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DATE: June 12, 2023
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WSR 23-13-035

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: Prescription drug label accessibility standards. The Pharmacy Quality Assurance Commission (commission) is considering amending WAC 246-945-015, WAC 246-945-016 and WAC 246-945-417, to establish prescription label accessibility standards, and is also considering new sections to chapter 246-945 WAC on the subject of prescription drug label accessibility**.**

This rulemaking is a continuation of discussions with interested parties and rulemaking work done under WSR 22-09-065. The commission is withdrawing the original CR-101 and filing this new CR-101 to consider an amendment of WAC 246-945-015 to clarify that the minimum requirements established regarding accessibility standards for prescription information apply to dispensing practitioners also.

Statutes authorizing the agency to adopt rules on this subject: RCW 18.64.005, RCW 69.41.240.

Reasons why rules on this subject may be needed and what they might accomplish: On October 22, 2021, the commission approved a petition requesting pharmacies provide accessible medication label options for patients. Minimum requirements for outpatient prescription labeling are described in WAC 246-945-016, but do not reference accommodations for patients who are visually impaired, blind, or have other disabilities requiring additional prescription label options. Clear comprehension of prescription drug label information is a matter of public health and safety for all persons, regardless of ability, and opening chapter 246-945 WAC would help align state regulatory standards with patient needs.

The commission also received and approved a petition in January 2022 requesting that translations of prescription directions on prescription labels be made available in multiple languages for ambulatory (community based) patients. The petition included an additional request to amend WAC 246-945-417 in order to establish a deadline by which pharmacy outpatient dispensing systems must comply with a requirement to translate prescription medication directions. Improving prescription information comprehension for individuals for whom English is not their primary language is also a matter of public health.

Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies: The Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA) expanded the FDA's authorities and strengthened the agency's ability to advance public health. Section 904 of the FDASIA established a working group to develop best practices regarding prescription drug label standards to better accommodate visually impaired or blind individuals. This led to a 2016 United States Government Accountability Office report recommending the provision of accessible prescription drug labels, including the use of large print, braille, and audible labels. The commission does not require coordination with the federal agencies responsible for the implementation or enforcement of prescription drug label accessibility guidelines.

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: June 12, 2023 **Name:** Teri Ferreira, RPh **Title:** Pharmacy Quality Assurance Chair	**Signature:**