
SUBSTITUTE HOUSE BILL 1165

State of Washington

61st Legislature

2009 Regular Session

By House Environmental Health (originally sponsored 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, Van De Wege, and Santos)

READ FIRST TIME 01/30/09.

1 AN ACT Relating to providing safe collection and disposal of
2 unwanted drugs from residential sources through a producer provided and
3 funded product stewardship program; reenacting and amending RCW
4 69.41.030; adding a new chapter to Title 70 RCW; creating a new
5 section; and prescribing penalties.

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

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

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

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

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

6 (3) "Department" means the department of ecology.

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

9 (5) "Drugs" means:

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

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

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

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

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

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

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

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

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

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

1 (12) "Producer" means the person who:

2 (a) Has legal ownership of the brand, brand name, or cobrand of the
3 covered product or manufactures a generic covered product sold in or
4 into Washington state. "Producer" does not include a retailer who puts
5 its store label on a covered product;

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

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

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

16 (14) "Residential sources" includes single and multiple family
17 residences, and locations where household drugs are unused, unwanted,
18 disposed, or abandoned, such as hospice services, nursing homes,
19 boarding homes, schools, foster care, day care, and other locations
20 where either people or their pet animals, or both, reside on a
21 temporary or permanent basis. This does not include airport security,
22 drug seizures by law enforcement, pharmacy waste, business waste, or
23 any other source identified by the department as a nonresidential or
24 business source.

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

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

31 NEW SECTION. **Sec. 3.** (1) Beginning January 1, 2012, every
32 producer of covered products sold in or into Washington state must
33 participate in a product stewardship program for unwanted products from
34 residential sources.

35 (2) Every producer must:

36 (a) Operate, either individually or jointly with other producers,
37 a product stewardship program approved by the department; or

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

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

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

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

18 (6) A producer, group of producers, or stewardship organization
19 operating or intending to operate a product stewardship program must
20 submit a product stewardship plan to the department prior to engaging
21 in the collection of unwanted covered products.

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

24 (1) Contact information, including:

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

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

28 (2) A collection system provision that describes:

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

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

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

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

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

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

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

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

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

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

32 (4) After January 1, 2011, each new producer and each producer new
33 to Washington state shall obtain a letter of approval from the
34 department for a new plan or join an approved plan upon initiating
35 sales in or into this state.

1 NEW SECTION. **Sec. 6.** (1) Any proposed change to a product
2 stewardship plan must have prior approval of the department except for
3 the following:

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

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

7 (2) The product stewardship program must inform the department of
8 changes in subsection (1)(a) and (b) of this section fifteen days prior
9 to the changes occurring.

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

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

18 (b) The amount, by weight, of unwanted products collected from
19 residential sources, including the amount by weight of unwanted
20 products collected at each drop-off site, if applicable, and the total
21 amount by weight collected by a mail-back system, if applicable;

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

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

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

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

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

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

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

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

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

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

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

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

24 (2) A product stewardship program must establish a toll-free
25 telephone number and web site where collection options will be
26 publicized and prepare educational and outreach materials describing
27 where and how to return unwanted drugs to the product stewardship
28 program. These materials must be provided to pharmacies, health care
29 facilities, and other interested parties for dissemination to
30 residential sources.

31 (3) A product stewardship program must annually evaluate the
32 effectiveness of its outreach and program activities. This evaluation
33 must include the percentage of residents that are aware of the program
34 and to what extent residents find the program convenient.

35 NEW SECTION. **Sec. 9.** (1) Each product stewardship program must
36 dispose of all unwanted products from residential sources at a

1 hazardous waste facility. However, unwanted products from residential
2 sources otherwise retain all other generator exemptions for household
3 hazardous waste. The hazardous waste facility must be:

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

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

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

11 (2) Product stewardship programs may petition the department for
12 approval to use final disposal technologies that provide superior
13 environmental and human health protection than provided by current
14 hazardous waste disposal technologies for drugs if and when those
15 technologies are proven and available. The proposed technology must
16 provide equivalent protection in each, and superior protection in one
17 or more, of the following areas:

18 (a) Monitoring of any emissions or waste;

19 (b) Worker health and safety;

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

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

23 (3) Each product stewardship program is encouraged to separate
24 unwanted products from their original containers, when appropriate,
25 prior to collection or disposal.

26 NEW SECTION. **Sec. 10.** If the department determines that it is
27 necessary to protect the public from imminent danger, it may
28 immediately amend, suspend, or cancel approval of a product stewardship
29 plan without giving the person operating the product stewardship
30 program an opportunity to be heard. However, the department shall give
31 the person operating the product stewardship program an opportunity to
32 be heard through proceedings consistent with the administrative
33 procedure act, chapter 34.05 RCW, within fifteen days after the date on
34 which the department takes any of those actions.

35 NEW SECTION. **Sec. 11.** (1) The department shall send a written
36 warning and a copy of this chapter and any rules adopted to implement

1 this chapter to a producer who is not participating in a product
2 stewardship program approved by the department and whose covered
3 product is being sold in or into the state.

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

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

18 (4) When a product stewardship program is found to be out of
19 compliance with: (a) The requirement to update its plan under section
20 5 of this act; (b) reporting requirements under section 7 of this act;
21 or (c) notification requirements under section 6 of this act, each
22 producer in the product stewardship program must first receive a
23 written warning including a copy of the requirements under this chapter
24 and must be give thirty days to correct the noncompliance. After
25 thirty days, each producer in the product stewardship program must be
26 assessed a penalty of five thousand dollars for the first violation and
27 ten thousand dollars for the second and each subsequent violation. A
28 subsequent violation occurs each thirty days of noncompliance with the
29 requirements under (a) through (c) of this subsection.

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

33 NEW SECTION. **Sec. 12.** (1) The department shall provide on its web
34 site a list of all producers participating in product stewardship
35 programs it has approved and a list of all producers it has identified
36 as noncompliant with this chapter and any rules adopted to implement
37 this chapter.

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

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

13 (4) A drug wholesaler who continues to sell a covered product from
14 a producer that is not participating in an approved product stewardship
15 program sixty days after receiving a written warning from the
16 department must be assessed a penalty of one thousand dollars for each
17 day of noncompliance.

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

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

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

29 (3) By December 31, 2014, the department shall report to the
30 appropriate committees of the legislature concerning the status of the
31 product stewardship program and recommendations for changes to the
32 provisions of this chapter.

33 (4) The department shall annually invite comments from health care
34 facilities, health care practitioners, pharmacists, local governments,
35 and citizens on their satisfaction with the services provided by a
36 product stewardship program. This information must be used by the
37 department in reviewing proposed plan updates and revisions.

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

5 NEW SECTION. **Sec. 14.** The department may establish fees for
6 administering this chapter. The fees may be charged to producers or to
7 persons operating a product stewardship program. All fees charged must
8 be based on factors relating to administering this chapter. Fees may
9 be established in amounts to fully recover and not to exceed expenses
10 incurred by the department in administering this chapter. The
11 department may use these fee revenues to reimburse the department for
12 its costs.

13 NEW SECTION. **Sec. 15.** The pharmaceutical product stewardship
14 program account is created in the custody of the state treasurer. All
15 receipts from fees and penalties collected under this chapter must be
16 deposited into the account. Expenditures from the account may be used
17 only for administering this chapter. Only the director of the
18 department or the director's designee may authorize expenditures from
19 the account. The account is subject to allotment procedures under
20 chapter 43.88 RCW, but an appropriation is not required for
21 expenditures.

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

1 **Sec. 17.** RCW 69.41.030 and 2003 c 142 s 3 and 2003 c 53 s 323 are
2 each reenacted and amended to read as follows:

3 (1) It shall be unlawful for any person to sell, deliver, or
4 possess any legend drug except upon the order or prescription of a
5 physician under chapter 18.71 RCW, an osteopathic physician and surgeon
6 under chapter 18.57 RCW, an optometrist licensed under chapter 18.53
7 RCW who is certified by the optometry board under RCW 18.53.010, a
8 dentist under chapter 18.32 RCW, a podiatric physician and surgeon
9 under chapter 18.22 RCW, a veterinarian under chapter 18.92 RCW, a
10 commissioned medical or dental officer in the United States armed
11 forces or public health service in the discharge of his or her official
12 duties, a duly licensed physician or dentist employed by the veterans
13 administration in the discharge of his or her official duties, a
14 registered nurse or advanced registered nurse practitioner under
15 chapter 18.79 RCW when authorized by the nursing care quality assurance
16 commission, an osteopathic physician assistant under chapter 18.57A RCW
17 when authorized by the board of osteopathic medicine and surgery, a
18 physician assistant under chapter 18.71A RCW when authorized by the
19 medical quality assurance commission, a physician licensed to practice
20 medicine and surgery or a physician licensed to practice osteopathic
21 medicine and surgery, a dentist licensed to practice dentistry, a
22 podiatric physician and surgeon licensed to practice podiatric medicine
23 and surgery, or a veterinarian licensed to practice veterinary
24 medicine, in any province of Canada which shares a common border with
25 the state of Washington or in any state of the United States:
26 PROVIDED, HOWEVER, That the above provisions shall not apply to sale,
27 delivery, or possession by drug wholesalers or drug manufacturers, or
28 their agents or employees, or to any practitioner acting within the
29 scope of his or her license, or to a common or contract carrier or
30 warehouseman, or any employee thereof, whose possession of any legend
31 drug is in the usual course of business or employment: PROVIDED
32 FURTHER, That nothing in this chapter or chapter 18.64 RCW shall
33 prevent a family planning clinic that is under contract with the
34 department of social and health services from selling, delivering,
35 possessing, and dispensing commercially prepackaged oral contraceptives
36 prescribed by authorized, licensed health care practitioners: PROVIDED
37 FURTHER, That nothing in this chapter shall prevent a licensed
38 producer, group of producers, or stewardship organization from

1 operating a pharmaceutical product stewardship program created under
2 chapter 70.-- RCW (the new chapter created in section 19 of this act)
3 for the collection, transportation, and disposal of unwanted legend and
4 nonlegend drugs from consumers or residential sources and not business
5 entities, for the purpose of disposing of the collected drugs in
6 compliance with the laws and rules of this state and the United States.

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

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

12 NEW SECTION. Sec. 18. Nothing in this chapter changes or limits
13 the authority of the Washington utilities and transportation commission
14 to regulate collection of solid waste, including curbside collection of
15 residential recyclable materials, nor does this chapter change or limit
16 the authority of a city or town to provide such service itself or by
17 contract under RCW 81.77.020.

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

20 NEW SECTION. Sec. 20. If any provision of this act or its
21 application to any person or circumstance is held invalid, the
22 remainder of the act or the application of the provision to other
23 persons or circumstances is not affected.

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

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