SHB 1852 - H AMD **878**
By Representative Thai

ADOPTED 02/09/2022

Strike everything after the enacting clause and insert the following:

"NEW SECTION. **Sec. 1.** A new section is added to chapter 18.64 RCW to read as follows:

(1) By July 1, 2024, the commission shall adopt rules establishing the requirements for the translation of prescription drug labels and prescription information.

(a) At a minimum, the rules must require:

(i) The translation of the directions for use and any auxiliary warnings that would otherwise be included on the prescription drug label;

(ii) The translated version and English language version of the directions for use appear on the prescription container or label; and

(iii) A pharmacy or nonresident pharmacy provide the translated directions for use, auxiliary warnings, and any other information required by the commission in rules if the language is one selected by the commission upon the request of a patient, patient's representative, or prescriber.

(b) Rules adopted under this section must establish the following:

(i) The languages for which translation is required;

(ii) The elements of a prescription drug label or other information, such as information sheets or side effects, that must be translated;

(iii) The pharmacies and settings that the translation requirements apply to;

(iv) The process for procuring or providing the translations;

(v) When a pharmacy or nonresident pharmacy must provide the translated prescription information; and

(vi) Any signage that a pharmacy must post to notify consumers of the availability of translated prescription information.

(2) When adopting rules establishing the languages for which translation is required, the commission shall choose at least 15 languages and aim to provide translations in all languages spoken by at least five percent of the state population or 1,000 people in Washington with limited English proficiency and must:

(a) Consult with the Washington state office of equity and the governor's interagency council on health disparities;

(b) Consider the percent of the population in Washington that speaks the language, that population's access to health care, and principles of equity; and

(c) At least every five years, reassess, update, and increase the number of languages as needed based upon the factors listed in this subsection.

(3) The commission may contract with a state or nonstate entity to implement and administer this section.

(4) Nothing in this section shall be construed to prohibit a pharmacy or nonresident pharmacy from providing translated directions for use, auxiliary warnings, side effects, or other prescription information beyond the languages selected by the commission or to a greater extent than required by the commission.

(5) A pharmacy, nonresident pharmacy, or pharmacist may not be held liable for good faith reliance on translated prescription information provided by or through a third party in compliance with the rules adopted by the commission in subsection (1) of this section if the pharmacy, nonresident pharmacy, or pharmacist contracted with the third party in good faith, and the pharmacy, nonresident pharmacy, or pharmacist was not negligent with regard to the alleged misconduct of the third party.

(6) The commission shall provide pharmacies and nonresident pharmacies a minimum of 120 days from the date rules are adopted under subsection (1) of this section to comply with the rules.

(7) This section applies only to outpatient prescriptions dispensed for home use that are intended for human use.

(8) This section does not apply to:

(a) Prepackaged emergency medications as provided in RCW 70.41.480; and

(b) Opioid overdose reversal medication distributed pursuant to RCW 70.41.485 and 71.24.594.

(9) By July 1, 2024, the commission shall adopt rules establishing other accessibility requirements for individuals who are

blind, low vision, or otherwise print disabled for prescription drug labels and prescription information.

(10) The commission may adopt any rules necessary to implement and administer this section.

(11) By July 1, 2023, the commission shall report to the relevant policy and fiscal committees of the legislature on the rule-making progress, including the selection of languages and the process for procuring or providing the translations.

(12) For purposes of this section, an "auxiliary warning" or "advisory label" is a cautionary warning label added onto a dispensed prescription drug label by a pharmacist in addition to the required prescription drug label to provide extra information to the patient on the safe administration, use, and storage of the prescription.

Sec. 2. RCW 18.64.390 and 2013 c 19 s 23 are each amended to read as follows:

(1) The commission may deny, revoke, or suspend a nonresident pharmacy license or impose a fine not to exceed ((~~one thousand dollars~~)) $1,000 per violation for failure to comply with any requirement of RCW 18.64.350 through 18.64.400 and section 1 of this act.

(2) The commission may deny, revoke, or suspend a nonresident pharmacy license or impose a fine not to exceed ((~~one thousand dollars~~)) $1,000 per violation for conduct that causes serious bodily or psychological injury to a resident of this state if the secretary has referred the matter to the regulatory or licensing agency in the state in which the pharmacy is located and that regulatory or licensing agency fails to initiate an investigation within ((~~forty-five~~)) 45 days of the referral under this subsection or fails to make a determination on the referral."

Correct the title.

EFFECT: (1) Requires the Pharmacy Quality Assurance Commission (Commission) to adopt rules establishing other accessibility requirements for individuals who are blind, low vision, or otherwise print disabled for prescription drug labels and prescription information by July 1, 2024, rather than authorizing the Commission to adopt these rules.

(2) Requires the rules adopted by the Commission to require the translated version and English language version of the directions for use to appear on the prescription container or label and to require pharmacies and nonresident pharmacies to provide the translated

directions for use, auxiliary warnings, and any other information required by the commission upon the request of a patient, patient's representative, or prescriber.

(3) Modifies the requirements for the selection of the languages for which translation is required, so that the Commission must select at least 15 languages, rather than up to 15, aim to provide translations in all languages spoken by at least five percent of the state population or 1,000 people in Washington with limited English proficiency, and reassess, update, and increase the number of languages as needed every five years, rather than ten years.

(4) Provides that a pharmacy, nonresident pharmacy, or pharmacist is not liable for the good faith reliance on translated prescription information if the pharmacy, nonresident pharmacy, or pharmacist was not negligent.

(5) Requires the Commission to provide pharmacies and nonresident pharmacies a minimum of 120 days from the date the rules are adopted to comply with the rules.

(6) Removes the provision that provides that for purposes of compliance with the bill's requirements, a pharmacy or nonresident pharmacy is not required to provide translated information beyond what is required by the Commission in rule.

(7) Requires the Commission to report to the Legislature by July 1, 2023, on the progress of the rule making.

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