

WSR 23-01-111

PREPROPOSAL STATEMENT OF INQUIRY

DEPARTMENT OF HEALTH

(Pharmacy Quality Assurance Commission)

[Filed December 19, 2022, 3:26 p.m.]

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, 69.41.075, 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.

Rule making 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.

Other Federal and State Agencies that Regulate this Subject and the Process Coordinating the Rule with These Agencies: Not applicable.

Process for Developing New Rule: 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 Haleigh Mauldin, P.O. Box 47852, Olympia, WA 98504-7852, phone 360-890-0720, fax 360-236-2321, TTY 711, email Haleigh.Mauldin@doh.wa.gov.

Additional comments: Rule development takes place in open public meetings prior to a formal rule proposal and comment period. All rule-making 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," and check the boxes next to either "Pharmacy Commission Meeting and Agenda" and/or "Pharmacy Commission Newsletter."

December 19, 2022
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Pharmacy Quality Assurance Chair