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: April 24, 2023
TIME: 3:59 PM

WSR 23-10-012

Agency: Department of Health- Pharmacy Quality Assurance Commission

Subject of possible rule making: Pharmacy wholesaler reporting of suspicious orders and zero reports. The Pharmacy Quality Assurance Commission (commission) is considering amending WAC 246-945-585, Wholesaler-Suspicious orders and due diligence, and creating a new section of rule in chapter 246-945 WAC to clarify expectations for wholesalers submitting suspicious order and zero order reports to the commission**.**

Statutes authorizing the agency to adopt rules on this subject: RCW 18.64.005, RCW 18.64.046

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. One of the new rules, WAC 246-945-585, requires that wholesalers report suspicious orders to the commission, as well as engage in due diligence to identify customers who might be diverting controlled substances or drugs of concern, and submit "zero' reports when no suspicious orders have been identified. The current rules require wholesalers to report to the commission suspicious orders within 5 business days of identification (WAC 246-945-585(1)(a)) and "zero" reports within 15 business days after the end of the calendar month (WAC 246-945-585(1)(b)).

Currently, there is no definition of "suspicious orders" in rule, and the commission believes that, without this definition, licensees may be over reporting, making the volume of reports difficult to manage. Since implementing the rule, the commission has determined there may be more streamlined ways for licensees to manage their zero order reports, such as storing their records on site, instead of reporting them to the commission on a monthly basis. Rulemaking may be necessary to clarify expectations and streamline reporting requirements for wholesalers.

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

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 to interested parties 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: April 21, 2023 **Name:** Teri Ferreira, RPh **Title:** Pharmacy Quality Assurance Chair	**Signature:**