

# **WEST VIRGINIA LEGISLATURE**

## **2018 REGULAR SESSION**

**Introduced**

### **House Bill 4483**

BY DELEGATE KESSINGER, HILL AND HANSHAW

[Introduced February 9, 2018; Referred  
to the Committee on Health and Human Resources  
then Finance.]

1 A BILL to amend and reenact §30-5-12b of the Code of West Virginia, 1931, as amended, relating  
2 to generic drug products; and making the provisions retroactive.

*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) "Generic name" means the official title of a drug or drug combination for which a new  
5 drug application, or an abbreviated new drug application, has been approved by the United States  
6 Food and Drug Administration and is in effect.

7 (3) "Substitute" means to dispense ~~without the prescriber's express authorization~~ a  
8 therapeutically equivalent generic drug product in the place of the drug ordered or prescribed.

9 (4) "Equivalent" means drugs or drug products which are the same amounts of identical  
10 active ingredients and same dosage form and which will provide the same therapeutic efficacy  
11 and toxicity when administered to an individual and is approved by the United States Food and  
12 Drug Administration.

13 (b) A pharmacist who receives a prescription for a brand name drug or drug product shall  
14 substitute a less expensive equivalent generic name drug or drug product unless in the exercise  
15 of his or her professional judgment the pharmacist believes that the less expensive drug is not  
16 suitable for the particular patient: *Provided*, That no substitution may be made by the pharmacist  
17 where the prescribing practitioner indicates that, in his or her professional judgment, a specific

18 brand name drug is medically necessary for a particular patient.

19 (c) A written prescription order shall permit the pharmacist to substitute an equivalent  
20 generic name drug or drug product except where the prescribing practitioner has indicated in his  
21 or her own handwriting the words "Brand Medically Necessary". The following sentence shall be  
22 printed on the prescription form. "This prescription may be filled with a generically equivalent drug  
23 product unless the words 'Brand Medically Necessary' are written, in the practitioner's own  
24 handwriting, on this prescription form.": *Provided*, That "Brand Medically Necessary" may be  
25 indicated on the prescription order other than in the prescribing practitioner's own handwriting  
26 unless otherwise required by federal mandate.

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

31 (e) No person may by trade rule, work rule, contract, or in any other way prohibit, restrict,  
32 limit, or attempt to prohibit, restrict, or limit the making of a generic name substitution under the  
33 provisions of this section. No employer or his or her agent may use coercion or other means to  
34 interfere with the professional judgment of the pharmacist in deciding which generic name drugs  
35 or drug products shall be stocked or substituted: *Provided*, That this section ~~shall~~ may not be  
36 construed to permit the pharmacist to generally refuse to substitute less expensive therapeutically  
37 equivalent generic drugs for brand name drugs and that any pharmacist so refusing shall be  
38 subject to the penalties prescribed in §30-5-34 of this code.

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

43 ~~(g) All savings in the retail price of the prescription shall be passed on to the purchaser;~~

44 ~~these savings shall be equal to the difference between the retail price of the brand name product~~  
45 ~~and the customary and usual price of the generic product substituted therefor: *Provided*, That in~~  
46 ~~no event shall such savings be less than the difference in acquisition cost of the brand name~~  
47 ~~product prescribed and the acquisition cost of the substituted product~~

48 (f) Each pharmacy shall maintain a record of any substitution of an equivalent generic  
49 name drug product for a prescribed brand name drug product on the file copy of a written,  
50 electronic or verbal prescription or chart order. ~~Such~~ The record shall include the manufacturer  
51 and generic name of the drug product selected.

52 (g) All drugs shall be labeled in accordance with the instructions of the practitioner.

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

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

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

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

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

64 (4) Labeling products with an expiration date.

65 (j) The West Virginia Board of Pharmacy shall promulgate rules in accordance with the  
66 provisions of §29A-1-1 *et seq.* of this code which establish a formulary of generic type and brand  
67 name drug products which are determined by the board to demonstrate significant biological or  
68 therapeutic inequivalence and which, if substituted, would pose a threat to the health and safety  
69 of patients receiving prescription medication. The formulary shall be promulgated by the board

70 within 90 days of the date of passage of this section and may be amended in accordance with the  
71 provisions of §29A-1-1 *et seq.* of this code.

72 ~~(m)~~ (k) No pharmacist shall may substitute a generic-named therapeutically equivalent  
73 drug product for a prescribed brand name drug product if the brand name drug product or the  
74 generic drug type is listed on the formulary established by the West Virginia Board of Pharmacy  
75 pursuant to this article or is found to be in violation of the requirements of the United States Food  
76 and Drug Administration.

77 ~~(n)~~ (l) Any pharmacist who substitutes any drug shall, either personally or through his or  
78 her agent, assistant, or employee, notify the person presenting the prescription of such  
79 substitution. The person presenting the prescription shall have the right to refuse the substitution.  
80 Upon request the pharmacist shall relate the retail price difference between the brand name and  
81 the drug substituted for it.

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

88 ~~(p)~~ (n) The West Virginia Board of Pharmacy shall promulgate rules in accordance with  
89 the provisions of §29A-1-1 *et seq.* of this code setting standards for substituted drug products,  
90 obtaining compliance with the provisions of this section, and the primary responsibility for  
91 enforcing the provisions of this section.

92 ~~(q)~~ (o) Any person shall have the right to may file a complaint with the West Virginia Board  
93 of Pharmacy regarding any violation of the provisions of this article. Such complaints shall be  
94 investigated by the Board of Pharmacy.

95 ~~(r)~~ (p) Fifteen days after the board has notified, by registered mail, a person, firm,

96 corporation or copartnership that such person, firm, corporation, or copartnership is suspected of  
97 being in violation of a provision of this section, the board shall hold a hearing on the matter. If, as  
98 a result of the hearing, the board determines that a person, firm, corporation, or copartnership is  
99 violating any of the provisions of this section, it may, in addition to any penalties prescribed by  
100 §30-5-22 of this code, suspend or revoke the permit of any person, firm, corporation or  
101 copartnership to operate a pharmacy.

102 ~~(s)~~ (q) No pharmacist or pharmacy complying with the provisions of this section shall may  
103 be liable in any way for the dispensing of a generic-named therapeutically equivalent drug,  
104 substituted under the provisions of this section, unless the generic-named therapeutically  
105 equivalent drug was incorrectly substituted.

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

110 ~~(u)~~ (s) Failure of a practitioner to specify that a specific brand name is necessary for a  
111 particular patient shall may not constitute evidence of negligence unless the practitioner had  
112 reasonable cause to believe that the health of the patient required the use of a certain product  
113 and no other.

NOTE: The purpose of this bill is to amend the way savings derived from the filling of generic drugs are distributed. The provisions of this section as amended in 2018 are to apply retroactively to pharmacy transactions occurring since 1978.

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