



PREPROPOSAL STATEMENT OF INQUIRY

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

Do NOT use for expedited rule making

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STATE OF WASHINGTON
FILED

DATE: November 18, 2025

TIME: 7:50 AM

WSR 25-23-064

Agency: Department of Health – Pharmacy Quality Assurance Commission

Subject of possible rule making: Prescription labeling accessibility rules. The Pharmacy Quality Assurance Commission (commission) is considering amending WAC 246-945-015 and 246-945-026 through 246-945-029 to refine the standards for dispensing practitioners and dispensing facilities subject to the commission's prescription labeling accessibility rules.

Statutes authorizing the agency to adopt rules on this subject: RCW 18.64.005, 69.41.240, and 69.50.301

Reasons why rules on this subject may be needed and what they might accomplish: The commission adopted new and amended rules (WAC 246-945-015 and 246-945-026 through 246-945-029) for prescription labeling accessibility standards under WSR 25-04-003 on January 22, 2025. The amended and new rules require dispensing facilities and dispensing practitioners to provide a means of access to patients with visual impairments or print disabilities, and patients with Limited English Proficiency (LEP) by supplying accessible prescription labels upon request. Acknowledging the need to give regulated practitioners and facilities time to implement the rules, the commission set an effective date of January 22, 2027.

During the implementation period, the commission received feedback from facilities and practitioners regarding the technological and fiscal challenges for providing the accessibility tools and methods listed in the adopted rules due to changes in the healthcare landscape that have occurred since the adoption of the rules. The commission determined at its October 16, 2025, business meeting that the accessible labeling rules would need to be revisited to consider how to best address implementation burdens while still fulfilling the original goal of ensuring meaningful access to accurate prescription information for all patients receiving prescribed medications in Washington.

Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies: The recently adopted rules in WAC 246-945-015 and 246-945-026 through 246-945-029 align with accessibility standards established in federal statute. 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 is not required to coordinate with federal agencies responsible for the implementation or enforcement of prescription drug label accessibility guidelines. Any rules the commission may adopt as a result of this rulemaking will take these guidelines into consideration.

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:

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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: November 18, 2025

Name: Hawkins DeFrance, PharmD

Title: Pharmacy Quality Assurance Commission Chair

Signature:

