
SECOND SUBSTITUTE SENATE BILL 5279

State of Washington

61st Legislature

2010 Regular Session

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

READ FIRST TIME 02/09/10.

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; amending RCW 18.64.005; reenacting
4 and amending RCW 69.41.030; adding a new section to chapter 18.64 RCW;
5 adding a new chapter to Title 70 RCW; creating a new section; and
6 prescribing penalties.

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

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

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

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

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

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

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

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

11 (5) "Drugs" means:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 (2) Every producer must:

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

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

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

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

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

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

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

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

28 (1) Contact information, including:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7 (2) The product stewardship program must inform the board of
8 changes in collection locations and producer participation in a product
9 stewardship program fifteen days prior 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 an annual report to the board 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 from each
20 collection method used;

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

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

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

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

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

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

6 (2) A product stewardship program must establish a toll-free
7 telephone number and web site where collection options will be
8 publicized and prepare educational and outreach materials describing
9 where and how to return unwanted drugs to the product stewardship
10 program. These materials must be provided to pharmacies, health care
11 facilities, and other interested parties for dissemination to
12 residential sources.

13 (3) A product stewardship program must annually evaluate the
14 effectiveness of its outreach and program activities. This evaluation
15 must include the percentage of residents that are aware of the program
16 and to what extent residents find the program convenient.

17 NEW SECTION. **Sec. 9.** (1) Each product stewardship program must
18 dispose of all unwanted products from residential sources at a
19 hazardous waste facility. However, unwanted products from residential
20 sources otherwise retain all other generator exemptions for household
21 hazardous waste. The hazardous waste facility must be:

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

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

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

29 (2) Product stewardship programs may petition the department of
30 ecology for approval to use final disposal technologies that provide
31 superior environmental and human health protection than provided by
32 current hazardous waste disposal technologies for drugs if and when
33 those technologies are proven and available. The proposed technology
34 must provide equivalent protection in each, and superior protection in
35 one or more, of the following areas:

36 (a) Monitoring of any emissions or waste;

37 (b) Worker health and safety;

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

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

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

6 NEW SECTION. **Sec. 10.** (1) The board may refuse, suspend or revoke
7 the license of a product stewardship program as provided in RCW
8 18.64.200.

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

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

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

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

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

1 5 of this act; (b) reporting requirements under section 7 of this act;
2 or (c) notification requirements under section 6 of this act, each
3 producer in the product stewardship program must first receive a
4 written warning including a copy of the requirements under this chapter
5 and must be give thirty days to correct the noncompliance. After
6 thirty days, each producer in the product stewardship program must be
7 assessed a penalty of five thousand dollars for the first violation and
8 ten thousand dollars for the second and each subsequent violation. A
9 subsequent violation occurs each thirty days of noncompliance with the
10 requirements under (a) through (c) of this subsection.

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

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

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

22 NEW SECTION. **Sec. 13.** (1) The board may adopt rules necessary to
23 implement, administer, and enforce this chapter.

24 (2) The board, in consultation with the department of ecology, may
25 establish performance standards for product stewardship programs and
26 may establish administrative penalties for failure to meet the
27 standards.

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

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

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

3 NEW SECTION. **Sec. 14.** The secretary of the department may
4 establish fees for administering this chapter as provided under RCW
5 43.70.250. The fees may be charged to producers or to persons
6 operating a product stewardship program. All fees charged must be
7 based on factors relating to administering this chapter. Fees may be
8 established in amounts to fully recover and not to exceed expenses
9 incurred by the board in administering this chapter. The board may use
10 these fee revenues to reimburse the department of ecology for its
11 costs.

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

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

23 (1) A producer, group of producers, or stewardship organization
24 must apply for a license from the board to operate a pharmaceutical
25 product stewardship program under chapter 70.-- RCW (the new chapter
26 created in section 21 of this act). The license entitles the holder to
27 operate a pharmaceutical product stewardship program for the
28 collection, transportation, and disposal of unwanted legend and
29 nonlegend drugs from consumers or residential sources and not business
30 entities.

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

33 (3) The board shall consider the past history of the applicant, the
34 firm officers, and employees when considering the application. A

1 finding of any drug offense is presumptive reason for denial or
2 revocation of the license by the board.

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

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

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

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

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

16 (1) It shall be unlawful for any person to sell, deliver, or
17 possess any legend drug except upon the order or prescription of a
18 physician under chapter 18.71 RCW, an osteopathic physician and surgeon
19 under chapter 18.57 RCW, an optometrist licensed under chapter 18.53
20 RCW who is certified by the optometry board under RCW 18.53.010, a
21 dentist under chapter 18.32 RCW, a podiatric physician and surgeon
22 under chapter 18.22 RCW, a veterinarian under chapter 18.92 RCW, a
23 commissioned medical or dental officer in the United States armed
24 forces or public health service in the discharge of his or her official
25 duties, a duly licensed physician or dentist employed by the veterans
26 administration in the discharge of his or her official duties, a
27 registered nurse or advanced registered nurse practitioner under
28 chapter 18.79 RCW when authorized by the nursing care quality assurance
29 commission, an osteopathic physician assistant under chapter 18.57A RCW
30 when authorized by the board of osteopathic medicine and surgery, a
31 physician assistant under chapter 18.71A RCW when authorized by the
32 medical quality assurance commission, a physician licensed to practice
33 medicine and surgery or a physician licensed to practice osteopathic
34 medicine and surgery, a dentist licensed to practice dentistry, a
35 podiatric physician and surgeon licensed to practice podiatric medicine
36 and surgery, or a veterinarian licensed to practice veterinary
37 medicine, in any province of Canada which shares a common border with

1 the state of Washington or in any state of the United States:
2 PROVIDED, HOWEVER, That the above provisions shall not apply to sale,
3 delivery, or possession by drug wholesalers or drug manufacturers, or
4 their agents or employees, or to any practitioner acting within the
5 scope of his or her license, or to a common or contract carrier or
6 warehouseman, or any employee thereof, whose possession of any legend
7 drug is in the usual course of business or employment: PROVIDED
8 FURTHER, That nothing in this chapter or chapter 18.64 RCW shall
9 prevent a family planning clinic that is under contract with the
10 department of social and health services from selling, delivering,
11 possessing, and dispensing commercially prepackaged oral contraceptives
12 prescribed by authorized, licensed health care practitioners.

13 (2) A pharmaceutical product stewardship program licensed by the
14 Washington state board of pharmacy may possess and transport drugs
15 provided that the product stewardship program complies with this
16 chapter.

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

20 (b) A violation of this section involving possession is a
21 misdemeanor.

22 **Sec. 18.** RCW 18.64.005 and 1990 c 83 s 1 are each amended to read
23 as follows:

24 The board shall:

25 (1) Regulate the practice of pharmacy and enforce all laws placed
26 under its jurisdiction;

27 (2) Prepare or determine the nature of, and supervise the grading
28 of, examinations for applicants for pharmacists' licenses;

29 (3) Establish the qualifications for licensure of pharmacists or
30 pharmacy interns;

31 (4) Conduct hearings for the revocation or suspension of licenses,
32 permits, registrations, certificates, or any other authority to
33 practice granted by the board, which hearings may also be conducted by
34 an administrative law judge appointed under chapter 34.12 RCW;

35 (5) Issue subpoenas and administer oaths in connection with any
36 hearing, or disciplinary proceeding held under this chapter or any
37 other chapter assigned to the board;

1 (6) Assist the regularly constituted enforcement agencies of this
2 state in enforcing all laws pertaining to drugs, controlled substances,
3 and the practice of pharmacy, or any other laws or rules under its
4 jurisdiction;

5 (7) Promulgate rules for the dispensing, distribution, wholesaling,
6 and manufacturing of drugs and devices and the practice of pharmacy for
7 the protection and promotion of the public health, safety, and welfare.
8 Violation of any such rules shall constitute grounds for refusal,
9 suspension, or revocation of licenses or any other authority to
10 practice issued by the board;

11 (8) Adopt rules establishing and governing continuing education
12 requirements for pharmacists and other licensees applying for renewal
13 of licenses under this chapter;

14 (9) Be immune, collectively and individually, from suit in any
15 action, civil or criminal, based upon any disciplinary proceedings or
16 other official acts performed as members of such board. Such immunity
17 shall apply to employees of the department when acting in the course of
18 disciplinary proceedings;

19 (10) Suggest strategies for preventing, reducing, and eliminating
20 drug misuse, diversion, and abuse, including professional and public
21 education, and treatment of persons misusing and abusing drugs;

22 (11) Conduct or encourage educational programs to be conducted to
23 prevent the misuse, diversion, and abuse of drugs for health care
24 practitioners and licensed or certified health care facilities;

25 (12) Monitor trends of drug misuse, diversion, and abuse and make
26 periodic reports to disciplinary boards of licensed health care
27 practitioners and education, treatment, and appropriate law enforcement
28 agencies regarding these trends;

29 (13) Enter into written agreements with all other state and federal
30 agencies with any responsibility for controlling drug misuse,
31 diversion, or abuse and with health maintenance organizations, health
32 care service contractors, and health care providers to assist and
33 promote coordination of agencies responsible for ensuring compliance
34 with controlled substances laws and to monitor observance of these laws
35 and cooperation between these agencies. The department of social and
36 health services, the department of labor and industries, and any other
37 state agency including licensure disciplinary boards, shall refer all
38 apparent instances of over-prescribing by practitioners and all

1 apparent instances of legend drug overuse to the department. The
2 department shall also encourage such referral by health maintenance
3 organizations, health service contractors, and health care providers;

4 (14) Adopt rules to implement, administer, and enforce the laws on
5 the collection, transportation, disposal, and possession of unwanted
6 drugs from residential sources through producer provided and funded
7 product stewardship programs under chapter 70.-- RCW (the new chapter
8 created in section 21 of this act).

9 NEW SECTION. **Sec. 19.** Nothing in this chapter changes or limits
10 the authority of the Washington utilities and transportation commission
11 to regulate collection of solid waste, including curbside collection of
12 residential recyclable materials, nor does this chapter change or limit
13 the authority of a city or town to provide such service itself or by
14 contract under RCW 81.77.020.

15 NEW SECTION. **Sec. 20.** Nothing in this chapter applies to
16 hospitals licensed under chapter 70.41 RCW, whose pharmaceutical wastes
17 are disposed of under rules and policies adopted by the department of
18 ecology.

19 NEW SECTION. **Sec. 21.** Sections 1 through 15, 19, and 20 of this
20 act constitute a new chapter in Title 70 RCW.

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

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

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