
HOUSE BILL 3064

State of Washington

60th Legislature

2008 Regular Session

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 01/21/08. Referred to Committee on Select Committee on Environmental Health.

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

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

7 NEW SECTION. **Sec. 1.** The legislature finds that a convenient,
8 safe, secure, and environmentally sound product stewardship program for
9 the collection, transportation, and disposal of unwanted drugs from
10 residential sources may help to avoid accidental poisonings, decrease
11 illegitimate access to drugs that can lead to abuse, and protect our
12 surface and groundwater. The legislature further finds that producers
13 of those drugs are the best entity to manage and finance the product
14 stewardship program.

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

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

18 (2) "Covered product" means all legend and nonlegend drugs.

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

3 (4) "Drugs" means:

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

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

10 (c) Substances, other than food, intended to affect the structure
11 or any function of the body of humans or other animals; or

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

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

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

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

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

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

28 (10) "Producer" means the person who:

29 (a) Has legal ownership of the brand, brand name, or cobrand of the
30 covered product sold in or into Washington state;

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

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

37 (11) "Product stewardship program" means a program for the

1 collection, transportation, and either recycling or disposal, or both,
2 of unwanted products that is financed as well as managed or provided by
3 the producers of those products.

4 (12) "Residential sources" includes single and multiple family
5 residences, and locations where household drugs are unused, unwanted,
6 disposed, or abandoned, such as hospice services, nursing homes,
7 boarding homes, schools, foster care, day care, and other locations
8 where either people or their pet animals, or both, reside on a
9 temporary or permanent basis. This does not include airport security,
10 drug seizures by law enforcement, pharmacy waste, business waste, or
11 any other source identified by the department of ecology as a
12 nonresidential or business source.

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

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

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

22 (2) Every producer must:

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

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

28 (3) Producers must pay all the administrative costs and operational
29 costs associated with their product stewardship program, including the
30 cost of the collection, transportation, and disposal of the unwanted
31 products that are collected from residential sources and the recycling
32 or disposal, or both, of its packaging.

33 (4) Product stewardship programs must be provided without charging
34 any fee at the time of sale of the covered product or at the time the
35 unwanted products from residential sources are delivered or collected
36 for disposal.

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

- 5 (a) The product stewardship plan as approved by the board;
- 6 (b) This chapter and other applicable statutes; and
- 7 (c) Any rules that may be adopted to implement this chapter.

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

- 13 (a) Contact information, including:
 - 14 (i) The individual and the entity submitting the plan; and
 - 15 (ii) A list of all producers participating in the product
16 stewardship program and their contact information;

- 17 (b) Performance goals, including:
 - 18 (i) Recovery goals for the first, second, and third years of the
19 product stewardship program, expressed as pounds per capita, and an
20 explanation of how the recovery goals have been set to recover a
21 significant percentage of unwanted product from residential sources
22 relative to the quantity of product that may be available for disposal;
23 and

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

- 28 (c) Design improvements, including how the formulation, prescribing
29 practices, packaging, and distribution of covered products and their
30 packaging might be improved to reduce waste, reduce toxicity, and
31 reduce environmental impacts;

- 32 (d) A collection system, including:
 - 33 (i) The location of collection sites used by the product
34 stewardship program;

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

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

3 (e) A handling and disposal system, including:

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

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

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

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

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

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

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

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

28 NEW SECTION. **Sec. 5.** Every product stewardship program, wherever
29 located, must be licensed by the board in accordance with section 17 of
30 this act before engaging in the collection of unwanted drugs from
31 residential sources from or within this state. Such a license may not
32 be granted prior to approval of the product stewardship plan by the
33 board.

34 NEW SECTION. **Sec. 6.** (1) All plans must be submitted to the board
35 by January 1, 2009.

1 (2) The board shall review each plan in consultation with the
2 department of ecology.

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

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

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

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

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

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

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

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

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

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

6 (3) Notwithstanding subsection (2) of this section, if the board
7 determines that it is necessary in order to protect the public from
8 imminent danger, the board may immediately amend, suspend, or cancel an
9 approval without giving the person operating the product stewardship
10 program an opportunity to be heard, but the board shall give that
11 person an opportunity to be heard through proceedings consistent with
12 the administrative procedure act, chapter 34.05 RCW, within fifteen
13 days after the date on which the board takes any of those actions.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

32 (3) The product stewardship program operator is also encouraged to
33 report to the board, throughout the reporting period and at the time of
34 the annual report, regarding the identity of any producer who the
35 product stewardship program operator has evidence of or believes is not
36 in compliance with this chapter.

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

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

5 NEW SECTION. **Sec. 10.** (1) Except as described in subsection (3)
6 of this section, each product stewardship program must dispose of all
7 unwanted products from residential sources at a hazardous waste
8 facility but otherwise retains all other generator exemptions for
9 household hazardous waste. Such a hazardous waste facility must be:

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

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

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

17 (2) Producers and stewardship organizations are encouraged to
18 invest in research to find disposal technologies that provide superior
19 protection to human health and the environment beyond that provided by
20 current hazardous waste disposal technologies.

21 (3)(a) Product stewardship programs may petition the department of
22 ecology for approval to use final disposal technologies that provide
23 superior environmental and human health protection than provided by
24 current hazardous waste disposal technologies for drugs, if and when
25 those technologies are proven and available. The proposed technology
26 must provide equivalent protection in each, and superior protection in
27 one or more, of the following areas:

28 (i) Monitoring of any emissions or waste;

29 (ii) Worker health and safety;

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

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

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

35 NEW SECTION. **Sec. 11.** (1) Producers who are participating in an

1 approved product stewardship program must be listed on the board's web
2 site. The board must list producers who have been identified as
3 noncompliant on the board's web site.

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

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

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

26 (5) The board shall send a written warning under this chapter to a
27 producer who operates a product stewardship program, or a person who
28 operates a product stewardship program on a producer's behalf, who
29 fails to submit a plan, plan revision, or annual report as required in
30 this chapter. The written warning must include compliance requirements
31 and notification that the compliance requirements must be met within
32 sixty days. If the compliance requirements are not met within sixty
33 days, the producer or other person who operates a product stewardship
34 program on the producer's behalf must be assessed a ten thousand dollar
35 penalty.

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

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

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

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

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

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

21 NEW SECTION. **Sec. 13.** The pharmaceutical product stewardship
22 programs account is created in the custody of the state treasurer. All
23 fines and penalties collected under section 11 of this act must be
24 deposited into the account. Expenditures from the account may be used
25 only for the administration of this chapter. Only the board may
26 authorize expenditures from the account. The account is subject to
27 allotment procedures under chapter 43.88 RCW, but an appropriation is
28 not required for expenditures.

29 NEW SECTION. **Sec. 14.** (1) A product stewardship program must
30 promote the use of the program and the proper disposal of drugs so that
31 collection options are widely understood by customers, pharmacists,
32 retailers of covered products, and health care practitioners including
33 doctors and other prescribers.

34 (2) A product stewardship program must establish a toll-free
35 telephone number and web site where collection options will be
36 publicized and prepare educational and outreach materials describing

1 where and how to return unwanted drugs to the product stewardship
2 program. These materials must be provided to pharmacies, health care
3 facilities, and other interested parties.

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

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

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

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

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

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

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

30 Upon a finding, after hearing, that a producer, as the term
31 "producer" is defined in section 2 of this act, or a license holder or
32 licensed entity, or any person in the employ of the licensee has
33 violated the laws of this chapter, this state, or the United States
34 relating to drugs, controlled substances, cosmetics, or nonprescription
35 drugs, or has violated any of the rules of the board of pharmacy, or

1 has been convicted of a felony, after the time of licensing, the board
2 has the power to impose the following penalties:

- 3 (1) A fine of ten thousand dollars per violation; or
- 4 (2) A fine of twenty-five thousand dollars per violation when the
5 violation is committed after a finding by hearing or agreed order of
6 the licensee under this section has become final.

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

9 (1) The producer, group of producers, or stewardship organization
10 wishing to operate a pharmaceutical product stewardship program must
11 apply for a no fee license of location from the board that entitles the
12 producer, group of producers, or stewardship organization to operate a
13 pharmaceutical product stewardship program for the collection,
14 transportation, and disposal of unwanted legend and nonlegend drugs
15 from consumers or residential sources and not business entities, for
16 the purpose of disposing of the collected drugs in compliance with the
17 laws and rules of this state and the United States.

18 (2) The producer, group of producers, or stewardship organization
19 may operate the pharmaceutical product stewardship program that
20 accomplishes activities listed in subsection (1) of this section upon
21 presentation of evidence as required and accepted by the board to
22 demonstrate competence and knowledge to operate the product stewardship
23 program. The board shall consider the past history of the applicant,
24 the firm officers, and employees when considering the application. A
25 finding of any drug offense is presumptive reason for denial of the
26 license by the board.

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

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

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

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

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

36 (5) Licensed entities licensed under this section may not engage in

1 activities involving the dispensing, manufacture, or wholesale of
2 drugs.

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

5 (7) The respective license is for a specified period ending on the
6 date to be determined by the secretary, and at the specified location.
7 Each owner shall, at the time of license renewal, file with the
8 department on an application provided by the board a declaration of
9 ownership and location. The declaration of ownership and location is
10 deemed presumptive evidence of ownership of the place of business
11 mentioned in the declaration of ownership and location. It is the duty
12 of the owner to immediately notify the department of any change of
13 location and ownership and to keep the license of location or the
14 renewal thereof properly exhibited in the place of business. Failure
15 to comply with this section is a misdemeanor, and each day in
16 noncompliance is deemed a separate offense.

17 (8) The board is authorized to establish licensing requirements for
18 additional entities and activities that the board finds necessary to
19 implement this chapter and chapter 70.-- RCW (sections 1 through 14 and
20 19 through 21 of this act).

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

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

24 NEW SECTION. **Sec. 20.** If any provision of this act or its
25 application to any person or circumstance is held invalid, the
26 remainder of the act or the application of the provision to other
27 persons or circumstances is not affected.

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

--- END ---