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**SUBSTITUTE SENATE BILL 5234**

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**State of Washington**

**62nd Legislature**

**2011 Regular Session**

**By** Senate Health & Long-Term Care (originally sponsored by Senators Kline, Swecker, Keiser, Rockefeller, Shin, Conway, Pridemore, Ranker, Pflug, Nelson, Chase, Kohl-Welles, Haugen, White, Regala, Murray, and Fraser)

READ FIRST TIME 02/08/11.

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 69.41.030, 18.64.005,  
4 and 42.56.270; 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 legislature finds that Washington state  
8 citizens benefit from the authorized use of prescription and over-the-  
9 counter medicines. The proper use of medicines helps to cure, treat,  
10 and prevent diseases, and to prolong life. Failure to properly dispose  
11 of leftover and expired medicines can lead to the illegal possession  
12 and abuse of potentially addictive medicines by others, and to the  
13 consumption of medicines by children and others, potentially causing  
14 addiction, poisonings, overdoses, and other harmful health effects.  
15 Moreover, disposing of medicines by flushing them down the toilet or  
16 placing them in the garbage can lead to the contamination of  
17 groundwater and other bodies of water, contributing to long-term harm  
18 to the environment and to animal life. The legislature finds that  
19 Washington residents need a safe method for disposal of medicines

1 through "take-back" programs that provide environmentally sound  
2 disposal of medicines with effective controls against diversion. The  
3 legislature intends that the costs of properly collecting and disposing  
4 of leftover and expired medicines be included in the producer's  
5 business costs, and further finds that the producers of the medicines  
6 are best positioned to efficiently develop and operate programs for the  
7 safe and convenient collection and disposal of unused medicines.

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

10 (1) "Corporation" means the medicine return corporation established  
11 in section 3 of this act.

12 (2)(a) "Covered drug" includes all legend and nonlegend drugs from  
13 residential sources sold in any form. This includes brand name and  
14 generic drugs.

15 (b) "Covered drug" does not include:

16 (i) Vitamins or supplement;

17 (ii) Herbal-based remedies and homeopathic drugs, products, or  
18 remedies;

19 (iii) Cosmetics, shampoos, sunscreens, toothpaste, lip balm,  
20 antiperspirants, or other personal care products that are regulated as  
21 both cosmetics and nonlegend drugs under the federal food, drug, and  
22 cosmetic act;

23 (iv) Drugs for which producers provide a take-back program as part  
24 of a federal food and drug administration managed risk evaluation and  
25 mitigation strategy (21 U.S.C. Sec. 355-1);

26 (v) Drugs that are biological products as defined by 21 C.F.R.  
27 600.3(h) as it exists on the effective date of this section if the  
28 producer already provides a take-back program; and

29 (vi) Pet pesticide products contained in pet collars, powders,  
30 shampoos, topical applications, or other forms.

31 (3) "Drug wholesaler" means a corporation, individual, or other  
32 entity which buys drugs or devices for resale and distribution to  
33 corporations, individuals, or entities other than consumers.

34 (4) "Drugs" means:

35 (a) Articles recognized in the official United States  
36 pharmacopoeia, the official national formulary, the official

1 homeopathic pharmacopoeia of the United States, or any supplement of  
2 the formulary or those pharmacopoeias;

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

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

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

10 (5) "Generic drug" means drugs that are chemically identical or  
11 bioequivalent to a brand name drug in dosage form, safety, strength,  
12 route of administration, quality, performance characteristics, and  
13 intended use. However, inactive ingredients may vary.

14 (6) "Legend drug" means any drugs, including controlled substances  
15 under chapter 69.50 RCW, that are required by any applicable federal or  
16 state law or regulation to be dispensed by prescription only or are  
17 restricted to use by practitioners only.

18 (7) "Nonlegend drug" means any drugs that may be lawfully sold  
19 without a prescription.

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

24 (9) "Producer" means the person who:

25 (a) Has legal ownership of the brand, brand name, or cobrand of the  
26 covered drug or manufactures a generic covered drug sold in Washington  
27 state. "Producer" does not include a retailer who puts its store label  
28 on a covered drug or a pharmacist who compounds a prescribed individual  
29 drug product for a patient;

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

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

36 (10) "Product stewardship program" means a statewide program for  
37 the collection, transportation, and disposal of unwanted covered drugs

1 that is financed by the producers of those products and managed by the  
2 corporation.

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

12 (12) "Unwanted covered drug" means any covered drug no longer  
13 wanted by its owner or that has been abandoned, discarded, or is  
14 intended to be discarded by its owner.

15 NEW SECTION. **Sec. 3.** (1) The medicine return corporation is  
16 established as a nonprofit product stewardship organization to finance  
17 and operate a product stewardship program for the collection,  
18 transportation, and disposal of unwanted covered drugs. Membership in  
19 the corporation must be open to all producers of covered drugs sold in  
20 the state and all producers of covered drugs sold in the state must  
21 participate in the corporation's product stewardship program.

22 (2)(a) The corporation must be incorporated as a nonprofit  
23 corporation under chapter 24.06 RCW. In its articles of incorporation,  
24 the corporation must list as its purpose to devise and administer a  
25 producer-funded product stewardship program to provide for the  
26 collection, transportation, and disposal of unwanted covered drugs in  
27 conjunction with the board of pharmacy and pursuant to chapter 70.---  
28 RCW (the new chapter created in section 22 of this act).

29 (b) The corporation's articles of incorporation must be filed with  
30 the secretary of state within sixty days of the effective date of this  
31 section.

32 (3) The corporation is managed by a board of directors, initially  
33 appointed by the secretary of the department of health. The board of  
34 directors is to be composed of representatives of producers whose  
35 covered drugs are sold in or into the state. Any producer of covered  
36 drugs, or representative of the producers, may submit recommendations

1 for members of the board of directors to the secretary of the  
2 department of health.

3 (a) The board of directors must include, at a minimum,  
4 representatives of:

- 5 (i) Two branded legend drugmakers;
- 6 (ii) Two generic legend drugmakers;
- 7 (iii) Two nonlegend drugmakers; and
- 8 (iv) Two biotechnology sector drugmakers.

9 (b) Additionally, four members of the legislature shall serve on  
10 the board as ex officio, nonvoting members, to be appointed as follows:

11 (i) One member from each of the two major caucuses in the senate,  
12 appointed by the president of the senate; and

13 (ii) One member from each of the two major caucuses in the house of  
14 representatives, appointed by the speaker of the house of  
15 representatives.

16 (4) The board of directors of the corporation shall:

17 (a) Prepare and adopt articles of incorporation and bylaws, and  
18 select a chair;

19 (b) Prepare and adopt a general plan of operation of procedures for  
20 the corporation. The plan of operation must include procedures for  
21 assessing costs and collecting funds from participating producers under  
22 section 6 of this act. The plan of operation must include a dispute  
23 mechanism through which a producer selling covered drugs in the state  
24 may challenge an assessment determination by the board of directors,  
25 and a mechanism by which the corporation may notify a producer selling  
26 covered drugs in the state that is failing to participate in the  
27 corporation and report such a producer to the board of pharmacy;

28 (c) By January 1, 2013, submit a proposed product stewardship  
29 program to the board of pharmacy for review in accordance with section  
30 4 of this act; the product stewardship program must be approved and  
31 licensed by the board of pharmacy prior to collecting unwanted covered  
32 drugs;

33 (d) By January 1, 2014, operate a product stewardship program in  
34 accordance with this act;

35 (e) Enter into contracts and agreements with other service  
36 providers and entities as necessary, useful, or convenient to provide  
37 all or portions of the product stewardship program;

1 (f) Take any legal action necessary or proper for the recovery of  
2 an assessment for, on behalf of, or against members of the corporation  
3 or other participating persons; and

4 (g) Perform any other functions as may be necessary or proper to  
5 provide the product stewardship program and to affect any or all of the  
6 purposes for which the corporation is organized.

7 (5) The members of the board of directors, including ex officio,  
8 nonvoting members, serve without compensation but are entitled to  
9 reimbursement, solely from the funds of the corporation, for expenses  
10 incurred in the discharge of their duties under this chapter. However,  
11 no reimbursement may be provided for meals or travel expenses.

12 (6) The corporation shall provide the product stewardship program  
13 described in this chapter without using state or local government  
14 funds.

15 (7) The board of pharmacy may audit the activities of the  
16 corporation as necessary. The board of pharmacy, department of  
17 ecology, or department of health staff may access any facilities or  
18 property of the corporation as necessary to conduct inspections or  
19 investigate complaints.

20 NEW SECTION. **Sec. 4.** (1)(a) Meetings of the corporation are  
21 subject to the open public meetings act, chapter 42.30 RCW, and must be  
22 open and public and all persons must be permitted to attend any meeting  
23 of the corporation. The corporation may hold executive sessions in  
24 accordance with RCW 42.30.110 and as needed to protect producer-  
25 provided information exempt from the public records act under RCW  
26 42.56.270(21), to evaluate the qualifications of an applicant for  
27 employment, and to review contracts or services of service providers.

28 (b) Except as provided in RCW 42.56.270, records of the corporation  
29 are subject to the public records act, chapter 42.56 RCW.

30 (2) In developing a proposed product stewardship program, the  
31 corporation must provide opportunities for public comment, including at  
32 least one public hearing. Notice of the public hearing must be  
33 provided by the corporation to the department of health, the board of  
34 pharmacy, the department of ecology, the Washington association of  
35 sheriffs and police chiefs, covered drug retailers, substance abuse  
36 professionals, local governments, solid waste professionals, water  
37 quality professionals, and the general public.

1 (3) After public comment has been received and by January 1, 2013,  
2 the corporation's proposed product stewardship program must be  
3 submitted to the board of pharmacy for review. The board of pharmacy  
4 shall consult with the department of ecology on any element of the  
5 proposed program including transportation and disposal systems, secure  
6 tracking and handling, package recycling, and public education. The  
7 board of pharmacy must consult with the Washington association of  
8 sheriffs and police chiefs on the adequacy of the proposed program's  
9 security measures for collection, transportation, and disposal of  
10 unwanted covered drugs.

11 (4) After the review and consultation under subsection (3) of this  
12 section and within ninety days after receipt of the proposed product  
13 stewardship program, the board of pharmacy must either approve or  
14 reject the corporation's proposed product stewardship program and, if  
15 rejected, provide reasons for rejection. If the program is rejected,  
16 the corporation must:

17 (a) Submit a revised product stewardship program within sixty days  
18 after receiving notice of the rejection; or

19 (b) Appeal the board of pharmacy's decision under the  
20 administrative procedure act, chapter 34.05 RCW, within sixty days  
21 after receiving notice of the rejection.

22 (5) The corporation shall annually invite comments from health care  
23 facilities, health care practitioners, pharmacists, local governments,  
24 law enforcement personnel, and citizens on their satisfaction with the  
25 services provided by the product stewardship program. This information  
26 must be used by the corporation in developing proposed product  
27 stewardship program updates and revisions. This information must also  
28 be provided to the board of pharmacy and must be used by the board of  
29 pharmacy in reviewing proposed program updates and revisions.

30 (6) At least every four years, the corporation must update its  
31 product stewardship program and submit the updated program to the board  
32 of pharmacy for review using the process described in subsections (3)  
33 and (4) of this section.

34 NEW SECTION. **Sec. 5.** The corporation's product stewardship  
35 program, which must be developed and reviewed according to section 4 of  
36 this act, must provide the following:

1 (1) A description of the proposed collection system. The  
2 collection system for all unwanted covered drugs must be safe, secure,  
3 and protect patient information. The collection system must be  
4 convenient and adequately serve the needs of residents in both urban  
5 and rural areas. The collection system must provide, at a minimum, one  
6 drop-off collection site in all counties in the state and one drop-off  
7 collection site in all cities with a population greater than ten  
8 thousand, on an ongoing, year-round basis. However, if a drop-off  
9 location cannot be arranged in a specific county or city, prepaid  
10 mailing envelopes must be provided;

11 (2) In accordance with requirements stated in sections 6(6) and 7  
12 of this act, the collection system shall incorporate drop-off  
13 collection sites for unwanted covered drugs in existence on the  
14 effective date of this section if they meet program requirements, and  
15 additional collectors to improve convenience and availability of  
16 services;

17 (3) A description of the handling and disposal system, including  
18 identification of and contact information for collectors, transporters,  
19 and waste disposal facilities in accordance with section 11 of this act  
20 to be used by the product stewardship program;

21 (4) A description of how the corporation will use existing  
22 providers of waste pharmaceutical services to the extent possible and  
23 in accordance with section 11 of this act;

24 (5) A description of how covered drugs will be separated from  
25 packaging to the extent possible to reduce transportation and disposal  
26 costs and how drug packaging will be recycled to the extent feasible;

27 (6) The policies and procedures to be followed by persons in charge  
28 of unwanted covered drugs collected pursuant to the product stewardship  
29 program;

30 (7) A description of how the collected, unwanted covered drugs are  
31 tracked through to final disposal and how safety and security is  
32 maintained;

33 (8) A description of how patient information on drug packaging will  
34 be kept secure during collection, transportation, and disposal;

35 (9) A description of the public education effort and communications  
36 strategy required in section 10 of this act; and

37 (10) Contact information for all drug producers participating in  
38 the corporation.

1           NEW SECTION.       **Sec. 6.**       (1) The corporation shall pay all  
2 administrative and operational costs related to the product stewardship  
3 program. Corporation costs must be financed by producers who sell  
4 covered drugs in this state. The corporation's board of directors  
5 shall determine a method for equitably apportioning costs among  
6 producers whose covered drugs are sold in or into this state, and  
7 determine the method and timing of assessment collection. Each  
8 producer selling covered drugs in this state must be assessed and is  
9 required to timely remit payment to the corporation for its share of  
10 the corporation's total costs. Moneys remitted to the corporation  
11 under this section must be retained by the corporation and used solely  
12 for the administration and operation of the product stewardship  
13 program. Administrative and operational costs related to the product  
14 stewardship program include the following:

15           (a) Secure collection containers for the required minimum number of  
16 collection sites described in section 5(1) of this act;

17           (b) Collection and transportation supplies for the required minimum  
18 number of collection sites described in section 5(1) of this act;

19           (c) Mailers and mailings if a mail-back system is developed;

20           (d) Transportation of all collected pharmaceuticals to final  
21 disposal, including costs of law enforcement escort if necessary;

22           (e) Environmentally sound disposal of all collected pharmaceuticals  
23 under section 11 of this act;

24           (f) Program promotion under section 10 of this act;

25           (g) State agency and board of pharmacy oversight to administer and  
26 enforce this chapter under subsection (7) of this section; and

27           (h) Reasonable costs for administration of the corporation, as  
28 determined necessary by the corporation's board of directors.

29           (2) The corporation must submit its method for equitably  
30 apportioning costs among producers and the method and timing of  
31 assessment collection developed under subsection (1) of this section to  
32 the board of pharmacy for its review or rejection. If rejected, the  
33 corporation must:

34           (a) Submit revised methods within sixty days after receiving notice  
35 of the rejection; or

36           (b) Appeal the board of pharmacy's decision under the  
37 administrative procedure act, chapter 34.05 RCW, within sixty days  
38 after receiving notice of the rejection.

1 (3) The corporation may, subject to board of pharmacy approval,  
2 adjust the apportionment of costs under subsection (2) of this section  
3 annually.

4 (4) The corporation's board of directors may offer incentives or  
5 payments to collectors if necessary to ensure the product stewardship  
6 program requirements for the minimum number of collection sites are  
7 met, as described in section 5(1) of this act.

8 (5) Producers may not impose a visible fee on consumers when  
9 covered drugs are purchased or returned.

10 (6) The total annual cost responsibility to the corporation,  
11 notwithstanding any penalties or fines, may not exceed two million five  
12 hundred thousand dollars per calendar year. This number must be  
13 annually adjusted for inflation starting in 2012. The corporation  
14 shall report actual annual expenditures and may comment on this limit  
15 to the corporation's total annual cost responsibility in their annual  
16 report to the board of pharmacy under section 9 of this act.

17 (7) The secretary of the department of health may establish fees  
18 for administering this chapter as provided under RCW 43.70.250. The  
19 fees may be charged to the corporation. The fees must be based on  
20 factors relating to administering this chapter. Fees may be  
21 established in amounts to fully recover expenses incurred by the board  
22 of pharmacy, but must not exceed fifteen percent of the total annual  
23 cost responsibility to the corporation under subsection (6) of this  
24 section. The board of pharmacy may use these fee revenues to reimburse  
25 the department of ecology for its costs. The board of pharmacy may  
26 prioritize the work to implement this chapter if fees are not adequate  
27 to fund all costs of administration. Fees paid under this subsection  
28 must be deposited into the pharmaceutical product stewardship program  
29 account under section 16 of this act.

30 (8) Any producer may appeal an assessment of charges or  
31 apportionment of costs to the board of pharmacy under the  
32 administrative procedure act, chapter 34.05 RCW.

33 NEW SECTION. **Sec. 7.** This chapter does not require any person to  
34 serve as a collector in the product stewardship program. A person may  
35 offer to serve as a collector, or may agree to serve as a collector in  
36 exchange for incentives or payment offered by the corporation's board  
37 of directors. Collectors may include law enforcement, pharmacies,

1 other relevant public or private locations, such as hospitals, senior  
2 centers, community health clinics, fire stations, veterinary clinics,  
3 or private sector collectors, and mail-back services, operating in  
4 accordance with state and federal laws and regulations for the handling  
5 of covered drugs and in compliance with this chapter.

6 NEW SECTION. **Sec. 8.** (1) Any proposed change to the product  
7 stewardship program must have prior approval of the board of pharmacy.

8 (2) The product stewardship program must inform the board of  
9 pharmacy of changes in collection locations in the product stewardship  
10 program fifteen days before the changes occur.

11 NEW SECTION. **Sec. 9.** (1) By June 30, 2015, and annually  
12 thereafter, the corporation must submit a report to the board of  
13 pharmacy describing the program's activities during the previous  
14 reporting period. The report must include the following:

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

17 (b) The amount, by weight, of unwanted covered drugs collected,  
18 including the amount by weight from each collection method used;

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

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

27 (e) A description of the public education and outreach activities  
28 in compliance with section 10 of this act implemented during the  
29 reporting period;

30 (f) A description of how collected packaging was recycled to the  
31 extent feasible, including the recycling facility or facilities used;  
32 and

33 (g) The total expenditure of the corporation during the reporting  
34 period, and whether the corporation foresees a need for adjustment of  
35 the total annual cost responsibility under section 6(6) of this act as  
36 a result of changes in volumes of collected drugs or other costs.

1 (2) The board of pharmacy must make reports submitted under this  
2 section available to the public.

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

6 NEW SECTION. **Sec. 10.** (1) The corporation must promote the use of  
7 the product stewardship program and the safe storage and proper  
8 disposal of covered drugs so that collection options are widely  
9 understood by customers, pharmacists, retailers of covered drugs, and  
10 health care practitioners including doctors and other prescribers.

11 (2) The corporation must establish a toll-free telephone number and  
12 web site where collection options will be publicized and prepare  
13 educational and outreach materials describing where and how to return  
14 unwanted covered drugs to the product stewardship program. These  
15 materials must be provided to pharmacies, health care facilities, and  
16 other interested parties for dissemination to residential sources.

17 (3) The department of health, the department of ecology, and local  
18 governments must promote the use of the product stewardship program and  
19 the program's toll-free telephone number and web site through existing  
20 educational methods.

21 (4) The corporation must annually evaluate the effectiveness of its  
22 outreach and program activities. At least every four years, this  
23 evaluation must include the percentage of residents that are aware of  
24 the program and to what extent residents find the program convenient.

25 NEW SECTION. **Sec. 11.** (1) Covered drugs collected under the  
26 product stewardship program must be disposed of at a properly permitted  
27 hazardous waste disposal facility, or at an in-state solid waste  
28 incinerator facility permitted under chapter 173-434 WAC, or at a  
29 properly permitted solid waste incinerator facility in a neighboring  
30 state or province.

31 (2) Unwanted covered drugs from residential sources retain all  
32 other generator exemptions for household hazardous waste.

33 (3) The corporation may petition the department of ecology for  
34 approval to use final disposal technologies that provide superior  
35 environmental and human health protection than provided by current the  
36 disposal technologies in subsection (1) of this section for drugs if

1 and when those technologies are proven and available. The proposed  
2 technology must provide equivalent protection in each, and superior  
3 protection in one or more, of the following areas:

4 (a) Monitoring of any emissions or waste;

5 (b) Worker health and safety;

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

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

9 NEW SECTION. **Sec. 12.** (1) The board of pharmacy may suspend in  
10 whole or in part the product stewardship program if it determines that  
11 it is necessary to protect the public from imminent danger. The board  
12 may refuse, suspend, or revoke the license of the product stewardship  
13 program as provided in RCW 18.64.200.

14 (2) If the board of pharmacy determines that the corporation is not  
15 in compliance with this chapter or the program standards adopted by the  
16 board of pharmacy under section 15 of this act, the board of pharmacy  
17 may send the corporation a written warning stating the program is not  
18 in compliance. The corporation has thirty days after receipt of the  
19 notice to come into compliance. If the corporation is not in  
20 compliance after thirty days, the board of pharmacy may assess a  
21 penalty of five thousand dollars for the first violation and ten  
22 thousand dollars for the second and each subsequent violation. A  
23 subsequent violation occurs each thirty days of noncompliance. This  
24 subsection does not preclude the board of pharmacy from suspending the  
25 product stewardship program.

26 (3) The corporation may appeal penalties prescribed under this  
27 section under the administrative procedure act, chapter 34.05 RCW.

28 (4) All penalties levied under this section must be deposited into  
29 the pharmaceutical product stewardship program account established  
30 under section 16 of this act.

31 NEW SECTION. **Sec. 13.** (1) The board of pharmacy shall send a  
32 written warning and a copy of this chapter and any rules adopted to  
33 implement this chapter to a producer who is not participating in the  
34 product stewardship program, or who is not remitting full payment to  
35 the corporation for its share of the corporation's total costs, and  
36 whose covered drug is being sold in the state.

1 (2) A producer not participating in the product stewardship  
2 program, or who is not remitting full payment to the corporation for  
3 its share of the corporation's total costs, whose covered drug  
4 continues to be sold in the state sixty days after receiving a written  
5 warning from the board of pharmacy must be assessed a penalty of ten  
6 thousand dollars for each calendar day that the violation continues.

7 (3) A producer may appeal penalties prescribed under this section  
8 under the administrative procedure act, chapter 34.05 RCW.

9 (4) All penalties levied under this section must be deposited into  
10 the pharmaceutical product stewardship program account established  
11 under section 16 of this act.

12 NEW SECTION. **Sec. 14.** Beginning in 2012, each drug wholesaler  
13 that sells any covered drug in the state must provide a list of  
14 producers of covered drugs to the board of pharmacy in a form  
15 determined by the board of pharmacy. Wholesalers must update the list  
16 by January 15th of each year.

17 NEW SECTION. **Sec. 15.** (1) The board of pharmacy may adopt rules  
18 necessary to implement, administer, and enforce this chapter.

19 (2) The board of pharmacy, in consultation with the department of  
20 ecology, may establish performance standards for the product  
21 stewardship program.

22 (3) By December 31, 2016, the board of pharmacy shall report to the  
23 appropriate committees of the legislature concerning the status of the  
24 product stewardship program and recommendations for changes to this  
25 chapter.

26 NEW SECTION. **Sec. 16.** The pharmaceutical product stewardship  
27 program account is created in the custody of the state treasurer. All  
28 receipts from fees and penalties collected under this chapter must be  
29 deposited into the account. Expenditures from the account may be used  
30 only for administering this chapter. Only the secretary of the  
31 department of health or the secretary's designee may authorize  
32 expenditures from the account. The account is subject to allotment  
33 procedures under chapter 43.88 RCW, but an appropriation is not  
34 required for expenditures.

1       **Sec. 17.** RCW 69.41.030 and 2010 c 83 s 1 are each amended to read  
2 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, or any of the following  
20 professionals in any province of Canada that shares a common border  
21 with the state of Washington or in any state of the United States: A  
22 physician licensed to practice medicine and surgery or a physician  
23 licensed to practice osteopathic medicine and surgery, a dentist  
24 licensed to practice dentistry, a podiatric physician and surgeon  
25 licensed to practice podiatric medicine and surgery, a licensed  
26 advanced registered nurse practitioner, or a veterinarian licensed to  
27 practice veterinary medicine: PROVIDED, HOWEVER, That the above  
28 provisions shall not apply to sale, delivery, or possession by drug  
29 wholesalers or drug manufacturers, or their agents or employees, or to  
30 any practitioner acting within the scope of his or her license, or to  
31 a common or contract carrier or warehouseman, or any employee thereof,  
32 whose possession of any legend drug is in the usual course of business  
33 or employment: PROVIDED FURTHER, That nothing in this chapter or  
34 chapter 18.64 RCW shall prevent a family planning clinic that is under  
35 contract with the department of social and health services from  
36 selling, delivering, possessing, and dispensing commercially  
37 prepackaged oral contraceptives prescribed by authorized, licensed  
38 health care practitioners.

1           (2) The product stewardship program created in chapter 70.-- RCW  
2 (the new chapter created in section 22 of this act) may possess and  
3 transport drugs provided that the product stewardship program complies  
4 with this chapter.

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

8           (b) A violation of this section involving possession is a  
9 misdemeanor.

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

12           The board shall:

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

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

17           (3) Establish the qualifications for licensure of pharmacists or  
18 pharmacy interns;

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

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

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

30           (7) Promulgate rules for the dispensing, distribution, wholesaling,  
31 and manufacturing of drugs and devices and the practice of pharmacy for  
32 the protection and promotion of the public health, safety, and welfare.  
33 Violation of any such rules shall constitute grounds for refusal,  
34 suspension, or revocation of licenses or any other authority to  
35 practice issued by the board;

36           (8) Adopt rules establishing and governing continuing education

1 requirements for pharmacists and other licensees applying for renewal  
2 of licenses under this chapter;

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

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

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

14 (12) Monitor trends of drug misuse, diversion, and abuse and make  
15 periodic reports to disciplinary boards of licensed health care  
16 practitioners and education, treatment, and appropriate law enforcement  
17 agencies regarding these trends;

18 (13) Enter into written agreements with all other state and federal  
19 agencies with any responsibility for controlling drug misuse,  
20 diversion, or abuse and with health maintenance organizations, health  
21 care service contractors, and health care providers to assist and  
22 promote coordination of agencies responsible for ensuring compliance  
23 with controlled substances laws and to monitor observance of these laws  
24 and cooperation between these agencies. The department of social and  
25 health services, the department of labor and industries, and any other  
26 state agency including licensure disciplinary boards, shall refer all  
27 apparent instances of over-prescribing by practitioners and all  
28 apparent instances of legend drug overuse to the department. The  
29 department shall also encourage such referral by health maintenance  
30 organizations, health service contractors, and health care providers;

31 (14) Adopt rules to implement, administer, and enforce the laws on  
32 the collection, transportation, disposal, and possession of unwanted  
33 covered drugs from residential sources through producer-provided and  
34 funded product stewardship programs under chapter 70.--- RCW (the new  
35 chapter created in section 22 of this act).

36 **Sec. 19.** RCW 42.56.270 and 2009 c 394 s 3 are each amended to read  
37 as follows:

1 The following financial, commercial, and proprietary information is  
2 exempt from disclosure under this chapter:

3 (1) Valuable formulae, designs, drawings, computer source code or  
4 object code, and research data obtained by any agency within five years  
5 of the request for disclosure when disclosure would produce private  
6 gain and public loss;

7 (2) Financial information supplied by or on behalf of a person,  
8 firm, or corporation for the purpose of qualifying to submit a bid or  
9 proposal for (a) a ferry system construction or repair contract as  
10 required by RCW 47.60.680 through 47.60.750 or (b) highway construction  
11 or improvement as required by RCW 47.28.070;

12 (3) Financial and commercial information and records supplied by  
13 private persons pertaining to export services provided under chapters  
14 43.163 and 53.31 RCW, and by persons pertaining to export projects  
15 under RCW 43.23.035;

16 (4) Financial and commercial information and records supplied by  
17 businesses or individuals during application for loans or program  
18 services provided by chapters 43.325, 43.163, 43.160, 43.330, and  
19 43.168 RCW, or during application for economic development loans or  
20 program services provided by any local agency;

21 (5) Financial information, business plans, examination reports, and  
22 any information produced or obtained in evaluating or examining a  
23 business and industrial development corporation organized or seeking  
24 certification under chapter 31.24 RCW;

25 (6) Financial and commercial information supplied to the state  
26 investment board by any person when the information relates to the  
27 investment of public trust or retirement funds and when disclosure  
28 would result in loss to such funds or in private loss to the providers  
29 of this information;

30 (7) Financial and valuable trade information under RCW 51.36.120;

31 (8) Financial, commercial, operations, and technical and research  
32 information and data submitted to or obtained by the clean Washington  
33 center in applications for, or delivery of, program services under  
34 chapter 70.95H RCW;

35 (9) Financial and commercial information requested by the public  
36 stadium authority from any person or organization that leases or uses  
37 the stadium and exhibition center as defined in RCW 36.102.010;

1 (10)(a) Financial information, including but not limited to account  
2 numbers and values, and other identification numbers supplied by or on  
3 behalf of a person, firm, corporation, limited liability company,  
4 partnership, or other entity related to an application for a horse  
5 racing license submitted pursuant to RCW 67.16.260(1)(b), liquor  
6 license, gambling license, or lottery retail license;

7 (b) Internal control documents, independent auditors' reports and  
8 financial statements, and supporting documents: (i) Of house-banked  
9 social card game licensees required by the gambling commission pursuant  
10 to rules adopted under chapter 9.46 RCW; or (ii) submitted by tribes  
11 with an approved tribal/state compact for class III gaming;

12 (11) Proprietary data, trade secrets, or other information that  
13 relates to: (a) A vendor's unique methods of conducting business; (b)  
14 data unique to the product or services of the vendor; or (c)  
15 determining prices or rates to be charged for services, submitted by  
16 any vendor to the department of social and health services for purposes  
17 of the development, acquisition, or implementation of state purchased  
18 health care as defined in RCW 41.05.011;

19 (12)(a) When supplied to and in the records of the department of  
20 (~~community, trade, and economic development~~) commerce:

21 (i) Financial and proprietary information collected from any person  
22 and provided to the department of (~~community, trade, and economic  
23 development~~) commerce pursuant to RCW 43.330.050(8); and

24 (ii) Financial or proprietary information collected from any person  
25 and provided to the department of (~~community, trade, and economic  
26 development~~) commerce or the office of the governor in connection with  
27 the siting, recruitment, expansion, retention, or relocation of that  
28 person's business and until a siting decision is made, identifying  
29 information of any person supplying information under this subsection  
30 and the locations being considered for siting, relocation, or expansion  
31 of a business;

32 (b) When developed by the department of (~~community, trade, and  
33 economic development~~) commerce based on information as described in  
34 (a)(i) of this subsection, any work product is not exempt from  
35 disclosure;

36 (c) For the purposes of this subsection, "siting decision" means  
37 the decision to acquire or not to acquire a site;

1 (d) If there is no written contact for a period of sixty days to  
2 the department of (~~community, trade, and economic development~~)  
3 commerce from a person connected with siting, recruitment, expansion,  
4 retention, or relocation of that person's business, information  
5 described in (a)(ii) of this subsection will be available to the public  
6 under this chapter;

7 (13) Financial and proprietary information submitted to or obtained  
8 by the department of ecology or the authority created under chapter  
9 70.95N RCW to implement chapter 70.95N RCW;

10 (14) Financial, commercial, operations, and technical and research  
11 information and data submitted to or obtained by the life sciences  
12 discovery fund authority in applications for, or delivery of, grants  
13 under chapter 43.350 RCW, to the extent that such information, if  
14 revealed, would reasonably be expected to result in private loss to the  
15 providers of this information;

16 (15) Financial and commercial information provided as evidence to  
17 the department of licensing as required by RCW 19.112.110 or  
18 19.112.120, except information disclosed in aggregate form that does  
19 not permit the identification of information related to individual fuel  
20 licensees;

21 (16) Any production records, mineral assessments, and trade secrets  
22 submitted by a permit holder, mine operator, or landowner to the  
23 department of natural resources under RCW 78.44.085;

24 (17)(a) Farm plans developed by conservation districts, unless  
25 permission to release the farm plan is granted by the landowner or  
26 operator who requested the plan, or the farm plan is used for the  
27 application or issuance of a permit;

28 (b) Farm plans developed under chapter 90.48 RCW and not under the  
29 federal clean water act, 33 U.S.C. Sec. 1251 et seq., are subject to  
30 RCW 42.56.610 and 90.64.190;

31 (18) Financial, commercial, operations, and technical and research  
32 information and data submitted to or obtained by a health sciences and  
33 services authority in applications for, or delivery of, grants under  
34 RCW 35.104.010 through 35.104.060, to the extent that such information,  
35 if revealed, would reasonably be expected to result in private loss to  
36 providers of this information;

37 (19) Information gathered under chapter 19.85 RCW or RCW 34.05.328  
38 that can be identified to a particular business; (~~and~~)

1           (20) Financial and commercial information submitted to or obtained  
2 by the University of Washington, other than information the university  
3 is required to disclose under RCW 28B.20.150, when the information  
4 relates to investments in private funds, to the extent that such  
5 information, if revealed, would reasonably be expected to result in  
6 loss to the University of Washington consolidated endowment fund or to  
7 result in private loss to the providers of this information; and  
8           (21) Producer information provided to the medicine return  
9 corporation or to the board of pharmacy under section 6 of this act to  
10 determine apportionment costs.

11           NEW SECTION.   **Sec. 20.** Nothing in this chapter changes or limits  
12 the authority of the Washington utilities and transportation commission  
13 to regulate collection of solid waste, including curbside collection of  
14 residential recyclable materials, nor does this chapter change or limit  
15 the authority of a city or town to provide the service itself or by  
16 contract under RCW 81.77.020.

17           NEW SECTION.   **Sec. 21.** Nothing in this chapter applies to  
18 hospitals licensed under chapter 70.41 RCW, whose pharmaceutical wastes  
19 are disposed of under rules and policies adopted by the department of  
20 ecology.

21           NEW SECTION.   **Sec. 22.** Sections 1 through 16, 20, and 21 of this  
22 act constitute a new chapter in Title 70 RCW.

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

27           NEW SECTION.   **Sec. 24.** This act must be liberally construed to  
28 carry out its purposes and objectives.

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