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HOUSE BILL 1165

State of Washington 61st Legislature 2009 Regular Session

By Representatives Morrell, Campbell, Priest, Dickerson, Hudgins, Rodne, Cody, Nelson, Chase, O'Brien, Dunshee, Kenney, Wood, Hunt, McCoy, Upthegrove, Hasegawa, Anderson, Appleton, Pedersen, Hunter, Darneille, Roberts, Rolfes, White, Kagi, Ormsby, Conway, Orwall, Simpson, Goodman, VanDeWege, and Santos

Read first time 01/14/09. Referred to Committee on Environmental Health.

AN ACT Relating to providing safe collection and disposal of unwanted drugs from residential sources through a producer provided and funded product stewardship program; reenacting and amending RCW 69.41.030; 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 ecology.

(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 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;

(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 or retail 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, nursing homes, 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 department 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, 2012, 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 approved by the department; or

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

(3) 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.

(4) 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.

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

(6) 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 department 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 collection system provision that describes:

(a) How unwanted products from residential sources will be collected in all counties in the state and, at a minimum, in all cities with populations greater than ten thousand, including if applicable, the location of each collection site and locations where mailers are available; and

(b) How the collection system will be convenient and adequate to serve the needs of residents in both urban and rural areas;

(3) A transportation and disposal system provision that includes the name, location, permit status, and record of any penalties,

violations, or regulatory orders received in the previous five years by each transporter and each hazardous waste disposal facility proposed to be used by the product stewardship program;

(4) Secure tracking and handling provision that includes how the unwanted products will be safely and securely tracked and handled from collection through final disposal, and the policies and procedures to be followed to ensure security;

(5) How the proposed product stewardship program will maximize the recycling of packaging that is collected with and separated from the unwanted product prior to disposal of the unwanted product, and how patient information on that packaging will be kept secure prior to and during recycling; and

(6) A description of the public education effort and outreach activities required under section 8 of this act and a methodology for evaluating the effectiveness of its outreach and program.

NEW SECTION. **Sec. 5.** (1) Product stewardship plans must be submitted to the department for approval. The initial plans must be submitted by January 1, 2011. The department may consult with other state agencies, including the board, on any element of the plan.

(2) Within ninety days after receipt of a plan, the department shall determine whether the plan complies with this chapter. If it approves a plan, the department shall notify the applicant of its approval. If it rejects a plan, the department shall notify the applicant of its decision and its reasons for rejecting the plan. An applicant whose plan has been rejected by the department may submit a revised plan to the department within sixty days after receiving notice of the rejection.

(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 department for review.

(4) After January 1, 2011, each new producer and each producer new to Washington state shall obtain a letter of approval from the department 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 department except for the following:

(a) Additions or changes to collection locations for unwanted products; or

(b) Additions of producers to a product stewardship program.

(2) The product stewardship program must inform the department of changes in subsection (1)(a) and (b) of this section 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 to the department an annual report 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 of unwanted products collected at each drop-off site, if applicable, and the total amount by weight collected by a mail-back system, if applicable;

(c) A description of the collection system provided in each county and in all cities with populations greater than ten thousand, including the location of each collection site and locations where mailers are provided, if applicable;

(d) The disposal facility or facilities used and facility location or locations, and the weight of unwanted products collected from residential sources disposed at each facility;

(e) If packaging is separated from the unwanted product prior to the disposal of the unwanted product, the amount and percentage of packaging recycled and the name and location of the material recovery facility to which it is delivered;

(f) Any penalties, violations, or regulatory orders received during the reporting period by each transporter and each disposal facility that was used;

(g) Whether policies and procedures for collecting, transporting,

and disposing of unwanted products, as established in the plan, were followed during the reporting period, and a description of any noncompliance;

(h) 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;

(i) A description of the public education and outreach activities implemented during the reporting period, including the methodology used and the results of evaluating the outreach and program activities;

(j) How the product stewardship program complied with any other elements in the plan approved by the department; and

(k) Any other information that the department may reasonably require.

(2) 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 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 separate unwanted products from their original containers, when appropriate, prior to collection or disposal.

NEW SECTION. **Sec. 10.** If the department 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 department shall give the person operating the product stewardship program an opportunity to be heard through proceedings consistent with the administrative procedure act, chapter 34.05 RCW, within fifteen days after the date on which the department takes any of those actions.

NEW SECTION. **Sec. 11.** (1) The department 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 department and whose covered product is being sold in or into the state.

(2) A producer not participating in a product stewardship program approved by the department whose covered product continues to be sold in or into the state sixty days after receiving a written warning from the department may be assessed a penalty of ten thousand dollars for each calendar day that the violation continues. The department may waive or reduce the penalty if the producer complies with this chapter and any rules adopted to implement this chapter, to protect public health, or for any other reason the department determines to be justified.

(3) If any producer fails to implement its approved plan, the department may assess a penalty of up to five thousand dollars for the first violation along with notification that the producer must implement its plan within thirty days of the violation. After thirty days, any producer failing to implement their approved plan may be assessed a penalty of up to ten thousand dollars for the second and each subsequent violation. A subsequent violation occurs each thirty days that the producer fails to implement the approved plan.

(4) Any producer, group of producers, or stewardship organization that does not comply 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, must first receive a written warning including a copy of the requirements under this chapter and must be given thirty days to correct the noncompliance. After thirty days, a person may be assessed a penalty of up to five thousand dollars for the first violation and up to ten thousand dollars for the second and each subsequent violation. A subsequent violation occurs each thirty days that the producer fails to comply with the requirements under (a) through (c) of this subsection. The department may waive or reduce the penalty if the producer, group of producers, or stewardship organization complies with this chapter and any rules adopted to implement this chapter, to protect public health, or for any other reason the department determines to be justified.

(5) 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.** (1) The department shall provide on its web site a list of all producers participating in product stewardship programs it has approved and a list of all producers it has identified as noncompliant with this chapter and any rules adopted to implement this chapter.

(2) Drug wholesalers must check the department's web site to determine if producers of products they are wholesaling in or into the state are in compliance with this chapter. If the drug wholesaler is unsure of the status of the producer or believes the producer is not in compliance with this chapter, the drug wholesaler shall contact the department to determine the producer's status.

(3) The department shall send a written warning and a copy of this chapter and any rules adopted to implement this chapter to a drug wholesaler known to be selling a product in or into the state from producers who are not participating in a product stewardship program or who are not in compliance with the chapter and rules adopted under this chapter.

(4) A drug wholesaler who continues to sell a covered product from a producer that is not participating in an approved product stewardship program sixty days after receiving a written warning from the department may be assessed a penalty of ten thousand dollars.

(5) 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. 13.** (1) The department may adopt rules necessary to implement, administer, and enforce this chapter. The department must consult with the board on rule development involving the secure collection, tracking, and handling of drugs collected under a product stewardship program.

(2) The department may establish performance standards for product stewardship programs and may establish administrative penalties for failure to meet the standards.

(3) By December 31, 2014, the department 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 department 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 department in reviewing proposed plan updates and revisions.

(5) The department shall consult with the board on proposed provisions of a product stewardship plan involving the secure collection, tracking, and handling of drugs collected under a product stewardship program required in section 4(4) of this act.

NEW SECTION. **Sec. 14.** The department may establish fees for administering this chapter. 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 department in administering this chapter. The department may use these fee revenues to reimburse the department 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 director of the department or the director'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 may, from time to time, 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 department under this chapter. The department 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.

Sec. 17. 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: PROVIDED FURTHER, That nothing in this chapter shall prevent a licensed producer, group of producers, or stewardship organization from operating a pharmaceutical product stewardship program created under chapter 70.-- RCW (the new chapter created in section 19 of this act) for the collection, transportation, and disposal of unwanted legend and nonlegend drugs from consumers or residential sources and not business entities, for the purpose of disposing of the collected drugs in compliance with the laws and rules of this state and the United States.

(2)(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.

NEW SECTION. **Sec. 18.** 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. 19.** Sections 1 through 16 and 18 of this act constitute a new chapter in Title 70 RCW.

NEW SECTION. **Sec. 20.** 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. 21.** This act must be liberally construed to carry out its purposes and objectives.

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