

WEST VIRGINIA LEGISLATURE

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2016 REGULAR SESSION

OFFICE WEST VIRGINIA
SECRETARY OF STATE

ENROLLED

House Bill 4033

(BY DELEGATES ELLINGTON, SUMMERS, HOUSEHOLDER,

ROHRBACH, STANSBURY, WAXMAN, PERDUE AND

RODIGHERO)

[Passed March 12, 2016; in effect ninety days from passage.]

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[Passed March 12, 2016; in effect ninety days from passage.]

1 AN ACT to amend and reenact §30-5-12b and §30-5-34 of the Code of West Virginia, 1931, as
2 amended, all relating to prohibiting the practice of pharmacist care without a license;
3 prohibiting assistance to practice of pharmacist care without registration; establishing a
4 criminal penalty for the illegal practice or pharmacy care or assisting in the practice of
5 pharmacy care; permitting the board to contact law enforcement with information
6 concerning a criminal offense; permitting the fining of a person practicing with an
7 encumbered license; permitting the fining of a person practicing with an encumbered
8 registration; and establishing a fine.

Be it enacted by the Legislature of West Virginia:

1 That §30-5-12b and §30-5-34 of the Code of West Virginia, 1931, as amended, be
2 amended and reenacted, all to read as follows:

**§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 not be construed
36 to permit the pharmacist to generally refuse to substitute less expensive therapeutically equivalent
37 generic drugs for brand name drugs and that any pharmacist so refusing shall be subject to the
38 penalties prescribed in section thirty-four of this article.

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 (h) 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 record shall include the manufacturer and
51 generic name of the drug product selected.

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

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

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

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

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

82 (o) Every pharmacy shall post in a prominent place that is in clear and unobstructed public
83 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) The West Virginia Board of Pharmacy shall promulgate rules in accordance with the
89 provisions of chapter twenty-nine-a of this code setting standards for substituted drug products,

90 obtaining compliance with the provisions of this section and enforcing the provisions of this
91 section.

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

95 (r) Fifteen days after the board has notified, by registered mail, a person, firm, corporation
96 or copartnership that such person, firm, corporation or copartnership is suspected of being in
97 violation of a provision of this section, the board shall hold a hearing on the matter. If, as a result
98 of the hearing, the board determines that a person, firm, corporation or copartnership is violating
99 any of the provisions of this section, it may, in addition to any penalties prescribed by section
100 twenty-two of this article, suspend or revoke the permit of any person, firm, corporation or
101 copartnership to operate a pharmacy.

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

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

110 (u) Failure of a practitioner to specify that a specific brand name is necessary for a
111 particular patient shall 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.

§30-5-34. Criminal offenses.

1 (a) When, as a result of an investigation under this article or otherwise, the board has
2 reason to believe that a person authorized under this article has committed a criminal offense

3 under this article, the board may bring its information to the attention of an appropriate law-
4 enforcement official.

5 (b) Any person who intentionally practices, or presents himself or herself out as qualified
6 to practice pharmacist care or to assist in the practice of pharmacist care, or uses any title, word
7 or abbreviation to indicate to or induce others to believe he or she is licensed to practice as a
8 pharmacist or pharmacist technician without obtaining an active, valid West Virginia license to
9 practice that profession; or

10 With a license that is:

11 (1) Expired, suspended or lapsed; or

12 (2) Inactive, revoked, suspended as a result of disciplinary action, or surrendered; is guilty
13 of a misdemeanor and, upon conviction thereof, shall be fined not more than ten thousand dollars.

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


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Chairman, House Committee


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Chairman, Senate Committee

Originating in the House.

In effect ninety days from passage.

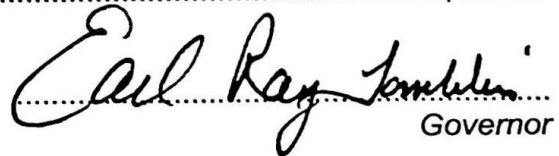

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Clerk of the House of Delegates


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Clerk of the Senate


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Speaker of the House of Delegates


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President of the Senate

The within is approved this the 24th
day of March, 2016.


.....
Governor

PRESENTED TO THE GOVERNOR

MAR 23 2015

Time 2:58 pm