Significant Legislative Rule Analysis

Chapter 246-480 WAC
Rules Concerning the
Drug Take-Back Program

March 08, 2019

SECTON 1:

Describe the proposed rule, including a brief history of the issue, and explain why the proposed rule is needed.

Background and overall description of program:

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.

A safe system for the collection and disposal of unused, unwanted, and expired medicines is a key element of a comprehensive strategy to prevent prescription drug abuse, but disposing of medicines by flushing them down the toilet or placing them in the garbage can contaminate groundwater and other bodies of water, contributing to long-term harm to the environment and animal life.

The proposed rule creates a new chapter to implement a single uniform, state-wide system of regulation for the safe and secure collection of medicines through a drug take-back system. This system was established by the Washington State Legislature in 2018 with Engrossed Substitute House Bill 1047 (chapter 196, laws of 2018). The law is codified as chapter 69.48 RCW. While several counties in Washington have already started developing and implementing similar programs, the 2018 Washington State Legislature established the first such program in the nation to be implemented state-wide. Existing county programs will be grandfathered into the state-wide program within twelve months of state-wide operation. Drug manufacturers are to pay into the system to fund the entire drug take-back program, including support of the Department of Health's work through an annual fee. The Department of Health (department) must provide oversight and enforcement of the program.

The basics of the statewide drug take-back system include drug collection, drug disposal, communication/media, and research/survey work to track efficacy of the program. Drug collection is done through kiosks (at pharmacies, clinics, law enforcement facilities, etc.), supplying postage-paid envelopes to return drugs via the mail, and holding drug take-back events. The actual management of the program's planning, funding and execution is through a drug take-back system "program operator." A program operator is a drug take-back organization, covered manufacturer, or group of covered manufacturers that implements or intends to implement a drug take-back program approved by the department. A "program operator" is not a state employee, but is established and funded through the pharmaceutical community to execute the drug take-back program.

The department's enforcement of the drug take-back program includes tracking covered drug manufacturers to help ensure all applicable entities are paying into the program. The enabling statute gives the department the authority to assess civil penalties up to $2,000 per each day an identified violation of chapter. 69.48 RCW continues. The department must also review and approve a program operator's proposal before it may be implemented. Other basic functions of the department include:

- Establishing initial and annual renewal fees to cover the cost of the department's work.
- Review and approval of a drug take-back program proposal before it may be implemented. This also includes review and approval of a program's annual reports and any significant changes being made by the program operator.
- Contracting with academic establishments and the Washington State Poison Control Center to track the program's efficacy by examining program awareness, rates of misuse and abuse of drugs, and diversion of drugs from sewers and septic systems. The department will also conduct its own independent survey work and will work with the program operator to determine any outreach and education efforts.
- Review and approval of petitions for use of certain drug disposal facilities in Washington State.
- Work with local health and the program operator to identify underserved areas in the state.
- Produce several legislative reports.

Description of proposed rule:

The enabling legislation (chapter 69.48 RCW) is very descriptive of how the drug take-back program is to be established and executed, including the functions that the department must perform. The proposed rule only touches on parts of the RCW needing more clarity. The proposed rule is primarily addressing administrative and oversight details to include:

- A process to identify covered manufacturers who must pay into the drug take-back program.
- The type of budget information required in the program operator's proposal submitted to the program for approval, as well as budget information submitted by the program operator with each annual report.
- The process to appeal department decisions.
- How to determine areas in the state being underserved by the drug take-back program.
- Information submitted to the department regarding drug disposal facilities.
- Setting fees.

The department intends to have a rule in place and effective by July 1, 2019. On that date, program proposals are due to the department for review and approval. The initial fee is due to the department on October 01, 2019. If approvals of the initial application go well with no rejections and rewrites, a drug take-back program could be expected to begin official operations by approximately May of 2020.

SECTION 2:

Is a Significant Analysis required for this rule?

Some of the proposed rules require significant analysis as described in RCW 34.05.328(5)(c)(iii)(A), (B), and (C) because they adopt substantive provisions of law pursuant to delegated legislative authority, the violation of which subjects a violator of such rule to a penalty or sanction; establishes, alters, or revokes any qualification or standard for the issuance, suspension, or revocation of a license or permit; and adopts a new, or makes significant amendments to, a policy or regulatory program.

However, the department has determined that following rules are not significant:

WAC with no significant impact	Justification
WAC 246-480-010 – Purpose and scope.	This section does not establish enforceable standards and does not meet the definition of a significant legislative rule. RCW 34.05.328(5)(c)(iii).
WAC 246-480-020 – Definitions	This section does not establish enforceable standards, but defines terms used throughout the rule set. This section does not meet the definition of a significant legislative rule. RCW 34.05.(5)(c)(iii).

SECTION 3:

Clearly state in detail the general goals and specific objectives of the statute that the rule implements.

Chapter 69.48 RCW describes the regulatory framework for the administration of unwanted medication disposal in Washington State. RCW 69.48.010(4) provides that,"…it is in the interest of public health to establish a single, uniform, statewide system of regulation for safe and secure collection of and disposal of medicines through a uniform drug "take-back" program operated and funded by drug manufacturers." Specifically, RCW 69.48180 requires that the department "…adopt any rules necessary to implement and enforce this chapter."

Overall the statute is prescriptive in how a take-back program is to be implemented, operated, and overseen. The rule serves to clarify some aspects of the statute to ensure potential program operators have direction on proposal requirements not clear in law as well as ensuring the department has the necessary detail to review proposals and monitor drug manufacturer and program operator compliance.

SECTION 4:

Explain how the department determined that the rule is needed to achieve these general goals and specific objectives. Analyze alternatives to rulemaking and the consequences of not adopting the rule.

The goals and objectives of the statute are met by providing a clearly written and appropriate rule that touches on areas of the RCW needing more clarity. This clarity gives the program operator(s) and the department necessary direction on how to perform administrative duties required in statute.

If the proposed rule is not adopted, there will be not be a clear and consistent framework for the program operator(s) and the department to follow when developing a proposal, implementing a program, and monitoring a program's compliance with 69.48 RCW.

SECTION 5:

Explain how the department determined that the probable benefits of the rule are greater than the probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

Below is a summary of each proposed rule section requiring analysis. With the exception of the fee section, the policies in this proposal create little to no additional cost to a drug take-back program operator not already incurred by the statute. It is focused on explaining how to complete the work related to department oversight established in statute, not creating new work for stakeholders. In some places the program operator is required to post information on their website. This also is a negligible cost in that this is data being collected and organized by the program operator already per the statute.

The fee section (WAC 246-480-990) below describes general estimates and cost projections the department uses to establish a fee. The fee is specifically dictated in

statute and must not exceed the department's administration, oversight, and enforcement costs.

With little-to-no additional costs created by the rule, the rule's implementation of oversight of a state-wide drug take-back program create an undeniable benefit to the public health of Washington State. The appropriate collection of covered drugs provides a number of benefits including but not limited to reduced illicit drug use, reduced unintentional poisoning, reduced water and other environmental pollution, improved water quality, and most importantly, increased appropriate drug disposal. Providing collection receptacles will encourage individual households, hospitals and healthcare facilities to avoid flushing pharmaceuticals resulting in preservation of water quality, aquatic life and ecosystems. The department's oversight and enforcement of this policy is key to the program's success.

1. WAC 246-480-030 – Identification of covered manufacturers. (New)

   Description: The proposed new rule clarifies small parts of the process in which drug wholesalers, retail pharmacies, private label distributors, and repackagers will identify drug manufacturers for the drugs sold in or into Washington State consistent with RCW 69.48.040, namely a reiteration that the department is committed to the enforcement of chapter 69.48 RCW and this new WAC chapter. The proposed rule also frames how the department will seek additional information from person or entities who may be covered manufacturers, but are not otherwise identified by drug wholesalers. At the request of stakeholders, this section also outlines a process to post identified covered manufacturers not complying with the secure medication return program to the department website.

   Cost/benefit analysis: This section would have negligible costs to manufacturers, wholesalers, and retail pharmacies above what is specifically required in statute (RCW 69.48.040) as part of the implementation of the secure medication return program.

2. WAC 246-480-040 – Drug take-back program proposal components. (New)

   Description: By July 1, 2019 a drug take-back program operator must submit a program proposal to the department for review and approval. The proposed new rule both clarifies and adds several details on information required in the proposal, information the department is required to collect according to chapter 69.48 RCW.

   The proposed new rule clarifies how to organize required information, such as using department forms, a table of contents, and implementation plans with dates. It also clarifies some needed details about drug collection systems (e.g. lists of drop-off sites and participating collectors).

Most significantly, this proposed rule section outlines how a program operator must organize and submit cost projections and, in future years, their expense data. The department worked with stakeholders to reach a level of detail that would be useful but not risky in disclosing proprietary information. Budget estimates would be separated into three main categories: administrative, drug collection and disposals, and communication/media.

Cost/benefit analysis: Additional costs to program operators outside of what is incurred in statute is negligible. Program operators would not incur additional labor or administrative costs to comply with this rule since it doesn't require information not already being collected or requires as part of the statute. It is possible that there actually may be a reduction in labor and administrative costs in the coming years since only one program proposal will be needed for the entire state of Washington as opposed to a program proposal for each county currently participating in a drug take back program. This rule provides public benefit by assuring that safe medication return programs are fully capable of meeting statutory requirements necessary to fully implement the program.

3. WAC 246-480-050 – Program application process—Program modification. (New)

Description: The proposed new rule requires that drug take-back proposals be on department forms, and describes the process to appeal via the administrative procedures act and chapter 246-10 WAC should the proposal be rejected by the department.

Cost/benefit analysis: There is no additional cost to a program operator in this proposed rule beyond what is required in statute.

4. WAC 246-480-060 – Collection of covered drugs—Underserved areas. (New)

Description: The proposed new rule describes data collection of population centers using mapping technology. It also described the criteria to be used when identifying underserved areas (e.g. number of collections sites, driving distances, and geographic features like islands or mountain ranges).

Cost/benefit analysis: There are no additional costs to persons or entities in the proposed rule outside of what the statute requires.

5. WAC 246-480-070 – Promotion (New)

Description: The propose new rule requires that approved program operators update their list of authorized collectors, sites, locations to receive mailers, and locations for safe medication return events at least quarterly on their website.

Cost/benefit analysis: No additional costs outside of statute are required by this proposed rule. The proposed rule merely requires the information be readily accessible to others. Patient and pharmacist education has helped to reduce improper drug disposal and increase use of proper disposal programs. However, broad promotion of the safe medication return program yields social benefits that far outweigh the costs of promotion.

6. WAC 246-480-080 – Disposal of covered drugs (New)

Description: The proposed new rule does not create additional requirements but clarifies jurisdictional issues for drug disposals. Other than department notification, disposal facilities used outside of Washington State would not require department approval nor are they required to adhere to Washington State law. Any petitions in Washington State needing department approval as outlined in RCW 69.48.080 (3) must be on department forms.

Cost/benefit analysis: The proposed rule does not incur costs to program operators outside of what is established in statute. It is intended to eliminate jurisdictional confusion and provides a lesser burden to program operators. Proper disposal of unused medications can improve the safety of communities and the environment by reducing the risk of accidental exposure or intentional misuse. In Washington State, over 251,000 pounds of unwanted medicines have been returned and safely destroyed since 2006.

7. WAC 246-480-090 – Program operator annual report (New)

Description: The proposed new rule merely states that annual reports to the department must be on department forms, and requires that expense data be organized in the same manner as their cost estimates in the initial proposal.

Cost/benefit analysis: The proposed rule does not incur additional work or cost to program operators not already in statute. Each area that requires reporting are only clarified in this rule proposal.

8. WAC 246-480-100 – Proprietary information (New)

Description: The proposed new rule reemphasizes and clarifies how the department will protect proprietary information of program operators and covered manufacturers from public disclosure requests. It clarifies parts of the disclosure process for stakeholders, including a program operator's right to file a motion to seek to prevent the release of any previously identified proprietary information.

Cost/benefit analysis: There is nothing in the proposed rule establishing a cost to program operators. The benefit of this section is to be as transparent as possible to affected parties.

9. WAC 246-480-990 – Fees (New)

Description: The department is required to collect a fee from the drug take-back program operator by October 01, 2019 and annually thereafter (RCW 69.48.120(2)). Starting in October 1, 2020 and every year thereafter, RCW 69.48.120(1) requires the department to establish a renewal fee that does not exceed ten percent of a program's annual expenditures reported for the previous calendar year.

Based on feedback from stakeholders, the department assumes at this time there will be a single program proposal (and fee) submitted by MED-Project by July 1, 2019. While the law does not require a single program to be in operation, the department does not anticipate there will be additional proposals submitted because to do so would duplicate efforts and costs paid for ultimately by the covered manufacturers.

The proposed new section would establish an initial fee of $700,000. Annual renewals fees could vary and is estimated at this time to not exceed approximately $500,000 each year. The department may increase the renewal fee for inflation according to RCW 69.48.120. If ten percent of a 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. The initial fee is set at a higher rate than renewal fees as a precautionary measure against unknowns in the first several years. There has never been a complete state-wide drug take-back program of this kind before so the department must rely on projections rather than established data. The department also anticipates higher enforcement costs in the first years.

The department anticipates approximately $300,000 in annual administrative costs. This includes costs for enforcement, credentialing, information technology, program oversight, surveys, and communications. The remaining annual costs of approximately $200,000 will be from department contracts required in statute. First, RCW 69.48.200(10(b) requires the department to contract with the state 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. Second, RCW 69.48.190 requires the department to issue a legislative report on November 15th after the first full year of implementation, and biennially thereafter. To produce the reports, the department is required to contract with an academic institution to conduct and evaluate research regarding 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.

Annual fees submitted to the department by October 1 of each year folds into an overall timeline combining calendar and state fiscal years. Each July 1, the program operator must submit its annual report (including their expense totals) detailing it's work for the prior calendar year. By August 1st of the same year the annual report is submitted, the department would notify the program operator of the renewal fee amount due that October. Fees collected in October will be used for department costs incurred during the state fiscal year (July – June) in which it is received. For example, the first renewal fee collected on October 1, 2020 would cover department costs incurred in state fiscal year 2021 – meaning from July 1, 2020 through June 30, 2021.

SECTION 6:

Identify alternative versions of the rule that were considered, and explain how the department determined that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives state previously.

The department worked closely with stakeholders and other interested parties to minimize the burden of these rules, beginning with the draft conceptual rule development process. The department scheduled three rule development workshops between August, 2018 and September, 2018. These meetings offered stakeholders, technical experts, and other interested parties the opportunity to engage in the draft rule development process. A department webpage dedicated to drug take-back program implementation and all of the activities related to conceptual rule development was established in July 2018. The webpage was updated regularly with meetings materials, including agendas, presentations, draft conceptual rules as they became available, and other relevant documentation.

To encourage public participation, comment, and engagement in the draft conceptual rue development process, a dedicated email account was established for comment. Public comment periods were provided at each of the three draft conceptual rule development meetings. Additionally, to expand the audience and increase access to the rule development process, the final draft conceptual rule development meeting held on September 24, 2108 was also broadcast as a listen-only, Go-To meeting. Additional stakeholder meetings were conducted over the phone and in person to continue the rule discussion through January, 2019.

The following is a summary of rule alternatives considered and later additions to the proposed rule to create a least burdensome set of requirements.

Enforcement. The department is requiring itself in WAC 246-480-030 to work with the drug take-back program operator to place a list of non-compliant covered drug

manufacturers on the department's website. This was at stakeholder suggestion and is intended to assist in the department's commitment to ensuring all covered drug manufacturers are identified and paying into the program. Stakeholders are particularly concerned about this because "free riders" result in higher costs to those manufacturers already following the law.

Drug take-back program budget estimates. First drafts of the rule proposal required a greater level of budget detail to be reported to the department. The department worked with stakeholders to find a level of detail that still allows the department to do its work and lowers the risk of a stakeholder's proprietary information being released through public disclosure. It is split into three main categories of administration, drug collection/disposal, and communications as reflected in WAC 246-480-040.

Underserved areas. At the request of stakeholders, the department included in WAC 246-480-060 the criteria the department and local health jurisdictions will use when determining underserved areas of the drug take-back program. This was added to ensure consistency across the state and predictability for the program operator.

Drug disposal. The department recognizes that disposal facilities not within Washington State are not subject to our statute or rules. Language was recently added to WAC 246-480-080 to clarify that drug take-back program operators do not need to petition the department for approval to use out of state facilities.

SECTION 7:

Determine that the rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.

The rule does not require those to whom it applies to take action that violates the requirements of federal or state law.

SECTION 8:

Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.

The rule does not impose more stringent performance requirements on private entities than on public entities.

SECTION 9:

Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary.

The rule does not differ from any applicable federal regulation or statute.

SECTION 10:

Demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.

Coordination with federal and state agencies themselves is not required. Overlap is minimal and includes laws governing how controlled substances are to be collected, transported, and disposed of. The statute and rule require the drug take-back program to detail how their statement of work does not conflict with state pharmacy laws and relevant federal laws.