



PROPOSED RULE MAKING

CR-102 (June 2024)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

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STATE OF WASHINGTON
FILED

DATE: August 08, 2024

TIME: 8:19 AM

WSR 24-17-006

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 23-01-111; 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: (describe subject) Expanding access to drugs stored outside of the pharmacy by unlicensed health care facility staff. The Pharmacy Quality Assurance Commission (commission) is proposing to amend WAC 246-945-455 which currently limits access to drugs stored outside of the pharmacy to only licensed health care professionals and may disrupt supply chain management in health care facilities.

Hearing location(s):

Date:	Time:	Location: (be specific)	Comment:
October 10, 2024	9:30 am	Physical Location: Department of Labor & Industries Room S117/118 7273 Linderson Way SW Tumwater, WA 98501 Virtual Location: Zoom Register in advance for this webinar at: https://us02web.zoom.us/j/87143495001 After registering, you will receive a confirmation email containing information about joining the webinar.	The commission will hold a hybrid hearing. Attendees are welcome to attend either in-person at the physical location or virtual via Zoom.

Date of intended adoption: 10/10/2024 (Note: This is **NOT** the **effective** date)

Submit written comments to:

Name Haleigh Mauldin
Address PO Box 47852, Olympia, WA 98504-7852
Email <https://fortress.wa.gov/doh/policyreview/>
Fax 360-236-2260
Other None

Beginning (date and time) The date and time of this filing
By (date and time) October 4, 2024 at midnight

Assistance for persons with disabilities:

Contact Haleigh Mauldin
Phone 360-890-0720
Fax 360-236-2260
TTY 711
Email PharmacyRules@doh.wa.gov
Other None

By (date) October 1, 2024

Purpose of the proposal and its anticipated effects, including any changes in existing rules: Prior to the commission's rules rewrite in 2020, WAC 246-873-070(3) permitted the director of a pharmacy at a hospital to "designate in

writing, by title and/or position those individuals who shall be authorized access to particular areas within the pharmacy, including authorization of access to keys and/or combinations." This provision was removed in the rules rewrite process. The current WAC 246-945-455(1)(c) reads, "Access [to drugs stored outside of the pharmacy] must be limited to health care professionals licensed under the chapters specified in RCW 18.130.040 acting within their scope..."

Under WAC 246-945-455(1)(c), unlicensed staff responsible for supporting supply chain management as a part of their scope of employment are not able to access certain drugs such as over-the-counter drugs or IV fluids, among others, without obtaining a health profession credential listed in RCW 18.130.040. The commission was informed of unintended disruption to the drug supply chain within institutional facilities by requiring only licensed health care professionals to access drugs stored outside of the pharmacy.

The proposed rule codifies guidance from the commission stating that unlicensed employees or contractors of a health care facility may access drugs listed in the facility's policies and procedures that are stored outside of the pharmacy in a designated area when they are acting within their scope of employment for the purposes of supply chain management. This proposal intends to reduce unintended disruption of facility supply chain management causing administrative burden on health care facilities and increase patient safety by releasing licensed staff to focus on patient care.

Reasons supporting proposal: As it is currently written, WAC 246-945-455 disrupts and puts strain on an already overwhelmed supply chain, unintentionally limiting access to patient care. Reducing strain on the supply chain within licensed facilities could protect patient and public health, safety, and welfare by allowing unlicensed employees or contractors to complete supply chain tasks so that licensed healthcare providers can engage in patient care. The proposed rules are needed for unlicensed staff to access drugs stored outside of the pharmacy to allow licensed staff to focus on patient care.

Statutory authority for adoption: RCW 18.64.005, RCW 69.41.075, and RCW 69.50.301

Statute being implemented: RCW 18.64.005

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

Name of proponent: (person or organization) Pharmacy Quality Assurance Commission

Type of proponent: Private. Public. Governmental.

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting	Haleigh Mauldin	111 Israel Rd SE, Tumwater, WA 98501	360-890-0720
Implementation	Haleigh Mauldin	111 Israel Rd SE, Tumwater, WA 98501	360-890-0720
Enforcement	Marlee B. 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 Haleigh Mauldin
 - Address PO Box 47852, Olympia, WA 98504-7852
 - Phone 360-890-0720

Fax 360-236-2260
TTY 711
Email PharmacyRules@doh.wa.gov
Other None

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.

SECTION 1

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.

On July 1, 2020, 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. In this rewrite, chapter 246-945 WAC was created, which includes WAC 246-945-455 that contains rules pertaining to drugs stored outside of a pharmacy. Previously, WAC 246-873-070(3) permitted the director of pharmacy at a hospital to "designate in writing, by title and/or position those individuals who shall be authorized access to particular areas within the pharmacy, including authorization of access to keys and/or combinations". This provision was removed in the chapter rewrite process. The current WAC 246-945-455(1)(c) reads, "Access [to drugs stored outside of

the pharmacy] must be limited to health care professionals licensed under the chapters specified in RCW 18.130.040 acting within their scope".

Under WAC 246-945-455(1)(c), unlicensed staff responsible for supporting supply chain management as a part of their scope of employment are not able to access certain drugs such as over-the-counter drugs or IV fluids—among others—without obtaining a health profession credential listed in RCW 18.130.040. The commission was informed of unintended disruption to the drug supply chain within institutional facilities by requiring only licensed health care professionals to access drugs stored outside of the pharmacy. In response, the commission determined in a guidance document that it would not find licensees deficient or take enforcement actions against licensees for violations of WAC 246-945-455(1)(c) if the following conditions are met:

- The unlicensed employee of a health care facility is operating within the scope of their employment;
- The unlicensed employee is only accessing drugs for the purposes of supply chain management within the health care facility;
- The unlicensed employee is only accessing drugs listed in a policy and procedure that is in a readily retrievable form;
- The unlicensed employee cannot access controlled substances under any circumstances or access drug products as part of dispensing a prescription or order; and
- The pharmacy meets all other requirements of WAC 246-945-455 and applicable laws.

The proposed rule language would codify the guidance the commission provided on access to drugs stored outside the pharmacy by unlicensed staff and review whether there are other unintended disruptions from WAC 246-945-455(1)(c) within health care facilities. The proposed rule also incorporates feedback received from interested parties since the guidance document went into effect.

Compliance with this rule would require a health care facility choosing to allow unlicensed staff to have access to drugs stored outside of the pharmacy to develop new policies, procedures, and training that detail scopes of employment and list drugs that will be accessed. The initial development of these documents would likely be a one-time cost that would require staff time and consultation with other relevant professions.

SECTION 2

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
446110	Pharmacies and Drug Stores	267*	\$19,161

*The Employment Security Department (ESD) reported 267 businesses categorized as Pharmacies and Drug Stores, but Department of Health staff reported the number of pharmacies as of April 2024, with 1,283 facilities being standalone pharmacies and 110 facilities being hospital pharmacies.

SECTION 3

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 246-945-455 Drugs stored outside of the pharmacy.

Description: WAC 246-945-455 states that each staff member of a healthcare facility must obtain at least a license of a health care professional listed in RCW 18.130.040 to be able to access drugs that are stored outside of the pharmacy for supply chain management within the facility. This requirement created unintended disruptions to the drug supply chain within healthcare facilities because historical practices permitted unlicensed employees of a health care facility to access certain drug products for supply chain management needs.

The proposed rule would provide a framework for unlicensed staff responsible for supply chain management to access drugs store outside of the pharmacy under certain conditions. Health care facilities that choose to allow this will need to develop policies, procedures, and conduct necessary training for unlicensed employees.

Cost(s): A health care facility choosing to allow unlicensed staff to have access to drugs stored outside of the pharmacy must develop new policies and procedures detailing scopes of employment and listing drugs that will be accessed. In addition to the development of new policies and procedures, health care facilities will need to train staff on the policies and procedures.

The guidance document, *Access to Drugs Stored Outside of the Pharmacy*, states that licensees would not be found deficient and the commission would not take enforcement action for violations as long as certain conditions are met. The conditions outlined in the guidance document are reflected in the proposed rule. One of the conditions in the guidance document, required licensees utilizing the guidance to have policies and procedures that lists the accessible drugs.

The process of creating new policies, procedures, and training would produce the majority of costs for the adoption of this rule. These documents would likely be developed by the responsible pharmacy manager. Commission staff estimate that the hours needed to develop adequate policies and procedures would be around 2-4 hours for conceptualization, 2-4 hours to review, 2-4 hours for other revisions or improvements, and 2-4 hours to create training modules to inform staff members with varying backgrounds and knowledge levels on the updated policies and procedures¹.

In Washington state the median wage for a responsible pharmacy manager is \$63.82² per hour. The hourly rate was then multiplied by 16 which encompasses the maximum hours estimated for development: 4 hours for conceptualization, 4 hours of revision, 4 hours of review, and 4 hours of training development. This would bring the total for a health care facility's compliance for this rule to be a maximum of \$1,021.12 for developing new policies and procedures. However, it is likely that some healthcare facilities that faced supply chain disruption have already developed new policies and procedures to meet the requirements in the guidance document, *Access to Drugs Stored Outside of the Pharmacy*.

The initial development of the policies and procedures is likely a one-time cost with smaller cost associated with updating, if necessary. To reduce costs, certain steps in the development process for new policies and procedures could be delegated to non-management personnel. Delegating parts of the conceptualization, drafting, and revisions to non-management staff could reduce some of the costs associated with labor. Parts of the process could be developed by a pharmacist, materials handler, administrative staff, and staff nurse, or other qualified personnel, then reviewed and finalized by management staff.

Summary of all Cost(s)

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

WAC Section and Title	Probable Cost(s)
WAC 246-945-455 Drugs stored outside of the pharmacy	<ul style="list-style-type: none">• Policies, Procedures, and Training Development \$1,021.12

The commission determined that the overall benefits of reducing unintended disruption of facility supply chain management causing administrative burden on health care facilities and increasing patient safety by releasing licensed staff to focus on patient care outweigh the cost of developing policies, procedures, and training.

SECTION 4

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.

No, the costs of the proposed rule \$1,021.12 are less than the minor cost threshold \$19,161.00.

Summary of how the costs were calculated

The costs of compliance for this rule were calculated by multiplying the salary of the responsible pharmacy manager which was \$63.82 per hour by the 16 hours needed for conceptualization, review, revisions, and training development. The maximum total cost of compliance for this rule was determined to be \$1,021.12.

¹ Time range determined via consultation with the staff pharmacist consultant, who is a licensed pharmacist.

² Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Employment and Wage Statistics*, Pharmacists, at <https://www.bls.gov/oes/current/oes291051.htm> (visited March 25, 2024).

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:

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

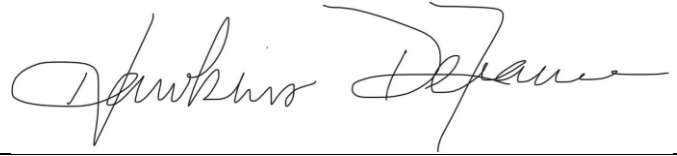
Name Haleigh Mauldin
Address PO Box 47852, Olympia, WA 98504-7852
Phone 360-890-0720
Fax 360-236-2260
TTY 711
Email PharmacyRules@doh.wa.gov
Other None

Date: August 7, 2024

Name: Hawkins DeFrance, PharmD

Title: Pharmacy Quality Assurance Commission Chair

Signature:



WAC 246-945-455 Drugs stored outside of the pharmacy. (1) In order for drugs to be stored in a designated area outside the pharmacy including, but not limited to, floor stock, in an emergency cabinet, in an emergency kit, or as emergency outpatient drug delivery from an emergency department at a registered institutional facility, the following conditions must be met:

(a) Drugs stored in such a manner shall remain under the control of, and be routinely monitored by, the supplying pharmacy;

(b) The supplying pharmacy shall develop and implement policies and procedures to prevent and detect unauthorized access, document drugs used, returned and wasted, and regular inventory procedures;

(c) Access to drugs stored in a designated area outside of the pharmacy must be limited to health care professionals licensed under the chapters specified in RCW 18.130.040 acting within their scope, and nursing students as provided in WAC 246-945-450, except as provided in subsection (2) of this section;

(d) The designated area is appropriately equipped to ensure security and protection from diversion or tampering; and

(e) The designated area must be located in a facility ((is-able)) licensed or otherwise authorized by law to possess and store drugs.

(2) An unlicensed employee or contractor of the receiving facility may access drugs stored in the designated area if all of the following are met:

(a) The unlicensed employee or contractor is acting within their scope of employment or contract;

(b) The unlicensed employee or contractor is accessing drugs for the purpose of supply chain management at the receiving facility;

(c) The unlicensed employee or contractor is only accessing drugs listed in a policy and procedure that is readily retrievable by the supplying pharmacy; and

(d) The unlicensed employee or contractor is not accessing controlled substances.

(3) For nursing homes and hospice programs an emergency kit or supplemental dose kit must comply with RCW 18.64.560.