

House Bill 3541

Sponsored by Representative THOMPSON; Representatives BENTZ, BREWER, CAMERON, CLEM, CONGER, ESQUIVEL, FREEMAN, GARRARD, GARRETT, GILLIAM, HUFFMAN, JENSON, JOHNSON, KENNEMER, KRIEGER, MATTHEWS, MCLANE, OLSON, READ, SCHAUFLE, SHEEHAN, SPRENGER, THATCHER, WAND, WEIDNER, WHISNANT, WINGARD, Senators BEYER, BOQUIST, DEVLIN, GEORGE, GIROD, KRUSE, MORSE, NELSON, TELFER, THOMSEN, WHITSETT, WINTERS

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**.

Prohibits pharmacist from dispensing drug that is not therapeutically equivalent to drug ordered or prescribed unless prescriber and patient have consented in writing.

A BILL FOR AN ACT

1
2 Relating to therapeutic substitution; amending ORS 689.515.

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

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

5 689.515. (1) As used in this section unless the context requires otherwise:

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

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

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

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

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

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

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

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

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 (3) A practitioner may specify in writing, by a telephonic communication or by electronic
2 transmission that there may be no substitution for the specified brand name drug in a prescription.

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

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

11 **(6) A pharmacist may not dispense a drug product that is not therapeutically equivalent**
12 **to the drug product originally ordered or prescribed by a prescriber unless the prescriber and**
13 **the patient have consented to the substitution in writing.**

14 [(6)] (7) If the practitioner prescribes a drug by its generic name, the pharmacist shall, consist-
15 ent with reasonable professional judgment, dispense or administer the lowest retail cost, effective
16 brand which is in stock.

17 [(7)] (8) Except as provided in subsection [(8)] (9) of this section, when a pharmacist dispenses
18 a substituted drug as authorized by subsection (2) of this section, the pharmacist shall label the
19 prescription container with the name of the dispensed drug. If the dispensed drug does not have a
20 brand name, the pharmacist shall label the prescription container with the generic name of the drug
21 dispensed along with the name of the drug manufacturer.

22 [(8)] (9) A prescription dispensed by a pharmacist must bear upon the label the name of the
23 medication in the container or shall be labeled as intended by the prescriber.

24 [(9)] (10) The substitution of any drug by a pharmacist or the pharmacist's employer pursuant
25 to this section does not constitute the practice of medicine.

26 [(10)] (11) A substitution of drugs made by a pharmacist or the pharmacist's employer in ac-
27 cordance with this section and any rules that the State Board of Pharmacy may adopt thereunder
28 does not constitute evidence of negligence if the substitution was made within reasonable and pru-
29 dent practice of pharmacy or if the substituted drug was accepted in a generally recognized
30 formulary or government list.

31 [(11)] (12) Failure of a practitioner to specify that no substitution is authorized does not con-
32 stitute evidence of negligence unless the practitioner knows that the health condition of the patient
33 for whom the practitioner is prescribing warrants the use of the brand name drug product and not
34 the substituted drug.

35