



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: June 05, 2025

TIME: 9:03 AM

WSR 25-13-005

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 25-05-060; 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: Inspection Requirements for Modifications or Remodels. The Pharmacy Quality Assurance Commission (commission) is proposing to amend WAC 246-945-230 to clarify circumstances necessitating a remodel inspection due to pharmaceutical facility modifications or remodels.

Hearing location(s):

| Date: | Time: | Location: (be specific) | Comment: |
|------------|----------|---|--|
| 08/14/2025 | 10:30 am | <p>Department of Labor & Industries 7273 Linderson Way SW Tumwater, WA 98501</p> <p>Virtual Location: Virtual: To access the meeting on February 6, 2025 at 9:30 am, go to https://us02web.zoom.us/j/86309299195 or https://zoom.us/join and use the Webinar ID 863 0929 9195 The access options include one tap mobile: +12532158782,,86309299195# US (Tacoma) +12532050468,,86309299195# US Or Telephone: Dial (for higher quality, dial a number based on your current location): +1 253 215 8782 US (Tacoma) +1 253 205 0468 US</p> | <p>The commission will hold a hybrid hearing. Attendees are welcome to attend either in-person at the physical location or virtual via Zoom.</p> |

Date of intended adoption: 08/14/2025 (Note: This is **NOT** the effective date)

Submit written comments to:

Name: Julia Katz

Address: PO Box 47852, Olympia, WA 98504-7852

Assistance for persons with disabilities:

Contact: Julia Katz

Phone: 360-236-4946

Email: PharmacyRules@doh.wa.gov

Fax: 360-236-2260

Other: <https://fortress.wa.gov/doh/policyreview/>

Beginning (date and time): The date and time of this filing

By (date and time): 07/31/2025 at 11:59 pm

Fax: 360-236-2260

TTY: 711

Email: PharmacyRules@doh.wa.gov

Other: None

By (date): 07/31/2025

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The purpose of the proposal is to amend WAC 246-945-230 to clarify circumstances necessitating a remodel inspection due to pharmaceutical facility modifications or remodels. As currently written, WAC 246-945-230(3)(a) states, "[a] modification or remodel of a pharmacy location includes changes to a previously approved area, room or pharmacy building which result in changes to the pharmacy that affects security, square footage, access to drugs, compounding or necessitates temporary relocation of pharmacy services." The proposed rule amends WAC 246-945-230 by moving this sentence from WAC 246-945-230(3)(a) to WAC 246-945-230(1)(e) and adding the following definitions to WAC 246-945-230(1) relating to remodel inspections: "Physical change," "functional change," and "modifications or remodels."

Reasons supporting proposal: Commission staff received feedback from interested parties about challenges discerning which modifications and remodels of licensed pharmaceutical facilities require notifying the commission and paying a facility inspection fee per WAC 246-945-230(3)(a). The commission voted to propose rulemaking to address the uncertainties at the December 12, 2024, business meeting.

Statutory authority for adoption: RCW 18.64.005

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 | Julia Katz | 111 Israel Rd SE, Tumwater, WA 98501 | 360-236-4946 |
| Implementation | Julia Katz | 111 Israel Rd SE, Tumwater, WA 98501 | 360-236-4946 |
| 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

Address

Phone

Fax

TTY

Email

Other

☒ No: Please explain: Proposed amendments to WAC 246-945-230(1) and WAC 246-945-230(3)(a) are exempt per RCW 34.05.328(5)(b)(iv) because the added definitions and removed language clarifies language of a rule without changing its effect.

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:

☐ [RCW 34.05.310](#) (4)(b)
(Internal government operations)

☐ [RCW 34.05.310](#) (4)(e)
(Dictated by statute)

☐ [RCW 34.05.310](#) (4)(c)
(Incorporation by reference)

☐ [RCW 34.05.310](#) (4)(f)
(Set or adjust fees)

☒ [RCW 34.05.310](#) (4)(d)
(Correct or clarify language)

☐ [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: The proposed rule language clarifies language of WAC 246-945-230 without changing its effect.

(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:

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

Name

Address

Phone

Fax

TTY


Email
Other

Date: June 5, 2025

Name: Hawkins DeFrance, PharmD

Title: Pharmacy Quality Assurance Commission Chair

Signature:

A handwritten signature in dark ink, appearing to read "Hawkins DeFrance", written in a cursive style.

WAC 246-945-230 General information, change of location, ownership or new construction. (1) The definitions in this subsection apply throughout WAC 246-945-230 through 246-945-247 unless otherwise specified:

(a) "License" includes "licensing," "licensure," "certificate," "certification," and "registration."

(b) "Facility" includes pharmacies, nonresident pharmacies, health care entities, hospital pharmacy associated clinics, wholesalers, and manufacturers.

(c) "Physical change" or "physical changes" are alterations to a previously approved space, including:

(i) Changes to structural element(s), such as walls, floors, and load bearing elements, or changes impacting square footage that negatively impact security as determined by the facility;

(ii) Changes to access to drugs or devices that negatively impact security as determined by the facility;

(iii) Changes that necessitate temporary relocation of pharmacy services; or

(iv) Addition of, or functional changes to, a compounding space.

(d) "Functional change" or "functional changes" are alterations to the intended purpose of the previously approved space, including repurposing a previously approved compounding space for a different function, such as conversion of a nonhazardous to a hazardous compounding space.

(e) "Modifications or remodels" are any physical changes or functional changes to a previously approved area, building, room, or compounding space of a facility. Facility changes due to routine maintenance or changes to equipment are not modifications or remodels, unless they are physical changes or functional changes.

(2) The commission shall license a facility that:

(a) Submits a completed application for the license applied for on forms provided by the commission;

(b) Pays the applicable fees in accordance with WAC 246-945-990 through 246-945-992. This fee will not be prorated under any circumstances;

(c) Undergoes an inspection by the commission if the facility is located in Washington pursuant to WAC 246-945-005 that results in either no deficiencies or an approved plan of correction; and

(d) Obtains a controlled substances registration from the commission and is registered with the DEA if the facility intends to possess or distribute controlled substances.

(3) Once an initial license is issued, a licensed facility must:

(a) Notify the commission and pay a facility inspection fee in lieu of paying an initial license fee for modifications or remodels. (~~(A modification or remodel of a pharmacy location includes changes to a previously approved area, room or pharmacy building which result in changes in the pharmacy that affects security, square footage, access to drugs, compounding or necessitates temporary relocation of pharmacy services.)~~)

(b) Submit a new application on forms provided by the commission and pay the initial license fee as established in WAC 246-945-990 through 246-945-992 if the facility changes location to a different

address. If located in Washington, a facility may not relocate prior to the inspection of the new premises.

(c) Notify the commission and pay the initial license fee in accordance with WAC 246-945-990 through 246-945-992 whenever there is a change of ownership. Change in ownership includes changes in business or organizational structure such as a change from sole proprietorship to a corporation, or a change of more than 50 percent ownership in a corporation.

(i) Upon receipt of a change of ownership application and fees, the purchaser may begin operations prior to the issuance of a new pharmacy license only when the purchaser and seller have a written power of attorney agreement. This agreement shall delineate that violations during the pending application process shall be the sole responsibility of the seller.

(ii) This agreement shall be provided to the commission upon request.

(d) Notify the commission within 30 days of any changes to the information provided on their application.

(e) Notify the commission of any changes in their responsible pharmacy manager in accordance with WAC 246-945-480, if a responsible pharmacy manager is required for initial licensure.

(f) Renew their license in accordance with WAC 246-945-990 through 246-945-992.

(4) A license is issued to a location and is not transferable.