WEST VIRGINIA LEGISLATURE

2018 REGULAR SESSION

Introduced

House Bill 4524

(BY DELEGATES ELLINGTON, SUMMERS AND ROHRBACH)

[Introduced February 13, 2018; Referred

to the Committee on Health and Human Resources

then the Judiciary.]

A BILL to amend and reenact §30-5-12b of the Code of West Virginia, 1931, as amended, relating to establishing guidelines for the substitution of certain biological pharmaceuticals by pharmacists.

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.

(a) As used in this section:

(1) "Biological product" means drugs or drug products as defined by 42 U.S.C. §262.

(2) "Biosimilar product" means drugs or drug products as defined by 41 U.S.C. §262(k) or have been approved based on an application filed under 21 U.S.C. §355(b)(2).

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

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

~~(2)~~ (5) "Generic name" means the official title of a drug or drug combination for which a new drug application, or an abbreviated new drug application, has been approved by the United States Food and Drug Administration and is in effect.

~~(3)~~ (6) "Substitute" means to dispense without the prescriber's express authorization a therapeutically equivalent generic drug product in the place of the drug ordered or prescribed.

~~(4) "Equivalent" means drugs or drug products which are the same amounts of identical~~

~~active ingredients and same dosage form and which will provide the same therapeutic efficacy and toxicity when administered to an individual and is approved by the United States Food and Drug Administration~~

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

(c) A pharmacist may substitute for a prescribed biological product if the following conditions are met:

(1) The substitute has been determined by the Food and Drug Administration to be biosimilar with the prescribed biological products; and

(2) The prescribing practitioner has:

(A) For a written or electronic prescription has indicated “may substitute”;

(B) The pharmacist has informed the customer of the substitution; and

(C) The pharmacist has notified the prescribing physician of the substitution within 10 days.

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

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

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

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

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

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

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

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

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

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

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

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

(4) Labeling products with an expiration date.

~~(l)~~ (m) The West Virginia Board of Pharmacy shall promulgate rules in accordance with the provisions of chapter 29a of this code which establish a formulary of generic type and brand name drug products which are determined by the board to demonstrate significant biological or therapeutic inequivalence and which, if substituted, would pose a threat to the health and safety of patients receiving prescription medication. The formulary shall be promulgated by the board within 90 days of the date of passage of this section and may be amended in accordance with the provisions of chapter 29a of this code.

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

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

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

~~(p)~~ (q) The West Virginia Board of Pharmacy shall promulgate rules in accordance with the provisions of chapter 29a of this code setting standards for substituted drug products, obtaining compliance with the provisions of this section and enforcing the provisions of this section.

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

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

~~(s)~~ (t) No pharmacist or pharmacy complying with the provisions of this section shall be

liable in any way for the dispensing of a generic-named therapeutically equivalent drug, substituted under the provisions of this section, unless the generic-named therapeutically equivalent drug was incorrectly substituted.

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

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

NOTE: The purpose of this bill is to provide definitions for biological and biosimilar products and clarify when a pharmacist may substitute a prescribed biological product.

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