HOUSE BILL REPORT
ESHB 1852

As Passed House:
February 9, 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:
Committee Activity:
Health Care & Wellness: 1/17/22, 1/31/22 [DPS].
Floor Activity:
Passed House: 2/9/22, 64-32.

Brief Summary of Engrossed Substitute Bill

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

HOUSE COMMITTEE ON HEALTH CARE & WELLNESS

Majority Report: The substitute bill be substituted therefor and the substitute bill do pass. Signed by 15 members: Representatives Cody, Chair; Bateman, Vice Chair; Schmick, Ranking Minority Member; Caldier, Assistant Ranking Minority Member; Bronoske, Davis, Harris, Macri, Maycumber, Riccelli, Rude, Simmons, Stonier, Tharinger and Ybarra.

Staff: Kim Weidenaar (786-7120).

Background:

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.

The Pharmacy Quality Assurance Commission regulates the practice of pharmacy, and the distribution, manufacturing, and delivery of pharmaceuticals within and into the state. State law requires the label of a prescription container to include the following: the name and address of the dispensing pharmacy, the prescription number, the name of the prescriber, the prescriber's directions, the name and strength of the medication, the name of the patient, the date, and the expiration date.

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) created a language access plan in accordance with the executive order, Improving Access to Services for Persons with Limited English Proficiency, issued August 11, 2000. The plan includes 10 elements, including written translations and notification of availability of language assistance at no cost. Under the plan, the FDA determined that in addition to English and Spanish, the agency will translate vital documents and critical consumer information into the six other most common spoken languages in the United States: Mandarin Chinese, Tagalog, Vietnamese, French, German, and Korean.

Summary of Engrossed Substitute Bill:

By July 1, 2024, the Pharmacy Quality Assurance Commission (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 that must be translated;
- the pharmacies and settings that the requirements apply to and when 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 choosing the languages, the 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 and 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 Commission may contract with a state or nonstate entity to implement and administer these requirements.

These requirements apply only to outpatient prescriptions dispensed for home use that are intended for human use and do not apply to prepackaged emergency medications or opioid 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. The commission must provide pharmacies and nonresident pharmacies a minimum of 120 days from the date rules are adopted to comply with the rules. The Commission is authorized to take enforcement action against a nonresident pharmacy for failure to comply with these requirements.

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

By July 1, 2023, the 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.

For these purposes, 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.

Effective Date: The bill takes effect 90 days after adjournment of the session in which the bill is passed.

Staff Summary of Public Testimony:

(In support) The team that brought this bill forward includes students from medicine, pharmacy, nursing, and other areas. The team was formed a year and a half ago to examine how to reduce the burden on the limited English proficiency (LEP) community. The team sought the input of others and consistently heard that translated prescriptions would have a huge impact after hearing stories of individuals ending up in the emergency room (ER) after taking many times the prescribed dose. Preventable medication errors happen at twice the rate in the LEP community, and this bill is long overdue. The health care system is already stretched to its limit, and we cannot afford medication errors.

It is difficult to take medication when you don't understand the language. Patients often leave the pharmacy having no idea what is on the label and so patients often come back to the doctor without having taken the medication or taking it incorrectly. Providers and pharmacists have seen the harm that misunderstanding a prescription's directions has caused. This harm includes more ER visits, longer hospitals stays, and more rehospitalization. In Washington, one in seven is an immigrant or refugee and up to 200 languages are spoken. For adults, becoming fully fluent takes seven to 10 years under ideal circumstances.

Family members and friends are often called on to translate for individuals with LEP. Sometimes this is difficult or uncomfortable for the patient, such as when women must rely on men to translate prescriptions related to women's health.

There are existing systems that provide these translations already and have helped others comply with similar requirements. These systems also allow for translation of drug information sheets. The National Institutes of Health awarded a grant to work on multi-language labels.

The most important factor for safely taking a prescription drug is the ability to read the label. Speaking a language other than English should not automatically put a patient at risk. The pandemic has only exacerbated health disparities and individuals with LEP have already waited long enough. Pharmacists need all available tools to help people, reduce health disparities, and improve health.

(Opposed) The idea of the bill is necessary, but the bill itself does not support patient safety and cannot be implemented as drafted. Pharmacy software and good, workable regulation

is needed. Requiring translations is already within the Pharmacy Quality Assurance Commission's (Commission) authority and the Commission is already working on this issue. This bill would result in dangerous arts and crafts. You cannot just paste these translations into the current pharmacy software. The timeline is not workable and would require pharmacies to choose between focusing on the pandemic or trying to comply with these requirements.

Pharmacies care about their patients and patient safety. However, there is a very limited amount of space on the prescription label and if too much information must fit on the label, the text will be too small to be helpful.

A regional framework should be applied to these requirements. In some areas, 15 languages may be too few and in others it may be too many, so there should be some flexibility. There also needs to be some consideration in how the translations are made so that pharmacists feel comfortable and understand that the translations are correct.

(Other) The goal of this bill is laudable and there is appreciation for the student's passion for this bill. However, there are some concerns about the bill. For example, the intent is to cover outpatient pharmacies, but that could be more explicitly stated in the bill and there should be exemptions for prepackaged medications. It is also unclear what the translation process really looks like. It is difficult to have both English and the translated version on the same bottle, and this process needs to be helpful and user friendly.

The Commission appreciates this bill being brought forward. Patient safety and equitable access are very important and the primary concern. However, there are concerns about implementing these requirements. There needs to be adequate time to develop the translations and to develop a process for the translations to be electronically retrieved. There are software vendors taking up this work already. The Commission would like a few technical amendments, including granting immunity to the Commission.

Due to language gaps, individuals with limited English proficiency often have a hard time understanding health information and harm can occur if individuals cannot understand prescription labels. However, changes to the bill are necessary. The Commission should be directed to develop rules selecting the languages, and the timeline should be moved back to 2025.

The number of languages should be reduced to five and the impact of this bill should be considered for small, independent pharmacies. The technology needed to translate and print these labels can be expensive. If pharmacies in rural and underserved communities close, the communities will be even more underserved.

Persons Testifying: (In support) Representative Cody; Amanda Kost, Harborview Family Medicine; Adithya Vegaraju and Luis Manriquez, Health Equity Circle; Ghazal Meratnia; Atia Iqbal, Refugee Connections Spokane; Jennifer Nguyen; Charles Lee, First Databank;

Joana Ramos, Washington State Coalition for Language Access; Nico Dimenstein; and Anthony Bui, Washington Chapter American Academy of Pediatrics.

(Opposed) Jenny Arnold, Washington State Pharmacy Association; Carolyn Logue, Washington Food Industry Association; and Mark Johnson, Washington Retail Association.

(Other) Deborah Rader, MultiCare Health System; Teri Ferreira, Pharmacy Quality Assurance Commission; and Lisa Thatcher, Washington State Hospital Association.

Persons Signed In To Testify But Not Testifying: Phuong Van; Shadan Abdali; Melanie Neff, Seattle Children's Hospital; and Kathleen Hennings.