occurs each thirty days of noncompliance with the requirements under (a) through (c) of this subsection.

(5) A producer or a product stewardship organization may appeal penalties prescribed under this section under the administrative procedure act, chapter 34.05 RCW.

(6) All penalties levied under this section must be deposited into the pharmaceutical product stewardship program account established under section 15 of this act.

NEW SECTION. **Sec. 12.** Beginning in 2012, each drug wholesaler that sells any covered product in or into the state must provide a list of producers of the covered product to the board. The list must be provided in a form determined by the board. Wholesalers must update the list by January 15th of each year.

NEW SECTION. **Sec. 13.** (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 product stewardship programs and may establish administrative penalties for failure to meet the standards.

(3) By December 31, 2015, the board shall report to the appropriate committees of the legislature concerning the status of the product stewardship program and recommendations for changes to the provisions of this chapter.

(4) The board shall annually invite comments from health care facilities, health care practitioners, pharmacists, local governments, and citizens on their satisfaction with the services provided by a product stewardship program. This information must be used by the

board, in consultation with the department of ecology, in reviewing proposed plan updates and revisions.

NEW SECTION. **Sec. 14.** The secretary of the department may establish fees for administering this chapter as provided under RCW 43.70.250. The fees may be charged to producers or to persons operating a product stewardship program. All fees charged must be based on factors relating to administering this chapter. Fees may be established in amounts to fully recover and not to exceed expenses incurred by the board in administering this chapter. The board may use these fee revenues to reimburse the department of ecology for its costs.

NEW SECTION. **Sec. 15.** The pharmaceutical product stewardship program account is created in the custody of the state treasurer. All receipts from fees and penalties collected under this chapter must be deposited into the account. Expenditures from the account may be used only for administering this chapter. Only the secretary of the department 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.

NEW SECTION. **Sec. 16.** If necessary to ensure that money is available in the pharmaceutical product stewardship program account created in section 15 of this act for the initial administration of the product stewardship program for unwanted drugs from residential sources, the director of the department of ecology may lend moneys from the state toxics control account created in RCW 70.105D.070 to the pharmaceutical product stewardship program account. These loaned moneys may be expended solely for the initial administration of the program by the board and the department of ecology under this chapter. The board shall repay the state toxics control account the amount of moneys loaned plus interest as determined by the state treasurer within two years of the date of the loan.

NEW SECTION. **Sec. 17.** A new section is added to chapter 18.64 RCW to read as follows:

(1) A producer, group of producers, or stewardship organization must apply for a license from the board to operate a pharmaceutical product stewardship program under chapter 70.-- RCW (the new chapter created in section 22 of this act). The license entitles the holder to operate a pharmaceutical product stewardship program for the collection, transportation, and disposal of unwanted legend and nonlegend drugs from consumers or residential sources and not business entities.

(2) The applicant must demonstrate the competence and knowledge to operate the product stewardship program.

(3) The board shall consider the past history of the applicant, the firm officers, and employees when considering the application. A finding of any drug offense is presumptive reason for denial or revocation of the license by the board.

(4) A license may not be granted prior to approval by the board of the product stewardship plan required under section 5 of this act.

(5) The license is for a specified period ending on the date to be determined by the secretary.

(6) A license may be revoked or suspended if a product stewardship program fails to comply with the approved elements of its product stewardship plan.

(7) The board, department of ecology, or department of health staff may access any facilities, property, or records of the product stewardship program as necessary to conduct inspections or investigate complaints.

Sec. 18. RCW 69.41.030 and 2003 c 142 s 3 and 2003 c 53 s 323 are each reenacted and 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, 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, or a veterinarian licensed to practice veterinary medicine, in any province of Canada which shares a common border with the state of Washington or in any state of the United States: 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) A pharmaceutical product stewardship program licensed by the Washington state board of pharmacy 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. 19. 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 drugs from residential sources through producer provided and funded product stewardship programs under chapter 70.-- RCW (the new chapter created in section 22 of this act).

NEW SECTION. **Sec. 20.** 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 such service itself or by contract under RCW 81.77.020.

NEW SECTION. **Sec. 21.** 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. 22.** Sections 1 through 16, 20, and 21 of this act constitute a new chapter in Title 70 RCW.

NEW SECTION. **Sec. 23.** 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. 24.** This act must be liberally construed to carry out its purposes and objectives.

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