ESHB 1852 - S AMD 1470 By Senator Keiser

8

19

25

- 1 Strike everything after the enacting clause and insert the 2 following:
- 3 "NEW SECTION. Sec. 1. A new section is added to chapter 18.64
 4 RCW to read as follows:
- 5 (1) By July 1, 2024, the commission shall adopt rules 6 establishing the requirements for the translation of prescription 7 drug labels and prescription information.
 - (a) At a minimum, the rules must require:
 - (i) The translation of the directions for use;
- 10 (ii) The translated version and English language version of the 11 directions for use appear on the prescription container or label; and
- (iii) A pharmacy or nonresident pharmacy provide the translated directions for use 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.
- 17 (b) Rules adopted under this section must establish the 18 following:
 - (i) The languages for which translation is required;
- 20 (ii) The elements of a prescription drug label, auxiliary 21 warnings, or other information, such as information sheets or side 22 effects, that must be translated;
- 23 (iii) The pharmacies and settings that the translation 24 requirements apply to;
 - (iv) The process for procuring or providing the translations;
- 26 (v) When a pharmacy or nonresident pharmacy must provide the translated prescription information;
- (vi) Any signage that a pharmacy must post to notify consumers of the availability of translated prescription information; and
- 30 (vii) Any notation that must appear on the prescription label to 31 notify the patient of additional translated prescription information.

(2) When adopting rules establishing the languages for which translation is required, the commission shall choose at least 15 languages with the goal of including 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) Beginning October 1, 2031, and every 10 years thereafter, 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:
- 35 (a) Prepackaged emergency medications as provided in RCW 36 70.41.480; and
- 37 (b) Opioid overdose reversal medication distributed pursuant to 38 RCW 70.41.485 and 71.24.594.
- 39 (9) By July 1, 2024, the commission shall adopt rules 40 establishing other accessibility requirements for individuals who are Code Rev/MW:akl 2 S-5086.1/22

- blind, low vision, or otherwise print disabled for prescription drug labels and prescription information.
- 3 (10) The commission may adopt any rules necessary to implement 4 and administer this section.
- 5 (11) By July 1, 2023, the commission shall report to the relevant 6 policy and fiscal committees of the legislature on the rule-making 7 progress, including the selection of languages and the process for 8 procuring or providing the translations.
- 9 **Sec. 2.** RCW 18.64.390 and 2013 c 19 s 23 are each amended to 10 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 16 17 pharmacy license or impose a fine not to exceed ((one thousand dollars)) \$1,000 per violation for conduct that causes serious bodily 18 or psychological injury to a resident of this state if the secretary 19 20 has referred the matter to the regulatory or licensing agency in the state in which the pharmacy is located and that regulatory or 21 licensing agency fails to initiate an investigation within ((forty-22 five)) 45 days of the referral under this subsection or fails to make 23 24 a determination on the referral."

ESHB 1852 - S AMD 1470 By Senator Keiser

11

12

13

1415

On page 1, line 2 of the title, after "labels;" strike the remainder of the title and insert "amending RCW 18.64.390; and adding a new section to chapter 18.64 RCW."

<u>EFFECT:</u> Removes the requirement that any auxiliary warning that would otherwise be on the label be translated.

Removes the definition of auxiliary label.

Requires the Pharmacy Commission to adopt rules establishing any notation that must appear on the prescription label to notify the patient of additional translated prescription information.

References auxiliary warnings in the list of items that the Commission must determine what elements of the label or other information must be translated.

Clarifies that when selecting at least 15 languages, the Pharmacy Commission does not have the responsibility to provide the translations but rather, the Pharmacy Commission has the goal of including all languages in rule spoken by at least 5% of the state population or 1,000 people in Washington.

Modifies the frequency for how often the Commission must reassess and update the languages to every ten years beginning October 1, 2031.

--- END ---