

CERTIFICATION OF ENROLLMENT
SECOND SUBSTITUTE HOUSE BILL 1161

67th Legislature
2021 Regular Session

Passed by the House March 8, 2021
Yeas 97 Nays 0

**Speaker of the House of
Representatives**

Passed by the Senate April 11, 2021
Yeas 48 Nays 0

President of the Senate

Approved

Governor of the State of Washington

CERTIFICATE

I, Bernard Dean, Chief Clerk of the House of Representatives of the State of Washington, do hereby certify that the attached is **SECOND SUBSTITUTE HOUSE BILL 1161** as passed by the House of Representatives and the Senate on the dates hereon set forth.

Chief Clerk

FILED

**Secretary of State
State of Washington**

SECOND SUBSTITUTE HOUSE BILL 1161

Passed Legislature - 2021 Regular Session

State of Washington **67th Legislature** **2021 Regular Session**

By House Appropriations (originally sponsored by Representatives Peterson, Davis, Pollet, and Thai)

READ FIRST TIME 02/22/21.

1 AN ACT Relating to modifying the requirements for drug take-back
2 programs; amending RCW 69.48.010, 69.48.050, 69.48.070, 69.48.120,
3 43.131.423, and 43.131.424; and creating a new section.

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

5 **Sec. 1.** RCW 69.48.010 and 2018 c 196 s 1 are each amended to
6 read as follows:

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

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

1 homes increase risks of drug abuse, overdoses, and preventable
2 poisonings.

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

9 (4) The legislature therefore finds that it is in the interest of
10 public health to establish a single, uniform, statewide system of
11 regulation for safe and secure collection and disposal of medicines
12 through ~~((a—uniform))~~ drug "take-back" programs operated and funded
13 by drug manufacturers.

14 NEW SECTION. **Sec. 2.** (1) The legislature finds that in 2018,
15 the legislature passed Engrossed Substitute House Bill No. 1047,
16 which required drug manufacturers that sell drugs into Washington to
17 operate a drug take-back program to collect and dispose of
18 prescription and over-the-counter drugs. Further, the legislature
19 finds that there is uncertainty about whether, under current law,
20 more than one drug take-back program may operate.

21 (2) Therefore, the legislature intends to clearly authorize the
22 department of health to approve and allow the operation of multiple
23 drug take-back programs that meet all statutory requirements.

24 **Sec. 3.** RCW 69.48.050 and 2018 c 196 s 5 are each amended to
25 read as follows:

26 (1) By July 1, 2019, a program operator must submit a proposal
27 for the establishment and implementation of a drug take-back program
28 to the department for approval. Proposals from new entities seeking
29 to become a program operator after July 1, 2019, may be submitted as
30 provided in subsection (7) of this section. The department shall
31 approve a proposed program if the applicant submits a completed
32 application, the proposed program meets the requirements of
33 subsection (2) of this section, and the applicant pays the
34 appropriate proposal review fee established by the department under
35 RCW 69.48.120. The department may approve drug take-back programs
36 proposed by one or more program operators consistent with the
37 provisions of this section.

1 (2) To be approved by the department, a proposed drug take-back
2 program, independent of any other operating program, must:

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

5 (b) Identify and provide contact information for the authorized
6 collectors for the proposed program, as well as the reasons for
7 excluding any potential authorized collectors from participation in
8 the program;

9 (c) Provide for a collection system that complies with RCW
10 69.48.060;

11 (d) Ensure that physical collection sites are the primary method
12 of collection across the state and that methods of supplementing
13 physical collection site service are the secondary methods for
14 collection as required by RCW 69.48.060(3) (b) through (d). A drug
15 take-back program's use of supplemental mail-back distribution
16 locations or periodic collection events in any areas underserved by
17 physical collection sites may provide collection services to no more
18 than 15 percent of the state's residents;

19 (e) Provide for a handling and disposal system that complies with
20 RCW 69.48.080;

21 ~~((e))~~ (f) Identify any transporters and waste disposal
22 facilities that the program will use;

23 ~~((f))~~ (g) Adopt policies and procedures to be followed by
24 persons handling covered drugs collected under the program to ensure
25 safety, security, and compliance with regulations adopted by the
26 United States drug enforcement administration, as well as any
27 applicable laws;

28 ~~((g))~~ (h) Ensure the security of patient information on drug
29 packaging during collection, transportation, recycling, and disposal;

30 ~~((h))~~ (i) Promote the program by providing consumers,
31 pharmacies, and other entities with educational and informational
32 materials as required by RCW 69.48.070;

33 ~~((i))~~ (j) Demonstrate adequate funding for all administrative
34 and operational costs of the drug take-back program, with costs
35 apportioned among participating covered manufacturers;

36 ~~((j))~~ (k) Set long-term and short-term goals with respect to
37 collection amounts and public awareness; and

38 ~~((k))~~ (l) Consider: (i) The use of existing providers of
39 pharmaceutical waste transportation and disposal services; (ii)

1 separation of covered drugs from packaging to reduce transportation
2 and disposal costs; and (iii) recycling of drug packaging.

3 (3) (a) No later than one hundred twenty days after receipt of a
4 drug take-back program proposal, the department shall either approve
5 or reject the proposal in writing to the applicant. The department
6 may extend the deadline for approval or rejection of a proposal for
7 good cause. If the department rejects the proposal, it shall provide
8 the reason for rejection.

9 (b) No later than ninety days after receipt of a notice of
10 rejection under (a) of this subsection, the applicant shall submit a
11 revised proposal to the department. The department shall either
12 approve or reject the revised proposal in writing to the applicant
13 within ninety days after receipt of the revised proposal, including
14 the reason for rejection, if applicable.

15 (c) If the department rejects a revised proposal, the department
16 may:

17 (i) Require the program operator to submit a further revised
18 proposal;

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

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

24 (iv) Find the covered manufacturer out of compliance with the
25 requirements of this chapter and take enforcement action as provided
26 in RCW 69.48.110.

27 (4) The program operator must (~~initiate operation of~~) fully
28 implement an approved drug take-back program no later than one
29 hundred eighty days after approval of the proposal by the department.

30 (5) (a) Proposed changes to an approved drug take-back program
31 that substantially alter program operations must have prior written
32 approval of the department. A program operator must submit to the
33 department such a proposed change in writing at least fifteen days
34 before the change is scheduled to occur. Changes requiring prior
35 approval of the department include changes to participating covered
36 manufacturers, collection methods, achievement of the service
37 convenience goal described in RCW 69.48.060, policies and procedures
38 for handling covered drugs, education and promotion methods, and
39 selection of disposal facilities.

1 (b) For changes to a drug take-back program that do not
2 substantially alter program operations, a program operator must
3 notify the department at least seven days before implementing the
4 change. Changes that do not substantially alter program operations
5 include changes to collection site locations, methods for scheduling
6 and locating periodic collection events, and methods for distributing
7 prepaid, preaddressed mailers.

8 (c) A program operator must notify the department of any changes
9 to the official point of contact for the program no later than
10 fifteen days after the change. A program operator must notify the
11 department of any changes in ownership or contact information for
12 participating covered manufacturers no later than ninety days after
13 such change.

14 ~~(6) ((No later than four years after a drug take-back program~~
15 ~~initiates operations))~~ By July 1, 2024, and every four years
16 thereafter, ~~((the))~~ all program operators must submit an updated
17 proposal to the department describing any substantive changes to
18 program elements described in subsection (2) of this section. The
19 department shall approve or reject the updated proposal using the
20 process described in subsection (3) of this section.

21 (7)(a) On July 1, 2021, the department will begin the review of
22 new proposals received by that date from entities seeking to become a
23 program operator.

24 (b) Beginning July 1, 2024, and every four years thereafter, the
25 department will review new proposals from entities seeking to become
26 a program operator.

27 (c) The department shall approve a proposal if it meets the
28 requirements in subsection (2) of this section and the applicant pays
29 the appropriate fee established by the department under RCW
30 69.48.120. The department must approve or reject proposals received
31 using the process provided in subsection (3) of this section.

32 (8)(a) If there is a single approved drug take-back program at
33 any time and that program operator intends to leave the program for
34 any reason, participating manufacturers must find a new entity to
35 take over operations of the existing program without a break in
36 program services. The new entity may not make changes to the
37 operations of the approved program, which must be consistent with the
38 proposal as it was approved by the department under this section, or
39 each covered manufacturer or group of covered manufacturers must
40 identify a new program operator to develop a new program proposal.

1 The department must accept new proposals from potential program
2 operators for a minimum of four months from the date the department
3 is notified of the program operator intending to cease operations, or
4 until a proposal is approved by the department. The department may
5 approve a proposal if it meets the requirements in subsection (2) of
6 this section and the applicant pays the appropriate fee established
7 by the department under RCW 69.48.120. The department must approve or
8 reject proposals received using the process described in subsection
9 (3) of this section.

10 (b) If there is a single approved drug take-back program, and
11 that program operator leaves the program and participating
12 manufacturers do not identify a program operator to take over the
13 approved program as provided in (a) of this subsection, all covered
14 manufacturers must participate in a new approved drug take-back
15 program as soon as one is approved.

16 (9) If there is more than one approved drug take-back program,
17 and a program operator for a drug take-back program leaves the
18 program for any reason and the covered manufacturers participating in
19 that program fail to identify a new entity to take over operations of
20 the existing program without a break in program services as described
21 in subsection (8)(a) of this section, those manufacturers must
22 immediately join an existing approved drug take-back program.

23 (10) A covered manufacturer may change the approved drug take-
24 back program it participates in but the covered manufacturer must
25 maintain continuous participation in an established drug take-back
26 program and may not leave an approved program until it transfers
27 participation to an approved drug take-back program that has begun
28 drug collection.

29 (11) The department shall make all proposals submitted under this
30 section available to the public and shall provide an opportunity for
31 written public comment on each proposal.

32 (12)(a) All program operators must collaborate to present a
33 consistent statewide drug take-back system for residents to ensure
34 that all state residents can easily identify, understand, and access
35 services provided by any approved drug take-back program. The
36 department may identify or clarify in rule additional requirements
37 for coordination or performance amongst program operators, if
38 necessary, to ensure consistent operation of the drug take-back
39 program. Requirements may include, but are not limited to: Consistent
40 drop box appearance and signage; consistent messaging in education

1 and outreach; and consistent metrics included in operator annual
2 reports as required in RCW 69.48.100 to ensure the department can
3 accurately analyze the data.

4 (b) Failure to comply with these requirements may result in
5 enforcement action against a program operator as authorized under RCW
6 69.48.110.

7 **Sec. 4.** RCW 69.48.070 and 2018 c 196 s 7 are each amended to
8 read as follows:

9 (1) A drug take-back program must develop and provide a system of
10 promotion, education, and public outreach about the safe storage and
11 secure collection of covered drugs. This system may include signage,
12 written materials to be provided at the time of purchase or delivery
13 of covered drugs, and advertising or other promotional materials. At
14 a minimum, each program must:

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

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

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

23 (d) Establish a toll-free telephone number and website
24 publicizing collection options and collection sites and discouraging
25 improper disposal practices for covered drugs, such as flushing them
26 or placing them in the garbage;

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

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

37 (g) Work with authorized collectors to develop a readily
38 recognizable, consistent design of collection receptacles, as well as
39 clear, standardized instructions for covered entities on the use of

1 collection receptacles. The department may provide guidance to
2 program operators on the development of the instructions and design;
3 and

4 (h) Annually report on its promotion, outreach, and public
5 education activities in its annual report required by RCW 69.48.100.

6 (2) If more than one drug take-back program is approved by the
7 department, the programs must coordinate their promotional activities
8 to ensure that all state residents can easily identify, understand,
9 and access the collection services provided by any drug take-back
10 program. Coordination efforts must include providing residents with a
11 single toll-free telephone number and single website to access
12 information about collection services for every approved program,
13 including presenting all available collection sites, mail-back
14 distribution locations, and take-back events to ensure residents are
15 able to access the most convenient method of collection, regardless
16 of the program operator, and must manage requests for prepaid,
17 preaddressed mailing envelopes from covered entities and from retail
18 pharmacies as provided in RCW 69.48.060(3)(e).

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

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

36 (5) The department:

37 (a) Shall conduct a survey of covered entities and a survey of
38 pharmacists, health care providers, and veterinarians who interact
39 with covered entities on the use of medicines after the first full
40 year of operation of the drug take-back program, and again every two

1 years thereafter. Survey questions must: Measure consumer awareness
2 of the drug take-back program; assess the extent to which collection
3 sites and other collection methods are convenient and easy to use;
4 assess knowledge and attitudes about risks of abuse, poisonings, and
5 overdoses from drugs used in the home; and assess covered entities'
6 practices with respect to unused, unwanted, or expired drugs, both
7 currently and prior to implementation of the drug take-back program;
8 and

9 (b) May, upon review of results of public awareness surveys,
10 direct a program operator for an approved drug take-back program to
11 modify the program's promotion and outreach activities to better
12 achieve widespread awareness among Washington state residents and
13 health care professionals about where and how to return covered drugs
14 to the drug take-back program.

15 **Sec. 5.** RCW 69.48.120 and 2018 c 196 s 12 are each amended to
16 read as follows:

17 (1) (a) (~~By July 1, 2019, the~~) The department shall: Determine
18 its costs for the administration, oversight, and enforcement of the
19 requirements of this chapter, including, but not limited to, a fee
20 for proposal review, and the survey required under RCW 69.48.200;
21 pursuant to RCW 43.70.250, set fees at a level sufficient to recover
22 the costs associated with administration, oversight, and enforcement;
23 and adopt rules establishing requirements for program operator
24 proposals.

25 (b) The department shall not impose any fees in excess of its
26 actual administrative, oversight, and enforcement costs. The fees
27 collected from each program operator in calendar year 2020 and any
28 subsequent year may not exceed ten percent of the program's annual
29 expenditures as reported to the department in the annual report
30 required by RCW 69.48.100 and determined by the department.

31 (c) Adjustments to the department's fees may be made annually and
32 shall not exceed actual administration, oversight, and enforcement
33 costs. Adjustments for inflation may not exceed the percentage change
34 in the consumer price index for all urban consumers in the United
35 States as calculated by the United States department of labor as
36 averaged by city for the twelve-month period ending with June of the
37 previous year.

38 (d) The annual fee set by the department shall be evenly split
39 amongst each approved program operator.

1 (e) The department shall collect annual operating fees from each
2 program operator by October 1, 2019, and annually thereafter.

3 (f) Between the effective date of this section and January 1,
4 2024, the department shall collect a nonrefundable one-time fee of
5 \$157,000 for review of proposals from each potential program operator
6 applicant as provided in RCW 69.48.050.

7 (2) All fees collected under this section must be deposited in
8 the secure drug take-back program account established in RCW
9 69.48.130.

10 **Sec. 6.** RCW 43.131.423 and 2018 c 196 s 26 are each amended to
11 read as follows:

12 The authorization for drug take-back programs created in chapter
13 196, Laws of 2018 and chapter . . . , Laws of 2021 (sections 1 through
14 5 of this act) shall be terminated on January 1, 2029, as provided in
15 RCW 43.131.424.

16 **Sec. 7.** RCW 43.131.424 and 2018 c 196 s 27 are each amended to
17 read as follows:

18 The following acts or parts of acts, as now existing or hereafter
19 amended, are each repealed, effective January 1, 2030:

20 (1) RCW 69.48.010 and 2021 c . . . s 1 (section 1 of this act) &
21 2018 c 196 s 1;

22 (2) RCW 69.48.020 and 2018 c 196 s 2;

23 ~~((2))~~ (3) RCW 69.48.030 and 2018 c 196 s 3;

24 ~~((3))~~ (4) RCW 69.48.040 and 2018 c 196 s 4;

25 ~~((4))~~ (5) RCW 69.48.050 and 2021 c . . . s 3 (section 3 of this
26 act) & 2018 c 196 s 5;

27 ~~((5))~~ (6) RCW 69.48.060 and 2018 c 196 s 6;

28 ~~((6))~~ (7) RCW 69.48.070 and 2021 c . . . s 4 (section 4 of this
29 act) & 2018 c 196 s 7;

30 ~~((7))~~ (8) RCW 69.48.080 and 2018 c 196 s 8;

31 ~~((8))~~ (9) RCW 69.48.090 and 2018 c 196 s 9;

32 ~~((9))~~ (10) RCW 69.48.100 and 2018 c 196 s 10;

33 ~~((10))~~ (11) RCW 69.48.110 and 2018 c 196 s 11;

34 ~~((11))~~ (12) RCW 69.48.120 and 2021 c . . . s 5 (section 5 of
35 this act) & 2018 c 196 s 12;

36 ~~((12))~~ (13) RCW 69.48.130 and 2018 c 196 s 13;

37 ~~((13))~~ (14) RCW 69.48.140 and 2018 c 196 s 14;

38 ~~((14))~~ (15) RCW 69.48.150 and 2018 c 196 s 15;

1 (~~(15)~~) (16) RCW 69.48.160 and 2018 c 196 s 16;
2 (~~(16)~~) (17) RCW 69.48.170 and 2018 c 196 s 17;
3 (~~(17)~~) (18) RCW 69.48.180 and 2018 c 196 s 18;
4 (~~(18)~~) (19) RCW 69.48.190 and 2018 c 196 s 19; and
5 (~~(19)~~) (20) RCW 69.48.200 and 2018 c 196 s 20.

--- **END** ---