Washington State
House of Representatives
Office of Program Research

BILL ANALYSIS

Health Care & Wellness Committee

HB 1852

Brief Description: Concerning language requirements for prescription drug labels.

Sponsors: Representatives Thai, Cody, Gregerson, Macri, Santos, Slatter, Valdez, Pollet and Riccelli.

Brief Summary of Bill

- Requires pharmacies to provide translated prescription directions and side effects, if requested, to the extent translations are provided by the Pharmacy Quality Assurance Commission.

Hearing Date: 1/17/22

Staff: Kim Weidenaar

Background:

The Pharmacy Quality Assurance Commission regulates the practice of pharmacy, and the distribution, manufacturing, and delivery of pharmaceuticals within and into the state. The label of a prescription container must 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

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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 Bill:

In addition to the English-language directions and side effects, beginning January 1, 2023, when a patient, patient's representative, or prescriber requests, a pharmacy or non-resident pharmacy must provide translated directions for use and the prescription drug's side effects on the prescription container or label.

The Pharmacy Quality Assurance Commission (Commission) must determine 15 languages for which translation is required. When choosing the languages, the Commission must consider the percent of the population in Washington that speaks the language, the population's access to health care, and principles of equity. The Commission must reassess and update the languages as needed every five years.

The Commission must make translations of directions and common side effects available in the selected languages and develop signage to notify the public of the availability of the translation service that pharmacies must post. To complete the translations the Commission may contract with a state or nonstate entity.

Pharmacies are not required to provide translations beyond those provided by the Commission, but a pharmacy may provide their own translations. Pharmacies are responsible only for the accuracy of the directions and side effects written in English. A pharmacy or pharmacist may not be held liable for relying in good faith on the translated directions or side effects provided by the Commission or for providing translated directions beyond those the Commission provided, if the translation was provided in good faith.

Appropriation: None.

Fiscal Note: Requested on January 10, 2022.

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