

# **WEST VIRGINIA LEGISLATURE**

**2017 REGULAR SESSION**

**Committee Substitute**

**for**

**Senate Bill 406**

BY SENATOR TAKUBO

[Originating in the Committee on the Judiciary;

reported on March 25, 2017]



1 A BILL to amend and reenact §30-5-12b of the Code of West Virginia, 1931, as amended, relating  
2 generally to generic drug products; providing definitions; providing that when a pharmacist  
3 substitutes a drug, the patient shall receive the savings which shall be equal to the  
4 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:*

1 That §30-5-12b of the Code of West Virginia, 1931, as amended, be amended and  
2 reenacted to read as follows:

**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           ~~(2)~~(4) “Generic name” means the official title of a drug or drug combination for which a  
17 new drug application, or an abbreviated new drug application, has been approved by the United  
18 States Food and Drug Administration and is in effect.

19           ~~(3)~~(5) “Substitute” means to dispense ~~without the prescriber’s express authorization~~ a  
20 therapeutically equivalent generic drug product in the place of the drug ordered or prescribed.

21           ~~(4)~~(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 no substitution may be made by the pharmacist  
29 where the prescribing practitioner indicates that, in his or her professional judgment, a specific  
30 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 shall indicate 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) No person may 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. No employer or his or her agent may use coercion or other means to  
46 interfere with the professional judgment of the pharmacist in deciding which generic name drugs  
47 or drug products shall be stocked or substituted: *Provided*, That this section shall not be construed  
48 to permit the pharmacist to generally refuse to substitute less expensive therapeutically equivalent  
49 generic drugs for brand name drugs and that any pharmacist so refusing shall be subject to the  
50 penalties prescribed in section thirty-four of this article.

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 ~~buyer~~ purchaser. Where substitution is proper, pursuant to this  
53 section, or where the practitioner prescribes the drug by generic name, the pharmacist shall,  
54 consistent with his or her professional judgment, dispense the lowest retail cost, effective brand  
55 which is in stock.

56 ~~(g) All savings in the retail price of the prescription shall be passed on to the purchaser;~~  
57 ~~these savings shall be equal to the difference between the retail price of the brand name product~~  
58 ~~and the customary and usual price of the generic product substituted therefor: *Provided*, That in~~  
59 ~~no event shall such savings be less than the difference in acquisition cost of the brand name~~  
60 ~~product prescribed and the acquisition cost of the substituted product.~~

61 (g) If a pharmacist substitutes a drug pursuant to the provisions of this section, the patient  
62 shall receive the savings which shall be equal to the difference in acquisition cost of the product

63 prescribed and the acquisition cost of the substituted product: *Provided*, That this subsection shall  
64 not apply if the patient is a covered individual.

65 (h) Each pharmacy shall maintain a record of any substitution of an equivalent generic  
66 name drug product for a prescribed brand name drug product on the file copy of a written,  
67 electronic or verbal prescription or chart order. Such record shall include the manufacturer and  
68 generic name of the drug product selected.

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

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

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

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

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

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

81 (4) Labeling products with an expiration date.

82 (l) The West Virginia Board of Pharmacy shall promulgate rules in accordance with the  
83 provisions of chapter twenty-nine-a of this code which establish a formulary of generic type and  
84 brand name drug products which are determined by the board to demonstrate significant  
85 biological or therapeutic inequivalence and which, if substituted, would pose a threat to the health  
86 and safety of patients receiving prescription medication. The formulary shall be promulgated by  
87 the board within ninety days of the date of passage of this section and may be amended in  
88 accordance with the provisions of said chapter.

89 (m) No pharmacist shall substitute a generic-named therapeutically equivalent drug  
90 product for a prescribed brand name drug product if the brand name drug product or the generic  
91 drug type is listed on the formulary established by the West Virginia Board of Pharmacy pursuant  
92 to this article or is found to be in violation of the requirements of the United States Food and Drug  
93 Administration.

94 (n) Any pharmacist who substitutes any drug shall, either personally or through his or her  
95 agent, assistant or employee, notify the person presenting the prescription of such substitution.  
96 The person presenting the prescription shall have the right to refuse the substitution. Upon  
97 request the pharmacist shall relate the retail price difference between the brand name and the  
98 drug substituted for it.

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

105 (p) The West Virginia Board of Pharmacy shall promulgate rules in accordance with the  
106 provisions of chapter twenty-nine-a of this code setting standards for substituted drug products,  
107 obtaining compliance with the provisions of this section and has the primary responsibility for  
108 enforcing the provisions of this section.

109 (q) Any person shall have the right to file a complaint with the West Virginia Board of  
110 Pharmacy regarding any violation of the provisions of this article. Such complaints shall be  
111 investigated by the Board of Pharmacy.

112 (r) Fifteen days after the board has notified, by registered mail, a person, firm, corporation  
113 or copartnership that such person, firm, corporation or copartnership is suspected of being in  
114 violation of a provision of this section, the board shall hold a hearing on the matter. If, as a result

115 of the hearing, the board determines that a person, firm, corporation or copartnership is violating  
116 any of the provisions of this section, it may, in addition to any penalties prescribed by section  
117 twenty-two of this article, suspend or revoke the permit of any person, firm, corporation or  
118 copartnership to operate a pharmacy.

119 (s) No pharmacist or pharmacy complying with the provisions of this section shall be liable  
120 in any way for the dispensing of a generic-named therapeutically equivalent drug, substituted  
121 under the provisions of this section, unless the generic-named therapeutically equivalent drug  
122 was incorrectly substituted.

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

127 (u) Failure of a practitioner to specify that a specific brand name is necessary for a  
128 particular patient shall not constitute evidence of negligence unless the practitioner had  
129 reasonable cause to believe that the health of the patient required the use of a certain product  
130 and no other.

Strike-throughs indicate language that would be stricken from a heading or the present law  
and underscoring indicates new language that would be added.