H-5015.1

SUBSTITUTE HOUSE BILL 3064

State of Washington 60th Legislature 2008 Regular Session

By House Select Committee on Environmental Health (originally sponsored by Representatives Morrell, Green, Appleton, Seaquist, VanDeWege, Upthegrove, Lantz, Kenney, Roberts, Simpson, Hunt, O'Brien, Linville, Ormsby, Wood, Campbell, Jarrett, and Hudgins)

READ FIRST TIME 02/04/08.

AN ACT Relating to providing safe collection and disposal of unwanted drugs from residential sources through a producer managed and funded product stewardship program; amending RCW 18.64.165; adding new sections to chapter 18.64 RCW; adding a new chapter to Title 70 RCW; prescribing penalties; and providing an effective date.

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

NEW SECTION. **Sec. 1.** 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 manage 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) "Drug wholesalers" means businesses that sell or distribute for resale drugs to any entity other than the consumer.

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

(6) "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.

(7) "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.

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

(9) "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.

(10) "Plan" means a product stewardship plan required under this chapter that describes the operation of a product stewardship program.

(11) "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 that meets the definition under (a) of this subsection and that producer has no physical presence in the United States; or

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

(12) "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.

(13) "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 of ecology as a nonresidential or business source.

(14) "Stewardship organization" means a person appointed by a producer to act as an agent on behalf of the producer to administer a product stewardship program.

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

NEW SECTION. **Sec. 3.** (1) Every producer of covered products sold in or into the state must participate in a product stewardship program for unwanted products from residential sources by January 1, 2010.

(2) Every producer must:

(a) Operate, either individually or collectively with other producers, a product stewardship program approved by the board; or

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

(3) Producers must pay all the administrative costs 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 packaging.

(4) Product stewardship programs 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) A producer required to establish a product stewardship program or stewardship organization who has entered into an agreement to operate a product stewardship program on a producer's behalf, must operate the product stewardship program in accordance with:

(a) The product stewardship plan as approved by the board;

(b) This chapter and other applicable statutes; and

(c) Any rules that may be adopted to implement this chapter.

NEW SECTION. **Sec. 4.** (1) A producer or group of producers who operates or wishes to operate a product stewardship program, or a stewardship organization that operates or wishes to operate a product stewardship program on a producer's behalf, must submit a plan to the board that includes the following:

(a) Contact information, including:

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

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

(b) Performance goals, including:

(i) Recovery goals for the first, second, and third years of the product stewardship program, expressed as pounds per capita, and an explanation of how the recovery goals have been set to recover a significant percentage of unwanted product from residential sources relative to the quantity of product that may be available for disposal; and

(ii) If packaging delivered into the program along with unwanted product is separated from the unwanted product prior to disposal of the unwanted product, how the proposed product stewardship program will maximize the recycling of that packaging;

(c) Design improvements, including how the formulation, prescribing practices, packaging, and distribution of covered products and their

packaging might be improved to reduce waste, reduce toxicity, and reduce environmental impacts;

(d) A collection system, including:

(i) The location of collection sites used by the product stewardship program;

(ii) How unwanted products from residential sources will be collected in all counties in the state and in all cities with populations of greater than ten thousand; and

(iii) How the collection program is convenient and adequate to serve the needs of residents in both urban and rural areas;

(e) A handling and disposal system, including:

(i) The location, permit status, and record of any penalties, violations, or regulatory orders received in the previous five years by the hazardous waste disposal facilities used by the product stewardship program;

(ii) A third-party audit of each disposal facility used by the product stewardship program, including documented compliance with all relevant local, state, national, and international laws;

(iii) The policies and procedures to be followed by persons transporting or disposing, or both, unwanted products from residential sources collected pursuant to the product stewardship program, including how compliance with relevant local, state, national, and international laws will be ensured; and

(iv) How the collected products will be tracked through to final disposal and how safety and security will be maintained;

(f) A description of the public education effort and communications strategy as required in section 14 (1) and (2) of this act; and

(g) How the product stewardship program addresses the requirements in section 17 of this act.

(2) If the board is satisfied that a proposed product stewardship plan complies with this chapter and any rules adopted to implement this chapter, the board shall approve the product stewardship plan.

(3) A plan submitted to the board must be available to the general public through the internet. Information within a plan that is deemed by the board as potentially creating a security risk may not be posted.

NEW SECTION. **Sec. 5.** Every product stewardship program, wherever located, must be licensed by the board in accordance with section 17 of

this act before engaging in the collection of unwanted drugs from residential sources from or within this state. Such a license may not be granted prior to approval of the product stewardship plan by the board.

NEW SECTION. **Sec. 6.** (1) All plans must be submitted to the board by January 1, 2009. Each plan submitted must include information, in addition to the plan itself, that readily identifies through a table or similar means how the requirements of this chapter and any rules adopted to implement this chapter have been met in relation to the content of the plan.

(2) The board shall review each plan and the accompanying information as described in subsection (1) of this section in consultation with the department of ecology.

(3) Within ninety days after receipt of a plan, the board shall determine whether the plan complies with this chapter. If the plan is approved, the board shall send a letter of approval. If a plan is rejected, the board shall provide the applicant with the reasons for rejecting the plan. If an applicant wishes to submit a revised plan, the revised plan must be submitted within sixty days after receipt of the letter of disapproval.

(4) Plans must be updated and submitted to the board for review at least every four years.

(5) After January 1, 2009, each new producer and each producer new to Washington state shall submit a plan to the board or join an approved plan prior to initiating sales in or into this state.

NEW SECTION. **Sec. 7.** (1) A person operating a product stewardship program may not make any substantive changes to the program without amending its plan and obtaining the board's prior written approval of the proposed changes, except as described in subsections (2) and (3) of this section.

(2) Additions and changes to collection locations for unwanted products from residential sources may be made without the board's prior written approval. The product stewardship program must inform the board of such an addition or change fifteen days prior to it occurring, and if there is no objection by the board, the change may occur.

(3) Additional producers may participate in an approved product stewardship program without the board's prior written approval. The product stewardship program must inform the board of such an addition within fifteen days of it occurring.

NEW SECTION. **Sec. 8.** (1) If the board determines that a product stewardship program is not being operated in accordance with the requirements of this chapter and rules adopted to implement this chapter, or if the board determines that there is an imminent danger to the public, the board may:

(a) Amend the approval of the plan by clarifying terms or conditions to ensure full implementation of the plan; or

(b) Suspend or cancel the approval of the plan.

(2) At least thirty days prior to amending, suspending, or canceling an approval pursuant to subsection (1) of this section, the board shall inform the person operating the product stewardship program of the action and provide them an opportunity to respond. The board may extend this time frame on a case-by-case basis.

(3) Notwithstanding subsection (2) of this section, if the board determines that it is necessary in order to protect the public from imminent danger, the board may immediately amend, suspend, or cancel an approval without giving the person operating the product stewardship program an opportunity to be heard, but the board shall give that person 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 board takes any of those actions.

NEW SECTION. **Sec. 9.** (1) For the purposes of this section, "reporting period" means the period commencing January 1st and ending December 31st of the same calendar year.

(2) On or before June 30, 2011, and in each subsequent year, every person operating a product stewardship program must prepare and submit to the board a written annual report describing the activities of the product stewardship program during the previous reporting period, including:

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

(b) The amount, by weight, of unwanted products collected from residential sources through collection services in each county, including documentation verifying collection and disposal of that material;

(c) The collection services provided in each county and in all cities with populations of greater than ten thousand, including the location of each collection service;

(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) At least every two years, documentation and summary results of the third-party audits conducted on each disposal facility that is used;

(g) Penalties, violations, or regulatory orders received during the reporting period, if any, by each disposal facility that is used;

(h) Whether policies and procedures for transporting and disposing unwanted products, as established in the plan, were followed during the reporting period, and a description of noncompliance with those policies and procedures, if any;

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

(j) A description of the public education effort and communication strategy implemented during the reporting period;

(k) A description of steps taken, if any, to improve the formulation, prescribing practices, packaging, and distribution of covered products and its packaging to reduce waste and reduce toxicity;

(l) A description of research, if any, regarding disposal techniques that provide superior protection to human health and the environment beyond that provided by current hazardous waste disposal techniques;

(m) How the product stewardship program attained the performance standards and recovery rates established in the program plan or set by the board, and if the program did not attain those performance standards and recovery rates, what actions it will take during the next reporting period to do so;

(n) How the product stewardship program complied with any other elements detailed in the plan approved by the board; and

(o) Any other information that the board may reasonably require.

(3) All reports submitted to the board must be made available to the department of ecology for review.

(4) A report submitted to the board must be made available to the general public through the internet. Information within a report that is deemed by the board as potentially creating a security risk may not be posted.

NEW SECTION. **Sec. 10.** (1) Except as described in subsection (3) of this section, each product stewardship program must dispose of all unwanted products from residential sources at a hazardous waste facility but otherwise retains all other generator exemptions for household hazardous waste. Such a 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) Producers and stewardship organizations are encouraged to invest in research to find disposal technologies that provide superior protection to human health and the environment beyond that provided by current hazardous waste disposal technologies.

(3)(a) 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:

(i) Monitoring of any emissions or waste;

(ii) Worker health and safety;

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

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

(b) The department of ecology must inform the board of its determination.

NEW SECTION. **Sec. 11.** (1) Producers who are participating in an approved product stewardship program must be listed on the board's web site. The board must list producers who have been identified as noncompliant on the board's web site.

(2) Drug wholesalers must check the board'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 board to determine the producer's status.

(3) The board shall send a written warning and a copy of the requirements of this chapter to a producer who is not a part of an approved product stewardship program and whose covered product is being sold in or into the state. The board shall also send written notification to a drug wholesaler known to be selling such a product in or into the state.

(4) Producers who are not participating in an approved product stewardship program and whose covered products continue to be sold into the state sixty days after receipt of the written warning, and drug wholesalers who sell products from producers who are not participating in an approved product stewardship program sixty days after receipt of the written warning, must pay a fine of ten thousand dollars per day of noncompliance, beginning sixty days after receipt of the written warning. The board is authorized to waive or reduce the fine if the producer becomes compliant, to protect public health, or for any other reasons the board determines to be justified.

(5) The board shall send a written warning under this chapter to a producer who operates a product stewardship program, or a person who operates a product stewardship program on a producer's behalf, who fails to submit a plan, plan revision, or annual report as required in

this chapter. The written warning must include compliance requirements and notification that the compliance requirements must be met within sixty days. If the compliance requirements are not met within sixty days, the producer or other person who operates a product stewardship program on the producer's behalf must be assessed a ten thousand dollar penalty.

(6) A violation of this chapter is a misdemeanor, and each calendar day of operation is deemed a separate offense.

NEW SECTION. **Sec. 12.** (1) The board and the department of ecology are authorized to adopt any rules necessary to enact, implement, administer, and enforce this chapter.

(a) If rules are found to be necessary, the board and the department of ecology are each authorized to require the producer or group of producers or a stewardship organization to develop and pay all costs of developing draft rules for submittal to the board or the department of ecology that may be used by the agencies if found to be suitable as a starting point for development of official rules.

(b) If requested to develop draft rules, the producer or group of producers or stewardship organization must convene a diverse stakeholder group to review and provide input for draft rule development in meetings open to the public. Recommendations made under draft rules must include the rationale that supports the recommendations.

(c) The board and the department of ecology may use any draft rules that are submitted as they deem appropriate to facilitate development of official rules.

(2) By June 2012, the board shall establish mandated performance standards and recovery rates for the fourth and subsequent program years and must establish a fine system for those producers and product stewardship programs that do not attain the mandated standards and rates.

(a) By December 2011, the producer or group of producers or a stewardship organization must develop and pay all costs for developing a report for submittal to the board that recommends and explains the rationale for recommended performance standards, recovery rates, and a fine system for nonattainment of mandated standards and rates for the fourth and subsequent program years.

(b) The producer or group of producers or stewardship organization must convene a diverse stakeholder group to review and advise regarding the development of the report in meetings open to the public.

(c) The board may use the report as it deems appropriate to facilitate establishment of performance standards, recovery rates, and a fine system.

(3) By December 31, 2013, the board shall report to the appropriate committees of the legislature concerning the status of the product stewardship program and recommend legislative action or modification to the rules, if necessary.

(4) The department of ecology, or its designee, is authorized to inspect, audit, or review the audits of disposal facilities that are utilized to fulfill the requirements of a product stewardship program.

(5) The board shall invite comments once a year from health care facilities, health care practitioners, pharmacists, local governments, and citizens to report their satisfaction with the services provided by a product stewardship program. This information must be used by the board in reviewing plan updates and revisions.

NEW SECTION. **Sec. 13.** The pharmaceutical product stewardship programs account is created in the custody of the state treasurer. All fines and penalties collected under section 11 of this act must be deposited into the account. Expenditures from the account may be used only for the administration of this chapter. Only the board 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. 14.** (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.

(3) Health care practitioners, health care facilities, pharmacists, drug wholesalers, drug retailers, waste companies, local and state agencies, charity organizations, and others are encouraged to promote the proper disposal of drugs and use of product stewardship programs.

(4) Pharmacies must provide information to consumers describing where and how to return unwanted drugs to a product stewardship program by providing a toll-free telephone number and web site established by the product stewardship programs and educational materials provided by product stewardship programs.

Sec. 15. RCW 18.64.165 and 1995 c 319 s 5 are each amended to read as follows:

The board shall have the power to refuse, suspend, or revoke the license of any manufacturer, wholesaler, pharmacy, shopkeeper, itinerant vendor, peddler, poison distributor, health care entity, ((~~or~~)) precursor chemical distributor, pharmaceutical product stewardship program, or any other board licensed entity upon proof that:

(1) The license was procured through fraud, misrepresentation, or deceit;

(2) The licensee has violated or has permitted any employee to violate any of the laws of this state or the United States relating to drugs, controlled substances, cosmetics, or nonprescription drugs, or has violated any of the rules and regulations of the board of pharmacy or has been convicted of a felony.

NEW SECTION. **Sec. 16.** A new section is added to chapter 18.64 RCW to read as follows:

Upon a finding, after hearing, that a producer, as the term "producer" is defined in section 2 of this act, or a license holder or licensed entity, or any person in the employ of the licensee has violated the laws of this chapter, this state, or the United States relating to drugs, controlled substances, cosmetics, or nonprescription drugs, or has violated any of the rules of the board of pharmacy, or has been convicted of a felony, after the time of licensing, the board has the power to impose a fine of ten thousand dollars per violation.

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

(1) The producer, group of producers, or stewardship organization wishing to operate a pharmaceutical product stewardship program must apply for a no fee license of location from the board that entitles the producer, group of producers, or stewardship organization 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, for the purpose of disposing of the collected drugs in compliance with the laws and rules of this state and the United States.

(2) The producer, group of producers, or stewardship organization may operate the pharmaceutical product stewardship program that accomplishes activities listed in subsection (1) of this section upon presentation of evidence as required and accepted by the board to demonstrate competence and knowledge to operate the product stewardship program. 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 of the license by the board.

(3) Such a license may not be granted prior to approval of the product stewardship plan by the board.

(4) The board shall require as part of the license application:

(a) Written operating policies and procedures meeting board guidelines;

(b) Procedures for periodically conducting background checks for firm officers and employees; and

(c) A specific written description of the business activities and limitations of practice.

(5) Licenses obtained under this section only allow for the collection and disposal of drugs.

(6) The license activity is limited to the specific activity and limits as approved by the board application.

(7) The respective license is for a specified period ending on the date to be determined by the secretary, and at the specified location. Each owner shall, at the time of license renewal, file with the department on an application provided by the board a declaration of ownership and location. The declaration of ownership and location is

deemed presumptive evidence of ownership of the place of business mentioned in the declaration of ownership and location. It is the duty of the owner to immediately notify the department of any change of location and ownership and to keep the license of location or the renewal thereof properly exhibited in the place of business. Failure to comply with this section is a misdemeanor, and each day in noncompliance is deemed a separate offense.

(8) The board is authorized to establish licensing requirements for additional entities and activities that the board finds necessary to implement this chapter and chapter 70.-- RCW (sections 1 through 14 and 19 through 21 of this act).

NEW SECTION. **Sec. 18.** Sections 1 through 14 and 19 through 21 of this act constitute a new chapter in Title 70 RCW.

NEW SECTION. **Sec. 19.** This act takes effect July 1, 2008.

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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