House Bill 2801

Sponsored by Representative ALONSO LEON, Senator MONNES ANDERSON; Representatives GREENLICK, KENY-GUYER, NOSSE, SCHOUTEN, Senators FAGAN, MANNING JR, STEINER HAYWARD

SUMMARY

The following summary is not prepared by the sponsors of the measure and is not a part of the body thereof subject to consideration by the Legislative Assembly. It is an editor's brief statement of the essential features of the measure **as introduced.**

Requires pharmacists to label prescription drugs in language other than English if patient to whom prescription drug is dispensed is person of limited English proficiency. Defines "limited English proficiency."

Takes effect on 91st day following adjournment sine die.

A BILL FOR AN ACT

Relating to prescription drug labeling; creating new provisions; amending ORS 689.505; and prescribing an effective date.

Be It Enacted by the People of the State of Oregon:

SECTION 1. Section 2 of this 2019 Act is added to and made a part of ORS chapter 689.

SECTION 2. (1) As used in this section, "limited English proficiency" means identifying as being, or evidently being, unable to speak, read or write in English at a level that enables understanding health-related pharmaceutical information communicated in English.

(2) A prescription drug dispensed by a pharmacist or pharmacy intern to a patient who is of limited English proficiency must bear a label both in English and in a language that the patient can read and understand if the language understood by the patient is one spoken by 0.2 percent or more of the population of this state as determined by the most recent Oregon census. The pharmacist or pharmacist intern shall determine whether the patient is of limited English proficiency.

(3) A pharmacy shall post in a conspicuous location, either at or adjacent to each counter over which prescription drugs are dispensed, a notification of the right to free, competent oral interpretation and translation services for patients who are of limited English proficiency. The notification must:

(a) Be written in the languages described in subsection (2) of this section.

(b) Meet the requirements for size, font and placement as determined by rules adopted by the State Board of Pharmacy under this section.

(4) A prescription drug label under this section must comply with ORS 689.505.

(5) A pharmacy may contract with a third party in order to comply with the requirements of this section.

(6) The board shall adopt rules to carry out this section.

SECTION 3. ORS 689.505 is amended to read:

689.505. (1)(a) Except as specifically provided by law **and in compliance with section 2 of this 2019 Act**, [*no person shall*] **a person may not** distribute or dispense any drug without affixing to the authorized container a clear and legible label, either printed or written, bearing the name of the drug and the name and place of business of the person distributing or dispensing the drug, and any

NOTE: Matter in **boldfaced** type in an amended section is new; matter [*italic and bracketed*] is existing law to be omitted. New sections are in **boldfaced** type.

other information required by state law or rules or federal law or regulations under whose supervision the drug is delivered or dispensed.

(b) Labeling requirements regarding any drug may be changed or exemption therefrom granted by the State Board of Pharmacy in the form of a special permit if the board determines that a change or exemption is in the best interest of public health and safety.

(2)(a) [*No*] **A** manufacturer or wholesaler subject to ORS 689.305 [*shall*] **may not** sell or otherwise distribute, or offer to sell or otherwise distribute, any drug for use in a:

(A) Parcel, package or container not bearing a label specifying the name, active ingredients or contents, quality and quantity of the drug.

(B) Misbranded parcel, package or container.

(b) A parcel, package or container is misbranded:

(A) If its labeling is false or misleading in any particular.

(B) Unless it bears a label containing the name and business address of the manufacturer, packer, distributor or wholesaler, and an accurate statement of the quantity of the drug in terms of weight, measure or numerical count, exclusive of wrappers, cartons, containers or other materials packed with such drug.

(C) In case it contains controlled substances [*which*] **that** the board finds and by rule designates after reasonable notice and opportunity for hearing to be habit forming, unless it bears the statement "Warning--May Be Habit Forming."

(D) Unless it bears a label with adequate directions for the safe use of the drug for specified conditions, and adequate warning against use in those pathological conditions or by children where such use may be dangerous to the health or welfare of a user.

(E) Unless it bears a label with true representations of the intended uses of the drug and no false claims or representations are made of the drug in accompanying literature or advertising.

(3) This section does not apply to parcels, packages or containers containing:

(a) Drugs prepared and packaged solely for use by a pharmacist in compounding prescriptions or for dispensing in dosage unit form upon a prescription, except that such parcels, packages or containers must bear the name and business address of the manufacturer and, if different, the name and business address of the distributor of the drug, and the legend "Caution: Federal Law Prohibits Dispensing Without Prescription" or an equivalent legend.

(b) Drugs intended solely for use in the professional diagnosis of disease, except that such parcels, packages or containers shall bear the statement "Diagnostic Reagent--For Professional Use Only."

(c) Coloring agents, emulsifiers, excipients, flavorings, lubricants, preservatives and other like inactive ingredients used in the manufacture of drugs.

(4) The board shall by rule exempt from any labeling or packaging requirement of this section drugs [*which*] **that** are, in accordance with the practice of the trade, to be processed, labeled or repacked in substantial quantities at establishments other than those where originally processed or packed. However, such drugs must not be adulterated or misbranded upon removal from such processing, labeling or repacking establishment.

(5) A pharmacist or pharmacy intern [*shall*] **may** not dispense, on the prescription of a practitioner, any drug without affixing to the container thereof a clear and legible label. The label may be printed or written. Except as provided in subsection (6) of this section, the pharmacist or pharmacy intern shall state or cause to be stated on the label the following:

(a) The name of the drug. If the dispensed drug does not have a brand name, the prescription

label shall indicate the generic name of the drug dispensed along with the name of the drug distributor or manufacturer, its quantity per unit and the directions for its use stated in the prescription. However, if the drug is a compound, the quantity per unit need not be stated.

(b) The name of the practitioner prescribing the drug.

(c) The name and place of business of the pharmacist or the name and place of business of the pharmacy for which the pharmacist or pharmacy intern is acting.

(d) The name of the patient, unless the drug is prescribed to a partner of a patient as defined in ORS 676.350 in accordance with rules adopted under ORS 676.350 authorizing the practice of expedited partner therapy.

(e) When applicable and as determined by the [*State Board of Pharmacy*] **board**, an expiration date after which the patient should not use the drug.

(6) If the prescribing practitioner so directs, the prescription label [*shall*] **may** not state the name and quantity per unit of the drug.

(7) The [*State Board of Pharmacy*] **board** shall determine those drugs [*which*] **that** must bear an expiration date under subsection (5)(e) of this section.

(8) As used in this section, "compound" means a drug containing two or more medically active ingredients.

(9) [*No*] **A** person [*shall*] **may not** deliver or dispense any drug for use by the ultimate consumer without labeling the drug container as required in this section.

(10) In addition to the labeling requirements imposed by subsections (1) to (9) of this section, the board may impose by rule requirements for drug code imprints on solid dose legend drugs.

SECTION 4. (1) Section 2 of this 2019 Act and the amendments to ORS 689.505 by section 3 of this 2019 Act become operative on January 1, 2020.

(2) The State Board of Pharmacy may take any action before the operative date specified in subsection (1) of this section that enables the board to exercise, on or after the operative date specified in subsection (1) of this section, all of the duties, functions and powers conferred on the board by section 2 of this 2019 Act and the amendments to ORS 689.505 by section 3 of this 2019 Act.

SECTION 5. This 2019 Act takes effect on the 91st day after the date on which the 2019 regular session of the Eightieth Legislative Assembly adjourns sine die.