



# PREPROPOSAL STATEMENT OF INQUIRY

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

Do NOT use for expedited rule making

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DATE: December 19, 2022

TIME: 3:26 PM

WSR 23-01-111

**Agency:** Department of Health- Pharmacy Quality Assurance Commission

**Subject of possible rule making:** The Pharmacy Quality Assurance Commission (commission) is reviewing existing rules (WAC 246-945-455) limiting access to drugs stored outside of the pharmacy in a health care facility to licensed health care professionals. The commission will consider adopting new requirements allowing access to drugs outside the pharmacy by unlicensed staff. The commission will also consider if other disruptions within the health care facilities, resulting from requirements within WAC 246-945-455, are necessary.

**Statutes authorizing the agency to adopt rules on this subject:** RCW 18.64.005; RCW 69.41.075; RCW 69.50.301

**Reasons why rules on this subject may be needed and what they might accomplish:** On July 1, 2020, chapter 246-945 WAC went into effect replacing all rules under the commission's authority, save temporary exceptions for some rules pertaining to continuing education requirements. WAC 246-945-455 now contains the 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. WAC 246-945-455(1)(c) about drugs stored outside of the pharmacy now reads, "Access 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 without obtaining a pharmacy assistant credential. Since WAC 246-945-455(1)(c) caused unintended disruptions in health care facilities, the commission determined at its December 3, 2021 business meeting that they would not find licensees deficient or take enforcement actions against licensees for violations of WAC 246-945-455(1)(c) if the conditions outlined in the associated guidance document are met.

Rulemaking is necessary to consider codifying the guidance the commission has provided on access to drugs 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.

**Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies:** N/A

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

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

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

Name: Haleigh Mauldin (If necessary)  
Name:

Address: PO 47852, Olympia, WA 98504-7852  
Phone: 360-890-0720  
Fax: 360-236-2321  
TTY: 711  
Email: [Haleigh.Mauldin@doh.wa.gov](mailto:Haleigh.Mauldin@doh.wa.gov)  
Web site:  
Other:

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

Additional comments: Rule development takes place in open public meetings prior to a formal rule proposal and comment period. All rulemaking notices are sent via GovDelivery. To receive notices, interested persons may sign up by going to: <https://public.govdelivery.com/accounts/WADOH/subscriber/new>. After signing up, please click open the box labeled "Health Systems Quality Assurance." Next, click open the box labeled "Health Professions," then check the boxes next to either "Pharmacy Commission Meeting and Agenda" and/or "Pharmacy Commission Newsletter."

**Date:** December 19, 2022

**Name:** Teri Ferreira, RPh

**Title:** Pharmacy Quality Assurance Chair

**Signature:**

A handwritten signature in black ink, appearing to read "Teri Ferreira". The signature is written in a cursive style with a horizontal line at the end.