

CHAPTER 246-XXX WAC
SECURE DRUG TAKE BACK PROGRAM
CONCEPTUAL DRAFT VERSION 2.43
98/203/18

WAC 246-XXX-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.

WAC 246-XXX-020 Definitions. The definitions in RCW 69.48.020 and RCW 69.48.060(3)(c)(iii) apply to this chapter unless the context clearly indicates otherwise.

WAC 246-XXX-030 Lists of manufacturers

(1) All drug wholesalers shall provide the list to the department identifying the drug manufacturers for the drugs they sell in or into Washington, consistent with RCW 69.48.040(1). Retail pharmacies, private label distributors, or repackagers shall provide the list identifying the drug manufacturers from which they obtain drugs they sell under their own label to the department consistent with RCW 69.48.040 (2).

(2) The department may issue a letter of inquiry to a person or entity if the department is seeking information to identify whether that person or entity is a covered manufacturer subject to chapter 69.48 RCW.

(3) The person or entity receiving, electronically or by hard copy, the letter of inquiry shall respond in sixty calendar days after receipt of the letter, stating whether (a) it sells drugs within the state or provides a drug for sale to a licensed retail pharmacy in the state, a private label distributor or repackager under their own label or (b) it does not believe it is a covered manufacturer and providing

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the information required in RCW 69.48.040(3). The response must be received by the department no later than the sixtieth calendar day.

- (4) The department shall review the inquiry response letter submitted under this section, and
 - (a) Notify the person or entity within a timeframe set by the department whether the response to inquiry letter adequately establishes that the person or entity is not a covered manufacturer; or
 - (b) If the information provided in the response letter establishes that the person or entity is a covered manufacturer, the department shall send the written notice, including a warning regarding the penalties for violation of this chapter, as authorized in RCW 69.48.110(2).

WAC 246-XXX-035 - Notification of Potential Authorized Collectors

At least one hundred twenty days prior to submitting a proposal under WAC 246-XXX-040 and an application under WAC 246-XXX-050, a program operator must notify potential authorized collectors of the opportunity to serve as an authorized collector for the program, consistent with RCW 69.48.060~~(1)(a)~~.

WAC 246-XXX-040 - Drug Take-Back Program Proposal Components

A drug take-back program proposal submitted by a program operator and reviewed under chapter 69.48 RCW and this chapter shall include, at a minimum, the following components:

- (1) Contact information for the program operator and each drug manufacturer participating in the drug take-back program.
- (2) Contact information for all potential authorized collectors contacted under WAC 246-XXX-035;
- (3) Contact information for the authorized collectors for the proposed program, as well as the reasons for excluding any potential authorized collectors from participation in the program.
- (4) A description of the proposed collection system to provide convenient, on-going collection services for all unwanted covered drugs from the covered entities in compliance with the provisions and requirements of chapter 69.48 RCW and this chapter, including but not limited to:
 - (a) A list of collection methods and participating collectors;
 - (b) A list of drop-off locations;
 - (c) A detailed description of how mail-back distribution locations or periodic collection events will be used to supplement service to any area of the state that is underserved by collection sites, as determined by the department consistent with RCW 69.48.060(3)(d);

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~~In areas determined by the department to be underserved by collection sites, under RCW 69.48.060(3)(d):~~

- (i) A detailed description of how periodic collection events will be scheduled and located if applicable; and
 - (ii) A description of how mail-back services will be provided, with an example of the pre-paid, pre-addressed mailers to be utilized;
- (5) A description of the handling and disposal system, including identification of and contact information from collectors, transporters, and waste disposal facilities to be used by the drug take-back program consistent with RCW 69.48.050, and this chapter;
- (6) A copy of the policies and procedures to be followed by persons handling unwanted covered drugs collected under the drug take-back program, including a description of:
- (a) How all collectors, transporters, and waste disposal facilities utilized will ensure the collected, unwanted covered drugs are safely and securely tracked from collection through final disposal;
 - (b) 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 the United States drug enforcement administration;
 - (c) How any pharmacy collection site will operate under applicable rules from the Washington state pharmacy commission; and
 - (d) A copy of the proposed agreement between the operator and the authorized collector that ensures all of the requirements of RCW 69.48.0650 are met. If the proposed agreement is modified, a copy of the modified agreement must be delivered to the department.
- (7) A description of how patient information on drug packaging will be protected during collection, transportation, and recycling and disposal;
- (8) A description of public education efforts and promotion strategy as required by RCW 69.48.070 and WAC 246-XXX-070;
- (9) Demonstration of adequate funding for all administrative and operational costs of the program, with costs apportioned among participating covered manufacturers;
- ~~(10) A detailed description of the geographical distribution of collection sites that will provide equitable and reasonably convenient ~~and equitable~~ access to all residents consistent with RCW 69.48.060 within a population center;~~
- ~~(11) (10) Provision for establishment of mail-back distribution locations or periodic collection events to supplement service to any area of the state that is underserved by collection sites, as~~

~~determined by the department consistent with RCW 69.48.060(3)(d);~~

- (11) Provision for establishment of a mail-back program that is free of charge to all covered entities and to retail pharmacies that offer to distribute prepaid, preaddressed mailing envelopes for the drug take-back program per RCW 69.48.060 (3) (e);
- (12) A description of proposed alternative collection methods to be implemented in compliance with RCW 69.48.060(3)(f), excluding controlled substances;
- (13) A proposal of the short-term and long-term goals of the drug take-back program for collection amounts and public awareness, education, and promotion;
- (14) A description of how the drug take-back program will consider:
 - (a) Use of existing providers of pharmaceutical waste transportation and disposal services;
 - (b) Separating covered drugs from packaging to reduce transportation and disposal costs; and
 - (c) Recycling of drug packaging.
- (15) A budget estimate for providing the statewide program, itemized by program categories, including but not limited to:
 - (a) Salaries;
 - (b) Benefits;
 - (c) Costs for collection and transportation supplies for each collection site;
 - (d) Costs to purchase secure collection receptacles for each collection site;
 - (e) Costs of ongoing maintenance or replacement of secure collection receptacles when requested by authorized collectors;
 - (f) Costs of pre-paid, pre-addressed mailers, and cost of mailer distribution;
 - (g) Compensation of authorized collectors, if applicable;
 - (h) Costs of take-back events, including the operational costs of periodic take-back events and any associated cost of law enforcement staff time;
 - (i) Cost of transportation of all collected covered drugs to final disposal itemized by collection method;
 - (j) Contracts for reverse distributing;
 - (k) Costs for actual destruction of drugs itemized by collection method utilized;
 - (l) Applicable state, local and federal taxes;
 - (m) State and local business licensing;
 - (n) Administrative costs, such as rent, utilities, phones, IT equipment, office supplies; and
 - (o) Advertising and marketing costs, including website maintenance and phone number maintenance.

~~(12)~~ (16) A description of how the program operator will work with the counties and the department to incorporate the local program into their proposed state-wide plan consistent with RCW 69.48.160(1)(b).

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WAC 246-XXX-050 Program application process

- (1) A drug take-back program operator seeking department approval must submit an application on forms provided by the department, supporting documentation consistent with RCW 69.48.050, and the following:
 - (a) The program proposal consistent with WAC 246-XXX-040;
 - (b) A table of contents clearly denoting, at a minimum, where each component specified in RCW 69.48.050 is located within the program proposal;
 - (c) The fee specified in WAC 246-XXX-XXX; and
 - (d) Other information as may be required by the department to process the application and assure compliance with chapter 69.48 RCW and these rules.
- (2) The department shall approve or reject a drug take-back program proposal in writing to the applicant within one hundred and twenty calendar days after receipt of the proposal consistent with RCW 69.48.050, including the opportunity to submit a revised proposal.
- (3) The department shall make all proposals submitted under this section available to the public on its website, and shall provide an opportunity for written public comment on each proposal.
- (3)(4) If the department notifies a program operator of the secretary's intent to deny the program proposal, the program operator 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. The authorized representative of the program operator must provide proof that the deficiencies which resulted in denial of the program proposal have been corrected before requesting reapproval. Program operators seeking reapproval shall follow the requirements outlined in this section.
- ~~(4) A program must be fully operational for collection, transportation and disposal of covered drugs no later than 180 days after the program proposal is approved by the department consistent with RCW 69.48.050(4).~~

WAC 246-XXX-060 Collection of covered drugs

- (1) Approved program operators must comply with all requirements describing drug collection in RCW 69.48.060.

~~(2) A drug take-back program's collection system must be accessible to all covered entities within all Washington state population centers consistent with RCW 69.48.060.~~

~~(3)~~(2) 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 system (GIS) mapping technology, and will publish updated population data to the department's website by January 1 of every year.

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WAC 246-XXX-070 Promotion

(1) Approved program operators must update their list of authorized collectors, sites, locations to receive mailers, and locations for drug take-back events at least quarterly on their website.

(2) Consistent with the authority in RCW 69.48.070 (5), the department will use the information collected and measured from the surveys described in RCW 69.48.070(5) to modify the program operators' promotion and outreach activities to better achieve the goals identified in RCW 69.48.070(5)(b).

WAC 246-XXX-080 Disposal of covered drugs

- (1) Covered drugs collected under a drug take-back program must be disposed of in a manner consistent with all requirements of RCW 69.48.080.
- (2) If use of a hazardous waste disposal facility as described in RCW 69.48.080(1) is unfeasible based on costs, logistics, or other considerations, the department, in consultation with the department of ecology, may grant approval for a program operator to dispose of some or all collected covered drugs at a permitted large municipal waste combustor facility that meets the requirements of 40 C.F.R. parts 60 and 62, as they exist on June 7, 2018. The petition to use a municipal waste facility must be submitted annually on a form established by the department. The petition will include documentation that the municipal waste combustor facility meets the requirements of this section.
- (3) As authorized in RCW 69.48.080 (3), a program operator may petition the department for approval to use final disposal technologies or processes that provide superior environmental and human health protection than those addressed in RCW 69.48.080 (1) or (2).
 - (a) The disposal petition must include, at a minimum, all of the following elements:
 - (i) A complete description of the technology or processes proposed;
 - (ii) Identification of the facilities to be utilized along with documentation establishing compliance with federal, ~~and state,~~ and local disposal requirements;
 - (iii) A complete description of how the proposed technology

or processes provide equivalent or superior protection in each of the following areas:

- (A) Monitoring of any emissions or waste;
- (B) Worker health and safety;
- (C) Air, water, or land emissions contributing to the persistent bio accumulative, and toxic pollution; and
- (D) Overall impact to the environment and human health.

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- (b) The disposal petition must be provided on a form approved by the department. In reviewing an alternative technologies disposal petition proposed under RCW 69.48.080 (3), the department will conduct the review as specified in RCW 69.48.080(3).
- (c) The department, in consultation with the department of ecology, may reject a disposal petition under this section if the technology or processes described in the petition are not consistent with the requirement described in RCW 69.48.080 and subsection (3) of this section. The rejection notification will include information about the program operator's rights to a hearing under the Administrative Procedure Act, chapter 34.05 RCW.

WAC 246-XXX-090 Administrative and operational costs and fees

A covered drug manufacturer or group of covered drug manufacturers shall pay all of the administrative and operational costs associated with establishing and implementing the drug take-back program in which they participate consistent with RCW 69.48.090 and this chapter.

WAC 246-XXX-100 Program Operator Annual Report

- (1) As required by RCW 69.48.100, each program operator shall submit an annual report to the department on a template developed by the department addressing all of the required elements in RCW 69.48.100.
- (2) The report must include:
 - (a) All of the elements identified and described in RCW 69.48.100; and
 - (b) A complete list of any potential authorized collectors that contacted the program offering to participate as a collector and the reasons for excluding any potential authorized collector from participation in the program; and
 - (c) A detailed summary of the program's annual expenditures, including but not limited to categorical transportation costs, administrative costs, and at a minimum, all of the following:
 - (i) Salaries and benefits for program staff;
 - (ii) Costs of collection and transportation supplies for each collection site;
 - (iii) Costs to purchase secure collection receptacles for each collection site;

- (iv) Costs of ongoing maintenance or replacement of secure collection receptacles when requested by authorized collectors;
- (v) Costs of prepaid, preaddressed mailers, and costs of mail;
- (vi) Compensation paid to authorized collectors, if applicable;
- (vii) Operations costs of periodic collection events, including the cost of law enforcement staff time;

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- (viii) Cost of transportation of all collected covered drugs to final disposal, itemized by each collection method utilized;
 - (ix) Costs for actual destruction of drugs, itemized by each collection method utilized;
 - (x) Advertising and marketing costs, including website maintenance and phone number maintenance; and
 - (xi) Administrative costs, such as rent, utilities, phones, internet technology (IT) equipment, offices supplies, state and local business licensing, and applicable state, local and federal taxes.
 - (xii) Administrative costs, such as rent, utilities, phones, internet technology (IT) equipment, offices supplies, state and local business licensing, and applicable state, local and federal taxes.
- (3) Within thirty days after each annual period of operation of an approved drug take-back program, the program operator shall submit an annual collection amount report to the department that provides the total amount, by weight, of covered drugs collected from each collection site during the prior year on a form provided by the department, consistent with RCW 69.48.100(2)
- (4) The department will make all reports submitted under RCW 69.48.100 available to the public on its website, consistent with RCW 69.48.100(3).

WAC 246-XXX-110 Proposed Changes to an Approved Program Plan

Consistent with RCW 69.48.050(5), proposed changes shall be submitted to the department within the timeframes specified in RCW 69.48.050(5), which varies depending on the nature of the proposed changes. Program operators are responsible for satisfying the requirements in RCW 69.48.050(5).

WAC 246-XXX-120 Updated Program Proposal Submission

Consistent with RCW 69.48.050(6), program operators shall submit an updated proposal to the department every four years describing any substantive changes to program elements in RCW 69.48.050(2) and WAC 246-XXX-040. The updated proposal shall be submitted and reviewed consistent with WAC 246-XXX-050.

