



PREPROPOSAL STATEMENT OF INQUIRY

CR-101 (October 2017) (Implements RCW 34.05.310)

Do NOT use for expedited rule making

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: February 14, 2025

TIME: 7:54 AM

WSR 25-05-060

Agency: Department of Health – Pharmacy Quality Assurance Commission

Subject of possible rule making: Licensed pharmaceutical facility inspection requirements for modifications or remodels. The Pharmacy Quality Assurance Commission (commission) is considering amending WAC 246-945-230 and potentially establishing a new section in chapter 246-945 WAC to clarify when facilities need to submit a modification or remodel application and what constitutes a modification or remodel.

Statutes authorizing the agency to adopt rules on this subject: RCW 18.64.005

Reasons why rules on this subject may be needed and what they might accomplish: Commission staff have received feedback from interested parties about challenges discerning which remodels and modifications of licensed facilities require notifying the commission and paying a facility inspection fee per WAC 246-945-230(3)(a). The commission voted to consider rulemaking to address the uncertainties at the December 12, 2024 business meeting. 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 commission is considering amending the provision to specify what, if any, modifications or remodels to a licensed facility’s compounding room or space can be made without notifying the commission and undergoing a remodel inspection. The commission may also consider further amendments to consider what constitutes a remodel or modification, when to notify the commission, and applicable facility types.

Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies: None

Process for developing new rule (check all that apply):

- Negotiated rule making
- Pilot rule making
- Agency study
- Other (describe) Collaborative rulemaking

Interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before publication by contacting:

Name: Julia Katz	(If necessary) Name:
Address: PO Box 47852, Olympia, WA 98504-7852	Address:
Phone: 360-502-5058	Phone:
Fax: 360-236-2901	Fax:
TTY: 711	TTY:
Email: PharmacyRules@doh.wa.gov	Email:
Web site: https://doh.wa.gov/	Web site:
Other: N/A	Other:

Additional comments: Interested parties can participate in the drafting of the proposed rules. The commission will conduct a series of rules workshops. Rulemaking notices will be delivered via the GovDelivery list. To receive notices, please go to: <https://public.govdelivery.com/accounts/WADOH/subscriber/new>. After signing in, please click open the box labeled "Health Systems Quality Assurance." Next click open the box labeled "Health Professions" and then click again on "Pharmacy Commission Meeting and Agenda" and/or "Pharmacy Commission Newsletter" You may also check the box next to one or more of the other professions or facilities listed to receive information related to that specific topic.

Date: February 12, 2025

Name: Hawkins DeFrance, PharmD

Title: Pharmacy Quality Assurance Commission Chair

Signature:

A handwritten signature in cursive script, appearing to read "Hawkins DeFrance", written in black ink on a white background.