



Concise Explanatory Statement, Safe Medication Return
Summary of public comments and changes to proposed language
September 2023

Second Substitute House Bill (2SHB) 1661 (Chapter 155, Laws of 2021) amended chapter 69.48 RCW to allow the Department of Health (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. 2SHB 1161 also gave the department rulemaking authority to identify or clarify additional requirements for coordination or performance amongst program operators, including consistent metrics in operator annual reports to ensure the department can accurately analyze data.

The department worked with interested parties to develop amendments to chapter 246-480 WAC, including two public virtual workshops and dissemination of multiple draft versions via GovDelivery. The department considered all comments and suggestions when finalizing proposed rule language. This adopted rule does the following:

- Repeals 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.
- Amends WAC 246-480-050 clarified the process for applying to the department.
- Amends WAC 246-480-070 clarified program operator requirements for coordinating to present a consistent statewide Safe Medication Return system as required by RCW 69.48.050(12) and RCW 69.48.070(1) and (2).
- Amends WAC 246-480-080 clarified and identified 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.
- Amends WAC 246-480-990 set a proposal review fee as required by RCW 69.48.120, clarified that approved program operators do not submit a proposal review fee, and clarified how the department will calculate approved program operator annual operating fees.

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September 2023

CES Table 1. Changes from the proposed to adopted rule based on public feedback

Change	Citation	Changes from proposed to adopted language	Reason	Related to comment summary
1.	WAC 246-480-070 (15)	Requirements of this section must be implemented by program operators within 180 days one year of the date the rule is adopted.	The department understands that printing new promotional materials creates costs. Therefore, to help mitigate costs the department adopted a final rule with an effective date of one year post adoption. This allows program operators time to develop, design, and print promotional materials, allows time for currently available materials to be utilized, and allows them to change out promotional materials at a regularly scheduled collection site visit. The department is unable to estimate the cost of printing new promotional materials because it is variable.	7 , 14 ,
2.	WAC 246-480-080 (2)(f)(i)	The locations where mailers were provided must include a list of: (i) Population-centers Zip codes where individuals requested mailers from website or toll-free telephone number. (ii) Population-centers Zip codes where households were sent mailers directly without requesting them. This list shall indicate percentage of population centerzip code households that were sent mailers; (iii) Nonresidential locations that are not mail-back distribution locations with addresses; and	The department understands that changing and adding reporting requirements creates costs. Therefore, to help mitigate costs the department adopted a final rule that changes reporting locations where mailers were provided by zip code rather than by population center. While this information provides the department substantially similar information it may reduce time for program operators to complete reporting requirements.	22

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September 2023

		(iv) Mail-back distribution locations with addresses.		
3.	WAC 246-480-080 (2)(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, or maintenance on a kiosk that does not contain an inner liner. The description of whether safety or security problems occurred during collection, transportation, or disposal of covered drugs must include:	Opening a kiosk that does not include an inner liner is not a safety and security problem. The department inadvertently omitted this exception in the proposed rule.	25
4.	WAC 246-480-080 (2)(k)(ii)	List or description of languages available on: the single website and program operator specific website; and the single toll-free telephone number and program operator specific telephone number; and all call centers associated with these the single toll-free telephone numbers and program operator specific telephone number. This list or description must include the, including name of language service providers, if where applicable;	Changes are for clarity only. They do not change the information required in the report.	23
5.	WAC 246-480-080 (2)(k)(iv)	Copies of all public promotional material, including signage and changes to websites and telephone number scripts, developed since last annual report;	Change is for clarity only. It does not change the information required in the report.	24

CES Table 2. Summary of public comments received on proposed rule

Item	Topic	Comments on proposed rule	Agency response
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1.	Agency authority	Proposed rule overreaches legislative authority in several proposed requirements.	The department has determined that the proposed rule is within department legislative authority. Please see agency response to comments about legislative authority on specific topics. <i>Was the rule changed as a result of these comments? No</i>
2.	Intent of 2SHB 1161	Proposed rule is consistent with intent of 2SHB 1161.	The department concurs. <i>Was the rule changed as a result of these comments? No</i>
3.	Ensuring ease of use to public	Consistent, unified “branding” of the website, educational materials, kiosk signage, and other program promotion materials will benefit public recognition, awareness, and trust in the statewide drug take-back system operating under state law. This will help ensure all residents can easily identify, understand, and access services provided by any approved drug take-back program. Consistent promotion will increase public awareness, understanding, and use of this already successful program. Increased use will remove more potentially harmful medicines from homes and reduce the risk of misuse, diversion, unintentional poisoning, and overdose. It will also keep medication out of the environment.	The department concurs. <i>Was the rule changed as a result of these comments? No</i>
4.	Transparency and comparison of programs	Proposed rule reporting requirements will allow the department, legislature, and interested parties to understand and compare the operations and performance of multiple programs.	The department concurs. <i>Was the rule changed as a result of these comments? No</i>
5.	Necessity	Aspects of the proposed rule are not necessary and will result in unexpected consequences detrimental to the statewide system’s success:	The department has determined that the proposed rule is necessary.

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6.	Cost benefit analysis	<p>Proposed rule imposes requirements with greater costs than benefits.</p> <p>The department's cost benefit analysis of proposed rule is incorrect and based on faulty data and analysis.</p>	<p>Many elements in the proposed rule have already been developed and are in place. Elements already in place present no additional cost to program operators. The proposed rule would codify these elements to ensure consistent operations in the future.</p> <p>The department has determined that the benefits of the proposed rule justify the cost.</p>
7.	Disproportionate costs among program operators and impact on manufacturer participation	<p>The proposed rule places responsibility, and therefore cost, on some program operators and not others.</p> <p>The proposed rule will disproportionately negatively impact the program operator that provides bulk of service in state.</p> <p>Meeting unnecessary requirements results in more costs to program operators that provide more program services.</p> <p>Manufacturers of covered drugs must choose which program operator to participate with. If one program operator is required to operate at a higher level of services that results in disproportionately higher costs, these manufacturers may be incentivized to switch to the lower cost program operator that provides lesser services.</p> <p>This creates a race to the bottom and decreases services available to the public.</p>	<p>The department determined that proposed rule amendments are necessary to ensure a consistent statewide system, ensure people can easily identify, understand, and access services provided by any approved program; ensure consistent operation amongst programs; and ensure consistent metrics so the department can accurately analyze program and system data.</p> <p>To mitigate the stated concerns, the department determined that extending the timeline for implementing proposed WAC 246-480-070 from 180 days to one year will mitigate program operator costs, as it would provide time to change kiosk signage during regularly scheduled collection site visits and update mail-back distribution location material during regular resupply.</p> <p><i>Was the rule changed as a result of these comments? Yes, WAC 246-480-070(15) has been amended to allow program operators one year to implement requirements of WAC 246-480-070. The originally filed proposed</i></p>

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			<i>rule required implementation within 180 days.</i>
8.	Impact on collection site participation	Proposed rule will likely create a chilling effect on program participation for currently participating collection sites.	<p>The proposed rule does not change requirements for participating sites. Changes in requirements pertain to program operator promotion and reporting and current and potential program operator fees.</p> <p><i>Was the rule changed as a result of these comments? No</i></p>
9.	Promotional material—program operator responsibility	<p>WAC 246-480-070(2) makes it clear that individual program operators are responsible for ensuring their own promotional materials meet the statutory and regulatory requirements. Since program operators are independent entities without the ability to control one another, one program operator should never be held responsible for another program operator's nonperformance.</p> <p>The proposed regulations establish that program operators are responsible for updating their collection sites, mail-back distribution locations, and take-back events on the single website.</p> <p>The rules should also clearly establish that a program operator will not be held responsible for the failure of another program operator to provide these updates.</p>	<p>Proposed WAC 246-480-070(2) establishes that “[e]ach 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.”</p> <p>Proposed WAC 246-480-070(9)(d) requires that “[E]ach 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.”</p> <p>The department will not consider a program operator responsible for another program operator's noncompliance. The department determined that proposed WAC 246-480-070 sufficiently establishes this.</p> <p><i>Was the rule changed as a result of these comments? No</i></p>
10.		The department should revise proposed WAC 246-480-070(14) to make it clear that newly approved program operators must coordinate with established program operators to conform their new	The department determined that program operator coordination required by chapter 69.48 RCW is a joint responsibility among all program operators.

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	<p>programs to the existing consistent statewide drug take-back system rather than requiring existing operators to adapt the consistent statewide system to each new program.</p> <p>As drafted, WAC 246-480-070(14) places responsibility for this coordination on established program operators. It should be the responsibility of newly approved program operators.</p>	<p>RCW 69.48.050(12) requires all program operators to collaborate to present a consistent statewide drug take-back system and RCW 69.48.070(2) requires programs to coordinate their promotional activities to ensure people can easily understand, identify, and access the collection services provided by any program. RCW 69.48.070(2) specifies that this must include coordinating to provide a single website and single toll-free phone number.</p> <p>The department review of proposed new programs includes evaluating the new program's plan for this required coordination. Newly approved program operators are required by statute to fully implement their program within 180 days of approval. This implementation includes coordinating promotional activities (including the single website and single toll-free phone number).</p> <p>The department determined that it would not be possible for a newly approved program operator to coordinate with existing program operators unless the existing program operators agree to that coordination.</p> <p>The proposed rule makes it clear that existing program operators share the responsibility for statutorily required coordination with newly approved program operators.</p> <p><i>Was the rule changed as a result of these comments? No</i></p>
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11.	Promotional material--equitable access	WAC 246-480-070(5) requirement that public promotional materials be accessible for those with limited English proficiency and people with disabilities aligns with RCW 69.48.070(1)(e) requirement that promotional material be "...readily understandable by all residents..."	<p>The department concurs.</p> <p><i>Was the rule changed as a result of these comments? No</i></p>
12.	Promotional material	<p>Established program operators should be allowed to continue to use existing promotional material.</p>	<p>Statute requires program operators to coordinate their promotional activities.</p> <p>The department has determined that promoting a single name for the statewide system will ensure the public can easily understand that the state-regulated drug take-back system established by chapter 69.48 RCW is a single, uniform, statewide system composed of programs operated by multiple department-approved program operators.</p> <p>The department is not aware of any current promotional material that includes a specific drug take-back program name. Current program operators use their name to promote their programs as is specifically allowed in the proposed rule (WAC 246-480-070(7)).</p> <p>General descriptions of a program operator's services, such as "Safely Dispose of Expired or Unwanted Medicine" or "Safely Dispose of Unused Medication" are not prohibited in the proposed rule.</p> <p>The department determined it likely that compliance with the proposed rule could be accomplished by</p>

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		<p>replacing program operator-specific websites/phone numbers with the single website/single toll-free telephone number on promotional material, adding the common mark to promotional material, and refraining from developing program-specific names in the future.</p> <p><i>Was the rule changed as a result of these comments? Yes, WAC 246-480-070(15) has been amended to allow program operators one year to implement requirements of WAC 246-480-070. The originally filed proposed rule required implementation within 180 days.</i></p>	
13.	Promotional material—ease of understanding for the public	<p>The proposed rule continues unjustified focus on eliminating branding that is recognized by residents and disregards current awareness of available drug take-back programs by focusing on department program name.</p> <p>Lack of accounting for the broad awareness of available drug take-back services in Washington ignores robust education and outreach already in place that renders the need for proposed promotion material changes unnecessary. (For example, awareness survey conducted by Idaho State University appears to focus on department program brand name rather than drug take-back services available in the state.)</p>	See answer to 12.
14.		Proposed rule requires unnecessary changes to promotional material which are costly and wasteful. When hypothetical benefits cited by the department are weighed against actual, more significant cost of the proposed	See answer to 12.

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		<p>rule, the probable costs of the proposed rule exceed the probable benefits.</p> <p>WAC 246-480-070(7) requires program operators to refer to the statewide drug take-back system as Safe Medication Return on all promotional material and prohibits program operators from using any other name to refer to their drug take-back program.</p> <p>Focusing on statewide drug take-back system branding is likely to generate confusion when program operators are forced to rename services residents are already familiar with.</p>	
15	Promotional material--use of program operator-specific website and phone number	<p>Proposed WAC 246-480-070(13)(b) allows program operators to include program operator-specific phone number on kiosks and mailer instructional inserts to inform the public how to receive support and provide comments about kiosk or mailer. Proposed rule should be revised to allow similar use of program operator-specific website.</p>	<p>Proposed WAC 246-480-070(11) allows program operators to include program operator-specific email address on kiosks and mailers to inform the public how to receive support or provide comments about kiosk or mailer.</p> <p>The department determined that providing an email address rather than a website address provides the public a more efficient way to receive support and provide comments to program operators.</p> <p>Providing a program operator-specific website would require the public to navigate that website to find an appropriate email address.</p> <p>The combination of WAC 246-480-070(13)(b) and WAC 246-480-070(11) would allow program operators to provide a phone number and email address to the public for the purpose</p>

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			<p>of receiving support and providing comments about kiosks and mailers.</p> <p><i>Was the rule changed as a result of these comments? No</i></p>
16.	Promotional material—program operator cooperation	Requiring more coordination between multiple program operators increases the costs to program operators, due partially to the additional negotiations that are required between the program operators and the vendors that support program operators.	<p>RCW 69.48.050(12) and RCW 69.48.070(2), require program operators to coordinate or collaborate to present a consistent statewide system that is easy for people to use and access and refer to consistent operation and messaging. The proposed rule sets minimum requirements presenting a consistent system. The department determined that this would reduce staff time required to negotiate the framework within which the required coordination and collaboration occur.</p> <p><i>Was the rule changed as a result of these comments? No</i></p>
17.	Promotional material—kiosk signage, mailer inserts, and brochures	<p>Department cost benefit analysis ignores program operator costs associated with printed and downloadable promotional materials.</p> <p>A commenter stated promotional material is produced in bulk and stored until needed and estimated the cost of revising promotional material to meet proposed will be over \$150,000. This will include the cost of materials and mileage and staff time to replace existing materials.</p> <p>Replacing promotional material imposes a cost on host sites due to disruption at collection sites and mail-back distribution sites.</p>	<p>The department determined that promotional material designed for multi-jurisdictional programs already produced but not yet distributed by program operators need not be wasted. Program operators could use this material in the other jurisdictions it pertains to.</p> <p>As specified in their approved plans, program operators monitor each of their kiosks several times per year. At least one of these monitoring visits is performed by program operator staff traveling to the kiosk site.</p> <p>Both program operators offer collection sites the option of choosing scheduled service. For scheduled service sites, program operator</p>

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	<p>Replacing promotional material imposes a cost on residents due to confusion and frustration.</p> <p>Developing and maintaining jurisdictional-specific promotional materials create additional complexities and increase costs.</p>	<p>technicians visit collection sites and assist to package and transport kiosk liners.</p> <p>The department identified potential cost-saving opportunities that could minimize disruption to host site staff and eliminate additional travel and mailing costs. These include updating kiosk signage during an in-person monitoring visit or a technician assisted scheduled collection visit and mailing updated signage and brochures to mail-back distribution locations in conjunction with standard replenishment of mailers and brochures.</p> <p>The department determined that, nationwide, some jurisdictions differ in the products they accept and do not accept and some require a jurisdictional-specific website on promotional material. While developing and maintaining jurisdictional-specific material may increase cost, program operators already do this for material in other jurisdictions. The department determined it is likely these existing systems can be used to minimize extra costs.</p> <p>The department determined it's likely that promoting one website and one toll-free phone number, rather than multiple websites and multiple phone numbers, will increase public understanding and ease of access to services.</p> <p><i>Was the rule changed as a result of these comments? No</i></p>
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September 2023

18.	Promotional material-- program operator coordinated single website	Department cost benefit analysis ignores program operator costs associated with revisions to the program operator coordinated single website.	Program operators have already cooperated to launch a single-website as required by RCW 69.48.070(2). This coordinated resource meets many of the proposed rule requirements. Program operators are aware of and have agreed to explore the feasibility and cost of the remaining unmet requirements that the proposed rule would codify. Proposed requirements not yet in place on the single website (medtakebackwashington.org) include: <ul style="list-style-type: none">• Describing why and how to safely store and securely dispose of medication (proposed WAC 246-480-070(9)(b)(i);• Describing the products that are accepted and not accepted;• Presenting all drug take-back events for all program operators in one table;• Providing a link to the department's Safe Medication Return webpage, and department contact information;• Adding a statement that the department welcomes comments, questions, and concerns. The department determined that the benefit of adding text to an existing website and adding a link from a website to the department's website outweighs the cost.
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September 2023

			<i>Was the rule changed as a result of these comments? No</i>
19.	Promotional material-- program operator coordinated single toll-free phone number	Department cost benefit analysis ignores program operator costs associated with revisions to the program operator coordinated single toll-free phone number	<p>Program operators have already cooperated to launch a single toll-free phone number as required by RCW 69.48.070(2). This coordinated resource meets many of the proposed rule requirements. Program operators are aware of and have agreed to explore the timeline and feasibility for implementing the remaining requirements that the proposed rule would codify.</p> <p>Proposed requirements not yet in place for the single toll-free phone number (844-4-TAKEBACK) include providing callers with information about:</p> <ul style="list-style-type: none">• All collection sites, mail-back distribution locations, and drug take-back events without requiring the caller to choose between program operators prior to receiving this information.• Why and how to safely store and securely dispose of medication.• Which products are accepted and not accepted.• The single website• The department's contact information <p>The department determined that the benefit of adding the remaining information to the existing telephone number outweighs the cost.</p>

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			<i>Was the rule changed as a result of these comments? No</i>
20.	Reporting—inner liner supplies	<p>Reporting requirements related to inner liner supply requests are unnecessary. RCW 69.48.100(2) already requires reporting kiosk-specific collection weights and prompt collection services. Proposed WAC 246-480-080(2)(d) reporting would not provide additional information.</p> <p>The department should revise WAC 246-480-080(2)(d) to delete requirement to report on prompt kiosk inner liner supply requests.</p>	<p>RCW 69.48.060(2)(a) requires collection sites (kiosk locations) to accept all covered drugs during the hours the authorized collector (pharmacy or law enforcement facility) is normally open for business with the public.</p> <p>RCW 69.48.060(2)(c) requires program operators to provide a service schedule that meets the needs of each collection site to ensure that each kiosk is serviced as often as necessary to avoid reaching capacity and that collected medication is transported to disposal in a timely manner, including a process for additional prompt collection service on notification from the collection site.</p> <p>RCW 69.48.060(3)(a) requires a program's collection system be safe, secure, and convenient on an ongoing, year-round basis and provide equitable and reasonably convenient access.</p> <p>Both current program operator approved plans offer collection sites two types of collection services (packaging and arranging transport of kiosk inner liners).</p> <ul style="list-style-type: none">• The default in both plans, is for the program operator or their contractor to visit the collection site and oversee inner liner packaging, provide new inner liner supplies, and arrange for the packaged inner liner to be transported.

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			<p>This is referred to as “scheduled” or “technician-assisted” collection in the approved plans and occurs on a set schedule that can be adjusted as needed. Collection sites can request additional prompt collection if a kiosk becomes full unexpectedly.</p> <ul style="list-style-type: none">• Collection sites can also choose to manage packaging and arranging transport themselves. This is referred to as “on-demand” or “self-service” in approved plans. It allows collection sites to package inner liners as soon as their kiosk becomes full but might not provide the certainty of regularly scheduled collection, including inner liner resupply. <p>Both program operators provide automatic replenishment of inner liner supplies to on-demand/self-service sites. Program operators ship a new set of three inner liner kits when either the first or second liner from the prior set is returned.</p> <p>The department determined that the weight of medication collected at a kiosk is one indicator of kiosk availability and collection site requests for prompt collection service is another indicator—for scheduled/technician-assisted sites. The department determined that reporting requests for prompt supply</p>
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			<p>of inner liner kits would provide a similar indicator for on-demand/self-service sites.</p> <p><i>Was the rule changed as a result of these comments? No</i></p>
21.	Reporting— program operator agreements with collection sites	<p>Reporting requirements related to program operator agreements with collection sites are unnecessary.</p> <p>The proposed regulations should not require program operators to report on whether agreements with collection sites include a requirement for collection site to report need for prompt collection, maintenance, or inner liner supply requests.</p> <p>Such reporting implies that this requirement should be part of collection site agreements. Collection sites are naturally incentivized to report these issues to program operators and nothing in statute mandates collection sites report a need for prompt collection, maintenance, or inner liner supply requests to program operators. Including this requirement in collection site agreements may depress collection site participation.</p> <p>Collection sites may view this proposal, coupled with the recent department decision that kiosks must be unlocked when collection sites are open for business with the public unless the kiosk is full or is damaged in a way that compromises security, as an indication that the department is looking to involve itself in collection site operations.</p>	<p>The department's decision that kiosks must be unlocked when the authorized collector is open to the public is outside the purview of the proposed rules. This decision ensures equitable and reasonably convenient access to kiosks. The department determined that it is not convenient for people to be required to request kiosks be unlocked and wait until pharmacy staff can unlock kiosks. The department determined that it is not equitable for some kiosks to be unlocked and readily available and others to be locked unless pharmacy staff unlock them on request.</p> <p><i>Was the rule changed as a result of these comments? No</i></p>

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Summary of public comments and changes to proposed language
September 2023

		<p>The department should delete requirement to report whether agreements with collection sites include a requirement for collection sites to notify program operator of the need for prompt collection and maintenance or inner liner supplies.</p>	
22.	Reporting—location of mailers provided	<p>Proposed rule WAC 246-480-080(2)(f) requires program operators to provide a list of population centers where individuals requested mailers and where mailers were sent to households directly. Established systems for determining residential mailing addresses rely on zip codes.</p> <p>WAC 246-480-080(2)(f) should be revised to align reporting with existing methods for identifying residential addresses.</p>	<p>The purpose of proposed WAC 246-480-080(2)(f)(i-ii) is to ensure the department can accurately analyze access to drug take-back mailers. The department agrees that reporting this information by zip code would be more efficient for program operators and would provide substantially the same data to the department.</p> <p><i>246-480-080(2)(f)(i) with change shown in red is below:</i></p> <p class="list-item-l1">(i) Population-centers Zip codes where individuals requested mailers from website or toll-free telephone number.</p> <p class="list-item-l1">(ii) Population-centers Zip codes where households were sent mailers directly without requesting them. This list shall indicate percentage of population-centerzip code households that were sent mailers;</p> <p class="list-item-l1">(iii) Nonresidential locations that are not mail-back distribution locations with addresses; and</p> <p class="list-item-l1">(iv) Mail-back distribution locations with addresses.</p> <p><i>Was the rule changed as a result of these comments? Yes, proposed WAC 246-480-080(2)(f)(i) and WAC 246-480-080(2)(f)(ii) were changed to</i></p>

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Concise Explanatory Statement, Safe Medication Return
Summary of public comments and changes to proposed language
September 2023

			<i>replace "Population Centers" with: Zip codes." The information provided in the report as a result of this change is substantially the same.</i>
23.	Reporting—list or description of available languages	<p>The department should clarify the proposed rule requirement to provide a list or description of languages used on websites and at call centers.</p> <p>It is preferable for program operators to report a list or description of language service providers rather than list all languages available through program operator translation services on websites. This recognizes that program operators will use third-party translation services that cover a host of languages, including the most common languages in Washington State. However, the current text is difficult to understand.</p>	<p>The department agrees that this language should be more clear. Proposed WAC 246-480-080(2)(k)(ii) with changes shown in red:</p> <p><i>List or description of languages available on: the single website and program operator specific website; and the single toll-free telephone number and program operator specific telephone number; and all call centers associated with these the single toll-free telephone numbers and program operator specific telephone number. This list or description must include the, including name-of language service providers, if where applicable;</i></p> <p><i>Was the rule changed as a result of these comments? Yes, proposed WAC 246-480-080(2)(k)(ii) was changed for clarification. The information provided in the report as a result of this change is substantially the same.</i></p>
24.	Reporting—promotional material developed since last annual report	<p>Proposed WAC 246-480-080(2)(k) requires program operators to provide a description of public education, outreach, and evaluation activities. Subsection WAC 246-480-080(2)(k)(iv) requires program operators to provide copies of all promotional material developed since the last annual report.</p> <p>Since “promotional material” includes both public and partner promotional material and WAC 246-480-080(2)(k) focuses specifically on public material, WAC 246-480-080(2)(k)(iv) should be</p>	<p>The department determined that the word “public” in proposed WAC 246-480-080(2)(k) provides context for the material required in WAC 246-480-080(2)(k)(iv). The department agrees that adding “public” to proposed WAC 246-480-080(k)(iv) would clarify this without changing the requirement.</p> <p>Proposed WAC 246-480-080(2)(k)(iv) with changes shown in red:</p> <p>Copies of all public promotional material, including signage and</p>

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Concise Explanatory Statement, Safe Medication Return
Summary of public comments and changes to proposed language
September 2023

		changed to clarify that it refers to public material.	changes to websites and telephone number scripts, developed since last annual report; <i>Was the rule changed as a result of these comments? Yes, proposed WAC 246-480-080(2)(k)(iv) was changed for clarification. This does not change the information required in the report.</i>
25.	Reporting—safety and security problems	<p>The department must revise proposed WAC 246-480-080(2)(j) to focus on actual threats to safety and security and to be consistent with statute.</p> <p>Current proposed WAC 246-480-080(2)(j) would require reporting on “safety or security problems” that are not unsafe, not unsecure, and not even problems. This would include:</p> <ul style="list-style-type: none">• Law enforcement agencies retrieving an item inadvertently deposited into a kiosk (which is authorized).• Kiosk maintenance that involves opening a kiosk, even when the maintenance improves security.• A pharmacy accidentally installing the wrong vendor’s inner liner in a kiosk (as this would not follow the processes described in the approved plan).	<p>RCW 69.48.080(4) requires program operators to notify the department as soon as practicable after encountering a safety or security problem during collection, transportation, or disposal of medication. RCW 69.48.100(1)(d) requires program operator annual reports to include whether any safety or security problems occurred. Chapter 69.48 RCW does not define “safety or security problem.”</p> <p>The department determined that instances where kiosks are opened for any reason other than packaging the inner liner for shipping or installing a new inner liner, increase opportunities for diversion which the department considers a safety and security problem.</p> <p>The department has further determined that situations where collection, transportation, or disposal differ from the processes described in the approved plan are likely to indicate a safety or security problem.</p> <p>Nothing in the rule prohibits program operators from including an objection to describing specific situations as a safety or security problem in their annual report.</p>

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Concise Explanatory Statement, Safe Medication Return
Summary of public comments and changes to proposed language
September 2023

		<p>The department agrees that opening an empty kiosk for maintenance purposes does not present a safety or security problem and has changed the proposed rule accordingly. The department expects maintenance required on a kiosk that contains an inner liner to be done after the inner liner is packaged for shipping, in which case it would not be considered a safety or security problem.</p> <p>Proposed WAC 246-480-080(2)(j) with changes shown in red:</p> <p>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, installing a new inner liner, or maintenance on a kiosk that does not contain an inner liner. The description of whether safety or security problems occurred during collection, transportation, or disposal of covered drugs must include:</p> <p><i>Was the rule changed as a result of these comments? Yes, proposed WAC 246-480-080(2)(j) was changed to clarify that opening an empty kiosk (one that does not contain an inner liner) for the purpose of maintenance is not a safety or security problem.</i></p>
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Concise Explanatory Statement, Safe Medication Return
Summary of public comments and changes to proposed language
September 2023

			<i>This does not substantially change the information required in the report</i>
26.	Reporting—kiosks unable to accept medication	<p>There is no need to require reporting on program operator identified issues related to kiosks not being available to accept covered drugs when the collection site is open for business.</p> <p>Reporting requirements regarding unavailable collection receptacles will interfere with collection site participation.</p> <p>This section of proposed rules creates redundant and unnecessary reporting requirements. RCW 69.48.100(2) already requires program operators to report site-specific collection weight information.</p> <p>Suggest deleting proposed WAC 246-480-080(2)(d)(ii).</p>	<p>RCW 69.48.060(2)(a) requires collection sites (kiosk locations) to accept all covered drugs during the hours the authorized collector (pharmacy or law enforcement facility) is normally open for business with the public.</p> <p>RCW 69.48.060(2)(c) requires program operators to provide a service schedule that meets the needs of each collection site to ensure that each kiosk is serviced as often as necessary to avoid reaching capacity and that collected medication is transported to disposal in a timely manner, including a process for additional prompt collection service on notification from the collection site.</p> <p>RCW 69.48.060(3)(a) requires a program's collection system be safe, secure, and convenient on an ongoing, year-round basis and provide equitable and reasonably convenient access.</p> <p>The department determined that proposed WAC 246-480-080(2)(d)(ii) would not impose any additional requirements on collection sites. WAC 246-480-080(2)(d)(ii) requires program operators to report program operator identified issues regarding kiosks not being able to accept medication. It does not require collection sites to report these issues.</p> <p>The department determined that program operators could comply with</p>

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Concise Explanatory Statement, Safe Medication Return
Summary of public comments and changes to proposed language
September 2023

		<p>this requirement using their available data from kiosk monitoring and inspection, requests for prompt services, and the provision of services in response to these requests.</p> <p>The department determined that compliance with WAC 246-480-080(2)(d)(ii) does not require program operators to identify individual collection sites. Required reporting could be quantitative by category.</p> <p>The department determined this data would ensure the department can accurately analyze kiosk accessibility without imposing burdensome reporting requirements on collection sites. While kiosk specific collection weight provides one indicator of kiosk accessibility, the department determined that other indicators, including program operator identified issues related to kiosks being unavailable, are needed to ensure accurate data analysis.</p> <p><i>Was the rule changed as a result of these comments? No.</i></p>
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Any person may petition the adoption or amendment of these rule in accordance with RCW 34.05.330.

For more information regarding these rules you may contact me by email at mary.kellington@doh.wa.gov or by phone at 360-236-2988.

cordially,

Mary Kellington
Program Manager

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