

House Bill 2786

Sponsored by Representative BUTLER (at the request of Darrell St. John)

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 purchaser and practitioner prescribing medications to authorize substitution of generic drugs. Specifies instructions required to authorized pharmacist to make substitution.

A BILL FOR AN ACT

1
2 Relating to substitution of generic drug for brand name drug; 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 solutions, 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*] **with** the prescriber's express authorization a dif-
16 ferent 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*] **If specifically authorized**
22 **by the purchaser [*instructs otherwise*], the 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.

30 (3) A practitioner [*may*] **must** specify in writing, by a telephonic communication or by electronic
31 transmission that [*there shall be no*] **a** substitution for the specified brand name drug in any pre-

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 prescription **may be made by the pharmacist if authorized by the purchaser.** The phrase [*no sub-*
 2 *stitution*] or the notation "N.S." "**substitution permitted**" or "**substitution authorized**" or words
 3 **of similar intent** must be in the practitioner's handwriting or, if the [*prohibition*] **authorization**
 4 was communicated by telephonic communication or electronic transmission, in the pharmacist's
 5 handwriting and shall not be preprinted or stamped or initialed on the prescription form.

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

12 (5) A pharmacist [*shall*] **may** substitute a drug product under this section only when **authorized**
 13 **to do so by the purchaser and the practitioner issuing the prescription and when** there will
 14 be a savings in or no increase in cost to the purchaser.

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

18 (7) Except as provided in subsection (8) of this section, when a pharmacist dispenses a substi-
 19 tuted drug as authorized by subsection (2) of this section, the pharmacist must label the prescription
 20 container with the name of the dispensed drug. If the dispensed drug does not have a brand name,
 21 the prescription label shall indicate the generic name of the drug dispensed along with the name
 22 of the drug manufacturer.

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

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

27 (10) No substitution of drugs made by a pharmacist or the pharmacist's employer in accordance
 28 with this section and any rules that the State Board of Pharmacy may adopt thereunder shall con-
 29 stitute evidence of negligence if the substitution was made within reasonable and prudent practice
 30 of pharmacy or if the substituted drug was accepted in a generally recognized formulary or gov-
 31 ernment list.

32 (11) [*Failure of*] **Authorization by** a practitioner [*to specify that no*] **allowing a** substitution [*is*
 33 *authorized*] does not constitute evidence of negligence unless the practitioner knows that the health
 34 condition of the patient for whom the practitioner is prescribing warrants the use of the brand name
 35 drug product and not the substituted drug.

36