

WEST VIRGINIA LEGISLATURE

2019 REGULAR SESSION

Enrolled

Committee Substitute

for

Senate Bill 369

SENATORS TAKUBO, STOLLINGS, AND BALDWIN, *original sponsors*

[Passed March 8, 2019; in effect 90 days from
passage]

1 AN ACT to amend and reenact §30-5-12b of the Code of West Virginia, 1931, as amended,
2 relating generally to generic drug products; providing definitions; providing that when a
3 pharmacist substitutes a drug the patient shall receive the savings which shall be equal to
4 the difference in acquisition cost of the product prescribed and the acquisition cost of the
5 substituted product; providing an exception for covered individuals; and clarifying that the
6 West Virginia Board of Pharmacy has primary responsibility for enforcement.

Be it enacted by the Legislature of West Virginia:

**ARTICLE 5. PHARMACISTS, PHARMACY TECHNICIANS, PHARMACY INTERNS,
AND PHARMACIES.**

**§30-5-12b. Definitions; selection of generic drug products; exceptions; records; labels;
manufacturing standards; rules; notice of substitution; complaints; notice and
hearing; immunity.**

1 (a) As used in this section:

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

4 (2) "Covered entity" means:

5 (A) Any hospital or medical service organization, insurer, health coverage plan, or health
6 maintenance organization licensed in the state that contracts with another entity to provide
7 prescription drug benefits for its customers or clients;

8 (B) Any health program administered by the state in its capacity as provider of health
9 coverage; or

10 (C) Any employer, labor union, or other group of persons organized in the state that
11 contracts with another entity to provide prescription drug benefits for its employees or members.

12 (3) "Covered individual" means a member, participant, enrollee, contract holder, policy
13 holder, or beneficiary of a covered entity who is provided a prescription drug benefit by a covered

14 entity. The term “covered individual” includes a dependent or other person provided a prescription
15 drug benefit through a policy, contract, or plan for a covered individual.

16 (4) “Generic name” means the official title of a drug or drug combination for which a new
17 drug application, or an abbreviated new drug application, has been approved by the United States
18 Food and Drug Administration and is in effect.

19 (5) “Substitute” means to dispense a therapeutically equivalent generic drug product in
20 the place of the drug ordered or prescribed.

21 (6) “Equivalent” means drugs or drug products which are the same amounts of identical
22 active ingredients and same dosage form and which will provide the same therapeutic efficacy
23 and toxicity when administered to an individual and is approved by the United States Food and
24 Drug Administration.

25 (b) A pharmacist who receives a prescription for a brand name drug or drug product shall
26 substitute a less expensive equivalent generic name drug or drug product unless, in the exercise
27 of his or her professional judgment, the pharmacist believes that the less expensive drug is not
28 suitable for the particular patient: *Provided*, That a substitution may not be made by the
29 pharmacist where the prescribing practitioner indicates that, in his or her professional judgment,
30 a specific brand name drug is medically necessary for a particular patient.

31 (c) A written prescription order shall permit the pharmacist to substitute an equivalent
32 generic name drug or drug product except where the prescribing practitioner has indicated in his
33 or her own handwriting the words “Brand Medically Necessary”. The following sentence shall be
34 printed on the prescription form: “This prescription may be filled with a generically equivalent drug
35 product unless the words ‘Brand Medically Necessary’ are written, in the practitioner’s own
36 handwriting, on this prescription form”: *Provided*, That “Brand Medically Necessary” may be
37 indicated on the prescription order other than in the prescribing practitioner’s own handwriting
38 unless otherwise required by federal mandate.

39 (d) A verbal prescription order shall permit the pharmacist to substitute an equivalent
40 generic name drug or drug product except where the prescribing practitioner indicates to the
41 pharmacist that the prescription is "Brand Necessary" or "Brand Medically Necessary". The
42 pharmacist shall note the instructions on the file copy of the prescription or chart order form.

43 (e) A person may not by trade rule, work rule, contract or in any other way prohibit, restrict,
44 limit, or attempt to prohibit, restrict, or limit the making of a generic name substitution under the
45 provisions of this section. An employer or his or her agent may not use coercion or other means
46 to interfere with the professional judgment of the pharmacist in deciding which generic name
47 drugs or drug products shall be stocked or substituted: *Provided*, That this section may not be
48 construed to permit the pharmacist to generally refuse to substitute less expensive therapeutically
49 equivalent generic drugs for brand name drugs and that any pharmacist so refusing is subject to
50 the penalties prescribed §30-5-34 of this code.

51 (f) A pharmacist may substitute a drug pursuant to the provisions of this section only where
52 there will be a savings to the purchaser. Where substitution is proper, pursuant to this section, or
53 where the practitioner prescribes the drug by generic name, the pharmacist shall, consistent with
54 his or her professional judgment, dispense the lowest retail cost-effective brand which is in stock.

55 (g) If a pharmacist substitutes a drug pursuant to the provisions of this section, the patient
56 shall receive the savings which shall be equal to the difference in the patient's acquisition cost of
57 the product prescribed and the acquisition cost of the substituted product: *Provided*, That this
58 subsection may not apply if the patient is a covered individual.

59 (h) Each pharmacy shall maintain a record of any substitution of an equivalent generic
60 name drug product for a prescribed brand name drug product on the file copy of a written,
61 electronic or verbal prescription or chart order. The record shall include the manufacturer and
62 generic name of the drug product selected.

63 (i) All drugs shall be labeled in accordance with the instructions of the practitioner.

64 (j) Unless the practitioner directs otherwise, the prescription label on all drugs dispensed
65 by the pharmacist shall indicate the generic name using abbreviations, if necessary, and either
66 the name of the manufacturer or packager, whichever is applicable in the pharmacist's discretion.
67 The same notation will be made on the original prescription retained by the pharmacist.

68 (k) A pharmacist may not dispense a product under the provisions of this section unless
69 the manufacturer has shown that the drug has been manufactured with the following minimum
70 good manufacturing standards and practices by:

71 (1) Labeling products with the name of the original manufacturer and control number;

72 (2) Maintaining quality control standards equal to or greater than those of the United States
73 Food and Drug Administration;

74 (3) Marking products with an identification code or monogram; and

75 (4) Labeling products with an expiration date.

76 (l) The West Virginia Board of Pharmacy shall promulgate rules in accordance with the
77 provisions of §29A-3-1 *et seq.* of this code which establish a formulary of generic type and brand
78 name drug products which are determined by the board to demonstrate significant biological or
79 therapeutic inequivalence and which, if substituted, would pose a threat to the health and safety
80 of patients receiving prescription medication. The formulary shall be promulgated by the board
81 within 90 days of the date of passage of this section and may be amended in accordance with the
82 provisions of that chapter.

83 (m) A pharmacist may not substitute a generic-named therapeutically equivalent drug
84 product for a prescribed brand name drug product if the brand name drug product or the generic
85 drug type is listed on the formulary established by the West Virginia Board of Pharmacy pursuant
86 to this article or is found to be in violation of the requirements of the United States Food and Drug
87 Administration.

88 (n) Any pharmacist who substitutes any drug shall, either personally or through his or her
89 agent, assistant, or employee, notify the person presenting the prescription of the substitution.

90 The person presenting the prescription may refuse the substitution. Upon request the pharmacist
91 shall relate the retail price difference between the brand name and the drug substituted for it.

92 (o) Every pharmacy shall post in a prominent place that is in clear and unobstructed public
93 view, at or near the place where prescriptions are dispensed, a sign which shall read: "West
94 Virginia law requires pharmacists to substitute a less expensive generic-named therapeutically
95 equivalent drug for a brand name drug, if available, unless you or your physician direct otherwise".
96 The sign shall be printed with lettering of at least one and one-half inches in height with
97 appropriate margins and spacing as prescribed by the West Virginia Board of Pharmacy.

98 (p) The West Virginia Board of Pharmacy shall promulgate rules in accordance with §29A-
99 3-1 *et seq.* of this code setting standards for substituted drug products and obtaining compliance
100 with the provisions of this section. The board has the primary responsibility for enforcing the
101 provisions of this section.

102 (q) Any person may file a complaint with the West Virginia Board of Pharmacy regarding
103 any violation of the provisions of this article. The complaints shall be investigated by the Board of
104 Pharmacy.

105 (r) Fifteen days after the board has notified, by registered mail, a person, firm, corporation,
106 or copartnership that the person, firm, corporation, or copartnership is suspected of being in
107 violation of a provision of this section, the board shall hold a hearing on the matter. If, as a result
108 of the hearing, the board determines that a person, firm, corporation, or copartnership is violating
109 any of the provisions of this section, it may, in addition to any penalties prescribed by §30-5-22 of
110 this code, suspend or revoke the permit of any person, firm, corporation, or copartnership to
111 operate a pharmacy.

112 (s) A pharmacist or pharmacy complying with the provisions of this section may not be
113 liable in any way for the dispensing of a generic-named therapeutically equivalent drug,
114 substituted under the provisions of this section, unless the generic-named therapeutically
115 equivalent drug was incorrectly substituted.

116 (t) In no event where the pharmacist substitutes a drug under the provisions of this section
117 may the prescribing physician be liable in any action for loss, damage, injury, or death of any
118 person occasioned by or arising from the use of the substitute drug unless the original drug was
119 incorrectly prescribed.

120 (u) Failure of a practitioner to specify that a specific brand name is necessary for a
121 particular patient may not constitute evidence of negligence unless the practitioner had
122 reasonable cause to believe that the health of the patient required the use of a certain product
123 and no other.

The Joint Committee on Enrolled Bills hereby certifies that the foregoing bill is correctly enrolled.

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Chairman, Senate Committee

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Chairman, House Committee

Originated in the Senate.

In effect 90 days from passage.

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Clerk of the Senate

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Clerk of the House of Delegates

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President of the Senate

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Speaker of the House of Delegates

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Day of, 2019.

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Governor