SENATE BILL REPORT
ESHB 1852

As of February 18, 2022

Title: An act relating to language requirements for prescription drug labels.

Brief Description: Concerning language requirements for prescription drug labels.

Sponsors: House Committee on Health Care & Wellness (originally sponsored by Representatives Thai, Cody, Gregerson, Macri, Santos, Slatter, Valdez, Pollet and Riccelli).

Brief History: Passed House: 2/9/22, 64-32.
Committee Activity: Health & Long Term Care: 2/18/22.

Brief Summary of Bill

- Requires the Pharmacy Quality Assurance Commission to adopt rules establishing requirements for the translation of prescription drug labels and other prescription information.

SENATE COMMITTEE ON HEALTH & LONG TERM CARE

Staff: Julie Tran (786-7283)

Background: The Pharmacy Quality Assurance Commission (Pharmacy Commission) regulates the practice of pharmacy, and the distribution, manufacturing, and delivery of pharmaceuticals within and into the state.

State law requires that a prescription container's label must include the dispensing pharmacy's name and address, the prescription number, the prescriber's name and directions, the medication's name and strength, the patient's name, the date, and the expiration date. The identification of the licensed pharmacist responsible for each dispensing of medication must either be recorded in the pharmacy's record system or on the prescription label. A violation of these requirements is a misdemeanor offense.

This analysis was prepared by non-partisan legislative staff for the use of legislative members in their deliberations. This analysis is not part of the legislation nor does it constitute a statement of legislative intent.

A nonresident pharmacy is a pharmacy located outside of Washington that ships, mails, or delivers, in any manner, except when delivered in person to an individual, controlled substances, legend drugs, or devices into the state. Nonresident pharmacies must be licensed by the Department of Health.

The United States Food and Drug Administration (FDA) has found that at least 60 million Americans age 4 and over speak a language other than English at home, and seven percent of Americans do not speak English at all. In 2014, FDA created a language access plan that is organized around ten elements, which includes written translations and notification of the availability of language assistance at no cost. FDA determined that vital documents and critical consumer information from the agency will be translated into six other most common spoken languages in the United States in addition to English and Spanish. Those six languages are French, German, Korean, Mandarin Chinese, Tagalog, and Vietnamese.

Summary of Bill: By July 1, 2024, the Pharmacy Commission must adopt rules establishing the requirements for the translation of prescription drug labels and prescription information. At a minimum, the rules must require:

- the translation of the directions for use and any auxiliary warnings that would otherwise be included on the prescription drug label;
- the translated version and English language version of the directions for use appear on the prescription container or label; and
- a pharmacy or nonresident pharmacy to 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.

The rules must establish:

- the languages for which translation is required;
- the elements of the prescription drug label or other information such as information sheets or side effects that must be translated;
- the pharmacies and settings that the requirements apply to and when the translated information must be provided;
- the process for procuring or providing the translations; and
- any signage that a pharmacy must post to notify consumers of the availability of translated prescription information.

When selecting the languages for the translations, the Pharmacy Commission must select at least 15 languages and aim to provide translations in all languages spoken by at least 5 percent of the state population or 1,000 people in Washington with limited English proficiency. The Pharmacy Commission must:

- consult with the Washington State Office of Equity and the Governor's Interagency Council on Health Disparities;
- consider the percent of the population in Washington that speaks the language, the population's access to health care, and principles of equity; and

- reassess, update, and increase the languages as needed at least every five years.

The Pharmacy Commission may contract with a state or nonstate entity to implement and administer these requirements. The Pharmacy Commission must provide pharmacies and nonresident pharmacies a minimum of 120 days from the date rules are adopted to comply with the rules. The Pharmacy Commission may deny, revoke, or suspend a nonresident pharmacy license or impose a fine not greater than $1,000 per violation for failure to comply with the requirements.

These requirements apply only to outpatient prescriptions dispensed for home use that are intended for home use. These requirements do not apply to prepackaged emergency medications andopioid overdose reversal medications distributed pursuant to statutory requirements for hospital emergency departments and certain behavioral health facilities.

A pharmacy or nonresident pharmacy is not prohibited from providing its own translations or providing translations beyond what is required in rule.

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 Pharmacy Commission 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.

By July 1, 2023, the Pharmacy Commission must report to the relevant policy and fiscal committees of the Legislature on the rulemaking progress, including the selection of languages and the process for procuring or providing the translations.

By July 1, 2024, the Pharmacy Commission must adopt rules establishing other accessibility requirements for individuals who are blind, low vision, or otherwise print-disabled for prescription drug labels and prescription information.

An auxiliary warning or advisory label is a cautionary warning label added onto a dispensed prescription label by a pharmacist in addition to the required prescription label to provide extra information to the patient on the safe administration, use, and storage of the prescription.

Appropriation: None.

Fiscal Note: Available.

Creates Committee/Commission/Task Force that includes Legislative members: No.

Effective Date: Ninety days after adjournment of session in which bill is passed.