

**WSR 23-15-102
PROPOSED RULES****DEPARTMENT OF HEALTH**

[Filed July 18, 2023, 4:04 p.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 22-01-170.

Title of Rule and Other Identifying Information: The department of health (department) is proposing amendments to rules about safe medication return to update rules about multiple program operators. The proposed amendments to WAC 246-480-050, 246-480-070, and 246-480-080 ensure a consistent statewide safe medication return system and allow the department to accurately analyze data. Proposed amendments to WAC 246-480-990 set a fee for proposal review as required by RCW 69.48.120 and provide transparency for the department's method of calculating program operator annual fees. The department is proposing deletion of WAC 246-480-010 in its entirety, as the purpose and scope of chapter 246-480 WAC is clear in statute.

Hearing Location(s): On August 29, 2023, at 11:00 [a.m.] A virtual public hearing, without a physical meeting space, is being offered. We invite you to participate in our public rules hearing using your computer, tablet, or smartphone. Register in advance for this webinar https://us02web.zoom.us/webinar/register/WN_LCQnBG7ASkSOQUIQIwVvg. After registering, you will receive a confirmation email containing information about joining the webinar.

Date of Intended Adoption: September 5, 2023.

Submit Written Comments to: Mary Kellington, P.O. Box 47852, Olympia, WA 98504-7852, email <https://fortress.wa.gov/doh/policyreview>, by August 29, 2023.

Assistance for Persons with Disabilities: Contact Mary Kellington, phone 360-236-2988, TTY 711, email SafeMedReturn@doh.wa.gov, by August 15, 2023.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: 2SHB 1161 (chapter 155, Laws of 2021) amended chapter 69.48 RCW to allow the department to approve multiple safe medication return program operators, added a requirement for program operators to coordinate to present a consistent statewide system, and directed the department to set a proposal review fee.

The department is proposing to repeal WAC 246-480-010 Purpose and scope, since the purpose and scope is clearly identified in the statute and therefore this section is not needed.

The proposed amendments to WAC 246-480-050 clarify the process for applying to the department.

The proposed amendments to WAC 246-480-070 clarify program operator requirements for coordinating to present a consistent statewide safe medication return system as required by RCW 69.48.050(12) and 69.48.070 (1) and (2). We anticipate this will make program operator coordination more efficient, increase public understanding of why and how to dispose of unwanted medication appropriately, increase use of safe medication return, and decrease inappropriate disposal of unwanted covered drugs.

The proposed amendments to WAC 246-480-080 clarify and identify additional requirements for program operator annual reports to ensure reporting consistency amongst program operators and ensure the department receives information necessary to allow for appropriate evaluation and enforcement. We anticipate that this will allow the department to accurately analyze data, improve the accuracy of program and

system evaluation, ensure the department can enforce chapter 69.48 RCW, and provide the public consistent information related to program operations.

The proposed amendments to WAC 246-480-990 Fees, set a proposal review fee as required by RCW 69.48.120, clarify that approved program operators do not submit a proposal review fee, and clarify how the department will calculate approved program operator annual operating fees. We anticipate that defining the department's method of calculating approved program operator annual operating fees will make this process more efficient for the department and transparent for program operators and the public.

Reasons Supporting Proposal: Current chapter 246-480 WAC establishes minimal requirements for implementing a secure drug take-back system (safe medication return) with a single program operator. 2SHB 1161 (chapter 155, Laws of 2021) amended chapter 69.48 RCW to allow multiple program operators.

Current rules do not allow for program proposals from potential safe medication return program operators or review fees associated with those proposals. They do not describe coordination and performance requirements necessary for the department to accurately analyze data to ensure program operator compliance within a multiple program operator system and to ensure a consistent statewide safe medication return system that allows the public to easily identify, understand, and access services and information provided by any approved program operator.

The proposed rules clarify requirements for coordination of promotion amongst program operators, including coordination related to the single website and single toll-free telephone number required by RCW 69.48.070. The proposed rule identifies and clarifies elements related to program operator annual reporting, establishes a proposal review fee for future program proposals, and provides transparency regarding how the department calculates program operator annual operating fees.

Statutory Authority for Adoption: RCW 69.48.180, 69.48.050, and 69.48.120.

Statute Being Implemented: 2SHB 1661 (chapter 155, Laws of 2021).

Rule is not necessitated by federal law, federal or state court decision.

Name of Proponent: Department of health, governmental.

Name of Agency Personnel Responsible for Drafting and Implementation: Mary Kellington, 111 Israel Road S.E., Tumwater, WA 98501, 360-236-2988; Enforcement: Samantha Zeller, 111 Israel Road S.E., Tumwater, WA 98501, 360-236-2847.

A school district fiscal impact statement is not required under RCW 28A.305.135.

A cost-benefit analysis is required under RCW 34.05.328. A preliminary cost-benefit analysis may be obtained by contacting Mary Kellington, P.O. Box 47852, Olympia, WA 98504-7852, phone 360-236-2988, TTY 711, email mary.kellington@doh.wa.gov.

This rule proposal, or portions of the proposal, is exempt from requirements of the Regulatory Fairness Act because the proposal:

Is exempt under RCW 19.85.025(4).

Explanation of exemptions: RCW 19.85.025(4) exempts rules where the department is able to demonstrate that the proposed rule does not affect small businesses. Proposed rule affects two program operators, Inmar Intelligence, Inc. and MED-Project. Both of these organizations operate in multiple states and employ more than 50 employees each. In-

mar Intelligence, Inc. and MED-Project are program operators approved under chapter 69.48 RCW (safe medication return). Future safe medication return program operators would also be affected by this rule. The department does not anticipate any small business will apply to become a program operator due to the scope and nature of required program activities.

Scope of exemption for rule proposal:
Is fully exempt.

July 18, 2023
Kristin Peterson, JD
Chief of Policy
for Umair A. Shah, MD, MPH
Secretary

OTS-4504.2

AMENDATORY SECTION (Amending WSR 19-14-090, filed 7/1/19, effective 8/1/19)

WAC 246-480-050 Program application. (1) A potential drug take-back program operator (~~must~~) shall submit to the department:

(a) Its (~~program~~) proposal (~~and~~) to be an approved program in the format provided by the department; and

(b) The proposal review fee in WAC 246-480-990.

(2) An approved drug take-back program operator shall submit to the department:

(a) Any substantial changes to an approved program (~~on forms~~) in the format provided by the department;

(b) The annual operating fee in WAC 246-480-990; and

(c) By July 1, 2024, and every four years thereafter, an updated proposal in the format provided by the department.

~~((2))~~ (3) 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~~) 28 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~~) 28 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.]

AMENDATORY SECTION (Amending WSR 19-14-090, filed 7/1/19, effective 8/1/19)

WAC 246-480-070 Promotion, education, and public outreach.

~~((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 website.))~~

(1) Program operators shall coordinate to present a consistent statewide drug take-back system as described in RCW 69.48.050 and 69.48.070.

(2) Each program operator is independently responsible for complying with all requirements of chapter 69.48 RCW and this chapter. Each program operator is responsible for their own promotional material.

(3) Collection sites at long-term care facilities and substance use disorder treatment programs are not available to the general public. Program operators shall exclude these collection sites from public promotional material.

(4) For the purpose of this section:

(a) "Promotional material" means promotion, education, and outreach material about the safe storage and secure collection of covered drugs and includes, but is not limited to: Websites; telephone numbers; secure collection receptacle (kiosk) signage; posters; brochures; mailer instructional inserts; advertising for drug take-back events; media material; and information for authorized collectors, collection sites, mail-back distribution locations, and take-back event partners.

(b) Public promotional material means promotional material focused on increasing understanding and use of safe medication return.

(c) Partner promotional material means promotional material focused on recruiting and educating authorized collectors, collection sites, mail-back distribution locations, and take-back event partners.

(5) Each program operator shall ensure their public promotional materials are easy for people to use and understand. This includes people with limited-English proficiency and people with disabilities including, but not limited to, people who are deaf or blind.

(6) Each program operator shall ensure their public promotional material describes how to access all collection sites, mail-back distribution locations, and take-back events regardless of program operator.

(7) Each program operator shall refer to the statewide drug take-back system as "Safe Medication Return" on all their 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.

(8) 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 must be included on all promotional material.

(9) Program operators shall ensure the single website required by RCW 69.48.070 presents a consistent statewide drug take-back system.

(a) The single website domain name must be descriptive of safe medication return, Washington's drug take-back system, and must not appear specific to any program operator.

(b) The single website must 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; and

(iii) The single toll-free telephone number.

(c) The single website must display all collection sites and mail-back distribution locations available to the general public for all program operators on one map and in one table. The single website must display all drug take-back events for all program operators in one table. This information must be searchable by zip code and city and must display all options regardless of program operator.

(d) Each program operator 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 must include, in a prominent place, links to the department's safe medication return website and contact information. The single website must inform the public that the department welcomes comments, questions, and concerns. The department shall provide program operators the appropriate URL and contact information.

(10) Program operator specific websites must present a consistent statewide drug take-back system.

(a) Program operator specific websites must include links to the single website described in subsection (9) of this section.

(b) Program operator specific websites must 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. Information about other program operator's collection sites, mail-back distribution locations, and take-back events must be at least as current as single website.

(c) Program operators shall not include program operator specific websites in any public promotional material.

(11) Program operators may include program operator specific email address on secure collection receptacles (kiosks) and mailer instructional inserts to inform the public how to receive support or provide comments about secure collection receptacle (kiosk) or mailer. Program operator specific email addresses must not be included on any other public promotional material.

(12) Program operators shall ensure the single toll-free telephone number required by RCW 69.48.070(2) and all call centers accessed through that single toll-free telephone number present a consistent statewide drug take-back system. The single toll-free telephone number and all call centers accessed through it must:

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

(b) 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; and

(iii) The single website.

(c) Provide callers with all collection sites, mail-back distribution locations, and drug take-back events available to the general public for all program operators based on location criteria provided by the caller. Callers shall not be required to choose between program operators to receive this information;

(d) Allow callers to order mail-back supplies; and

(e) 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.

(13) Program operator specific telephone numbers and call centers must present a consistent statewide drug take-back system.

(a) Program operator specific telephone numbers and call centers must present all collection sites, mail-back distribution locations, and take-back events available to the general public 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 public promotional material, except on secure collection receptacles (kiosks) and mailer instructional inserts to inform the public how to receive support and provide comments about secure collection receptacle (kiosk) or mailer.

(14) Current program operators shall coordinate with newly approved program operators to ensure subsections (1), (9), and (12) of this section are met within 180 days of the department's approval of a new program operator's proposal.

(15) Requirements of this section must 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.]

AMENDATORY SECTION (Amending WSR 19-14-090, 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)) in the format provided 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).))~~ To ensure consistency of program operator reporting and ensure the department can accurately analyze the data, the annual program report must include the following:

(a) A list of covered manufacturers participating with the program operator.

(b) The amount, by weight, of covered drugs collected, including the amount by weight from each collection method used.

(c) The list of collection sites with addresses must:

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

(ii) Also be provided as a map; and

(iii) Identify any retail pharmacy, hospital or clinic with an on-site pharmacy, or law enforcement agency that offered to partici-

pate 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.

(d) A description of prompt collection, maintenance, and kiosk inner liner supply requests.

(i) Describe whether agreements with collection sites include requirement for collection site to report need for prompt collection, maintenance, or inner liner supplies.

(ii) Describe any instances where program operator identified issues related to collection receptacle (kiosk) 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 inner liner supplies; and average number of days between request and collection or response.

(iii) Describe any instances where requests for prompt collection, maintenance, or inner liner supplies were not provided by the program operator as described in their approved plan. The description shall include the reason prompt collection, maintenance, or inner liner supplies were not provided and the number of days between request and collection or response.

(e) The number of mailers provided must be reported by zip code and must include the number of mailers provided for each of the following categories:

(i) Directly to individuals as the result of requests made through 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.

(f) The locations where mailers were provided must 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) Nonresidential locations that are not mail-back distribution locations with addresses; and

(iv) Mail-back distribution locations with addresses.

(g) Dates and locations of collection events held.

(h) A description of collection sites, mail-back distribution locations, take-back events, and other methods for accessing safe medication return in areas outside of population centers.

(i) 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.

(ii) 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.

(i) Transporters and disposal facilities used.

(j) Safety or security problems including, but not limited to, all instances where collection, transportation, or disposal did not follow processes described in the approved plan, including processes for prompt collection and maintenance. Safety and security problems described must include any instances where a secure collection receptacle (kiosk) is opened for a reason other than packaging the inner liner for shipping or installing a new inner liner. The description of whether safety or security problems occurred during collection, transportation, or disposal of covered drugs must include:

(i) Whether the problem occurred during collection, transportation, or disposal;

(ii) Whether the problem met criteria for reporting to law enforcement, Washington state pharmacy quality assurance commission, United States Drug Enforcement Administration, or other entity and whether the operator can confirm that the reporting happened;

(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; and

(vi) Changes to policies, procedures, or tracking mechanisms to address the problem and improve safety and security.

(k) Description of public education, outreach, and evaluation activities implemented shall include the following. "Promotional material" shall have the same definition as in WAC 246-480-070(4):

(i) List of languages that printed or downloadable public promotional material are available in, with description of any printed or downloadable promotional material not available in these languages. List or description of languages used in any television, radio, social media, or other nonprint promotional material;

(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 and all call centers associated with these telephone numbers, 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 promotional material, 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 nonresidential 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 (g)(v) of this subsection.

(l) Description of how collected packaging was recycled to the extent feasible.

(m) 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.

(n) 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.

(o) The program's annual expenditures, itemized by program category shall be organized using the criteria 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.]

AMENDATORY SECTION (Amending WSR 19-14-090, 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.)~~ (1) Until January 1, 2024, a potential program operator applicant submitting a proposal in accordance with RCW 69.48.050(8) shall submit a nonrefundable proposal review fee of \$157,000 to the department when they submit their proposal.

(2) After January 1, 2024, a potential program operator applicant shall submit a nonrefundable proposal review fee of \$63,000 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.

(3) 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.

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

(5) Each program operator shall submit their annual operating fee to the department by October 1st 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.]

REPEALER

The following section of the Washington Administrative Code is repealed:

WAC 246-480-010 Purpose and scope.