GENERIC EQUIVALENT DRUG LAW - SUBSTITUTIONS, POSTING REQUIREMENTS, POWERS AND DUTIES OF DEPARTMENT AND IMMUNITY OF PHARMACISTS UNDER CERTAIN CIRCUMSTANCES

Act of Jul. 20, 2016, P.L. 830, No. 95 Cl. 35

Session of 2016
No. 2016-95

SB 514

AN ACT

Amending the act of November 24, 1976 (P.L.1163, No.259), entitled "An act relating to the prescribing and dispensing of generic equivalent drugs," further providing for definitions, for substitutions, for posting requirements, for powers and duties of Department of Health and for immunity of pharmacists under certain circumstances.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. Section 2 of the act of November 24, 1976 (P.L.1163, No.259), referred to as the Generic Equivalent Drug Law, is amended by adding definitions to read:

Section 2. As used in this act:

"Biological product" shall have the same meaning as "biological product" in the Public Health Service Act (58 Stat. 682, 42 U.S.C. § 201 et seq.).

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"Interchangeable biological product" means a biological product licensed by the United States Food and Drug Administration and determined to meet the safety standards for interchangeability pursuant to the Public Health Service Act (58 Stat. 682, 42 U.S.C. § 201 et seq.) or a biological product approved under section 505 of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040, 21 U.S.C. § 355) and determined by the United States Food and Drug Administration to be therapeutically equivalent to a prescribed biological product.

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Section 2. Section 3(c) and (d) of the act are amended and the section is amended by adding subsections to read:

Section 3. * * *

(a.1) A pharmacist may substitute a biological product for a prescribed biological product only if:

(1) the biological product is an interchangeable biological product and has been determined by the United States Food and Drug Administration to be interchangeable with the prescribed product;

(2) the prescriber does not designate verbally or in writing on the prescription that substitution is prohibited; and

(3) the person presenting the prescription receives notification of such substitution in the same manner provided in subsection (b).

(a.2) Within 72 hours following the dispensing of an interchangeable biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescriber the specific product provided to the patient, including the name of the product and the manufacturer. The communication shall be conveyed by making an entry in the electronic health record of the patient, as defined in the act of July 5, 2012 (P.L.1042, No.121), known as the "Pennsylvania eHealth

Information Technology Act," or through an electronic prescribing technology, a pharmacy benefit management system or a pharmacy record, that is electronically accessible by the prescriber. Entry into an electronic records system as described in this subsection is presumed to provide notice to the prescriber. Otherwise, within 72 hours, the pharmacist shall communicate the interchangeable biological product dispensed to the prescriber, using facsimile, telephone, electronic transmission or other prevailing means, provided that the communication shall not be required where:

(1) there is no United States Food and Drug Administration-approved interchangeable biological product for the biological product prescribed; or

(2) it is a refill prescription where the interchangeable biological product dispensed is the same interchangeable biological product which was dispensed at the prior filling of the prescription.

(a.3) Subsections (a.1) and (a.2) may not apply to a biological product which may be dispensed without a prescription.

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(c) Any pharmacist substituting a less expensive drug product **or interchangeable biological product** shall charge the purchaser the regular and customary retail price for the generically equivalent drug **or interchangeable biological product.**

(d) Each pharmacist shall maintain a record of any substitution of a generically equivalent drug product **or interchangeable biological product** for a prescribed brand name drug.

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Section 3. Sections 4 and 5(a) and (b) of the act, amended July 11, 1990 (P.L.509, No.121), are amended to read:

Section 4. (a) 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: "Pennsylvania law permits pharmacists to substitute a less expensive generically equivalent drug **or interchangeable biological product** for a brand name drug unless you or your physician direct otherwise."

(b) Every pharmacy shall post in a conspicuous place, easily accessible to the general public, a list of commonly used generically equivalent drugs **and interchangeable biological products** containing the generic **or nonproprietary** names and brand names where applicable.

(c) Each pharmacy shall have available to the public a price listing of brand name and generic equivalent drug products **and interchangeable biological products** available at the pharmacy for selection by the purchaser.

Section 5. (a) The Department of Health shall have the power and its duty shall be to:

(1) Administer and enforce the provisions of this act.

(2) Adopt necessary regulations consistent with this act.

(3) Publicize the provisions of this act.

(4) Publish by notice in the Pennsylvania Bulletin the addition or deletion of generically equivalent drugs **and interchangeable biological products** and any determination by the secretary to not recognize a generically equivalent drug **or interchangeable biological product** in accordance with subsection (b). The department shall also provide notice that a complete list of generically equivalent drugs **and**

interchangeable biological products may be obtained from the United States Food and Drug Administration. This notice shall be published at least every three months.

(b) The secretary, with the advice of the Pennsylvania Drug, Device and Cosmetic Board, may determine that a drug shall not be recognized as a generically equivalent drug **or interchangeable biological product** for purposes of substitution in Pennsylvania and the time after which recognition shall be restored.

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Section 4. Section 6(a) and (b) of the act are amended to read:

Section 6. (a) No pharmacist complying with the provisions of this act shall be liable in any way for the dispensing of a generically equivalent drug **or interchangeable biological product** unless the generically equivalent drug **or interchangeable biological product** was incorrectly substituted.

(b) In no event when a pharmacist substitutes a drug **or interchangeable biological product** shall the prescriber be liable in any action for loss, damage, injury or death or any person occasioned by or arising from the use of the substituted drug **or interchangeable biological product** unless the original drug was incorrectly prescribed.

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Section 5. This act shall take effect in 60 days.

APPROVED--The 20th day of July, A.D. 2016.

TOM WOLF