

A-Engrossed Senate Bill 698

Ordered by the Senate April 15
Including Senate Amendments dated April 15

Sponsored by Senator MONNES ANDERSON, Representative NOSSE; Senators BEYER, BURDICK, DEMBROW, FAGAN, MANNING JR, STEINER HAYWARD, THATCHER, Representatives ALONSO LEON, GORSEK, KENY-GUYER, MCLAIN, MEEK, PILUSO, POWER, PRUSAK, REARDON, SALINAS, SANCHEZ, SCHOUTEN

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.

[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."]

Directs State Board of Pharmacy to adopt rules to require prescription drugs for specified persons be labeled or dispensed with informational insert in English and other language. Specifies languages other than English to be used on label and insert and allows board to require additional languages.

Directs board to adopt rules to require pharmacy to post signage regarding patients' right to free, competent oral interpretation and translation services.

Becomes operative January 1, 2021.

Takes effect on 91st day following adjournment sine die.

A BILL FOR AN ACT

1
2 Relating to prescription drug labeling; creating new provisions; amending ORS 689.505; and pre-
3 scribing an effective date.

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

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

6 **SECTION 2. (1) The State Board of Pharmacy shall adopt rules to require that, if a pa-
7 tient is of limited English proficiency and the prescribing practitioner, patient or an au-
8 thorized representative of the patient so requests, a prescription drug dispensed by a
9 pharmacist or pharmacy intern bear a label, or be dispensed with an informational insert, in
10 both English and in a language that the patient can read and understand. The rules adopted
11 under this section must:**

12 **(a) Define "limited English proficiency."**

13 **(b) Determine the pharmacies to which the requirements of this section apply, and in-
14 clude at least pharmacies located in hospitals and in drug stores.**

15 **(c)(A) Require that labels and informational inserts be available in at least the following
16 languages:**

17 **(i) Spanish.**

18 **(ii) Chinese.**

19 **(iii) Vietnamese.**

20 **(iv) Russian.**

21 **(v) Korean.**

22 **(vi) Japanese.**

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.

1 (vii) Tagalog.

2 (viii) Arabic.

3 (ix) Khmer.

4 (x) Persian.

5 (xi) Nepali.

6 (xii) Somali.

7 (xiii) Karen.

8 (xiv) Swahili.

9 (B) Allow the board to require that labels and informational inserts be available in addi-
10 tional languages in response to the demographics of communities in this state, and to consult
11 the most recent American Community Survey from the United States Census Bureau and
12 other resources as necessary to determine the language needs of each community.

13 (d) Establish a list of statements for prescription drug labels and informational inserts
14 that must be available in the languages described in paragraph (c) of this subsection.

15 (e) Determine for which prescription drugs it is appropriate to include an informational
16 insert.

17 (2)(a) A pharmacy may contract with a third party for the translation of the labels and
18 informational inserts required under subsection (1) of this section.

19 (b) A pharmacy, pharmacist or pharmacy intern that dispenses a prescription drug in
20 compliance with the requirements of subsection (1) of this section may not be held liable for
21 injuries resulting from the actions of a third party if the pharmacy from which the label or
22 informational insert was dispensed entered into a contract with the third party in good faith,
23 and the pharmacy, pharmacist or pharmacy intern was not negligent with regard to the al-
24 leged misconduct of the third party.

25 (3) The board may adopt other rules as necessary to carry out this section.

26 (4) The board shall, in consultation with the Oregon Health Authority, adopt rules to
27 require that a pharmacy post signage to provide notification of the right to free, competent
28 oral interpretation and translation services for patients who are of limited English profi-
29 ciency. Rules adopted under this subsection must comply with any relevant federal laws and
30 regulations.

31 **SECTION 3.** ORS 689.505 is amended to read:

32 689.505. (1)(a) Except as specifically provided by law **and in compliance with section 2 of this**
33 **2019 Act**, [no person shall] **a person may not** distribute or dispense any drug without affixing to
34 the authorized container a clear and legible label, either printed or written, bearing the name of the
35 drug and the name and place of business of the person distributing or dispensing the drug, and any
36 other information required by state law or rules or federal law or regulations under whose super-
37 vision the drug is delivered or dispensed.

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

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

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

45 (B) Misbranded parcel, package or container.

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

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

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

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

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

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

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

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

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

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

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

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

35 (a) The name of the drug. If the dispensed drug does not have a brand name, the prescription
36 label shall indicate the generic name of the drug dispensed along with the name of the drug dis-
37 tributor or manufacturer, its quantity per unit and the directions for its use stated in the pre-
38 scription. However, if the drug is a compound, the quantity per unit need not be stated.

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

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

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

45 (e) When applicable and as determined by the [*State Board of Pharmacy*] **board**, an expiration

1 date after which the patient should not use the drug.

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

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

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

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

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

12 **SECTION 4. (1) Section 2 of this 2019 Act and the amendments to ORS 689.505 by section**
13 **3 of this 2019 Act become operative on January 1, 2021.**

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

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

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