

SHB 1047 - H AMD 659

By Representative Peterson

WITHDRAWN 02/09/2018

1 Strike everything after the enacting clause and insert the
2 following:

3 "NEW SECTION. **Sec. 1.** LEGISLATIVE FINDINGS. (1) Abuse, fatal
4 overdoses, and poisonings from prescription and over-the-counter
5 medicines used in the home have emerged as an epidemic in recent
6 years. Poisoning is the leading cause of unintentional injury-related
7 death in Washington, and more than ninety percent of poisoning deaths
8 are due to drug overdoses. Poisoning by prescription and over-the-
9 counter medicines is also one of the most common means of suicide and
10 suicide attempts, with poisonings involved in more than twenty-eight
11 thousand suicide attempts between 2004 and 2013.

12 (2) Home medicine cabinets are the most common source of
13 prescription drugs that are diverted and misused. Studies find about
14 seventy percent of those who abuse prescription medicines obtain the
15 drugs from family members or friends, usually for free. People who
16 are addicted to heroin often first abused prescription opiate
17 medicines. Unused, unwanted, and expired medicines that accumulate in
18 homes increase risks of drug abuse, overdoses, and preventable
19 poisonings.

20 (3) A safe system for the collection and disposal of unused,
21 unwanted, and expired medicines is a key element of a comprehensive
22 strategy to prevent prescription drug abuse, but disposing of
23 medicines by flushing them down the toilet or placing them in the
24 garbage can contaminate groundwater and other bodies of water,
25 contributing to long-term harm to the environment and animal life.

26 (4) The legislature therefore finds that it is in the interest of
27 public health to establish a safe and secure method for collection
28 and disposal of medicines through a drug "take-back" program operated
29 and funded by drug manufacturers.

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

4 (1) "Authorized collector" means any of the following persons or
5 entities that have entered into an agreement with a program operator
6 to collect covered drugs:

7 (a) A person or entity that is registered with the United States
8 drug enforcement administration and that qualifies under federal law
9 to modify its registration to collect controlled substances for the
10 purpose of destruction;

11 (b) A law enforcement agency; or

12 (c) An entity authorized by the department to provide an
13 alternative collection mechanism for certain covered drugs that are
14 not controlled substances, as defined in RCW 69.50.101.

15 (2) "Collection site" means the location where an authorized
16 collector operates a secure collection receptacle for collecting
17 covered drugs.

18 (3) "Covered drug" means a drug from a covered entity that the
19 covered entity no longer wants and that the covered entity has
20 abandoned or discarded or intends to abandon or discard. "Covered
21 drug" includes legend drugs and nonlegend drugs, brand name and
22 generic drugs, drugs for veterinary use, and drugs in medical devices
23 and combination products, including prefilled injector products with
24 a retractable or otherwise securely covered needle.

25 (4) "Covered entity" means a state resident or other nonbusiness
26 entity and includes an ultimate user, as defined by regulations
27 adopted by the United States drug enforcement administration.
28 "Covered entity" does not include a business generator of
29 pharmaceutical waste, such as a hospital, clinic, health care
30 provider's office, veterinary clinic, pharmacy, or law enforcement
31 agency.

32 (5) "Covered manufacturer" means a person, corporation, or other
33 entity engaged in the manufacture of drugs sold in or into Washington
34 state. "Covered manufacturer" does not include a retail pharmacy that
35 sells a drug under the retail pharmacy's store label if the
36 manufacturer of the drug is identified under section 4 of this act.

37 (6) "Department" means the department of health.

38 (7)(a) "Drug" means:

39 (i) Substances recognized as drugs in the official United States
40 pharmacopoeia, official homeopathic pharmacopoeia of the United

1 States, or official national formulary, or any supplement to any of
2 them;

3 (ii) Substances intended for use in the diagnosis, cure,
4 mitigation, treatment, or prevention of disease in human beings or
5 animals;

6 (iii) Substances other than food, minerals, or vitamins that are
7 intended to affect the structure or any function of the body of human
8 beings or animals; and

9 (iv) Substances intended for use as a component of any article
10 specified in (a)(i), (ii), or (iii) of this subsection.

11 (b) "Drug" does not include:

12 (i) Vitamins or supplements;

13 (ii) Herbal-based remedies and homeopathic drugs, products, or
14 remedies;

15 (iii) Controlled substances contained in schedule I of the
16 uniform controlled substances act, chapter 69.50 RCW;

17 (iv) Cosmetics, shampoos, sunscreens, toothpaste,
18 antiperspirants, or other personal care products that are regulated
19 as both cosmetics and nonprescription drugs under the federal food,
20 drug, and cosmetic act, 21 U.S.C. Sec. 301 et seq.;

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

24 (vi) Drugs that are biological products, as defined in RCW
25 69.41.110, if the producer provides a separate drug take-back
26 program;

27 (vii) Drugs that are used solely in a clinical setting; or

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

30 (8) "Drug take-back organization" means an organization
31 designated by a manufacturer or group of manufacturers to act as an
32 agent on behalf of each manufacturer to develop and implement a drug
33 take-back program.

34 (9) "Drug take-back program" or "program" means a program
35 implemented by a program operator for the collection, transportation,
36 and disposal of covered drugs.

37 (10) "Drug wholesaler" means an entity licensed as a wholesaler
38 under chapter 18.64 RCW.

39 (11) "Generic drug" means a drug that is chemically identical or
40 bioequivalent to a brand name drug in dosage form, safety, strength,

1 route of administration, quality, performance characteristics, and
2 intended use. The inactive ingredients in a generic drug need not be
3 identical to the inactive ingredients in the chemically identical or
4 bioequivalent brand name drug.

5 (12) "Legend drug" means a drug, including a controlled substance
6 under chapter 69.50 RCW, that is required by any applicable federal
7 or state law or regulation to be dispensed by prescription only or
8 that is restricted to use by practitioners only.

9 (13) "Mail-back program" means a method of collecting covered
10 drugs from covered entities by using prepaid, preaddressed mailing
11 envelopes.

12 (14) "Manufacture" has the same meaning as in RCW 18.64.011.

13 (15) "Nonlegend drug" means a drug that may be lawfully sold
14 without a prescription.

15 (16) "Pharmacy" means a place licensed as a pharmacy under
16 chapter 18.64 RCW.

17 (17) "Program operator" means a drug take-back organization,
18 covered manufacturer, or group of covered manufacturers that
19 implements or intends to implement a drug take-back program approved
20 by the department.

21 (18) "Retail pharmacy" means a place licensed as a pharmacy under
22 chapter 18.64 RCW for the retail sale and dispensing of drugs.

23 (19) "Secretary" means the secretary of health.

24 NEW SECTION. **Sec. 3.** REQUIREMENT TO PARTICIPATE IN A DRUG TAKE-
25 BACK PROGRAM. A covered manufacturer must establish and implement a
26 drug take-back program that complies with the requirements of this
27 chapter. A manufacturer that becomes a covered manufacturer after the
28 effective date of this section must, no later than six months after
29 the date on which the manufacturer became a covered manufacturer,
30 participate in an approved drug take-back program or establish and
31 implement a drug take-back program that complies with the
32 requirements of this chapter. A covered manufacturer may establish
33 and implement a drug take-back program independently, as part of a
34 group of covered manufacturers, or through membership in a drug take-
35 back organization.

36 NEW SECTION. **Sec. 4.** IDENTIFICATION OF COVERED MANUFACTURERS.
37 (1) No later than ninety days after the effective date of this
38 section, a drug wholesaler that sells a drug in or into Washington

1 must provide a list of drug manufacturers to the department in a form
2 agreed upon with the department. A drug wholesaler must provide an
3 updated list to the department on January 15th of each year.

4 (2) No later than ninety days after the effective date of this
5 section, a retail pharmacy must provide written notification to the
6 department identifying the drug manufacturer from which the retail
7 pharmacy obtains a drug that the retail pharmacy sells under its
8 store label.

9 (3) A person or entity that receives a letter of inquiry from the
10 department regarding whether or not it is a covered manufacturer
11 under this chapter shall respond in writing no later than sixty days
12 after receipt of the letter. If the person or entity does not believe
13 it is a covered manufacturer for purposes of this chapter, it shall:
14 (a) State the basis for the belief; (b) provide a list of any drugs
15 it sells, distributes, repackages, or otherwise offers for sale
16 within the state; and (c) identify the name and contact information
17 of the manufacturer of the drugs identified under (b) of this
18 subsection.

19 NEW SECTION. **Sec. 5.** DRUG TAKE-BACK PROGRAM APPROVAL. (1) By
20 October 1, 2019, a program operator must submit a proposal for the
21 establishment and implementation of a drug take-back program to the
22 department for approval. The department shall approve a proposed
23 program if the applicant submits a completed application, the
24 proposed program meets the requirements of subsection (2) of this
25 section, and the applicant pays the appropriate fee established by
26 the department under section 12 of this act.

27 (2) To be approved by the department, a proposed drug take-back
28 program must:

29 (a) Identify and provide contact information for the program
30 operator and each participating covered manufacturer;

31 (b) Identify and provide contact information for the authorized
32 collectors for the proposed program, as well as the reasons for
33 excluding any potential authorized collectors from participation in
34 the program;

35 (c) Provide for a collection system that complies with section 6
36 of this act;

37 (d) Provide for a handling and disposal system that complies with
38 section 8 of this act;

- 1 (e) Identify any transporters and waste disposal facilities that
2 the program will use;
- 3 (f) Adopt policies and procedures to be followed by persons
4 handling covered drugs collected under the program to ensure safety,
5 security, and compliance with regulations adopted by the United
6 States drug enforcement administration, as well as any applicable
7 laws;
- 8 (g) Ensure the security of patient information on drug packaging
9 during collection, transportation, recycling, and disposal;
- 10 (h) Promote the program by providing consumers, pharmacies, and
11 other entities with educational and informational materials and
12 evaluate the effectiveness of promotion, outreach, and public
13 education activities, as required by section 7 of this act;
- 14 (i) Demonstrate adequate funding for all administrative and
15 operational costs of the drug take-back program, with costs
16 apportioned among participating covered manufacturers according to
17 sales revenues in Washington state;
- 18 (j) Set long-term and short-term goals with respect to collection
19 amounts and public awareness; and
- 20 (k) Consider: (i) The use of existing providers of pharmaceutical
21 waste transportation and disposal services; (ii) separation of
22 covered drugs from packaging to reduce transportation and disposal
23 costs; and (iii) recycling of drug packaging.
- 24 (3)(a) No later than one hundred twenty days after receipt of a
25 drug take-back program proposal, the department shall either approve
26 or reject the proposal in writing to the applicant. The department
27 may extend the deadline for approval or rejection of a proposal for
28 good cause. If the department rejects the proposal, it shall provide
29 the reason for rejection.
- 30 (b) No later than sixty days after receipt of a notice of
31 rejection under (a) of this subsection, the applicant shall submit a
32 revised proposal to the department. The department shall either
33 approve or reject the revised proposal in writing to the applicant
34 within ninety days after receipt of the revised proposal, including
35 the reason for rejection, if applicable.
- 36 (c) If the department rejects a revised proposal, the department
37 may:
- 38 (i) Require the program operator to submit a further revised
39 proposal;

1 (ii) Develop and impose changes to some or all of the revised
2 proposal to address deficiencies;

3 (iii) Require the covered manufacturer or covered manufacturers
4 that proposed the rejected revised proposal to participate in a
5 previously approved drug take-back program; or

6 (iv) Find the covered manufacturer out of compliance with the
7 requirements of this chapter and take enforcement action as provided
8 in section 11 of this act.

9 (4) The program operator must initiate operation of an approved
10 drug take-back program no later than ninety days after approval of
11 the proposal by the department.

12 (5)(a) Proposed changes to an approved drug take-back program
13 that substantively alter program operations must have prior written
14 approval of the department. A program operator must submit to the
15 department such a proposed change in writing at least thirty days
16 before the change is scheduled to occur. Changes requiring prior
17 approval of the department include changes to participating covered
18 manufacturers, collection methods, achievement of the service
19 convenience goal described in section 6 of this act, policies and
20 procedures for handling covered drugs, education and promotion
21 methods, and selection of disposal facilities.

22 (b) For changes to a drug take-back program that do not
23 substantively alter program operations, a program operator must
24 notify the department at least fifteen days before implementing the
25 change. Changes that do not substantively alter program operations
26 include changes to collection site locations, methods for scheduling
27 and locating periodic collection events, and methods for distributing
28 prepaid, preaddressed mailers.

29 (c) A program operator must notify the department of any changes
30 to the official point of contact for the program no later than
31 fifteen days after the change. A program operator must notify the
32 department of any changes in ownership or contact information for
33 participating covered manufacturers no later than thirty days after
34 such change.

35 (6) No later than four years after a drug take-back program
36 initiates operations, and every four years thereafter, the program
37 operator must submit an updated proposal to the department describing
38 any substantive changes to program elements described in subsection
39 (2) of this section. The department shall approve or reject the

1 updated proposal using the process described in subsection (3) of
2 this section.

3 (7) The department shall make all proposals submitted under this
4 section available to the public and shall provide an opportunity for
5 written public comment on each proposal.

6 NEW SECTION. **Sec. 6.** COLLECTION SYSTEM. (1)(a) At least one
7 hundred twenty days prior to submitting a proposal under section 5 of
8 this act, a program operator must notify potential authorized
9 collectors of the opportunity to serve as an authorized collector for
10 the proposed drug take-back program. A program operator must commence
11 good faith negotiations with a potential authorized collector no
12 later than thirty days after the potential authorized collector
13 expresses interest in participating in a proposed program.

14 (b) A person or entity may serve as an authorized collector for a
15 drug take-back program voluntarily or in exchange for compensation,
16 but nothing in this chapter requires a person or entity to serve as
17 an authorized collector.

18 (c) A drug take-back program must include as an authorized
19 collector any retail pharmacy, hospital or clinic with an on-site
20 pharmacy, or law enforcement agency that offers to participate in the
21 program without compensation and meets the requirements of subsection
22 (2) of this section. Such a pharmacy, hospital, clinic, or law
23 enforcement agency must be included as an authorized collector in the
24 program no later than ninety days after receiving the offer to
25 participate.

26 (d) A drug take-back program may also locate collection sites at:

27 (i) A long-term care facility where a pharmacy, or a hospital or
28 clinic with an on-site pharmacy, operates a secure collection
29 receptacle;

30 (ii) A substance use disorder treatment program, as defined in
31 RCW 71.24.025; or

32 (iii) Any other authorized collector willing to participate as a
33 collection site and able to meet the requirements of subsection (2)
34 of this section.

35 (2)(a) A collection site must accept all covered drugs from
36 covered entities during the hours that the authorized collector is
37 normally open for business with the public.

1 (b) A collection site located at a long-term care facility may
2 only accept covered drugs that are in the possession of individuals
3 who reside or have resided at the facility.

4 (c) A collection site must use secure collection receptacles in
5 compliance with state and federal law, including any applicable on-
6 site storage and collection standards adopted by rule pursuant to
7 chapter 70.95 or 70.105 RCW and United States drug enforcement
8 administration regulations. The program operator must provide a
9 service schedule that meets the needs of each collection site to
10 ensure that each secure collection receptacle is serviced as often as
11 necessary to avoid reaching capacity and that collected covered drugs
12 are transported to final disposal in a timely manner, including a
13 process for additional prompt collection service upon notification
14 from the collection site. Secure collection receptacle signage must
15 prominently display a toll-free telephone number and web site for the
16 program so that members of the public may provide feedback on
17 collection activities.

18 (d) An authorized collector must comply with applicable
19 provisions of chapters 70.95 and 70.105 RCW, including rules adopted
20 pursuant to those chapters that establish collection and
21 transportation standards, and federal laws and regulations governing
22 the handling of covered drugs, including United States drug
23 enforcement administration regulations.

24 (3)(a) A drug take-back program's collection system must be safe,
25 secure, and convenient on an ongoing, year-round basis and must
26 provide equitable access for residents across the state.

27 (b) In establishing and operating a collection system, a program
28 operator must give preference to locating collection sites at retail
29 pharmacies, hospitals or clinics with on-site pharmacies, and law
30 enforcement agencies.

31 (c)(i) Each population center must have a minimum of one
32 collection site, plus one additional collection site for every twenty
33 thousand residents of the city or town located within the population
34 center. Collection sites must be geographically distributed to
35 provide reasonably convenient and equitable access to all residents
36 of the population center.

37 (ii) On islands and in areas outside of population centers, a
38 collection site must be located at the site of each potential
39 authorized collector that is regularly open to the public, unless the
40 program operator demonstrates to the satisfaction of the department

1 that a potential authorized collector is unqualified or unwilling to
2 participate in the drug take-back program, in accordance with the
3 requirements of subsection (1) of this section.

4 (iii) For purposes of this section, "population center" means a
5 city or town and the unincorporated area within a ten-mile radius
6 from the center of the city or town.

7 (d) A program operator must hold periodic collection events to
8 supplement service to any area of the state that is underserved by
9 collection sites, as determined by the department, in consultation
10 with the local health jurisdiction. The program operator, in
11 consultation with the department, local law enforcement, the local
12 health jurisdiction, and the local community, must determine the
13 frequency and location of these collections events, to be held at
14 least twice a year, unless otherwise determined through consultation
15 with the local community. The program must arrange periodic
16 collection events in advance with local law enforcement agencies and
17 conduct periodic collection events in compliance with United States
18 drug enforcement administration regulations and protocols and
19 applicable state laws.

20 (e) Upon request, a drug take-back program must provide a mail-
21 back program free of charge to covered entities and to retail
22 pharmacies that offer to distribute prepaid, preaddressed mailing
23 envelopes for the drug take-back program. A drug take-back program
24 must permit covered entities to request prepaid, preaddressed mailing
25 envelopes through the program's web site, the program's toll-free
26 telephone number, and a request to a pharmacist at a retail pharmacy
27 distributing the program's mailing envelopes.

28 (f) The program operator must provide alternative collection
29 methods for any covered drugs, other than controlled substances, that
30 cannot be accepted or commingled with other covered drugs in secure
31 collection receptacles, through a mail-back program, or at periodic
32 collection events. The department shall review and approve of any
33 alternative collection methods prior to their implementation.

34 NEW SECTION. **Sec. 7.** DRUG TAKE-BACK PROGRAM PROMOTION. (1) A
35 drug take-back program must develop and provide a system of
36 promotion, education, and public outreach about the safe storage and
37 secure collection of covered drugs. This system may include signage,
38 written materials to be provided at the time of purchase or delivery

1 of covered drugs, and advertising or other promotional materials. At
2 a minimum, each program must:

3 (a) Promote the safe storage of legend drugs and nonlegend drugs
4 by residents before secure disposal through a drug take-back program;

5 (b) Discourage residents from disposing of covered drugs in solid
6 waste collection, sewer, or septic systems;

7 (c) Promote the use of the drug take-back program so that where
8 and how to return covered drugs is widely understood by residents,
9 pharmacists, retail pharmacies, health care facilities and providers,
10 veterinarians, and veterinary hospitals;

11 (d) Establish a toll-free telephone number and web site
12 publicizing collection options and collection sites and discouraging
13 improper disposal practices for covered drugs, such as flushing them
14 or placing them in the garbage;

15 (e) Prepare educational and outreach materials that: Promote safe
16 storage of covered drugs; discourage the disposal of covered drugs in
17 solid waste collection, sewer, or septic systems; and describe how to
18 return covered drugs to the drug take-back program. The materials
19 must use plain language and explanatory images to make collection
20 services and discouraged disposal practices readily understandable to
21 all residents, including residents with limited English proficiency;

22 (f) Disseminate the educational and outreach materials described
23 in (e) of this subsection to pharmacies, health care facilities, and
24 other interested parties for dissemination to covered entities;

25 (g) Work with authorized collectors to develop a readily
26 recognizable, consistent design of collection receptacles, as well as
27 clear, standardized instructions for covered entities on the use of
28 collection receptacles. The department may provide guidance to
29 program operators on the development of the instructions and design;

30 (h) Conduct a survey of covered entities and a survey of
31 pharmacists, health care providers, and veterinarians who interact
32 with covered entities on the use of medicines after the first full
33 year of operation of the drug take-back program, and again every two
34 years thereafter. Survey questions must: Measure consumer awareness
35 of the drug take-back program; assess the extent to which collection
36 sites and other collection methods are convenient and easy to use;
37 assess knowledge and attitudes about risks of abuse, poisonings, and
38 overdoses from drugs used in the home; and assess covered entities'
39 practices with respect to unused, unwanted, or expired drugs, both
40 currently and prior to implementation of the drug take-back program.

1 Draft survey questions must be submitted to the department for review
2 and comment no later than thirty days prior to initiation of a
3 survey. The drug take-back program must report all data and the
4 results of the surveys to the department and make the results
5 available on the program's web site no later than ninety days after
6 the end of the survey period; and

7 (i) Annually evaluate the effectiveness of its promotion,
8 outreach, and public education, and include this evaluation in its
9 annual report required by section 10 of this act.

10 (2) If more than one drug take-back program is approved by the
11 department, the programs must coordinate their promotional activities
12 to ensure that all state residents can easily identify, understand,
13 and access the collection services provided by any drug take-back
14 program. Coordination efforts must include providing residents with a
15 single toll-free telephone number and single web site to access
16 information about collection services for every approved program.

17 (3) Pharmacies and other entities that sell medication in the
18 state are encouraged to promote secure disposal of covered drugs
19 through the use of one or more approved drug take-back programs. Upon
20 request, a pharmacy must provide materials explaining the use of
21 approved drug take-back programs to its customers. The program
22 operator must provide pharmacies with these materials upon request
23 and at no cost to the pharmacy.

24 (4) The department, the health care authority, the department of
25 social and health services, the department of ecology, and any other
26 state agency that is responsible for health, solid waste management,
27 and wastewater treatment shall, through their standard educational
28 methods, promote safe storage of prescription and nonprescription
29 drugs by covered entities, secure disposal of covered drugs through a
30 drug take-back program, and the toll-free telephone number and web
31 site for approved drug take-back programs. Local health jurisdictions
32 and local government agencies are encouraged to promote approved drug
33 take-back programs.

34 NEW SECTION. **Sec. 8.** DISPOSAL AND HANDLING OF COVERED DRUGS.

35 (1) Covered drugs collected under a drug take-back program must be
36 disposed of at a permitted hazardous waste disposal facility that
37 meets the requirements of 40 C.F.R. parts 264 and 265, as they exist
38 on the effective date of this section.

1 (2) If use of a hazardous waste disposal facility described in
2 subsection (1) of this section is unfeasible based on cost,
3 logistics, or other considerations, the department, in consultation
4 with the department of ecology, may grant approval for a program
5 operator to dispose of some or all collected covered drugs at a
6 permitted large municipal waste combustor facility that meets the
7 requirements of 40 C.F.R. parts 60 and 62, as they exist on the
8 effective date of this section.

9 (3) A program operator may petition the department for approval
10 to use final disposal technologies or processes that provide superior
11 environmental and human health protection than that provided by the
12 technologies described in subsections (1) and (2) of this section, or
13 equivalent protection at less cost. In reviewing a petition under
14 this subsection, the department shall take into consideration
15 regulations or guidance issued by the United States environmental
16 protection agency on the disposal of pharmaceutical waste. The
17 department, in consultation with the department of ecology, shall
18 approve a disposal petition under this section if the disposal
19 technology or processes described in the petition provides equivalent
20 or superior protection in each of the following areas:

21 (a) Monitoring of any emissions or waste;

22 (b) Worker health and safety;

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

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

26 (4) If a drug take-back program encounters a safety or security
27 problem during collection, transportation, or disposal of covered
28 drugs, the program operator must notify the department as soon as
29 practicable after encountering the problem.

30 NEW SECTION. **Sec. 9.** PROGRAM FUNDING. (1) A covered
31 manufacturer or group of covered manufacturers must pay all
32 administrative and operational costs associated with establishing and
33 implementing the drug take-back program in which they participate.
34 Such administrative and operational costs include, but are not
35 limited to: Collection and transportation supplies for each
36 collection site; purchase of secure collection receptacles for each
37 collection site; ongoing maintenance or replacement of secure
38 collection receptacles when requested by authorized collectors;
39 prepaid, preaddressed mailers; compensation of authorized collectors,

1 if applicable; operation of periodic collection events, including the
2 cost of law enforcement staff time; transportation of all collected
3 covered drugs to final disposal; environmentally sound disposal of
4 all collected covered drugs in compliance with section 8 of this act;
5 and program promotion and outreach.

6 (2) A program operator, covered manufacturer, authorized
7 collector, or other person may not charge:

8 (a) A specific point-of-sale fee to consumers to recoup the costs
9 of a drug take-back program; or

10 (b) A specific point-of-collection fee at the time covered drugs
11 are collected from covered entities.

12 NEW SECTION. **Sec. 10.** ANNUAL PROGRAM REPORT. (1) By April 30th
13 after the first full year of implementation, and each April 30th
14 thereafter, a program operator must submit to the department a report
15 describing implementation of the drug take-back program during the
16 previous calendar year. The report must include:

17 (a) A list of covered manufacturers participating in the drug
18 take-back program;

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

21 (c) The following details regarding the program's collection
22 system: A list of collection sites with addresses; the number of
23 mailers provided; locations where mailers were provided, if
24 applicable; dates and locations of collection events held, if
25 applicable; and the transporters and disposal facility or facilities
26 used;

27 (d) Whether any safety or security problems occurred during
28 collection, transportation, or disposal of covered drugs, and if so,
29 completed and anticipated changes to policies, procedures, or
30 tracking mechanisms to address the problem and improve safety and
31 security;

32 (e) A description of the public education, outreach, and
33 evaluation activities implemented;

34 (f) The results of the program's surveys of covered entities and
35 pharmacists, health care providers, and veterinarians;

36 (g) A description of how collected packaging was recycled to the
37 extent feasible;

38 (h) A summary of the program's goals for collection amounts and
39 public awareness, the degree of success in meeting those goals, and

1 if any goals have not been met, what effort will be made to achieve
2 those goals the following year; and

3 (i) The program's annual expenditures, itemized by program
4 category.

5 (2) The department shall make reports submitted under this
6 section available to the public through the internet.

7 NEW SECTION. **Sec. 11.** ENFORCEMENT AND PENALTIES. (1) The
8 department may audit or inspect the activities and records of a drug
9 take-back program to determine compliance with this chapter or
10 investigate a complaint.

11 (2)(a) The department shall send a written notice to a covered
12 manufacturer that fails to participate in a drug take-back program as
13 required by this chapter. The notice must provide a warning regarding
14 the penalties for violation of this chapter.

15 (b) A covered manufacturer that receives a notice under this
16 subsection (2) may be assessed a penalty if, sixty days after receipt
17 of the notice, the covered manufacturer continues to sell a covered
18 drug in or into the state without participating in a drug take-back
19 program approved under this chapter.

20 (3)(a) The department may send a program operator a written
21 notice warning of the penalties for noncompliance with this chapter
22 if it determines that the program operator's drug take-back program
23 is in violation of this chapter or does not conform to the proposal
24 approved by the department. The department may assess a penalty on
25 the program operator and participating covered manufacturers if the
26 program does not come into compliance by thirty days after receipt of
27 the notice.

28 (b) The department may immediately suspend operation of a drug
29 take-back program and assess a penalty if it determines that the
30 program is in violation of this chapter and the violation creates a
31 condition that, in the judgment of the department, constitutes an
32 immediate hazard to the public or the environment.

33 (4)(a) The department shall send a written notice to a drug
34 wholesaler or a retail pharmacy that fails to provide a list of drug
35 manufacturers to the department as required by section 4 of this act.
36 The notice must provide a warning regarding the penalties for
37 violation of this chapter.

38 (b) A drug wholesaler or retail pharmacy that receives a notice
39 under this subsection may be assessed a penalty if, sixty days after

1 receipt of the notice, the drug wholesaler or retail pharmacy fails
2 to provide a list of drug manufacturers.

3 (5) In enforcing the requirements of this chapter, the
4 department:

5 (a) May require an informal administrative conference;

6 (b) May require a person or entity to engage in or refrain from
7 engaging in certain activities;

8 (c) May, in accordance with RCW 43.70.095, assess a civil fine of
9 up to two thousand dollars. Each day upon which a violation occurs or
10 is permitted to continue constitutes a separate violation. In
11 determining the appropriate amount of the fine, the department shall
12 consider the extent of harm caused by the violation, the nature and
13 persistence of the violation, the frequency of past violations, any
14 action taken to mitigate the violation, and the financial burden to
15 the entity in violation; and

16 (d) May not prohibit a covered manufacturer from selling a drug
17 in or into the state of Washington.

18 NEW SECTION. **Sec. 12.** DEPARTMENT FEE. (1)(a) By July 1, 2019,
19 the department shall: Determine its costs for the administration,
20 oversight, and enforcement of the requirements of this chapter,
21 including the survey required under section 20 of this act; pursuant
22 to RCW 43.70.250, set fees at a level sufficient to recover the costs
23 associated with administration, oversight, and enforcement; and adopt
24 rules establishing requirements for program operator proposals.

25 (b) The department shall collect fees from each program operator
26 by October 1, 2019, and annually thereafter.

27 (2) All fees collected under this section must be deposited in
28 the secure drug take-back program account established in section 13
29 of this act.

30 NEW SECTION. **Sec. 13.** SECURE DRUG TAKE-BACK PROGRAM ACCOUNT.
31 The secure drug take-back program account is created in the state
32 treasury. All receipts received by the department under this chapter
33 must be deposited in the account. Moneys in the account may be spent
34 only after appropriation. Expenditures from the account may be used
35 by the department only for administering and enforcing this chapter.

36 NEW SECTION. **Sec. 14.** ANTITRUST IMMUNITY. The activities
37 authorized by this chapter require collaboration among covered

1 manufacturers. These activities will enable safe and secure
2 collection and disposal of covered drugs in Washington state and are
3 therefore in the best interest of the public. The benefits of
4 collaboration, together with active state supervision, outweigh
5 potential adverse impacts. Therefore, the legislature intends to
6 exempt from state antitrust laws, and provide immunity through the
7 state action doctrine from federal antitrust laws, activities that
8 are undertaken, reviewed, and approved by the department pursuant to
9 this chapter that might otherwise be constrained by such laws. The
10 legislature does not intend and does not authorize any person or
11 entity to engage in activities not provided for by this chapter, and
12 the legislature neither exempts nor provides immunity for such
13 activities.

14 NEW SECTION. **Sec. 15.** FEDERAL LAW. This chapter is void if a
15 federal law, or a combination of federal laws, takes effect that
16 establishes a national program for the collection of covered drugs
17 that substantially meets the intent of this chapter, including the
18 creation of a funding mechanism for collection, transportation, and
19 proper disposal of all covered drugs in the United States.

20 NEW SECTION. **Sec. 16.** LOCAL LAWS. (1)(a) For a period of
21 eighteen months after a drug take-back program approved under section
22 5 of this act begins operating, a county may enforce a grandfathered
23 ordinance. During that eighteen-month period, if a county determines
24 that a covered manufacturer is in compliance with its grandfathered
25 ordinance, the department shall find the covered manufacturer in
26 compliance with the requirements of this chapter with respect to that
27 county.

28 (b) In any county enforcing a grandfathered ordinance as
29 described in (a) of this subsection, the program operator of an
30 approved drug take-back program must work with the county and the
31 department to incorporate the local program into the approved drug
32 take-back program on or before the end of the eighteen-month period.

33 (2) After the effective date of this section, a political
34 subdivision may not enact or enforce a local ordinance that requires
35 a retail pharmacy, clinic, hospital, or local law enforcement agency
36 to provide for collection and disposal of covered drugs from covered
37 entities.

1 (3) For purposes of this section, "grandfathered ordinance" means
2 a pharmaceutical product stewardship or drug take-back ordinance
3 that: (a) Is in effect on the effective date of this section; and (b)
4 the department determines meets or exceeds the requirements of this
5 chapter with respect to safe and secure collection and disposal of
6 unwanted medicines from residents, including the types of drugs
7 covered by the program, the convenience of the collection system for
8 residents, and required promotion of the program.

9 NEW SECTION. **Sec. 17.** PUBLIC DISCLOSURE. Proprietary
10 information submitted to the department under this chapter is exempt
11 from public disclosure under RCW 42.56.270. The department may use
12 and disclose such information in summary or aggregated form that does
13 not directly or indirectly identify financial, production, or sales
14 data of an individual covered manufacturer or drug take-back
15 organization.

16 NEW SECTION. **Sec. 18.** RULE MAKING. The department shall adopt
17 any rules necessary to implement and enforce this chapter.

18 NEW SECTION. **Sec. 19.** REPORT TO LEGISLATURE. (1) No later than
19 thirty days after the department first approves a drug take-back
20 program under section 5 of this act, the department shall submit an
21 update to the legislature describing rules adopted under this chapter
22 and the approved drug take-back program.

23 (2) By November 15th after the first full year of operation of an
24 approved drug take-back program and biennially thereafter, the
25 department shall submit a report to the legislature. The report must:

26 (a) Describe the status of approved drug take-back programs;

27 (b) Evaluate the secure medicine collection and disposal system
28 and the program promotion, education, and public outreach
29 requirements established by this chapter;

30 (c) Evaluate, to the extent feasible, the impact of approved drug
31 take-back programs on: Awareness and compliance of residents with
32 safe storage of medicines in the home and secure disposal of covered
33 drugs; rates of misuse, abuse, overdoses, and poisonings from
34 prescription and nonprescription drugs; and diversions of covered
35 drugs from sewer, solid waste, and septic systems. To conduct this
36 evaluation, the department may rely on available data sources,
37 including the prescription drug monitoring program and public health

1 surveys such as the Washington state healthy youth survey. The
2 department may also consult with other state and local agencies and
3 interested stakeholders; and

4 (d) Provide any recommendations for legislation.

5 NEW SECTION. **Sec. 20.** (1)(a) The department shall contract with
6 the statewide program of poison and drug information services
7 identified in RCW 18.76.030 to conduct a survey of residents to
8 measure whether the secure medicine collection and disposal system
9 and the program promotion, education, and public outreach
10 requirements established in this chapter have led to statistically
11 significant changes in: (i) Resident attitudes and behavior on safe
12 storage and secure disposal of prescription and nonprescription
13 medications used in the home; and (ii) the rates of abuse or misuse
14 of or accidental exposure to prescription and nonprescription drugs.

15 (b) The survey of residents must include telephone follow-up with
16 users of the program's emergency telephone service. The survey must
17 be conducted before the secure medicine collection and disposal
18 system is implemented and again no earlier than four years after the
19 system is implemented.

20 (2) The statewide program of poison and drug information services
21 shall report the survey results to the legislature and the department
22 of health within six months of completion of the survey.

23 (3) This section expires July 1, 2026.

24 **Sec. 21.** RCW 42.56.270 and 2017 c 317 s 17 are each amended to
25 read as follows:

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

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

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

37 (3) Financial and commercial information and records supplied by
38 private persons pertaining to export services provided under chapters

1 43.163 and 53.31 RCW, and by persons pertaining to export projects
2 under RCW 43.23.035;

3 (4) Financial and commercial information and records supplied by
4 businesses or individuals during application for loans or program
5 services provided by chapters 43.325, 43.163, 43.160, 43.330, and
6 43.168 RCW, or during application for economic development loans or
7 program services provided by any local agency;

8 (5) Financial information, business plans, examination reports,
9 and any information produced or obtained in evaluating or examining a
10 business and industrial development corporation organized or seeking
11 certification under chapter 31.24 RCW;

12 (6) Financial and commercial information supplied to the state
13 investment board by any person when the information relates to the
14 investment of public trust or retirement funds and when disclosure
15 would result in loss to such funds or in private loss to the
16 providers of this information;

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

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

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

25 (10)(a) Financial information, including but not limited to
26 account numbers and values, and other identification numbers supplied
27 by or on behalf of a person, firm, corporation, limited liability
28 company, partnership, or other entity related to an application for a
29 horse racing license submitted pursuant to RCW 67.16.260(1)(b),
30 marijuana producer, processor, or retailer license, liquor license,
31 gambling license, or lottery retail license;

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

37 (11) Proprietary data, trade secrets, or other information that
38 relates to: (a) A vendor's unique methods of conducting business; (b)
39 data unique to the product or services of the vendor; or (c)
40 determining prices or rates to be charged for services, submitted by

1 any vendor to the department of social and health services for
2 purposes of the development, acquisition, or implementation of state
3 purchased health care as defined in RCW 41.05.011;

4 (12)(a) When supplied to and in the records of the department of
5 commerce:

6 (i) Financial and proprietary information collected from any
7 person and provided to the department of commerce pursuant to RCW
8 43.330.050(8); and

9 (ii) Financial or proprietary information collected from any
10 person and provided to the department of commerce or the office of
11 the governor in connection with the siting, recruitment, expansion,
12 retention, or relocation of that person's business and until a siting
13 decision is made, identifying information of any person supplying
14 information under this subsection and the locations being considered
15 for siting, relocation, or expansion of a business;

16 (b) When developed by the department of commerce based on
17 information as described in (a)(i) of this subsection, any work
18 product is not exempt from disclosure;

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

21 (d) If there is no written contact for a period of sixty days to
22 the department of commerce from a person connected with siting,
23 recruitment, expansion, retention, or relocation of that person's
24 business, information described in (a)(ii) of this subsection will be
25 available to the public under this chapter;

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

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

35 (15) Financial and commercial information provided as evidence to
36 the department of licensing as required by RCW 19.112.110 or
37 19.112.120, except information disclosed in aggregate form that does
38 not permit the identification of information related to individual
39 fuel licensees;

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

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

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

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

17 (19) Information gathered under chapter 19.85 RCW or RCW
18 34.05.328 that can be identified to a particular business;

19 (20) Financial and commercial information submitted to or
20 obtained by the University of Washington, other than information the
21 university is required to disclose under RCW 28B.20.150, when the
22 information relates to investments in private funds, to the extent
23 that such information, if revealed, would reasonably be expected to
24 result in loss to the University of Washington consolidated endowment
25 fund or to result in private loss to the providers of this
26 information;

27 (21) Market share data submitted by a manufacturer under RCW
28 70.95N.190(4);

29 (22) Financial information supplied to the department of
30 financial institutions or to a portal under RCW 21.20.883, when filed
31 by or on behalf of an issuer of securities for the purpose of
32 obtaining the exemption from state securities registration for small
33 securities offerings provided under RCW 21.20.880 or when filed by or
34 on behalf of an investor for the purpose of purchasing such
35 securities;

36 (23) Unaggregated or individual notices of a transfer of crude
37 oil that is financial, proprietary, or commercial information,
38 submitted to the department of ecology pursuant to RCW
39 90.56.565(1)(a), and that is in the possession of the department of

1 ecology or any entity with which the department of ecology has shared
2 the notice pursuant to RCW 90.56.565;

3 (24) Financial institution and retirement account information,
4 and building security plan information, supplied to the liquor and
5 cannabis board pursuant to RCW 69.50.325, 69.50.331, 69.50.342, and
6 69.50.345, when filed by or on behalf of a licensee or prospective
7 licensee for the purpose of obtaining, maintaining, or renewing a
8 license to produce, process, transport, or sell marijuana as allowed
9 under chapter 69.50 RCW;

10 (25) Marijuana transport information, vehicle and driver
11 identification data, and account numbers or unique access identifiers
12 issued to private entities for traceability system access, submitted
13 by an individual or business to the liquor and cannabis board under
14 the requirements of RCW 69.50.325, 69.50.331, 69.50.342, and
15 69.50.345 for the purpose of marijuana product traceability.
16 Disclosure to local, state, and federal officials is not considered
17 public disclosure for purposes of this section;

18 (26) Financial and commercial information submitted to or
19 obtained by the retirement board of any city that is responsible for
20 the management of an employees' retirement system pursuant to the
21 authority of chapter 35.39 RCW, when the information relates to
22 investments in private funds, to the extent that such information, if
23 revealed, would reasonably be expected to result in loss to the
24 retirement fund or to result in private loss to the providers of this
25 information except that (a) the names and commitment amounts of the
26 private funds in which retirement funds are invested and (b) the
27 aggregate quarterly performance results for a retirement fund's
28 portfolio of investments in such funds are subject to disclosure;

29 (27) Proprietary financial, commercial, operations, and technical
30 and research information and data submitted to or obtained by the
31 liquor and cannabis board in applications for marijuana research
32 licenses under RCW 69.50.372, or in reports submitted by marijuana
33 research licensees in accordance with rules adopted by the liquor and
34 cannabis board under RCW 69.50.372; (~~and~~)

35 (28) Trade secrets, technology, proprietary information, and
36 financial considerations contained in any agreements or contracts,
37 entered into by a licensed marijuana business under RCW 69.50.395,
38 which may be submitted to or obtained by the state liquor and
39 cannabis board; and

1 (29) Proprietary information filed with the department of health
2 under chapter 69.--- RCW (the new chapter created in section 25 of
3 this act).

4 **Sec. 22.** RCW 69.41.030 and 2016 c 148 s 11 are each amended to
5 read as follows:

6 (1) It shall be unlawful for any person to sell, deliver, or
7 possess any legend drug except upon the order or prescription of a
8 physician under chapter 18.71 RCW, an osteopathic physician and
9 surgeon under chapter 18.57 RCW, an optometrist licensed under
10 chapter 18.53 RCW who is certified by the optometry board under RCW
11 18.53.010, a dentist under chapter 18.32 RCW, a podiatric physician
12 and surgeon under chapter 18.22 RCW, a veterinarian under chapter
13 18.92 RCW, a commissioned medical or dental officer in the United
14 States armed forces or public health service in the discharge of his
15 or her official duties, a duly licensed physician or dentist employed
16 by the veterans administration in the discharge of his or her
17 official duties, a registered nurse or advanced registered nurse
18 practitioner under chapter 18.79 RCW when authorized by the nursing
19 care quality assurance commission, a pharmacist licensed under
20 chapter 18.64 RCW to the extent permitted by drug therapy guidelines
21 or protocols established under RCW 18.64.011 and authorized by the
22 commission and approved by a practitioner authorized to prescribe
23 drugs, an osteopathic physician assistant under chapter 18.57A RCW
24 when authorized by the board of osteopathic medicine and surgery, a
25 physician assistant under chapter 18.71A RCW when authorized by the
26 medical quality assurance commission, or any of the following
27 professionals in any province of Canada that shares a common border
28 with the state of Washington or in any state of the United States: A
29 physician licensed to practice medicine and surgery or a physician
30 licensed to practice osteopathic medicine and surgery, a dentist
31 licensed to practice dentistry, a podiatric physician and surgeon
32 licensed to practice podiatric medicine and surgery, a licensed
33 advanced registered nurse practitioner, a licensed physician
34 assistant, a licensed osteopathic physician assistant, or a
35 veterinarian licensed to practice veterinary medicine: PROVIDED,
36 HOWEVER, That the above provisions shall not apply to sale, delivery,
37 or possession by drug wholesalers or drug manufacturers, or their
38 agents or employees, or to any practitioner acting within the scope
39 of his or her license, or to a common or contract carrier or

1 warehouse operator, or any employee thereof, whose possession of any
2 legend drug is in the usual course of business or employment:
3 PROVIDED FURTHER, That nothing in this chapter or chapter 18.64 RCW
4 shall prevent a family planning clinic that is under contract with
5 the health care authority from selling, delivering, possessing, and
6 dispensing commercially prepackaged oral contraceptives prescribed by
7 authorized, licensed health care practitioners: PROVIDED FURTHER,
8 That nothing in this chapter prohibits possession or delivery of
9 legend drugs by an authorized collector or other person participating
10 in the operation of a drug take-back program authorized in chapter
11 69.--- RCW (the new chapter created in section 25 of this act).

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

15 (b) A violation of this section involving possession is a
16 misdemeanor.

17 NEW SECTION. Sec. 23. A new section is added to chapter 69.50
18 RCW to read as follows:

19 It is not a violation of this chapter to possess or deliver a
20 controlled substance in compliance with chapter 69.--- RCW (the new
21 chapter created in section 25 of this act).

22 NEW SECTION. Sec. 24. A new section is added to chapter 70.95
23 RCW to read as follows:

24 An authorized collector regulated under chapter 69.--- RCW (the
25 new chapter created in section 25 of this act) is not required to
26 obtain a permit under RCW 70.95.170 unless the authorized collector
27 is required to obtain a permit under RCW 70.95.170 as a consequence
28 of activities that are not directly associated with the collection
29 facility's activities under chapter 69.--- RCW (the new chapter
30 created in section 25 of this act).

31 NEW SECTION. Sec. 25. Sections 2 through 20 of this act
32 constitute a new chapter in Title 69 RCW."

33 Correct the title.

EFFECT: Increases dates in the bill by one year. Makes a technical change to reflect legislation enacted in 2017.

--- END ---