

House Bill 2753

Sponsored by Representatives SALINAS, NOSSE

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 pharmacist to substitute prescribed brand name drug with generic name drug product.
Declares emergency, effective on passage.

A BILL FOR AN ACT

1
2 Relating to pharmaceutical substitutions; creating new provisions; amending ORS 689.515; and de-
3 claring an emergency.

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

5 **SECTION 1.** ORS 689.515 is amended to read:

6 689.515. (1) As used in this section unless the context requires otherwise:

7 (a) "Brand name" means the proprietary or trade name selected by the manufacturer and placed
8 upon a drug, its container, label or wrapping at the time of packaging.

9 (b) "Dosage form" means the physical formulation or medium in which the product is intended,
10 manufactured and made available for use, including but not limited to tablets, capsules, oral sol-
11 utions, aerosols, ointments, inhalers and suppositories, and the particular form of which utilizes a
12 specific technology or mechanism to control, enhance or direct the release, targeting, systemic ab-
13 sorption or other delivery of a dosage regimen in the body.

14 (c) "Generic name" means the official title of a drug or drug ingredients published in the latest
15 edition of the official Pharmacopoeia, Homeopathic Pharmacopoeia or Formulary.

16 (d) "Substitute" means to dispense without the prescriber's express authorization a different
17 drug product in place of the drug ordered or prescribed.

18 (e) "Therapeutically equivalent" means drugs that are approved by the United States Food and
19 Drug Administration for interstate distribution and the Food and Drug Administration has deter-
20 mined that the drugs will provide essentially the same efficacy and toxicity when administered to
21 an individual in the same dosage regimen.

22 (2) Except as limited by subsections (3) and (5) of this section, unless the purchaser instructs
23 otherwise, a pharmacist [*may*] **shall** substitute as follows:

24 (a) A drug product with the same generic name in the same strength, quantity, dose and dosage
25 form as the prescribed drug which is, in the pharmacist's professional opinion, therapeutically
26 equivalent.

27 (b) When the prescriber is not reasonably available for consultation and the prescribed drug
28 does not utilize a unique delivery system technology, an oral tablet, capsule or liquid form of the
29 prescribed drug so long as the form dispensed or administered has the same strength, dose and dose
30 schedule and is therapeutically equivalent to the drug prescribed.

31 (3) A practitioner may specify in writing, by a telephonic communication or by electronic

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 transmission that there may be no substitution for the specified brand name drug in a prescription.

2 (4) A pharmacy shall post a sign in a location easily seen by patrons at the counter where
 3 prescriptions are dispensed or administered stating that, "This pharmacy may be able to substitute
 4 a less expensive drug which is therapeutically equivalent to the one prescribed by your doctor un-
 5 less you do not approve." The printing on the sign must be in block letters not less than one inch
 6 in height. If the pharmacist has reasonable cause to believe that the purchaser cannot read the sign
 7 or comprehend its content, the pharmacist shall endeavor to explain the meaning of the sign.

8 (5) A pharmacist may substitute a drug product under this section only when there will be a
 9 savings in or no increase in cost to the purchaser.

10 (6) If the practitioner prescribes a drug by its generic name, the pharmacist shall, consistent
 11 with reasonable professional judgment, dispense or administer the lowest retail cost, effective brand
 12 which is in stock.

13 (7) Except as provided in subsection (8) of this section, when a pharmacist dispenses a substi-
 14 tuted drug as authorized by subsection (2) of this section, the pharmacist shall label the prescription
 15 container with the name of the dispensed drug. If the dispensed drug does not have a brand name,
 16 the pharmacist shall label the prescription container with the generic name of the drug dispensed
 17 along with the name of the drug manufacturer.

18 (8) A prescription dispensed by a pharmacist must bear upon the label the name of the
 19 medication in the container or [shall] **must** be labeled as intended by the prescriber.

20 (9) The substitution of any drug by a pharmacist or the pharmacist's employer pursuant to this
 21 section does not constitute the practice of medicine.

22 (10) A substitution of drugs made by a pharmacist or the pharmacist's employer in accordance
 23 with this section and any rules that the State Board of Pharmacy may adopt thereunder does not
 24 constitute evidence of negligence if the substitution was made within reasonable and prudent prac-
 25 tice of pharmacy or if the substituted drug was accepted in a generally recognized formulary or
 26 government list.

27 (11) Failure of a practitioner to specify that no substitution is authorized does not constitute
 28 evidence of negligence unless the practitioner knows that the health condition of the patient for
 29 whom the practitioner is prescribing warrants the use of the brand name drug product and not the
 30 substituted drug.

31 **SECTION 2. The amendments to ORS 689.515 by section 1 of this 2019 Act apply to drug**
 32 **products prescribed on and after the operative date of this 2019 Act.**

33 **SECTION 3. (1) The amendments to ORS 689.515 by section 1 of this 2019 Act become**
 34 **operative on January 1, 2020.**

35 **(2) The State Board of Pharmacy may take any action before the operative date specified**
 36 **in subsection (1) of this section that is necessary to enable the board to exercise, on and**
 37 **after the operative date specified in subsection (1) of this section, all of the duties, functions**
 38 **and powers conferred on the board by the amendments to ORS 689.515 by section 1 of this**
 39 **2019 Act.**

40 **SECTION 4. This 2019 Act being necessary for the immediate preservation of the public**
 41 **peace, health and safety, an emergency is declared to exist, and this 2019 Act takes effect**
 42 **on its passage.**