

**Chapter 246-480 WAC
DRUG TAKE-BACK PROGRAM**

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WAC

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WAC 246-480-010 Purpose and scope. The purpose of this chapter is to:

(1) Establish a single uniform, statewide system of regulation for safe and secure collection and disposal of medicines through a uniform drug take-back program, operated and funded by drug manufacturers, and regulated by the department of health consistent with chapter 69.48 RCW.

(2) Establish criteria and an approval process for program operators to operate a drug take-back program under chapter 69.48 RCW.

(3) Ensure every covered manufacturer whose drugs are sold in or into Washington complies with chapter 69.48 RCW and this chapter.

[Statutory Authority: RCW 69.48.180 and 69.48.120. WSR 19-14-090, § 246-480-010, filed 7/1/19, effective 8/1/19.]

WAC 246-480-020 Definitions. The definitions in RCW 69.48.020 apply to this chapter unless the context clearly indicates otherwise.

[Statutory Authority: RCW 69.48.180 and 69.48.120. WSR 19-14-090, § 246-480-020, filed 7/1/19, effective 8/1/19.]

WAC 246-480-030 Identification of covered manufacturers. (1) Upon review of an inquiry response letter described in RCW 69.48.040(3), the department shall notify the person or entity in writing whether or not the person or entity is considered a covered manufacturer. If the department determines that the person or entity is a covered manufacturer, the written notice will include a warning regarding the penalties for violation of this chapter, as authorized in RCW 69.48.110(2).

(2)(a) Within thirty days after the first full year of a drug take-back program's implementation, and annually thereafter, the department may provide a list of covered manufacturers potentially not participating in a drug take-back program to each approved program operator.

(b) Within thirty days of receiving such a list, approved program operators may provide any comments on the list to the department.

(c) Within thirty days of receiving and considering any approved program operator comments, the department may publish on its website a list of all covered manufacturers not participating in a drug take-back program.

(3) The department shall remove any covered manufacturer identified in the published list if the covered manufacturer participates in an approved drug take-back program.

[Statutory Authority: RCW 69.48.180 and 69.48.120. WSR 19-14-090, § 246-480-030, filed 7/1/19, effective 8/1/19.]

WAC 246-480-040 Drug take-back program proposal components. In addition to this section, the drug take-back proposal must comply with chapter 69.48 RCW. Each proposal must be on a form provided by the department and must:

(1) Contain a table of contents clearly denoting, at a minimum, where each component specified in RCW 69.48.050 is located within the program proposal;

(2) Provide a description of a drug collection system that includes:

(a) A list of participating authorized collectors;

(b) A list of drop-off (kiosk) locations; and

(c) A detailed description of how mail-back distribution locations or periodic collection events will be used.

(3) Demonstrate that the policies and procedures to be followed by persons handling unwanted covered drugs collected under the drug take-back program as required in RCW 69.48.050 (2)(f) includes:

(a) How all entities participating in the drug take-back program will operate under all applicable federal and state laws and rules including, but not limited to, United States Drug Enforcement Administration rules; and

(b) How any pharmacy collection sites will operate under applicable rules from the Washington state pharmacy quality assurance commission.

(4) Include a detailed description of the geographical distribution of collection sites that will provide equitable and reasonably convenient access to all residents consistent with RCW 69.48.060;

(5) Include a budget estimate for providing the statewide program. Estimates must show total costs for each of the categories described in this subsection and a sum total of all program costs representing the totals for each category:

(a) Category 1: Administrative costs. A total for all administrative costs must include, but is not limited to:

(i) Contracted and employed personnel overhead costs;

(ii) Legal fees;

(iii) Local and state business licensing fees;

(iv) Local, state, and federal taxes;

(v) Property costs, including rentals;

(vi) Utilities, phone, and internet; and

(vii) General equipment and supplies.

(b) Category 2: Collection and disposal costs. A total for all collection and disposal costs must include, but is not limited to:

(i) Collection, transportation, and disposal of drugs;

(ii) Purchase, maintenance, and replacement of collection receptacles;

(iii) Compensation of authorized collectors, if separate from personnel costs in (a)(i) of this subsection; and

(iv) Production, distribution, and postage of mailers.

(c) Category 3: Communication costs. A total for all communication costs must include, but is not limited to:

- (i) Advertising;
- (ii) Marketing;
- (iii) Website creation and maintenance; and
- (iv) Operation of a toll-free phone number.

(6) Describe how the program operator will work with Washington state counties and the department to incorporate local programs into their proposed statewide plan consistent with RCW 69.48.160 (1)(b); and

(7) Include an implementation plan and schedule for initiating operation of the approved drug take-back program.

[Statutory Authority: RCW 69.48.180 and 69.48.120. WSR 19-14-090, § 246-480-040, filed 7/1/19, effective 8/1/19.]

WAC 246-480-050 Program application. (1) A drug take-back program operator must submit its program proposal and substantial changes to an approved program on forms provided by the department.

(2) If the department takes enforcement action as provided in RCW 69.48.050 (3)(c)(iv), the applicant through its authorized representative may request an adjudicative proceeding under chapter 246-10 WAC. A request for an adjudicative proceeding must be in writing, state the basis for contesting the adverse action, include a copy of the adverse notice and be served on and received by the department within twenty-eight days of the program operator's receipt of the adverse notice. If a request for adjudicative proceeding is not received by the department within twenty-eight days of the date of the program operator's receipt of the adverse notice, the secretary's decision is final.

[Statutory Authority: RCW 69.48.180 and 69.48.120. WSR 19-14-090, § 246-480-050, filed 7/1/19, effective 8/1/19.]

WAC 246-480-060 Collection of covered drugs—Underserved areas.

(1) To assist the program operators in complying with RCW 69.48.060 (3)(c) and (d), the department will determine and locate each population center consistent with RCW 69.48.060 and this chapter using geographical information systems (GIS) mapping technology, and will publish updated population data to the department's website annually.

(2) The department, in consultation with the local health jurisdiction, will determine underserved areas described in RCW 69.48.060(3) using the following criteria:

- (a) Population density of counties;
- (b) Estimated number of participating collection sites;
- (c) Travel distances and times;
- (d) Accessible public facilities such as libraries, town halls, and police and fire departments; and
- (e) Geographic features that may inhibit access to collection locations such as mountains and islands.

[Statutory Authority: RCW 69.48.180 and 69.48.120. WSR 19-14-090, § 246-480-060, filed 7/1/19, effective 8/1/19.]

WAC 246-480-070 Promotion. Approved program operators must update their list of authorized collectors, collection sites, locations

to receive mailers, and locations for drug take-back events at least quarterly on their web site.

[Statutory Authority: RCW 69.48.180 and 69.48.120. WSR 19-14-090, § 246-480-070, filed 7/1/19, effective 8/1/19.]

WAC 246-480-080 Program operator annual report. (1) To comply with RCW 69.48.100(1), each program operator shall submit an annual report to the department by July 1st on a form developed by the department.

(2) In addition to the elements identified and described in RCW 69.48.100, the report must include a summary of the program's annual expenditures organized using the same criteria as described in WAC 246-480-040(5).

[Statutory Authority: RCW 69.48.180 and 69.48.120. WSR 19-14-090, § 246-480-080, filed 7/1/19, effective 8/1/19.]

WAC 246-480-090 Proprietary information. (1) Consistent with RCW 69.48.170, chapter 42.56 RCW, and other applicable laws, proprietary information submitted to the department under chapter 69.48 RCW is exempt from public disclosure. The manufacturer or drug take-back organization must identify in writing the information it considers proprietary when submitting information to the department. Information automatically disclosable under law may not be marked proprietary. Information not deemed automatically disclosable cannot be marked as proprietary in their entirety.

(2) If the department receives a request for disclosure under chapter 42.56 RCW which includes information identified by the manufacturer or drug take-back organization as proprietary, the department will notify the manufacturer or drug take-back organization of the status of such documents prior to their release. The manufacturer or drug take-back organization may seek to enjoin the release of the information as provided under RCW 42.56.540.

[Statutory Authority: RCW 69.48.180 and 69.48.120. WSR 19-14-090, § 246-480-090, filed 7/1/19, effective 8/1/19.]

WAC 246-480-990 Fees. This section establishes the initial and annual fees for a program operator implementing a drug take-back program under chapter 69.48 RCW and this chapter.

(1) Initial fee. By no later than October 1, 2019, a program operator shall submit to the department an initial fee of seven hundred thousand dollars.

(2) Renewal fee.

(a) By August 1, 2020, and each August 1st thereafter, the department shall notify a program operator the amount of its annual renewal fee as determined according to RCW 69.48.120. Renewal fees will reflect the department's actual administrative, oversight, enforcement, and contractual costs for that fiscal year, or not more than ten percent of the program operator's annual expenses as reported on July 1st of each year, whichever amount is smaller.

(b) By October 1, 2020, and each October 1st thereafter, a program operator shall submit to the department the renewal fee.

[Statutory Authority: RCW 69.48.180 and 69.48.120. WSR 19-14-090, § 246-480-990, filed 7/1/19, effective 8/1/19.]