WEST VIRGINIA LEGISLATURE

2018 REGULAR SESSION

ENROLLED

Committee Substitute

for

House Bill 4524

(BY DELEGATES ELLINGTON, SUMMERS AND ROHRBACH)

[Passed March 10, 2018; in effect ninety days from passage.]

AN ACT to amend the Code of West Virginia, 1931, as amended, by enacting a new section designated as § 30-5-12c relating to establishing guidelines for the substitution of certain biological pharmaceuticals by pharmacists; defining terms; providing for guidelines relating to substitution of interchangeable biological products; establishing communication requirements between the pharmacists and prescriber relating to substitution of interchangeable biological products; requiring maintenance of records relating to biological products dispensed for at least two years; providing for emergency rules; establishing manufacturing standards; clarifying process for complaints; and providing for immunity for certain actions.

Be it enacted by the Legislature of West Virginia:

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

§30-5-12c. Substitution of biological product: Definitions; selection of interchangeable biological products; exceptions; records; labels; manufacturing standards; emergency rules; complaints; and immunity.

(a) As used in this section:

"Biological product" means the same as that term is defined in 42 U.S.C.§ 262.

"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.

"Interchangeable biological product" means a biological product that the federal Food and Drug Administration has:

(1) Licensed and determined meets the standards for interchangeability pursuant to 42 U.S.C § 262(k)(4); or

(2) Determined is therapeutically equivalent as set forth in the latest edition of or supplement to the federal Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations.

"Proper name" means the nonproprietary name of a biological product.

"Substitute" means to dispense without the prescriber's express authorization an interchangeable biological product in the place of the drug ordered or prescribed.

(b) Except as limited by subsection (c) and unless instructed otherwise by the patient, a pharmacist who receives a prescription for a specific biological product shall select a less expensive interchangeable biological 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. The pharmacist shall provide notice to the patient or the patient's designee regarding the selection of a less expensive interchangeable biological product.

(c) If, in the professional opinion of the prescriber, it is medically necessary that an equivalent drug product or interchangeable biological product not be selected, the prescriber may so indicate by certifying that the specific brand-name drug product prescribed, or the specific brand-name biological product prescribed, is medically necessary for that particular patient. In the case of a prescription transmitted orally, the prescriber must expressly indicate to the pharmacist that the specific brand-name drug product prescribed, or the specific biological product prescribed is medically necessary.

(d) (1) Within five business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate the specific product provided to the patient, including the name of the product and the manufacturer, to the prescriber through any of the following electronic records systems:

(A) An interoperable electronic medical records system;

(B) An electronic prescribing technology;

(C) A pharmacy benefit management system; or

(D) A pharmacy record.

(2) Communication through an electronic records system as described in §30-5-12c(d)(1) of this code is presumed to provide notice to the prescriber.

(3) If the pharmacist is unable to communicate pursuant to an electronic records system the pharmacist shall communicate to the prescriber which biological product was dispensed to the patient using facsimile, telephone, electronic transmission, or other prevailing means.

(4) Communication is not required under this subsection when:

(A) There is no Federal Food and Drug Administration approved interchangeable biological product for the product prescribed; or

(B) A refill prescription is not changed from the product dispensed on the prior filling of the prescription.

(e) The pharmacist shall maintain a record of the biological product dispensed for at least two years. Such record shall include the manufacturer and proper name of the interchangeable biological product selected.

(f) All biological products shall be labeled in accordance with the instructions of the practitioner.

(g) Unless the practitioner directs otherwise, the prescription label on all biological products dispensed by the pharmacist shall indicate the proper 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.

(h) A pharmacist may not dispense a product under the provisions of this section unless the manufacturer has shown that the biological product 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.

(i) The West Virginia Board of Pharmacy shall promulgate emergency rules pursuant to the provisions of §29A-3-15 of this code setting standards for substituted interchangeable biological products, obtaining compliance with the provisions of this section, and enforcing the provisions of this section.

(j) 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.

(k) No pharmacist or pharmacy complying with the provisions of this section shall be liable in any way for the dispensing of an interchangeable biological product substituted under the provisions of this section, unless the interchangeable biological product was incorrectly substituted.

(l) In no event where the pharmacist substitutes an interchangeable biological product 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 biological product unless the original biological product was incorrectly prescribed.

(m) 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.

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

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The within ..... this the.....

day of ....., 2018.

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Governor