

Report to the Legislature

Safe Medication Return Program Report (ESHB 1047)

June 2020

RCW 69.48.190

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Office of Health Professions



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Executive Summary

The Washington State Legislature passed [Engrossed Substitute House Bill 1047](#) (Chapter 196, Laws of 2018), codified as chapter [69.48 RCW](#), which provided for the creation of a statewide program for the public to return unused medications. This program, known as a drug take-back program or safe medication return program, is funded by covered drug manufacturers¹. It provides the public with collection kiosks, prepaid and preaddressed mail-back envelopes, and public medication return events.

The Department of Health (department) is required to report on the creation of rules to implement HB 1047 and to offer a summary review of the approved program within 30 days of the department approving a safe medication return program. The department approved a proposal from MED-Project on May 25, 2020 to operate the program.

After the program has been operational for one year, the department will issue a follow-up report to evaluate the program's effectiveness, and will report these findings to the legislature on the following November 15 and every two years thereafter.

Introduction

¹ "Covered manufacturer" means a person, corporation, or other entity engaged in the manufacture of covered drugs sold in or into Washington. Exceptions are provided for private label companies, repackagers, and non-profit entities under certain circumstances (see [RCW 69.48.020 \(6\)](#) for further details).

In 2018, the Washington State Legislature enacted [Engrossed Substitute House Bill 1047](#), codified as [chapter 69.48 RCW](#), regarding the establishment of a unified, statewide safe medication return program.² The program will provide residents secure and convenient ways to safely dispose of unwanted or expired medications via collection kiosks, prepaid and preaddressed mail-back envelopes, and public medication return events for areas that have not met the convenience standard set in [RCW 69.48.060\(3\)\(c\)\(1\)](#). The law requires covered drug manufacturers to fund the safe medication return program which will be run by an approved program operator.

The Department of Health (department) will serve in a regulatory and oversight role, and will adopt rules necessary to implement and enforce chapter 69.48 RCW. The department's oversight included reviewing any proposals received by potential program operators by July 1 of 2019, as required in RCW 69.48.050(1), approving proposals submitted that meet statutory requirements, and working with the program operator(s) to ensure statutory requirements are met.

After the program has been operational for one year, the department will report on the program's effectiveness, and will share these findings with the legislature on November 15 of that year and on that date every two years thereafter.

² Commonly known as a drug take-back program.³ Examples include using department forms, a table of contents, and implementation plans with dates.

Rules Summary

Chapter 69.48 RCW provides a robust structure for how the drug take-back program is to be established and operated. The rules developed by the department add clarity to administrative and oversight details. These include:

- Establishing a process to identify covered manufacturers who must pay into the secure medication return program;
- Identifying the budget information required in the program operator’s proposal to the department, as well as budget information submitted by the program operator with each annual report;
- Describing the process to appeal department decisions;
- Creating a method for determining areas in the state being underserved by the secure medication return program; and
- Setting fees.

[WAC 246-480-010](#) – Purpose and Scope

The secure medication return program established in Chapter 69.48 RCW is supplemented by Chapter 246-480 WAC. The first section outlines the purpose and scope of the chapter.

[WAC 246-480-020](#) – Definitions

Definitions for this chapter of code are derived from Chapter 69.48 RCW. There are no additional definitions created in WAC.

[WAC 246-480-030](#) – Identification of covered manufacturers.

Drug wholesalers, retail pharmacies, private label distributors, and repackagers will identify drug manufacturers for the drugs sold in Washington, consistent with RCW 69.48.040. The rule reiterates the department’s commitment to enforcement of chapter 69.48 RCW and frames how the department will obtain additional information from entities who may be covered manufacturers, but are not otherwise identified by drug wholesalers. At the request of stakeholders, this section outlines a process to post a list of covered manufacturers not complying with the secure medication return program to the department website. This serves to alert the public to a manufacturer’s non-compliance with the law while the department explores enforcement action, as authorized in RCW 69.48.110.

[WAC 246-480-040](#) – Drug take-back program proposal components.

Program operators will submit cost projections and expense data on department-designed forms. The department worked with stakeholders to create a level of detail that would be

useful, but not risk disclosing proprietary information. Budget estimates will be separated into three main categories: administrative, drug collection and disposals, and communication/media.

WAC 246-480-040 clarifies how to organize required information³ and elaborates on requirements⁴ for drug collection systems.

[WAC 246-480-050](#) – Program application process—Program modification.

Secure medication return proposals will be submitted on forms designed by the department. The section also includes a description of the appeals process⁵ for applicants pursuing the contract for a program should the application be rejected.

[WAC 246-480-060](#) – Collection of covered drugs—underserved areas.

The department will be required to identify population centers using data and mapping technology. Criteria to identify underserved areas will include, but not be limited to, number of collections sites, travel times, and geographic features like islands or mountain ranges.

[WAC 246-480-070](#) – Promotion

Program operators will be required to update at least quarterly on their website their list of authorized collectors, sites, locations to receive mailers, and locations for safe medication return events.

[WAC 246-480-080](#) – Program operator annual report

Each program operator shall submit an annual report by July 1. This report must be on the approved department form, include elements described in RCW 69.48.100, and include a summary of the program’s annual expenditures.

[WAC 246-480-090](#) – Proprietary information

Proprietary information is exempt from public disclosure requests provided the manufacturer identifies in writing the information it considers proprietary. Any information that is automatically disclosable cannot be considered proprietary. The department will follow the public disclosure process identified under chapter 42.56 RCW. Program operators will have the right to file a motion to prevent the release of any previously identified proprietary information.

³ Examples include using department forms, a table of contents, and implementation plans with dates.

⁴ e.g. lists of drop-off sites and participating collectors

⁵ The process will be through the administrative procedures act and chapter 246-10 WAC

[WAC 246-480-990](#) – Fees

The department is required to establish initial and annual fees for a drug take-back program operator. This section sets the initial fee at \$700,000 with a requirement that it be paid by the operator no later than October 1, 2019 and every October 1 thereafter.

The fee will cover the department's administrative costs, which includes enforcement, credentialing, information technology, program oversight, surveys, and communications. It will also cover the costs of two contracts required by statute. The first will be a contract with the Washington Poison Center to conduct resident surveys measuring the secure medication return program's effect on safe storage and secure disposal of medication, and rates of abuse, misuse or exposure to medication. The second contract will be with an academic institution that will collaborate with the department to issue a report on November 15 after the first full year of drug collection, and biennially thereafter. This institution will provide the department with an evaluation of the program's effect on awareness and compliance of safe medication storage and disposal; rates of misuse, abuse, and overdoses; and medications detected in sewer, solid waste, and septic systems.

The department will also establish a renewal fee. The program operator will be notified of the renewal cost by August 1, 2020 and every August 1 thereafter. The renewal will not exceed ten percent of the program's annual expenditures reported for the previous calendar year. Fees collected in October will be used for department costs incurred during the state fiscal year in which it is received. The department may increase the renewal fee for inflation according to RCW 69.48.120. If ten percent of the program operator's annual expenses for a particular year happen to be less than the anticipated renewal amount, the department must accept the lower amount for that year.

Approved Safe Medication Return plan summary

A single program operator proposal was received by the department on July 1, 2019. The initial proposal was rejected as it did not meet all statutory and rule requirements (RCW 69.48.050(3)(a)). As allowed by RCW 69.48.050(3)(b), the potential program operator was given an opportunity to submit a revised proposal, which was received by the department on February 24, 2020. The revised proposal was approved on May 25, 2020.

The approved program operator, MED-Project, is the program operator for the existing county-level drug take-back programs in Washington state and has been operational in Washington since 2016. The approved statewide program is similar to the existing county programs.

To collect the medications, the program will locate drop boxes, or kiosks, at participating authorized collector sites such as retail pharmacies and law enforcement offices. Although not required to participate, authorized collectors are encouraged to do so to best meet the needs of their customers and Washington residents. Pre-paid, pre-addressed mail-back envelopes will also be available. Residents and pharmacies may request mail-back envelopes through MED-Project's toll-free number or website. A convenience standard is established requiring one kiosk for each population center (a city or town and the unincorporated area within a ten-mile radius from its center) and an additional kiosk per each additional 50,000 residents⁶. Areas in which the convenience standard has not been met will receive supplemental service in the form of mail-back distribution locations or take-back days. Per RCW 69.48.060(3)(d), MED-Project will consult with the department, local law enforcement, local health agencies, and the local community when determining how to supplement service in an area.

MED-Project will provide an alternative collection method for covered drugs that cannot be accepted or comingled with other covered drugs, such as inhalers and pre-filled injector products. These non-comingled drugs will be returned using mail-back packages⁷ as the alternative collection method. These mailers will be available upon request through the MED-Project website or toll-free number. House Bill 1047 requires existing programs be folded into the statewide drug take-back program. To ensure a seamless transition, MED-Project will work with the department and counties to provide continued convenient and uninterrupted access to drug take-back programs.

⁶ Residents who live outside a population center and do not have ready access to kiosks may choose to take advantage of the mail-back option. They can request free pre-paid/pre-addressed mail back envelopes be sent to their homes.

⁷ Any resident or pharmacy can request the pre-paid, pre addressed mail-back envelopes and Med-Project will send them to any Washington resident/pharmacy's address. The mail-back distribution locations will be located in areas underserved by kiosks (underserved defined in [RCW 69.48.060\(3\)\(d\)](#)). This allows residents to obtain mail-back envelopes without having to request them online/over the phone.

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