



PROPOSED RULE MAKING

CR-102 (July 2022)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

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STATE OF WASHINGTON
FILED

DATE: July 27, 2023

TIME: 2:54 PM

WSR 23-16-071

Agency: Department of Health - Pharmacy Quality Assurance Commission

Original Notice

Supplemental Notice to WSR

Continuance of WSR

Preproposal Statement of Inquiry was filed as WSR 20-17-123 ; or

Expedited Rule Making--Proposed notice was filed as WSR _____; or

Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1); or

Proposal is exempt under RCW _____.

Title of rule and other identifying information: Increasing access to medications used for the treatment of opioid use disorder or its symptoms using remote dispensing sites. The Pharmacy Quality Assurance Commission (commission) is proposing a new section in chapter 246-945 WAC for the implementation of Substitute Senate Bill (SSB) 6086 (chapter 244, Laws of 2020), an act relating to increasing access to medications for OUD. Creating new WAC 246-945-457, Remote dispensing sites for opioid use disorder (OUD) medications.

Hearing location(s):

Date:

Time:

Location: (be specific)

Comment:

10/19/2023

9:20 a.m.

Physical location:
Labor & Industries Building
7273 Linderson Way SW
Tumwater, WA 98501

Virtual:
Please download and import the following iCalendar (.ics) fields to your calendar system.

Daily:
https://us02web.zoom.us/webinar/tZwvcu-orjooGdL0ucE3WWkJLsRorLzko_bx/ics?icsToken=98tyKuGgrD4sGtSUshqBRpw-AI_4M_TziH5BjadxzArmJnNkVQjcGvFwPaBTCtPf

Topic: PQAC Business Meeting 2023

To access the meeting on October 19, 2023 at 9 a.m., go to <https://zoom.us/join> or <https://us02web.zoom.us/j/88256001236> and use the Webinar ID 861 1495 8466

The access options include one tap mobile: US:

	<p>+12532158782,,86114958466# or +16699009128,,86114958466#</p> <p>Or Telephone: Dial(for higher quality, dial a number based on your current location): US: +1 253 215 8782 or +1 669 900 9128 or +1 346 248 7799 or +1 669 444 9171 or +1 386 347 5053 or +1 564 217 2000 or +1 646 558 8656 or +1 646 931 3860 or +1 301 715 8592 or +1 312 626 6799 Webinar ID: 861 1495 8466</p> <p>International numbers available: https://us02web.zoom.us/j/86114958466</p>	
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Date of intended adoption: 10/19/2023 (Note: This is **NOT** the effective date)

<p>Submit written comments to: Name: Joshua Munroe Address: PO Box 47852 Olympia, WA 98504-7852 Email: https://fortress.wa.gov/doh/policyreview Fax: 360-236-2901 Other: N/A By (date) 10/5/2023</p>	<p>Assistance for persons with disabilities: Contact Joshua Munroe Phone: 360-502-5058 Fax: 360-236-2901 TTY: 711 Email: PharmacyRules@doh.wa.gov Other: N/A By (date) 10/12/2023</p>
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Purpose of the proposal and its anticipated effects, including any changes in existing rules:
The Washington state legislature passed SSB 6086, an act relating to increasing access to medications for people with opioid use disorder (OUD). This law allows a pharmacy to extend its pharmacy license to a remote dispensing site where technology is used to dispense medications used for the treatment of OUD or its symptoms.

SSB 6086 requires the commission to adopt rules that establish the minimum standards for OUD medication remote dispensing sites. The minimum standards must address who may access medications at the remote dispensing site pursuant to a valid prescription or chart order. The minimum standards must also require that the pharmacy is responsible for stocking and maintaining a perpetual inventory of the OUD medications stored in or at the remote dispensing site (referred to as the “supplying pharmacy” in the rule language).

Current rules in chapter 246-945 WAC cover requirements for drugs stored outside of a pharmacy but restrict their location to a facility that is otherwise able to store and possess drugs (i.e., a licensed pharmaceutical firm). The proposed rules are necessary to establish enforceable minimum standards as directed by SSB 6086 for OUD medication remote dispensing sites. As the statute specifically requires rulemaking, no other alternatives were considered.

Reasons supporting proposal: The commission is required by SSB 6086 to establish minimum standards for remote OUD medication dispensing sites. Opioid use disorder is a public health crisis and remote dispensing sites registered under this provision have the potential for increased access to treatment and patient care for individuals experiencing OUD.

Statutory authority for adoption: RCW 18.64.005 and Substitute Senate Bill 6086 (chapter 244, Laws of 2020) codified as RCW 18.64.600

Statute being implemented: Substitute Senate Bill 6086 (chapter 244, Laws of 2020) codified as RCW 18.64.600

Is rule necessary because of a:

Federal Law? Yes No

Federal Court Decision? Yes No

State Court Decision? Yes No

If yes, CITATION:

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: None

Type of proponent: Private Public Governmental
Name of proponent: (person or organization) Pharmacy Quality Assurance Commission

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting:	Joshua Munroe	111 Israel Rd SE, Tumwater, WA 98501	360-502-5058
Implementation:	Joshua Munroe	111 Israel Rd SE, Tumwater, WA 98501	360-502-5058
Enforcement:	Marlee O'Neill	111 Israel Rd SE, Tumwater, WA 98501	360-480-9108

Is a school district fiscal impact statement required under [RCW 28A.305.135](#)? Yes No

If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:

Name:
Address:
Phone:
Fax:
TTY:
Email:
Other:

Is a cost-benefit analysis required under [RCW 34.05.328](#)?

Yes: A preliminary cost-benefit analysis may be obtained by contacting:
Name: Joshua Munroe
Address: PO Box 47852 Olympia, WA 98504-7852
Phone: 360-502-5058
Fax: 360-236-2901
TTY: 711
Email: PharmacyRules@doh.wa.gov
Other: N/A

No: Please explain:

Regulatory Fairness Act and Small Business Economic Impact Statement
Note: The [Governor's Office for Regulatory Innovation and Assistance \(ORIA\)](#) provides support in completing this part.

(1) Identification of exemptions:
This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see [chapter 19.85 RCW](#)). For additional information on exemptions, consult the [exemption guide published by ORIA](#). Please check the box for any applicable exemption(s):

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.061](#) because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.
Citation and description:

This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by [RCW 34.05.313](#) before filing the notice of this proposed rule.

This rule proposal, or portions of the proposal, is exempt under the provisions of [RCW 15.65.570\(2\)](#) because it was adopted by a referendum.

- This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025\(3\)](#). Check all that apply:
- | | |
|---|---|
| <input type="checkbox"/> RCW 34.05.310 (4)(b)
(Internal government operations) | <input type="checkbox"/> RCW 34.05.310 (4)(e)
(Dictated by statute) |
| <input type="checkbox"/> RCW 34.05.310 (4)(c)
(Incorporation by reference) | <input type="checkbox"/> RCW 34.05.310 (4)(f)
(Set or adjust fees) |
| <input type="checkbox"/> RCW 34.05.310 (4)(d)
(Correct or clarify language) | <input type="checkbox"/> RCW 34.05.310 (4)(g)
(i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit) |
- This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025\(4\)](#) (does not affect small businesses).
- This rule proposal, or portions of the proposal, is exempt under RCW _____.

Explanation of how the above exemption(s) applies to the proposed rule:

(2) Scope of exemptions: *Check one.*

- The rule proposal is fully exempt (*skip section 3*). Exemptions identified above apply to all portions of the rule proposal.
- The rule proposal is partially exempt (*complete section 3*). The exemptions identified above apply to portions of the rule proposal, but less than the entire rule proposal. Provide details here (consider using [this template from ORIA](#)):
- The rule proposal is not exempt (*complete section 3*). No exemptions were identified above.

(3) Small business economic impact statement: *Complete this section if any portion is not exempt.*

If any portion of the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

- No Briefly summarize the agency's minor cost analysis and how the agency determined the proposed rule did not impose more-than-minor costs.
- Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses and a small business economic impact statement is required. Insert the required small business economic impact statement here:

A brief description of the proposed rule including the current situation/rule, followed by the history of the issue and why the proposed rule is needed. A description of the probable compliance requirements and the kinds of professional services that a small business is likely to need in order to comply with the proposed rule.

The Washington state legislature passed SSB 6086, an act relating to increasing access to medications for people with OUD. This law allows a pharmacy to extend its pharmacy license to a remote dispensing site where technology is used to dispense medications used for the treatment of OUD or its symptoms.

The commission completed a two-and-a-half-year process to consolidate and streamline all rules under its authority related to the practice of pharmacy, effective July 1, 2020. In this rewrite, the commission sought to create a set of rules more adaptable to the future of the practice of pharmacy and the technologies it may employ. As a part of this goal, the new chapter (chapter 246-945 WAC) includes rules related to remote dispensing more generally (see WAC 246-945-430 and 246-945-455). However, under current law, the remote dispensing site would need to hold a license as a pharmaceutical firm (i.e., a pharmacy or health care entity). A pharmacy license is a license of location and extending it to a remote dispensing site was not permitted prior to the enactment of SSB 6086 and therefore the existing rules cannot be applied to this new registration.

SSB 6086 requires the commission to adopt rules establishing the minimum standards for OUD medication remote dispensing sites. The minimum standards must include, but are not limited to, specifying who may retrieve the OUD medications stored in or at the dispensing site, and requiring the pharmacy be responsible for stocking and maintaining a perpetual inventory of the OUD medications stored in or at the remote dispensing site.

The proposed rule achieves these minimum standards set in the bill by requiring pharmacies to comply with the following, in addition to all applicable regulations in Title 21 of the Code of Federal Regulations:

- 1) The supplying pharmacy must separately register each remote dispensing site with the commission by completing and returning an application form supplied by the commission and pay applicable fees established by the Secretary.
- 2) Medications stored in registered remote dispensing sites shall remain under the control of, and be routinely monitored by, the supplying pharmacy.
- 3) The supplying pharmacy shall develop and implement policies and procedures to:
 - a) Prevent and detect unauthorized access to the registered remote dispensing site;
 - b) Document medications used, returned, and wasted from the registered remote dispensing site;

- c) Require the supplying pharmacy to perform a perpetual inventory of medications stored at the registered remote dispensing site; and
 - d) Ensure that only the supplying pharmacy is stocking medications stored at a registered remote dispensing site.
- 4) Access and retrieval of medications from the registered remote dispensing site, other than by the supplying pharmacy, must be:
- a) Pursuant to a valid prescription or chart order; and
 - b) Limited to health care professionals licensed under the chapters specified in RCW 18.130.040 who are acting within their scope of practice, and nursing students as provided in WAC 246-945-450.
- 5) The supplying pharmacy shall ensure the registered remote dispensing site is appropriately equipped to secure and protect medications from diversion or tampering.

Pharmacies that choose to participate in the program must secure and regularly monitor medications stored in remote dispensing sites. Supplying pharmacies must also develop and implement policies establishing their own security, documentation and inventory standards. Finally, these pharmacies must also provide security measures to protect medications from diversion or tampering in line with their own security policies and procedures.

The application to register an OUD medication remote dispensing site has been available since July 1, 2020, accompanied by a policy statement outlining the commission’s expectations for compliance, but the proposed rule is necessary to codify the minimum standards applicable to OUD medication remote dispensing sites so that the requirements are enforceable.

After the commission approved the proposed rule language for remote OUD dispensing sites, the Washington legislature passed Second Engrossed Second Substitute Senate Bill (2E2SSB) 5536 (chapter 1, Laws of 2023 1st Special Session). 2E2SSB 5536 amended RCW 18.64.600 to update the phrase “medications approved by the United States food and drug administration for the treatment of opioid use disorder” to “medications used for the treatment of opioid use disorder or its symptoms.” Commission staff updated the proposed remote OUD dispensing site rule language draft and presented it on June 15, 2023 at a commission business meeting. The commission moved to accept the updated language.

Identification and summary of which businesses are required to comply with the proposed rule using the North American Industry Classification System (NAICS).

SBEIS Table 1. Summary of Businesses Required to comply to the Proposed Rule

NAICS Code (4, 5 or 6 digit)	NAICS Business Description	Number of businesses in Washington State	Minor Cost Threshold = 1% of Average Annual Payroll
44611	Pharmacies	885	\$5,794.56

The NAICS code provided for pharmacies in Washington state is the code from 2017. While an updated code exists as of 2022 (456110), there is not yet data to establish a minor cost threshold for the 2022 code. As a result, the next most recent code from 2017 was used for the purpose of providing accurate minor cost thresholds which pulls payroll and gross business income data from 2020.

Analysis of probable costs of businesses in the industry to comply to the proposed rule and includes the cost of equipment, supplies, labor, professional services, and administrative costs. The analysis considers if compliance with the proposed rule will cause businesses in the industry to lose sales or revenue.

WAC 246-945-247 Remote dispensing sites for opioid use disorder medications.

Description:

The proposed rule provides a regulatory framework in which pharmacies may choose to use a remote dispensing site to make medications to treat OUD and its symptoms available to the public. Participating pharmacies will need to acquire and maintain a dispensing machine or structure, provide security for said machine or structure, develop policies and procedures for managing the remote OUD dispensing site, and maintain a perpetual inventory of the OUD medications stored in or at the dispensing site.

Cost(s):

For a business to implement an OUD remote dispensing site registered under SSB 6086 and in compliance with WAC 246-945-457, there may be both initial one-time costs as well as annual recurring costs. One-time costs are defined as costs that occur only once. Annual recurring costs are costs that are anticipated to repeat every year.

One-time costs: In order to dispense OUD medications remotely, the proposed rule requires a dispensing machine or structure where the medications are stored. Dispensing systems vary widely and range in one-time cost from \$1,000 to \$38,000^{1,2} due to the amount of technology incorporated into the dispensing function. The dispensing system technology is used to dispense designated medication and can be as simple as a secure storage container or cabinet which authorized personnel can retrieve medications from or could be a fully automated system including automated dispensing. Recent installations of vending machines in Eastern Washington capable of dispensing naloxone specifically priced the machines at \$5,000 each.³ Another option is to rent a dispensing system, which range in cost from \$50 to \$150⁴ in recurrent monthly costs (or a recurrent annual cost of \$600 to \$1,800) and would not be a one-time cost but a recurrent cost.

The physical location and security of remote OUD dispensing devices could result in different costs for each business. It is the responsibility of the supplying pharmacy to ensure that the location and the level of security are appropriate to the drugs that are being stored. As an example for naloxone, some entities implementing remote OUD dispensing devices placed and may place these devices immediately outside of public buildings⁵ or even in the lobbies of buildings where there is an access need for such substances⁶. Individual businesses may choose to keep their own dispensing devices outside and/or further away from their physical business site. While devices solely dispensing naloxone would not need a license from the commission, but devices registered under this credential may include naloxone among other medications used for the treatment of OUD or its symptoms.

Remote placement could result in more comprehensive security measures to comply with WAC 246-945-457(2) which states that pharmacies using remote OUD dispensing sites must ensure medications stored on those sites “remain under the control of, and be routinely monitored by, the supplying pharmacy.” The means of monitoring the sites is not specified in rule, meaning that pharmacies may elect to use security camera systems—which cost about \$200 on average for an outdoor camera system⁷ (not including upkeep costs)—or even additional security personnel to comply with the proposed rule.

Staff time will be needed to comply with the proposed rule to develop policies and procedures. This work would likely be done by the responsible pharmacy manager. The median salary for pharmacists (who serve as pharmacy managers) is approximately \$80/hour in Washington state⁸. The commission estimates that writing these policies and procedures will take between 3 and 10 hours, assuming the pharmacy has other policies and procedures in place that they can base the new ones off. The commission estimates that writing all policy and procedures documents would range in cost from \$240 to \$800.

The commission assumes there are potential unknown one-time costs related to the security needs of the remote dispensing site—security cameras and/or locks—as required by the statute and proposed rule. These costs would be largely dependent on the type of dispensing system used and how much security is already incorporated into the dispensing machine or structure where the medications are stored.

Annual Recurring costs: The commission estimates that completing the registration form will take one hour per year and will be completed by the responsible pharmacy manager (who earns approximately \$80/hour in Washington state).

Staff time will be needed to maintain and stock the remote dispensing site. The commission estimates this task could take 1-2 hours each month, or 12-24 hours per year. As this is a nondiscretionary task, it may be delegated per WAC 246-945-315 and performed either by a pharmacist or by a pharmacy intern or technician under the immediate supervision of a pharmacist.

¹ Smith, A. (2021). *How much does a vending machine service cost?* Costowl.com <https://www.costowl.com/b2b/office-vending-machine-service-cost.html>

² ModeSens. (2021). *Moet & Chandon*. Modesens.com. https://modesens.com/product/moet-and-chandon-mo-and-eumlt-and-chandon-champagne-vending-machine-30102308/?country=us&language=en&refinfo=gSH_ggfMoetChanduh-HoGaKiDi30102308

³ [Narcan vending machines? Moses Lake and Wenatchee now have them; Omak is next | Columbia Basin | ifiberone.com](#)

⁴ Smith, A. (2021). *How much does a vending machine service cost?* Costowl.com <https://www.costowl.com/b2b/office-vending-machine-service-cost.html>

⁵ [Philadelphia opioid use: New program provides access to free Narcan in vending machines - 6abc Philadelphia](#)

⁶ [Naloxone vending machines make life-saving medication easily available in Michigan jails and communities - Center for Behavioral Health and Justice - Wayne State University](#)

⁷ [How Much Do Security Cameras Cost on Average in 2022](#)

⁸ Salary.com (2021, October 29). *Pharmacy Manager salary in Washington*. Salary.com. <https://www.salary.com/research/salary/benchmark/pharmacist-manager-salary/wa>. Salary figures determined from selecting the occupation and searching by annual salaries in Washington State, reporting median.

The median salary for pharmacy interns and pharmacy technicians in Washington state is \$19/hour⁹. The median salary for pharmacists is \$80/hour in Washington state¹⁰. The commission estimates this could cost between \$228 to \$2,184 annually. The upper end of the estimated range accounts for the possibility that the pharmacy technician is working concurrently with the supervising pharmacist on maintenance and stocking, requiring a sum of both positions' median wages.

Subsection (4) of the proposed language focuses on patient access of the remote OUD site and retrieval of medications held and dispensed at that site. There are no anticipated additional costs to the patient as the access and retrieval of OUD medications would not be different between visiting a remote dispensing site and a pharmacy site.

Summary of all Cost(s)

SBEIS Table 2. Summary of Section 3 probable cost(s)

WAC Section and Title	Probable Cost(s)
WAC 246-945-457 Remote dispensing sites for opioid use disorder medications	<ul style="list-style-type: none"> • One-time costs: <ul style="list-style-type: none"> ○ Dispensing device (purchase): \$1,000 - \$38,000 ○ Policies and procedures: \$240 - \$800 ○ Security (cameras and locks): \$200 • Annual recurring costs <ul style="list-style-type: none"> ○ Registration form (time): \$80 ○ Stocking and maintaining (time): \$228 - \$2,184 ○ Dispensing device (rental): \$600 - \$1,800

*Table columns are not intended to be summed as some costs are duplicative (e.g., dispensing device (purchase) and dispensing device (rental fee)).

The commission does not anticipate compliance with the proposed rule will cause businesses to lose any sales or revenue. The commission believes that by allowing a pharmacy to choose (by way of this proposed rule) to extend their licenses to register OUD medication remote dispensing sites, both sales and revenue could potentially increase.

Analysis on if the proposed rule may impose more than minor costs for businesses in the industry. Includes a summary of how the costs were calculated.

The estimated costs of the proposed rule may exceed the minor cost threshold for businesses.

Summary of how the costs were calculated

The minor cost threshold for pharmacies as of 2020 is \$5,794.56, based on 1% of Average Annual Payroll as calculated by data collected by the U.S. Bureau of Labor Statistics (SBEIS Table 1.). SBEIS Table 3 is a summary of first year costs per business.

SBEIS Table 3. Summary of Probable Costs per Business

	Probable Minimum Cost	Probable Maximum Cost
One-time costs (not including dispensing device)	\$240	\$800
Annual Recurring costs (not including dispensing device)	\$308	\$2,264
Dispensing device options		
Dispensing device (purchase); Total cost	\$1,000	\$38,000
Dispensing device (purchase); Depreciated* annual cost (12 years) ¹¹	\$83	\$3,167

⁹ Salary.com (2021, October 29). *Pharmacy Technician salary in Washington*. Salary.com. <https://www.salary.com/research/salary/benchmark/pharmacy-technician-i-salary/wa>. Salary figures determined from selecting the occupation and searching by annual salaries in Washington State, reporting median.

¹⁰ Salary.com (2021, October 29). *Pharmacist salary in Washington*. Salary.com. <https://www.salary.com/research/salary/benchmark/pharmacist-salary/wa>. Salary figures determined from selecting the occupation and searching by annual salaries in Washington State, reporting median.

¹¹ Vendsoft. "most vending machines last 12 to 24 years," accessed July 18, 2022. [10 mistakes of a novice vending machine operator - VendSoft](#)

Dispensing device (purchase); Depreciated* annual cost (24 years)	\$42	\$1,583
Dispensing device (annual rental)	\$600	\$1,800
First year costs		
Probable first year costs** with PURCHASE of dispensing device (12 years)	\$631	\$6,231
Probable first year costs** with PURCHASE of dispensing device (24 years)	\$590	\$4,647
Probable first year costs** with RENTAL of dispensing device	\$1,148	\$4,864

*Straightline depreciation for equipment purchase was conducted by (device purchase cost – salvage value) / useful life years to get the annual depreciation. Salvage value was assumed at \$0. After calculating, figures were rounded up to the nearest dollar. Purchase price does not include the cost of maintenance or repair.

**First year costs were calculated by adding the one-time costs + one year of annual recurring costs + dispensing device option specified.

Based on the cost analysis conducted in above (SBEIS Table 2) and (SBEIS Table 3) it is possible (although the commission believes unlikely) that pharmacies may exceed the minor cost threshold of \$5,794.56 if they decide to purchase a dispensing device, that has a life expectancy of 12 years, which result in \$6,231 in the first year, to comply with the proposed rule.

Determination on if the proposed rule may have a disproportionate impact on small businesses as compared to the 10 percent of businesses that are the largest businesses required to comply with the proposed rule.

Based on the reported cost range for securing the OUD dispensing unit and providing security for that unit, we believe the proposed rule may have a disproportionate impact on small businesses as compared to the 10 percent of businesses that are the largest businesses required to comply with the proposed rule.

Explanation of the determination

The commission acknowledges that, as with any regulatory proposal that features some financial cost, there could be additional impacts on smaller businesses due to factors such as community need, geographical location¹², and demands on pharmacy personnel to ensure compliance. The costs of acquiring dispensing units have a broad range and the commission feels it is unlikely that pharmacies would need to pursue the more costly options in terms of unit acquisition and security measures. However, some smaller businesses may determine that they must explore the higher cost options for the purpose of complying with the regulations established by the commission in order to guarantee the integrity of the dispensing unit and ensure the medications are kept secure for individuals that would benefit from the service.

If the proposed rule has a disproportionate impact on small businesses, the following steps have been identified and taken to reduce the costs of the rule on small businesses.

1. **Reducing, modifying, or eliminating substantive regulatory requirements;**
2. **Simplifying, reducing, or eliminating recordkeeping and reporting requirements;**
3. **Reducing the frequency of inspections;**
4. **Delaying compliance timetables;**
5. **Reducing or modifying fine schedules for noncompliance; or**
6. **Any other mitigation techniques including those suggested by small businesses or small business advocates.**

If costs cannot be reduced an explanation has been provided below about why the costs cannot be reduced.

1. The regulatory requirements established both by the passage of SSB 6086 and the commission cannot be reduced, modified, or eliminated. Doing so would either violate statute or negatively affect the safety, integrity, and security of the OUD medications to be provided by this rulemaking.

¹² [Nearly half a million Washingtonians live in pharmacy deserts | Urban@UW](#)

2. The recordkeeping and reporting requirements are necessary to register and track participating pharmacies. The costs incurred by filing paperwork and establishing policies and procedures represent a small percentage of the reported costs. Compliance with the commission's rules also facilitate compliance with DEA requirements for these sites. Additionally, the requirement for the pharmacy to maintain a perpetual inventory for the remote dispensing site is in the statute and the commission's rule cannot loosen that requirement.
3. Inspection frequency cannot be reduced but the inspection time and costs would not change by any notable amount for participating pharmacies. Inspections are based on the pharmacy itself and the remote OUD site is technically part of that pharmacy due to the licensing requirements. Delaying inspections of the site would mean delaying inspections of the pharmacy which would negatively impact patient safety.
4. Compliance timetables are not a concern for the commission considering the OUD dispensing site program is voluntary and pharmacies may choose to participate at a time of their convenience.
5. There are no plans to reduce or modify fine schedules for noncompliance. The commission's ability to impose fines is limited by statute.
6. The majority of the commission's identified mitigation techniques involve communicating to licensees that the financial cost for compliance in the remote OUD dispensing site program is tied to providing both a dispensing unit and security for that unit. The commission could then inform smaller businesses about more cost-effective options for dispensing unit and security prices that would fall well under the minor cost threshold reported in Section 2 of this document.

The commission will not take action against licensees solely on the amount of financial investment undertaken by the licensee to establish the units. Inspectors will value compliance with the rule equally, regardless of the cost the licensee took on to comply. Inspectors will also provide technical assistance on how to comply with the rule through various means.

It is also important to let licensees know that, as reported in a prior section, the type of dispensing device does not affect the quality of the product delivered to individuals. Inspectors may also provide technical assistance to help pharmacies with compliance matters as needed.

Description of how small businesses were involved in the development of the proposed rule.

The commission conducted an initial rules workshop for interested parties at the October 1, 2020 business meeting. In the weeks preceding the workshop, the commission sent public notice to interested parties via GovDelivery, soliciting preliminary feedback prior to the October meeting. One comment in general support of the rulemaking was received by the Olympia Bupe Clinic, the entity that helped develop the language for SSB 6086.

The estimated number of jobs that will be created or lost in result of the compliance with the proposed rule.

The proposed rule is about remote dispensing sites where technology is used to dispense OUD medications, so the commission does not anticipate pharmacies adding or removing jobs at existing pharmacies. This rule does allow pharmacies to add a remote dispensing site where technology is used to dispense medications for the treatment of OUD and its symptoms. If a pharmacy elects to add one of these sites, they may be able to dispense these medications with less staff persons than through alternate license pathways.

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

Name: Joshua Munroe
Address: PO Box 47852 Olympia, WA 98504-7852
Phone: 360-502-5058
Fax: 360-236-2901
TTY: 711
Email: PharmacyRules@doh.wa.gov
Other: N/A

Signature:

Place signature here

Date: 7/27/2023

Name: Kenneth Kenyon, PharmD, MBA

Title: Pharmacy Quality Assurance Commission Chair

A handwritten signature in black ink that reads "Ken Kenyon". The signature is written in a cursive, slightly slanted style. The first "Ken" is written with a large, sweeping "K" that loops back. The second "Kenyon" is written with a similar "K" and a more fluid, connected "enyon".

NEW SECTION

WAC 246-945-457 Remote dispensing sites for opioid use disorder medications. A pharmacy may extend its license to register a remote dispensing site where technology is used to dispense medications used for treatment of opioid use disorder or its symptoms. A pharmacy using this registration is the supplying pharmacy and must comply with subsections (1) through (5) of this section and all applicable regulations in Title 21 of the Code of Federal Regulations.

(1) The supplying pharmacy must separately register each remote dispensing site with the commission by completing and returning an application form supplied by the commission and pay applicable fees established by the secretary.

(2) Medications stored in registered remote dispensing sites shall remain under the control of, and be routinely monitored by, the supplying pharmacy.

(3) The supplying pharmacy shall develop and implement policies and procedures to:

(a) Prevent and detect unauthorized access to the registered remote dispensing site;

(b) Document medications used, returned, and wasted from the registered remote dispensing site;

(c) Require the supplying pharmacy to perform a perpetual inventory of medications stored at the registered remote dispensing site; and

(d) Ensure that only the supplying pharmacy is stocking medications stored at a registered remote dispensing site.

(4) Access and retrieval of medications from the registered remote dispensing site, other than by the supplying pharmacy, must be:

(a) Pursuant to a valid prescription or chart order; and

(b) Limited to health care professionals licensed under the chapters specified in RCW 18.130.040 who are acting within their scope of practice, and nursing students as provided in WAC 246-945-450.

(5) The supplying pharmacy shall ensure the registered remote dispensing site is appropriately equipped to secure and protect medications from diversion or tampering.