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**Within Chapter 246-480 WAC
Secure Drug Take Back Program
WAC 246-480-010 Purpose and scope; WAC 246-480-070 Promotion; WAC 246-480-080
Program operator annual report; and WAC 246-480-990 Fees**

CONCEPTUAL DRAFT VERSION 3.0

~~**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 246-480-070 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.~~

- (1) Program operators shall coordinate to present a consistent statewide drug take-back system as described in RCW 69.48.050(12) and RCW 69.48.070(1)-(2). Program operators shall ensure all promotional materials are easy to use and understand, including for residents with limited English proficiency.
- (2) For the purpose of this section, "promotional material" means promotion, education, and outreach material and includes but is not limited to: websites; telephone numbers; secure collection receptacle signage; posters; brochures; mailer instructional inserts; advertising for drug take-back events; media material; and information for current and potential drug manufacturers, authorized

collectors, collection sites, mail-back distribution locations, and take-back event partners.

(3) Program operators shall refer to the statewide drug take-back system as "Safe Medication Return" on all promotional material. Program operators shall not use any other name to refer to their drug take-back program. Nothing in this section prohibits inclusion of program operator name in or on promotion, education, or outreach material.

(4) Program operators shall coordinate to develop a Safe Medication Return logo or mark and shall use the logo or mark to promote Safe Medication Return as the statewide drug take-back system.

(a) The logo or mark must be approved by the department prior to use by any program operator.

(b) The logo or mark shall be included on all promotional material.

(5) The program operator single website required by RCW 69.48.070(2) shall allow covered entities to access all

program operators' services and information through the single website. The single website shall ensure that the public can easily understand how to access all services and information.

(a) The single website domain name shall be descriptive of Safe Medication Return, Washington's drug take-back system, and shall not appear specific to any program operator.

(b) The single website shall describe the statewide Safe Medication Return system including, but not limited to, information on:

(i) Why and how to safely store and securely dispose of medication, including discouraging disposal of medication down drains or in the garbage,

(ii) What Safe Medication Return accepts and does not accept.

(iii) the single toll-free telephone number.

- (c) The single website shall display all collection sites and mail-back distribution locations for all program operators on one map and in one table. The single website shall display all drug take-back events for all program operators in one table. This information shall be searchable by zip code and city and shall display all options regardless of program operator.
- (d) All program operators shall update their collection sites, mail-back distribution locations, and locations and dates for drug take-back events on the single website at least quarterly.
- (e) The single website shall include, in a prominent place, a link to the department's Safe Medication Return website and contact information. The single website shall inform the public that the department welcomes comments, questions, and concerns. The department shall provide program operators the appropriate URL and contact information.

(6) Program operator specific websites shall present a consistent statewide drug-take back system in a way that ensures that the public can easily identify, understand, and access services provided by any approved drug take-back program.

(a) Program operator specific websites shall include links to the single website.

(b) Program operator specific websites shall present all collection sites, mail-back distribution locations, and take-back events for all program operators whenever presenting information about any collection site, mail-back distribution location, or take-back event.

(c) Program operators shall not include operator specific websites in any promotional material, except where necessary:

(i) To inform current and potential drug manufacturers, authorized collectors, collection

sites, mail-back distribution locations, and take-back event partners how to receive support and information;

(ii) On secure collection receptacles and mailer instructional inserts to inform the public how to receive support or provide information about secure collection receptacle or mailer.

(7) The program operator single toll-free telephone number required by RCW 69.48.070(2) shall allow callers to access all services and information provided by any program operator in a way that callers can easily understand. All call centers accessed through the single toll-free telephone number shall meet all requirements for single toll-free telephone number.

(a) The single toll-free telephone number shall:

(i) Answer calls 24 hours a day, seven days a week;

- (ii) Be accessible to people who are deaf or have difficulty hearing and to people who are nonverbal or have difficulty speaking;
 - (iii) Be accessible to people with limited English proficiency.
- (b) The single toll-free telephone number shall allow callers to access information about the statewide Safe Medication Return system including, but not limited to:
- (i) Why and how to safely store and securely dispose of medication, including discouraging disposal of medication down drains or in the garbage;
 - (ii) What Safe Medication Return accepts and does not accept;
 - (iii) The single website.
- (c) The single toll-free telephone number shall provide callers with all collection sites, mail-back distribution locations, and drug take-back events for

all program operators based on caller location criteria. Callers shall not be required to choose between program operators to receive this information.

- (d) The single toll-free telephone number shall allow callers to order mail-back supplies.
 - (e) The single toll-free telephone number shall provide the department's contact information to callers who would like to provide feedback, including comments, questions, and concerns. The department shall provide program operators the appropriate contact information.
- (8) Program operator specific telephone numbers and call centers shall present a consistent statewide drug-take back system in a way that ensures that the public can easily identify, understand, and access services provided by any approved drug take-back program.

- (a) Program operator specific telephone numbers and call centers shall present all collection sites, mail-back distribution locations, and take-back events for all

program operators whenever presenting information about any collection site, mail-back distribution location, or take-back event.

(b) Program operators shall not include program specific telephone numbers in any promotional material, except where necessary:

(i) To inform current and potential drug manufacturers, authorized collectors, collection sites, mail-back distribution locations, and take-back event partners how to receive support and information;

(ii) On secure collection receptacles and mailer instructional inserts to inform the public how to receive support and provide information about secure collection receptacle or mailer.

(9) Current program operators shall coordinate with newly approved program operators to ensure subsections (5) and (7) of this section are met within 180 days of the

department's approval of a new program operator's proposal.

- (10) Requirements of WAC 246-480-070 shall be implemented by program operators within 180 days of the date the rule is adopted.

[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.]

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WAC 246-480-080 Program operator annual report.

(1) Each program operator shall submit an annual report to the department by July 1st ~~on a form developed~~ in the format requested by the department.

(2) Annual program reports shall include all elements required by RCW 69.48.100. In addition, to ensure consistency of program operator reporting and ensure the department can accurately analyze data and enforce chapter 69.48 RCW, the following elements identified and described in RCW 69.48.100 shall be provided as follows:

(a) List of collection sites shall:

(i) Indicate collection sites added since previous annual report was submitted to the department;

(ii) Identify collection sites where collection receptacles remain locked unless a covered entity requests they be unlocked so covered drugs can be deposited. Program operators shall collect this information in a manner that minimizes authorized

collector reporting, for example, by asking authorized collector organizations annually or observing during routine secure collection receptacle inspections;

- (iii) Describe whether agreements with collection sites include requirement for collection site to report need for prompt collection, maintenance, or supplies;
- (iv) Describe any instances where program operator identified issues related to receptacle not being available to accept covered drugs when collection site was open for business, including issues identified during program operator inspection of receptacles; number of requests for prompt collection, maintenance, or supplies; and average number of days between request and collection or response;
- (v) Describe any instances where requests for prompt collection, maintenance, or supplies were not

provided by the program operator as described in their approved plan. The description shall include the reason prompt collection, maintenance, or supplies was not provided and the number of days between request and collection or response;

(vi) Describe any retail pharmacy, hospital or clinic with an on-site pharmacy, or law enforcement agency that offered to participate and was not included as an authorized collector within 90 days of the program operator receiving offer;

(A) If potential authorized collector was included later, describe reason for delay.

(B) If potential authorized collector was not included, describe reason for exclusion.

(vii) List all law enforcement, retail pharmacies, and hospitals or clinics with on-site pharmacies on islands and outside population centers and

indicate whether they are authorized collectors.

For each law enforcement facility, retail pharmacy, and hospital or clinic with on-site pharmacy that is not an authorized collector, describe the reason they are not participating. Include recruitment efforts and the result of those efforts; and

(viii) Also be provided as a map that clearly shows the location of collection sites.

(b) Number of mailers provided shall include number provided:

(i) Directly to individuals through requests to website or toll-free telephone number;

(ii) Directly to households without anyone requesting them;

(iii) To retail pharmacies that are not mail-back distribution locations;

- (iv) To other businesses or organizations that are not mail-back distribution locations; and
 - (v) To mail-back distribution locations.
- (c) Locations where mailers were provided shall include a list of:
- (i) Population centers where individuals requested mailers from website or toll-free telephone number;
 - (ii) Population centers where households were sent mailers directly without requesting them. This list shall indicate percentage of population center households that were sent mailers;
 - (iii) Non-residential locations that are not mail-back distribution locations. This list shall include addresses; and
 - (iv) Mail-back distribution locations with addresses.

(d) Safety or security problems include, but are not limited to, all instances where collection, transportation, or disposal did not follow standard processes as described in approved plan. The description of whether safety or security problems occurred during collection, transportation, or disposal of covered drugs shall include:

- (i) Whether problem occurred during collection, transportation, or disposal;
- (ii) Whether problem met criteria for reporting to law enforcement, Washington State Pharmacy Quality Assurance Commission, United States Drug Enforcement Administration, or other entity and whether required reports were made;
- (iii) If covered drugs were lost during transportation, whether transporter has policies for safely managing undeliverable packages that might include drugs;

- (iv) If transporter delivered covered drugs to the wrong address, description of attempts to retrieve covered drugs and whether those attempts were successful;
 - (v) Program operator actions to ensure problem was reported, if required; appropriate investigation occurred; and risk of similar problem occurring in the future was minimized.
- (e) Description of public education, outreach, and evaluation activities implemented shall include:
- (i) List of languages print or downloadable promotional and educational material are available in, with description of any limitations or excluded material. List or description of languages used in media outreach;
 - (ii) List or description of languages available on single website and program operator specific website and single toll-free telephone number and

program operator specific telephone number,
including name of language service provider, if
applicable;

(iii) Description of how these languages or language
services meet the language needs of people in
Washington;

(iv) Copies of all promotion and education materials,
including signage and changes to websites and
telephone number scripts, developed since last
annual report;

(v) Description of how education and outreach efforts
were implemented including:

(A) Date, type, and description of all social
media and email promotion activity;

(B) Date, frequency, reach, and description of
outreach for radio, television, print, and
digital media platforms;

(C) List of brochures and posters available from single website and program operator specific website, number of times each was viewed, and number of times each was downloaded;

(D) Name, address, facility type, and date of email or hard copy distribution of brochures and posters to non-residential entities; and

(E) Total number of views and number of unique visitors for each page of single website and program operator specific website.

(vi) Description of evaluation activities shall include:

(A) Evaluation of comments, questions, and concerns received from the public including evaluation of feedback themes and actions

program operator has implemented or planned
in response to feedback; and

(B) Evaluation of public education and outreach
efforts including evaluation of education
and outreach implementation described in
(2) (e) (v) of this section.

(f) Summary of the program's goals for collection amounts
and public awareness shall include:

(i) Description of goals for the reporting year;

(ii) Description of goals for the following year,
including identification of any unmet goals
carried forward; and

(iii) Description of how program operator calculates
or quantifies progress toward goals, including
any percentages included in goals.

(g) Summary of degree of success in meeting goals shall
include description of why goals were not met and what

effort program operator will make to achieve those goals the following year.

- (h) ~~(2) In addition to the elements identified and described in RCW 69.48.100, the report must include a summary of t~~The program's annual expenditures, itemized by program category shall be 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 246-480-990 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.~~

~~After January 1, 2024, all potential program operator applicants shall submit a nonrefundable proposal review fee of sixty-three thousand dollars to the department when they submit their proposal in accordance with RCW 69.48.050(1). Approved program operators submitting updated proposals to the department do not submit a proposal review fee.~~

- ~~(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.~~

(2) All program operators' annual operating fees shall be identical. Each program operator's annual operating fee shall not exceed the lesser of:

(a) The department's estimated actual administrative, oversight, enforcement, and contractual costs for that fiscal year divided by the number of approved program operators; or

(b) Ten percent of the lowest annual expenditures reported to the department in any program operator's annual report and determined by the department.

(3) Annually, on or before September 1, the department shall notify each program operator the amount of the program operator's annual operating fee.

(4) Each program operator shall submit their annual operating fee to the department by October 1 each year.

[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.]