WSR 22-09-065
PREPROPOSAL STATEMENT OF INQUIRY
DEPARTMENT OF HEALTH
(Pharmacy Quality Assurance Commission)
[Filed April 19, 2022, 10:27 a.m.]

Subject of Possible Rule Making: Chapter 246-945 WAC, Prescription drug label accessibility standards. The pharmacy quality assurance commission (commission) is opening WAC 246-945-016 and 246-945-417 to consider including prescription label accessibility standards, and is also considering new sections to chapter 246-945 WAC on the subject of prescription drug label accessibility.

Statutes Authorizing the Agency to Adopt Rules on this Subject: RCW 18.64.005 and 69.41.240.

Reasons Why Rules on this Subject may be Needed and What They Might Accomplish: On September 8, 2021, the commission received a petition requesting pharmacies provide accessible medication label options for patients. On October 22, 2021, the commission voted to approve the petition and consider rule making. Minimum requirements for outpatient prescription labeling are described in WAC 246-945-016, but does not reference accommodations for patients who are visually impaired, blind, or have other disabilities requiring additional prescription label options provided by their pharmacy. 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 a petition on January 13, 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. The commission voted to approve the petition and consider rule making pertaining to the provision of translated prescription information by pharmacies on January 28, 2022. Improving prescription information comprehension for individuals for whom English is not their primary language is also a matter of public health.

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: Collaborative.

Interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before publication by contacting Joshua Munroe, P.O. Box 47852, Olympia, WA 98504-7852, phone 360-236-2987, TTY 711, email PharmacyRules@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," then check the boxes next to either "Pharmacy Commission Meeting and Agenda" and/or "Pharmacy Commission Newsletter."

April 18, 2022
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Pharmacy Quality Assurance Chair