



# PROPOSED RULE MAKING

## CR-102 (December 2017) (Implements RCW 34.05.320)

Do NOT use for expedited rule making

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STATE OF WASHINGTON  
FILED

DATE: April 03, 2019

TIME: 9:53 AM

WSR 19-08-085

Agency: Department of Health

☒ Original Notice

☐ Supplemental Notice to WSR

☐ Continuance of WSR

☒ Preproposal Statement of Inquiry was filed as WSR 18-14-020 ; or

☐ Expedited Rule Making--Proposed notice was filed as WSR ; or

☐ Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1).

☐ Proposal is exempt under RCW .

**Title of rule and other identifying information:** (describe subject) Chapter 246-480 WAC, Drug take-back program. The department is proposing to create a new chapter of rules to clarify implementation of certain aspects of administrative and regulatory standards for the safe and secure collection and disposal of unwanted medicines through a uniform drug take-back program as established in chapter 69.48 RCW. Specific aspects addressed in this proposal include information required in drug take-back program proposals and other reports, department audits, proprietary information, and establishes a department fee.

**Hearing location(s):**

Date:	Time:	Location: (be specific)	Comment:
05/08/2019	2:00 pm	Washington State Department of Health Town Center Building 2, Rm #158 111 Israel Road SE Tumwater, WA 98501	

**Date of intended adoption:** 05/22/2019 (Note: This is NOT the effective date)

**Submit written comments to:**

Name: Carly Bartz-Overman

Address: Department of Health

P.O. Box 47850

Olympia, WA 98504-7850

Email: <https://fortress.wa.gov/doh/policyreview>

Fax: 360-236-2901

Other:

By (date) 05/08/2019

**Assistance for persons with disabilities:**

Contact Carly Bartz-Overman

Phone: 360-236-4698

Fax:

TTY: (360) 833-6388 or 711

Email: [carly.bartz-overman@doh.wa.gov](mailto:carly.bartz-overman@doh.wa.gov)

Other:

By (date) 05/01/2019

**Purpose of the proposal and its anticipated effects, including any changes in existing rules:** The department is statutorily responsible for the oversight and enforcement of the state-wide drug take-back program and is required to adopt rules for that purpose. The proposed rules primarily address administrative details about how to submit reports and petitions to the department for approval, and explain the level of information and formatting required, when applicable. It also provides details and direction about public disclosure, and determining a drug take-back's underserved areas to create predictability and transparency for stakeholders.

<b>Reasons supporting proposal:</b> The proposed rules give the department and the drug take-back program operator needed detail to ensure proper departmental review and oversight of the drug take-back program. Areas of clarity include details needed in a drug take-back proposal and annual reports for department review (e.g. cost projections and expenses), enforcement procedures, and the department's fee.			
Abuse, fatal overdoses, and poisonings from prescription and over-the-counter medicines used in the home have emerged as an epidemic in recent years. Poisoning is the leading cause of unintentional injury-related death in Washington State, and more than ninety percent of poisoning deaths are due to drug overdoses. Poisoning by prescription and over-the-counter medicines is also one of the most common means of suicide and suicide attempts, with poisonings involved in more than twenty-eight thousand suicide attempts between 2004 and 2013.			
<b>Statutory authority for adoption:</b> RCW 69.48.180			
<b>Statute being implemented:</b> Chapter 69.48 RCW			
<b>Is rule necessary because of a:</b>			
Federal Law?		<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Federal Court Decision?		<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
State Court Decision?		<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
If yes, CITATION:			
<b>Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:</b> None			
<b>Name of proponent:</b> (person or organization)		Department of Health <div style="float: right;"> <input type="checkbox"/> Private  <input type="checkbox"/> Public  <input checked="" type="checkbox"/> Governmental         </div>	
<b>Name of agency personnel responsible for:</b>			
	Name	Office Location	Phone
Drafting:	Carly Bartz-Overman	111 Israel Road SE, Tumwater WA 98501	360-236-3044
Implementation:	Carly Bartz-Overman	111 Israel Road SE, Tumwater WA 98501	360-236-3044
Enforcement:	Carly Bartz-Overman	111 Israel Road SE, Tumwater WA 98501	360-236-3044
<b>Is a school district fiscal impact statement required under RCW 28A.305.135?</b>			<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
If yes, insert statement here:			
The public may obtain a copy of the school district fiscal impact statement by contacting: Name: Address: Phone: Fax: TTY: Email: Other:			
<b>Is a cost-benefit analysis required under RCW 34.05.328?</b>			
<input checked="" type="checkbox"/> Yes: A preliminary cost-benefit analysis may be obtained by contacting: Name: Carly Bartz-Overman Address: P.O. Box 47850 Olympia WA, 98504-7850 Phone: 360-236-4698 Fax: 360-236-2901 TTY: (360) 833-6388 or 711 Email: carly.bartz-overman@doh.wa.gov			

Other:

☐ No: Please explain:

**Regulatory Fairness Act Cost Considerations for a Small Business Economic Impact Statement:**

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see chapter 19.85 RCW). Please check the box for any applicable exemption(s):

☐ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.061 because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.

Citation and description:

☐ This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by RCW 34.05.313 before filing the notice of this proposed rule.

☐ This rule proposal, or portions of the proposal, is exempt under the provisions of RCW 15.65.570(2) because it was adopted by a referendum.

☒ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.025(3). Check all that apply:

☐ RCW 34.05.310 (4)(b)  
(Internal government operations)

☒ RCW 34.05.310 (4)(c)  
(Incorporation by reference)

☐ RCW 34.05.310 (4)(d)  
(Correct or clarify language)

☒ RCW 34.05.310 (4)(e)  
(Dictated by statute)

☒ RCW 34.05.310 (4)(f)  
(Set or adjust fees)

☐ RCW 34.05.310 (4)(g)  
((i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit)

☐ This rule proposal, or portions of the proposal, is exempt under RCW .

Explanation of exemptions, if necessary:

**COMPLETE THIS SECTION ONLY IF NO EXEMPTION APPLIES**

If the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

☐ No Briefly summarize the agency's analysis showing how costs were calculated.

☐ Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses, and a small business economic impact statement is required. Insert statement here:

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

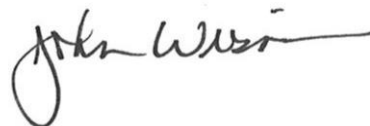
Name:  
Address:  
Phone:  
Fax:  
TTY:  
Email:  
Other:

**Date:** 4/3/2019

**Name:** John Wiesman, DrPH, MPH

**Title:** Secretary of Health

**Signature:**



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

NEW SECTION

**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.

NEW SECTION

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

NEW SECTION

**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 web site 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.

## NEW SECTION

**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 take into account:

(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 take into account:

(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)(A) of this subsection; and

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

(c) Category 3: Communication costs. A total for all communication costs must take into account:

(i) Advertising;

(ii) Marketing;

(iii) Web site 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.

#### NEW SECTION

**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.

#### NEW SECTION

**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 web site 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) Driving 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.

#### NEW SECTION

**WAC 246-480-070 Promotion.** 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 web site.

#### NEW SECTION

**WAC 246-480-080 Disposal of covered drugs.** (1) A program operator's use of disposal or combustor facilities described in RCW 69.48.080 which reside outside of Washington state do not require department approval. Prior to using any out-of-state disposal or combustor facility, a program operator shall:

(a) Notify the department in writing. The notice shall include the facility's:

- (i) Name;
- (ii) Type;
- (iii) Address; and
- (iv) Federal or state waste permit type and number.

(b) Abide by the waste disposal laws of that state or jurisdiction.

(2) Prior to using a permitted large municipal waste combustor facility within Washington state, a program operator shall submit a request in writing to the department for approval.

(3) Petitions for use of final disposal technologies as described in RCW 69.48.080(3) within Washington state must be made on forms provided by the department.

#### NEW SECTION

**WAC 246-480-090 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).

#### NEW SECTION

**WAC 246-480-100 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

#### NEW SECTION

**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.