

WSR 25-13-005

PROPOSED RULES

DEPARTMENT OF HEALTH

(Pharmacy Quality Assurance Commission)

[Filed June 5, 2025, 9:03 a.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 25-05-060.

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): On August 14, 2025, at 10:30 a.m., at the Department of Labor and Industries, 7273 Linderson Way S.W., Tumwater, WA 98501; or virtually via Zoom at <https://us02web.zoom.us/j/86309299195> or <https://zoom.us/join>, Webinar ID 863 0929 9195; or One-tap mobile +12532158782,,86309299195# U.S. (Tacoma), +12532050468,,86309299195# U.S.

The commission will hold a hybrid hearing. Attendees are welcome to attend either in person at the physical location or virtually via Zoom.

Date of Intended Adoption: August 14, 2025.

Submit Written Comments to: Julia Katz, P.O. Box 47852, Olympia, WA 98504-7852, email [PharmacyRules@doh.wa.gov](mailto:PharmacyRules@doh.wa.gov), fax 360-236-2260, <https://fortress.wa.gov/doh/policyreview/>, beginning the date and time of this filing, by July 31, 2025, at 11:59 p.m.

Assistance for Persons with Disabilities: Contact Julia Katz, phone 360-236-4946, fax 360-236-2260, TTY 711, email [PharmacyRules@doh.wa.gov](mailto:PharmacyRules@doh.wa.gov), by July 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 rule making 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.

Rule is not necessitated by federal law, federal or state court decision.

Name of Proponent: Pharmacy quality assurance commission, governmental.

Name of Agency Personnel Responsible for Drafting and Implementation: Julia Katz, 111 Israel Road S.E., Tumwater, WA 98501, 360-236-4946; Enforcement: Marlee B. O'Neill, 111 Israel Road S.E., Tumwater, WA 98501, 360-480-9108.

A school district fiscal impact statement is not required under RCW 28A.305.135.

A cost-benefit analysis is not required under RCW 34.05.328. Proposed amendments to WAC 246-945-230 (1) and (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.

This rule proposal, or portions of the proposal, is exempt from requirements of the Regulatory Fairness Act because the proposal:

Is exempt under RCW 19.85.025(3) as the rules only correct typographical errors, make address or name changes, or clarify language of a rule without changing its effect.

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

Scope of exemption for rule proposal:

Is fully exempt.

June 5, 2025

Hawkins DeFrance, PharmD, Chair  
Pharmacy Quality Assurance Commission

## RDS-6289.1

AMENDATORY SECTION (Amending WSR 24-11-060, filed 5/13/24, effective 6/13/24)

**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.