

HOUSE AMENDMENTS TO HOUSE BILL 3103

By COMMITTEE ON HEALTH CARE

April 27

1 On page 5 of the printed bill, delete lines 22 through 45.

2 On page 6, delete lines 1 through 38 and insert:

3 “**SECTION 4.** ORS 689.515 is amended to read:

4 “689.515. (1) As used in this section unless the context requires otherwise:

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

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

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

14 “(d) ‘Substitute’ means to dispense without the prescriber’s express authorization a different
15 drug product in place of the drug ordered or prescribed.

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

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

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

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

29 “(3) A practitioner may specify in writing, by a telephonic communication or by electronic
30 transmission that there *[shall]* **may** be no substitution for the specified brand name drug in *[any]* a
31 prescription. *[The phrase ‘no substitution’ or the notation ‘N.S.’ must be in the practitioner’s hand-
32 writing or, if the prohibition was communicated by telephonic communication or electronic trans-
33 mission, in the pharmacist’s handwriting and shall not be preprinted or stamped or initialed on the
34 prescription form.]*

35 “(4) *[Every]* A pharmacy shall post a sign in a location easily seen by patrons at the counter

1 where prescriptions are dispensed or administered stating that, 'This pharmacy may be able to sub-
2 stitute a less expensive drug which is therapeutically equivalent to the one prescribed by your
3 doctor unless you do not approve.' The printing on the sign [*shall*] **must** be in block letters not less
4 than one inch in height. If the pharmacist has reasonable cause to believe that the purchaser cannot
5 read the sign or comprehend its content, the pharmacist shall endeavor to explain the meaning of
6 the sign.

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

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

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

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

20 "(9) The substitution of any drug by a [*licensed*] pharmacist or the pharmacist's employer pur-
21 suant to this section does not constitute the practice of medicine.

22 "(10) [*No*] **A** substitution of drugs made by a pharmacist or the pharmacist's employer in ac-
23 cordance with this section and any rules that the State Board of Pharmacy may adopt thereunder
24 [*shall*] **does not** constitute evidence of negligence if the substitution was made within reasonable
25 and prudent practice of pharmacy or if the substituted drug was accepted in a generally recognized
26 formulary or 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."

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