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WSR 23-18-046

PREPROPOSAL STATEMENT OF INQUIRY

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

Do **NOT** use for expedited rule making

Agency: Department of Health- Pharmacy Quality Assurance Commission

Subject of possible rule making: Pharmacy registration for mobile opioid treatment program units. The Pharmacy Quality Assurance Commission (commission) is considering amending WACs 246-945-060 and 246-945-250 and adding new sections in chapter 246-945 WAC to exempt mobile opioid treatment program (OTP) units from having to obtain separate registrations, as long as they are covered under the OTP site's controlled substance registration, and to develop more comprehensive facility requirements for analytical laboratories and dog handlers among other facilities that are licensed under the other controlled substance registration.

Statutes authorizing the agency to adopt rules on this subject: RCW 18.64.005 and 69.50.302

Reasons why rules on this subject may be needed and what they might accomplish: In July 2021, the federal Drug Enforcement Agency (DEA) lifted its moratorium on mobile OTP units, eliminating a separate registration requirement for OTP units by adding a "mobile component" to their existing registration. The Washington Department of Health (department) adopted permanent rules for licensed behavioral health agencies to approve these units as an extension of an existing OTP license and certification, though they must also register with the commission to possess controlled substances by obtaining the “other controlled substance registration.”

While state law currently requires each mobile OTP unit to register separately with the commission, RCW 69.50.302(d) allows the commission to waive by rule the requirement for registration of certain entities upon finding it consistent with public health and safety. The commission is considering amending WAC 246-945-060 and WAC 246-945-250 to exempt mobile OTP units from having to register separately with the commission. The commission is also considering adding new sections to chapter 246-945 WAC to develop more comprehensive facility requirements for other controlled substance registrants, focusing on enhancing drug security and product integrity.

Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies: The commission is coordinating with department staff who license behavioral health agencies, as well as with the Health Care Authority’s State Opioid Treatment Authority.

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:

	(If necessary)
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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: 8/31/2023

Name: Kenneth Kenyon, PharmD, BCPS

Title: Pharmacy Quality Assurance Commission Chair

Signature: