HOUSE AMENDED

PRIOR PRINTER'S NOS. 401, 1554 PRINTER'S NO. 2336

THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 405 Session of 2013

INTRODUCED BY VANCE, ERICKSON, BAKER, BROWNE, FONTANA, KASUNIC, MENSCH, KITCHEN, SOLOBAY, VOGEL, FOLMER, TARTAGLIONE, LEACH, WHITE, WAUGH, McILHINNEY, COSTA, EICHELBERGER, GREENLEAF, DINNIMAN, WILEY, HUGHES, SCHWANK AND BLAKE, FEBRUARY 8, 2013

AS REPORTED FROM COMMITTEE ON HEALTH, HOUSE OF REPRESENTATIVES, AS AMENDED, SEPTEMBER 24, 2014

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 defined in 42 U.S.C. § 262(i) (relating to regulation of biological products).

~~"Biosimilar" means a biological product licensed by the United States Food and Drug Administration pursuant to 42 U.S.C. § 262(k) (relating to regulation of biological products) or~~ <--

~~approved based on an application filed under 21 U.S.C. § 355(b)(2) (relating to new drugs) that is highly similar to the prescribed biological product.~~

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~~"Interchangeable biosimilar" means a biosimilar that the United States Food and Drug Administration has determined satisfies the standards set forth in 42 U.S.C. § 262(k)(4) (relating to regulation of biological products), the Reference Product for such biosimilar as defined in 42 U.S.C. § 262(i)(4), or with respect to a biosimilar filed under 21 U.S.C. § 355(b)(2) (relating to new drugs), a biosimilar determined by the United States Food and Drug Administration to be therapeutically equivalent to the prescribed brand name biological product.~~

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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 42 U.S.C. § 262(K)(4) (RELATING TO REGULATION OF BIOLOGICAL PRODUCTS) OR A BIOLOGICAL PRODUCT DETERMINED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION TO BE THERAPEUTICALLY EQUIVALENT AS SET FORTH IN THE LATEST EDITION OR SUPPLEMENT OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, SOMETIMES REFERRED TO AS THE "ORANGE BOOK." <--

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Section 2. Section 3(c) and (d) of the act are amended and the section is amended by adding ~~a subsection~~ SUBSECTIONS to read: <--

Section 3. * * *

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

(1) ~~The biosimilar product has been determined by the United States Food and Drug Administration to be interchangeable with the prescribed product;~~ THE BIOLOGICAL PRODUCT HAS BEEN DETERMINED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION TO BE INTERCHANGEABLE WITH OR THERAPEUTICALLY EQUIVALENT TO THE PRESCRIBED PRODUCT; <--

(2) ~~The~~ THE prescriber does not designate verbally or in writing on the prescription that substitution is prohibited; AND <--

(3) ~~The~~ THE person presenting the prescription receives notification of such substitution in the same manner provided in subsection (b)~~;~~. <--

~~(4) The pharmacist notifies the prescriber either verbally, in writing, or by facsimile, e-mail or other electronic transmission and as soon as practicable but no later than 72 hours after dispensing, except that such notification shall not be required for a prescription refill when the refilled biological product is the same as the product last dispensed by the pharmacist; and~~ <--

~~(5) The pharmacy and the prescriber retain a written or electronic record of the biosimilar substitution for a period of no less than two years.~~

(A.2) WITHIN 72 HOURS FOLLOWING THE DISPENSING OF A 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 OR A PHARMACY RECORD THAT IS ELECTRONICALLY ACCESSIBLE BY PRESCRIBERS. IF NO SYSTEM IS AVAILABLE BETWEEN THE PHARMACIST AND THE PRESCRIBER, THE PHARMACIST SHALL COMMUNICATE THE 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 BIOLOGICAL PRODUCT DISPENSED IS THE SAME BIOLOGICAL PRODUCT WHICH WAS DISPENSED AT THE PRIOR FILLING OF THE PRESCRIPTION AND THE PRESCRIBER WAS NOTIFIED OF THE PREVIOUS SUBSTITUTION.

~~(a.2) Subsection (a.1)~~ (A.3) SUBSECTIONS (A.1) AND (A.2) shall 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 ~~biosimilar~~ BIOLOGICAL PRODUCT shall charge the purchaser the regular and customary retail price for the generically equivalent drug or interchangeable ~~biosimilar~~ BIOLOGICAL PRODUCT. <--

(d) Each pharmacist shall maintain a record of any substitution of a generically equivalent drug product or interchangeable ~~biosimilar~~ 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 ~~biosimilar~~ 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 ~~biosimilars~~ BIOLOGICAL PRODUCTS containing the generic 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 ~~biosimilars~~ 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 ~~biosimilars~~ BIOLOGICAL PRODUCTS and any determination by the secretary to not recognize a generically equivalent drug or interchangeable ~~biosimilar~~ BIOLOGICAL PRODUCT in accordance with subsection (b). The department shall also provide notice that a complete list of generically equivalent drugs and interchangeable ~~biosimilars~~ 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 ~~biosimilar~~ 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 ~~biosimilar~~ BIOLOGICAL PRODUCT unless the generically equivalent drug or interchangeable ~~biosimilar~~ BIOLOGICAL PRODUCT was incorrectly substituted. <-- <-- <--

(b) In no event when a pharmacist substitutes a drug or interchangeable ~~biosimilar~~ 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 ~~biosimilar~~ BIOLOGICAL PRODUCT unless the original drug was incorrectly prescribed. <-- <--

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~~Section 5. This act shall take effect in 60 days.~~ <--

SECTION 5. THE ADDITION OF SECTION 3(A.2) OF THE ACT SHALL EXPIRE FIVE YEARS FROM THE EFFECTIVE DATE OF THIS ACT. <--

SECTION 6. THIS ACT SHALL TAKE EFFECT AS FOLLOWS:

(1) THE ADDITION OF SECTION 3(A.2) OF THE ACT SHALL TAKE EFFECT JANUARY 1, 2015, OR IMMEDIATELY, WHICHEVER IS LATER.

(2) THE REMAINDER OF THIS ACT SHALL TAKE EFFECT IN 60 DAYS.