

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

SENATOR VANCE, PUBLIC HEALTH AND WELFARE, REPORTED AS AMENDED,
NOVEMBER 13, 2013

AN ACT

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

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

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

12 Section 2. As used in this act:

13 "Biological product" shall have the same meaning as defined
14 in 42 U.S.C. § 262(i) (relating to regulation of biological
15 products).

16 "Biosimilar" means a biological product licensed by the
17 United States Food and Drug Administration pursuant to 42 U.S.C.
18 § 262(k) (RELATING TO REGULATION OF BIOLOGICAL PRODUCTS) OR

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1 APPROVED BASED ON AN APPLICATION FILED UNDER 21 U.S.C. §
2 355(B)(2) (RELATING TO NEW DRUGS) THAT IS HIGHLY SIMILAR TO THE
3 PRESCRIBED BIOLOGICAL PRODUCT.

4 * * *

5 "Interchangeable biosimilar" means a biosimilar product <--
6 licensed by the United States Food and Drug Administration
7 pursuant to 42 U.S.C. § 262(k)(4). MEANS A BIOSIMILAR THAT THE <--
8 UNITED STATES FOOD AND DRUG ADMINISTRATION HAS DETERMINED
9 SATISFIES THE STANDARDS SET FORTH IN 42 U.S.C. § 262(K)(4)
10 (RELATING TO REGULATION OF BIOLOGICAL PRODUCTS), THE REFERENCE
11 PRODUCT FOR SUCH BIOSIMILAR AS DEFINED IN 42 U.S.C. § 262(I)(4),
12 OR WITH RESPECT TO A BIOSIMILAR FILED UNDER 21 U.S.C. §
13 355(B)(2) (RELATING TO NEW DRUGS), A BIOSIMILAR DETERMINED BY
14 THE UNITED STATES FOOD AND DRUG ADMINISTRATION TO BE
15 THERAPEUTICALLY EQUIVALENT TO THE PRESCRIBED BRAND NAME
16 BIOLOGICAL PRODUCT.

17 * * *

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

20 Section 3. * * *

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

23 (1) The biosimilar product has been determined by the United
24 States Food and Drug Administration to be interchangeable with
25 the prescribed product for the indicated use.; <--

26 (2) The prescriber does not designate verbally or in writing
27 on the prescription that substitution is prohibited.; <--

28 (3) The person presenting the prescription provides written <--
29 consent for such substitution. RECEIVES NOTIFICATION OF SUCH <--
30 SUBSTITUTION IN THE SAME MANNER PROVIDED IN SUBSECTION (B);

1 ~~(4) The pharmacist notifies the prescriber in writing and as~~ <--
2 ~~soon as practicable but no later than 72 hours after dispensing.~~
3 EITHER VERBALLY, IN WRITING, OR BY FACSIMILE, E-MAIL OR OTHER <--
4 ELECTRONIC TRANSMISSION AND AS SOON AS PRACTICABLE BUT NO LATER
5 THAN 72 HOURS AFTER DISPENSING, EXCEPT THAT SUCH NOTIFICATION
6 SHALL NOT BE REQUIRED FOR A PRESCRIPTION REFILL WHEN THE
7 REFILLED BIOLOGICAL PRODUCT IS THE SAME AS THE PRODUCT LAST
8 DISPENSED BY THE PHARMACIST; AND

9 (5) The pharmacy and the prescriber retain a written OR <--
10 ELECTRONIC record of the biosimilar substitution for a period of
11 no less than five TWO years. <--

12 (A.2) SUBSECTION (A.1) SHALL NOT APPLY TO A BIOLOGICAL <--
13 PRODUCT WHICH MAY BE DISPENSED WITHOUT A PRESCRIPTION.

14 * * *

15 (c) Any pharmacist substituting a less expensive drug
16 product or interchangeable biosimilar shall charge the purchaser
17 the regular and customary retail price for the generically
18 equivalent drug or interchangeable biosimilar.

19 (d) Each pharmacist shall maintain a record of any
20 substitution of a generically equivalent drug product or
21 interchangeable biosimilar for a prescribed brand name drug.

22 * * *

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

25 Section 4. (a) Every pharmacy shall post in a prominent
26 place that is in clear and unobstructed public view, at or near
27 the place where prescriptions are dispensed, a sign which shall
28 read: "Pennsylvania law permits pharmacists to substitute a less
29 expensive generically equivalent drug or interchangeable
30 biosimilar for a brand name drug unless you or your physician

1 direct otherwise."

2 (b) Every pharmacy shall post in a conspicuous place, easily
3 accessible to the general public, a list of commonly used
4 generically equivalent drugs and interchangeable biosimilars
5 containing the generic names and brand names where applicable.

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

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

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

13 (2) Adopt necessary regulations consistent with this act.

14 (3) Publicize the provisions of this act.

15 (4) Publish by notice in the Pennsylvania Bulletin the
16 addition or deletion of generically equivalent drugs and
17 interchangeable biosimilars and any determination by the
18 secretary to not recognize a generically equivalent drug or
19 interchangeable biosimilar in accordance with subsection (b).

20 The department shall also provide notice that a complete list of
21 generically equivalent drugs and interchangeable biosimilars may
22 be obtained from the United States Food and Drug Administration.
23 This notice shall be published at least every three months.

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

30 * * *

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 unless the generically equivalent drug or interchangeable biosimilar was incorrectly substituted.

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

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