

## Concise Explanatory Statement WAC Chapter 246-480

TOPIC	CITATION	COMMENTS ON PROPOSED RULES	AGENCY RESPONSE
<b>Definitions</b>	WAC 246-480-020	<p>Comment suggested “covered entity” should be further defined in WAC to make it clear that covered entities are state residents and other nonbusiness, nongovernment entities, and does not include business generators of waste.</p>	<p>The department does not believe this clarification is necessary. The RCW notes in its definition that covered entities are state residents or other nonbusiness entities which includes the ultimate user of a drug. It goes on to say that business generators of waste are not included and lists examples of those not included.</p> <p><i>Was the rule changed as a result of these comments? No</i></p>
<b>Program Proposal Requirements</b>	WAC 246-480-040	<p>Comment suggested that the rule should define the department’s oversight processes to ensure potential authorized collectors have been made aware of the opportunity to participate in the program and that qualified authorized collectors are appropriately included in the drug take-back program in a timely manner.</p>	<p>The Department of Health does not define its processes in rule in order to ensure the department has the ability to update and shift processes in order to best meet statute requirements and intent.</p> <p><i>Was the rule changed as a result of these comments? No</i></p>
	WAC 246-480-040	<p>Comment suggested that the rule should require program operators to submit information with the program proposal on:</p> <p>List of potential authorized collectors notified about the opportunity;</p> <p>Potential authorized collectors that have volunteered to participate and/or distribute mailers; and</p> <p>Reasons potential authorized collectors were excluded from the program.</p>	<p>RCW 69.48.050(2)(b) requires that program proposals include authorized collectors participating in the program as well as reasoning for excluding any potential authorized collectors. This would include both potential authorized collectors notified about the opportunity and those that volunteer to participate.</p> <p>RCW 69.48.060(3)(e) requires program operators to provide free prepaid, preaddressed envelopes to covered entities and retail pharmacies when they are requested. At the time of the program proposal, there will not be an operational program, so requests for these mailers will not be able to be made yet.</p>

			<p>If mailers are provided to supplement underserved areas as described in RCW 69.48.060(3)(d), the location of those mailer distribution sites will be determined by the program operator, in consultation with the department, local law enforcement, local health jurisdiction, and local community.</p> <p><i>Was the rule changed as a result of these comments? No</i></p>
	WAC 246-480-040	<p>Comment suggested that a template of a collector agreement should be provided in the program proposal so the department can ensure the agreement's policies for monitoring and servicing a collection receptacle comply with the RCW's requirements, Drug Enforcement Administration (DEA) regulations, and other applicable laws and regulations.</p>	<p>An example of a collector agreement is listed as supplemental information to be included in a program proposal on the program proposal form.</p> <p><i>Was the rule changed as a result of these comments? No</i></p>
	WAC 246-480-040(5)	<p>Comment suggested WAC 246-480-040(5) and WAC 246-480-090 should be revised such that detailed itemized information be provided for each of the subcategories, not just as lump sums in 3 categories, and that all individual program expenditures must be reported.</p>	<p>The department consulted with various stakeholders to determine the most effective way for the program operator to share annual program costs with the department in both the program proposal and annual reports. The department determined that the inclusion of three categories of cost types, along with descriptions of what is to be included in those categories, is the best way to ensure all program costs are included while also ensuring that collecting the listed information doesn't become an undue burden on the program operator.</p> <p><i>Was the rule changed as a result of these comments? No</i></p>
	WAC 246-480-040	<p>Comment expressed concerns about the use of forms for program proposals as they are complex and long documents. Requiring program operators to use forms for program proposals as noted in WAC 246-480-040 may be difficult and leave out necessary information. It is</p>	<p>The department intends for an initial form with demographic information to be filled out with a list of all required components to be included in the proposal as supplemental information. This will allow the department to have a signed form associated with each proposal and allow the program operator the flexibility to provide the department with a proposal in the form they have submitted to the counties for review and approval.</p>

		recommended that the department use a template, rather than a form.	<i>Was the rule changed as a result of these comments?</i> No
	WAC 246-480-040(5)	Comment recommended changing the wording in WAC 246-480-040(5) to clarify that each cost category must include, but is not limited to, these cost examples.	The department agrees  <i>Was the rule changed as a result of these comments?</i> Yes  WAC 246-480-040(5) was amended to clarify that the requirements in WAC do not need to be exhaustive.
	WAC 246-480-040(5)(b)(iii)	Comment noted a typo in WAC 246-480-040(5)(b)(iii)- “A”:  (iii) Compensation of authorized collectors, if separate from personnel costs in (a)(i)(A)	The department agrees.  <i>Was the rule changed as a result of these comments?</i> Yes  The “(A)” in the internal citation of the subsection was removed from WAC 246-480-040(5)(b)(iii).
<b>Underserved Areas</b>	WAC 246-480-060(2)(c)	Comment noted “driving distances and times” could exclude residents who rely on public transit systems or transportation modalities other than personal motor vehicles and may impact access for those in urban centers and rural communities.  “Travel distances and times” better aligns with the law’s intent to consider access for all residents in the determination of underserved areas.	The department agrees. This is a better clarification of what was intended.  <i>Was the rule changed as a result of these comments?</i> Yes  WAC 246-480-060(2)(c) was changed to describe “travel distances” instead of “driving distances.”
	WAC 246-480-060(2)	Comment suggested that when determining underserved areas, the rule should consider additional criteria such as the number, geographic distribution of collection sites, and accessibility through public transportation to ensure the program is equitable and reasonably convenient for residents.	WAC 246-480-060(b) requires the number of existing collection sites to be used when determining underserved areas. RCW 69.48.060(3)(a) states that a program’s collection system must provide equitable and reasonably convenient access. This, coupled with an update from “driving distances and times” to “travel distances and times” in WAC 246-480-060(2)(c), will ensure that

			underserved areas will receive equitable access to the drug take-back program.  <i>Was the rule changed as a result of these comments? No</i>
	WAC 246-480-060(2)(a)	Comment suggested the rule should expand population density of counties to explicitly include consideration of population density in cities, towns, and unincorporated areas.	The language in WAC 246-480-060(2)(a) does not limit the consideration of population density to only the county level. Cities, towns, and unincorporated areas, where applicable, may also be considered when determining underserved areas.  <i>Was the rule changed as a result of these comments? No</i>
<b>Program Promotion</b>	WAC 246-480-070	Comment suggested “collection” should be inserted in front of “sites” for clarity:  <b>WAC 246-480-070</b> Promotion. Approved program operators must update their list of authorized collectors, <b>collection</b> sites, locations to receive mailers, and locations for drug take-back events at least quarterly on their web site.	The department agrees this addition clarifies our original intent of the proposed rule.  <i>Was the rule changed as a result of these comments? Yes</i>  The term “sites” in this section was amended to “collection sites.”
	WAC 246-480-070	Comment suggested removing this section and rely on the requirements in RCW 69.48.070 in order to give the program operator the flexibility to tailor promotion, education, and public outreach appropriately and to avoid limiting program operator opportunities to be responsive to community needs.	In order for the drug take-back program to be successful, it is imperative that Washington residents have access to up-to-date information on the locations of drug take-back sites and mailers as well as locations and dates of any drug take-back events coordinated by the program operator.  The department does not believe that requiring the program operator to update their list of authorized collectors, collection sites, mailer locations, or drug take-back events on their website on a quarterly basis will hinder the operator’s ability to respond to community needs or restrict the operator’s flexibility in its promotion of the program.

			<i>Was the rule changed as a result of these comments? No</i>
<b>Disposal of Covered Drugs</b>	WAC 246-480-080	<p>Concerns were raised about the disposal section and asked for assurances that the department would review proposed disposal facilities/technologies to determine if they meet applicable state and federal regulations around the disposal of pharmaceutical waste.</p> <p>It was suggested that the rule should reiterate the disposal facility requirements stated in RCW 69.48.080, such as the preferred disposal method noted in RCW 69.48.080(1).</p> <p>Comments requested the department remove the language stating it does not require approval for out of state facilities and, instead, should address issue of jurisdictional authority if and when such issues arise.</p>	<p>The department does not intend to reiterate RCW 69.48.080 as it is clear in RCW.</p> <p>The department is able to monitor the program operator's compliance with state and federal law around disposal of collected drugs without including that process in rule.</p> <p>The department understands the federal requirements that apply to all facilities disposing of controlled substances. It intends to track all disposal facilities used by the program operator to ensure that applicable DEA and EPA regulations are met. If the department does not believe it has the jurisdictional authority to approve or deny a proposed disposal facility, it may reach out to the appropriate regulatory authority.</p> <p>There are already mechanisms in RCW 69.48.050(5)(a) for program operators to notify the department about the disposal sites it intends to use after the program has begun operating, and the program proposal form notes that information about disposal site type and permit number is required supplemental information to be included. It was determined that this section was not necessary in WAC.</p> <p><i>Was the rule changed as a result of these comments? Yes</i></p> <p>Removed proposed WAC 246-480-080, renumbered the remaining WAC sections accordingly.</p>
	<b>Additional comments were received in relation to the former section WAC 245-480-080. They have been included for reference below.</b>		

	WAC 246-480-080	Comment expressed satisfaction with the clarification in WAC 246-480-080 that disposal requirements in RCW 69.48.080 apply to disposal sites within Washington state.	The department appreciates the feedback.
	WAC 246-480-080	Comment suggested establishing contingency requirements for the program operator to report safety or security problems that arise with the collection, transportation, and disposal of covered drugs or if there are changes to environmental or human health as a result of facility practices or unforeseen circumstances. The rule should require the program operator to report changes in disposal facility status or unforeseen circumstances that could impact environmental and public health to the department.	Per RCW 69.48.080(4), any safety or security problem encountered in the collection, disposal, or transportation of covered drugs must be reported to the department by the program operator.
	WAC 246-480-080	Comments requested further explanation as to why WAC 246-480-080 diverged from language in RCW 69.48.080.	The department is tasked with developing a rule that meets applicable state and federal regulations and WAC 246-480-080 was determined to need further clarification on what disposal methods the state is able to approve.
<b>Program Operator Annual Reports</b>	WAC 246-480-090(2)	Comment suggested replacing the phrase “the report must include a summary of the program’s annual expenditures” in WAC 246-480-090(2) with “the report must provide a complete reporting by category of the program’s annual expenditures”.	WAC 246-480-090(2) notes that the summary of the program’s annual expenditures must use the same criteria described in WAC 246-480-040(5). By referencing WAC 246-480-040(5), the department can ensure consistency in the reporting between program proposals and annual reports submitted by the program operator.  <i>Was the rule changed as a result of these comments? No</i>

	<p>WAC 246-480-090</p>	<p>Comment stated that the rule should require program operators to submit information in the annual report on:</p> <p>List of potential authorized collectors notified about the opportunity;</p> <p>Potential authorized collectors that have volunteered to participate and/or distribute mailers; and</p> <p>Reasons potential authorized collectors were excluded from the program.</p>	<p>RCW 69.48.060(1)(c) requires program operators to include all potential authorized collectors that offer to participate in the program without compensation.</p> <p>RCW 69.48.060(1)(a) has a one-time requirement for potential program operators to reach out to potential authorized collectors to notify them of the opportunity to participate in the drug take-back program. If a program operator has met the convenience standard described in RCW 69.48.060(3)(c) and/or supplemented underserved areas as required in RCW 69.48.060(d), the department cannot require the program operator to solicit additional sites.</p> <p>As the list of potential authorized collectors notified is included in the program proposal, it is unnecessary to include this information in the annual report.</p> <p>If potential authorized collectors volunteer to participate, and/or distribute mailers, and are not included in the program by the program operator, the authorized collector may make a complaint to the department. RCW 69.48.110 provides for the enforcement actions the department may take.</p> <p>RCW 69.48.100(1)(c) requires the program operator to include in the annual report the location of collection sites and locations where prepaid, preaddressed mailers were provided.</p> <p><i>Was the rule changed as a result of these comments?</i> No</p>
	<p>WAC 246-480-090</p>	<p>Comment suggested adding “the amount, by weight, of covered drugs collected, sent to each disposal facility used by the program” as a requirement in the program operator annual report</p>	<p>Within thirty days after each annual period of operation of an approved drug take-back program, the program operator is required to report the total amount, by weight, of covered drugs collected at each collection site, per RCW 69.48.100(2).</p>

			<p>Chapter 69.48 RCW does not require the program operator to include information on the amount of drugs sent to each disposal facility, and the department has not determined a compelling reason to do so at this time.</p> <p><i>Was the rule changed as a result of these comments? No</i></p>
	WAC 246-480-090	<p>Comment expressed concerns about the use of forms for annual reports as program operator annual reports are complex and long documents. Requiring program operators to use forms for annual reports as noted in WAC 246-480-090 may be difficult and leave out necessary information. It is recommended that the department use a template, rather than a form.</p>	<p>The department intends for an initial form with demographic information to be filled out with a list of all required components to be included in the annual report as supplemental information. This will allow the department to have a signed form associated with each annual report and allow the program operator the flexibility to provide the department with an annual report in the format they have submitted to the counties for review and approval.</p> <p><i>Was the rule changed as a result of these comments? No</i></p>
<b>Proprietary Information</b>	WAC 246-480-100(1)	<p>Comment requested the department strike the last two sentences from WAC 246-480-100(1) in order to be consistent with 69.48.170 RCW and to streamline the language.</p>	<p>The department intends this language to clarify that information automatically disclosable under law cannot be marked as “proprietary” as well as clarifying that information not deemed automatically disclosable cannot, in its entirety, be marked as proprietary. While this language does not create a new law or procedure for the department, it was included as an assurance of our process to the regulated community in order to reduce apprehension and confusion regarding proprietary information needed by the department to fulfill chapter 69.48 RCW.</p> <p><i>Was the rule changed as a result of these comments? No</i></p>
<b>General Comments</b>	Ch. 246-480 WAC	<p>Comments requested the rule to restate requirements from RCW, such as all requirements in RCW 69.48.050.</p>	<p>Chapter 69.48 RCW is very prescriptive so the department intends the rule to simply clarify only those areas of the RCW necessary for the department to adequately perform its duties. These generally address administrative and oversight details. Rules are intended to clarify laws or set requirements as specifically dictated by law, not to reiterate</p>



		<p>was is already in the law. Restating the requirements in not necessary.</p> <p><i>Was the rule changed as a result of these comments? No</i></p>
Ch. 246-480 WAC	<p>Comment stated that participation in the drug take-back program should be voluntary for community pharmacies.</p>	<p>RCW 69.48.060 (1) (b) notes that participation in the program by authorized collectors, such as retail pharmacies, is voluntary.</p> <p>The rule does not make any changes to the voluntary participation by authorized collectors.</p> <p><i>Was the rule changed as a result of these comments? No</i></p>
Ch. 246-480 WAC	<p>Comment suggested the drug take-back program should work like other stewardship programs to protect the environment and protect against misuse of drugs.</p>	<p>The statewide drug take-back program is similar to other stewardship programs and does have a focus on protecting Washington waterways and acts as a prevention tool to help reduce the misuse, abuse, and accidental poisoning by prescription and over the counter drugs.</p> <p><i>Was the rule changed as a result of these comments? No</i></p>
Ch. 246-480 WAC	<p>Comment stated that the department should focus on reducing dispensing by empowering prescribing providers to prescribe less.</p> <p>The department should not focus on retrieving medications after they have been dispensed as it would be expensive and not effective.</p>	<p>HB 1427 was enacted in 2017 and directs five health care prescribing boards and commissions (medical, dental, nursing, osteopathic and podiatric) to adopt opioid prescribing rules by January 1, 2019. These five boards and commissions have all since adopted new prescribing standards in an effort to help reduce overall opioid dispensing.</p> <p>Chapter 246-480 WAC and Chapter 69.48 RCW are intended to give Washington residents a safe, secure, and environmentally responsible way to dispose of medications. These efforts, combined with other prevention efforts across the state, are intended to work in tandem to reduce overall medication abuse, misuse, and accidental poisonings.</p>

		<p>This system does not track drugs that have been collected. It is a program that gives patients/Washington residents options for convenient and free ways to return unused medications.</p> <p><i>Was the rule changed as a result of these comments? No</i></p>
Ch. 246-480 WAC	<p>Comment raised concerns about Washington State's status as a sanctuary area. Concerns were also raised about Washington residents and veterans not receiving adequate health care as well as the loss of federal funding for Western State Hospital requiring state residents to make up the shortfall.</p>	<p>Chapter 246-480 WAC does not include regulations around sanctuary cities, veteran and resident access to health care, or the management of Western Hospital. These issue are not germane to this rule or the underlying statute.</p> <p><i>Was the rule changed as a result of these comments? No</i></p>
Ch. 246-480 WAC	<p>Comments raised concerns that this statute will raise drug prices.</p>	<p>Chapter 69.48 RCW established the drug take-back program. Chapter 246-480 WAC simply clarifies administrative areas of the statute and does not change the funding mechanism for the statewide drug take-back program.</p> <p><i>Was the rule changed as a result of these comments? No</i></p>
Ch. 246-480 WAC	<p>Comment supports the proposed appeals process noted in WAC 246-480-050(2), but requests the department extend this appeals process to other sections of Chapter 246-480 WAC.</p>	<p>Chapter 246-10 WAC provides the adjudicative proceeding that can be used for all appeals to department decisions. This process was included in WAC 246-480-050 as reference, but does not mean that chapter 246-10 WAC isn't applicable to the entirety of chapter 246-480 WAC.</p> <p><i>Was the rule changed as a result of these comments? No</i></p>
Ch. 246-480 WAC	<p>Comments expressed general satisfaction with sections WAC 246-480-030; WAC 246-480-040; WAC 246-480-050; WAC 246-480-060; WAC 246-480-080; WAC 246-480-090; WAC 246-480-100</p>	<p>The department appreciates the feedback.</p> <p><i>Was the rule changed as a result of these comments? No</i></p>