



RULE-MAKING ORDER

PERMANENT RULE ONLY

CR-103P (December 2017)
(Implements RCW 34.05.360)

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: October 03, 2025

TIME: 8:49 AM

WSR 25-21-016

Agency: Department of Health – Pharmacy Quality Assurance Commission

Effective date of rule:

Permanent Rules

- ☒ 31 days after filing.
☐ Other (specify) _____ (If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be stated below)

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

- ☐ Yes ☒ No If Yes, explain:

Purpose: Inspection Requirements for Modifications or Remodels. The Pharmacy Quality Assurance Commission (commission) is adopting amendments to WAC 246-945-230 to clarify circumstances necessitating a remodel inspection due to pharmaceutical facility modifications or remodels.

Citation of rules affected by this order:

New: None
Repealed: None
Amended: WAC 246-945-230
Suspended: None

Statutory authority for adoption: RCW 18.64.005

Other authority: None

PERMANENT RULE (Including Expedited Rule Making)

Adopted under notice filed as WSR 25-13-005 on June 5, 2025.

Describe any changes other than editing from proposed to adopted version:

As part of the public hearing process on August 14, 2025, the commission adopted a clarifying and non-substantive revision in the definition of “physical change” or “physical changes” from the proposed to adopted version. The definition of “physical change” or “physical changes” is one of two terms to delineate when an inspection may be warranted to a modification or remodel of a pharmaceutical facility. The revision clarifies that negative impacts to security apply to both changes impacting structural elements and changes impacting square footage in WAC 246-945-230(1)(c)(i). WAC 246-945-230(1)(c)(i) has been revised to, “changes to structural element(s), such as walls, floors, and load bearing elements, that negatively impact security as determined by the facility” and new WAC 246-945-230(1)(c)(ii) reads, “changes impacting square footage that negatively impact security as determined by the facility.” Revising WACs 246-945-230(1)(c)(i) and 246-945-230(1)(c)(ii) ensures that negative impacts to security are applicable to both changes to structural elements and changes to square footage.

If a preliminary cost-benefit analysis was prepared under RCW 34.05.328, a final cost-benefit analysis is available by contacting:

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

**Note: If any category is left blank, it will be calculated as zero.
No descriptive text.**

**Count by whole WAC sections only, from the WAC number through the history note.
A section may be counted in more than one category.**

The number of sections adopted in order to comply with:

Federal statute:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Federal rules or standards:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Recently enacted state statutes:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>

The number of sections adopted at the request of a nongovernmental entity:

New	<u>0</u>	Amended	<u>1</u>	Repealed	<u>0</u>
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The number of sections adopted on the agency's own initiative:

New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted in order to clarify, streamline, or reform agency procedures:

New	<u>0</u>	Amended	<u>1</u>	Repealed	<u>0</u>
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The number of sections adopted using:

Negotiated rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Pilot rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Other alternative rule making:	New	<u>0</u>	Amended	<u>1</u>	Repealed	<u>0</u>

Date Adopted: 10/2/2025

Name: Hawkins DeFrance, PharmD

Title: Pharmacy Quality Assurance Commission Chair

Signature:



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 that negatively impact security as determined by the facility;

(ii) Changes impacting square footage that negatively impact security as determined by the facility;

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

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

(v) 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.