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H.837

Introduced by Representatives McCarthy of St. Albans City, Beyor of  
Highgate, Connor of Fairfield, Consejo of Sheldon, Dickinson  
of St. Albans Town, Keenan of St. Albans City, Pearce of  
Richford, Savage of Swanton, and Weed of Enosburgh

Referred to Committee on

Date:

Subject: Health; pharmacists; biological products; generics

Statement of purpose of bill as introduced: This bill proposes to direct  
pharmacists to fill prescriptions for biological products with an interchangeable  
biological product unless otherwise specified by the prescriber or the  
purchaser.

An act relating to generic substitution for biological products

It is hereby enacted by the General Assembly of the State of Vermont:

Sec. 1. 18 V.S.A. § 4601 is amended to read:

§ 4601. DEFINITIONS

~~For the purposes of~~ As used in this chapter, unless the context otherwise  
clearly requires:

(1) “Brand name” means the registered trademark name given to a drug  
or biological product by its manufacturer or distributor;

1           (2) “Generic name” means the official name of a drug product as  
2 established by the United States Adopted Names Council (USAN) or its  
3 successor, if applicable;.

4           (3) “Pharmacist” means a natural person licensed by the ~~state board of~~  
5 ~~pharmacy~~ State Board of Pharmacy to prepare, compound, dispense, and sell  
6 drugs, medicines, chemicals, and poisons;.

7           (4) “Generic drug” means a drug listed by generic name and considered  
8 to be chemically and therapeutically equivalent to a drug listed by brand name,  
9 as both names are identified in the most recent edition of the federal Food and  
10 Drug Administration’s “Orange Book” of approved drug products;.

11           (5) “Prescriber” means any duly licensed physician, dentist,  
12 veterinarian, or other practitioner licensed to write prescriptions for the  
13 treatment or prevention of disease in man or animal;.

14           (6) “Biological product” means a virus; therapeutic serum; toxin;  
15 antitoxin; vaccine; blood; blood component or derivative; allergenic product;  
16 protein, except any chemically synthesized polypeptide; or analogous product;  
17 or arsphenamine, derivative of arsphenamine, or any other trivalent organic  
18 arsenic compound; applicable to the prevention, treatment, or cure of a disease  
19 or condition in human beings.

20           (7) “Interchangeable” means that a biological product that is  
21 biologically highly similar to a reference product and can be expected to

1 produce the same clinical result in any given patient in accordance with the  
2 provisions of 42 U.S.C. § 262(k) may be substituted for the reference product  
3 without the intervention of the prescriber.

4 (8) "Reference product" means the single biological product licensed  
5 pursuant to 42 U.S.C. § 262(a) against which the U.S. Food and Drug  
6 Administration has evaluated another product to determine whether they are  
7 interchangeable.

8 Sec. 2. 18 V.S.A. § 4605 is amended to read:

9 § 4605. ALTERNATIVE DRUG OR BIOLOGICAL PRODUCT

10 SELECTION

11 (a)(1) When a pharmacist receives a prescription for a drug which is  
12 listed either by generic name or brand name in the most recent edition of the  
13 U.S. Department of Health and Human Services' publication Approved Drug  
14 Products With Therapeutic Equivalence (the "Orange Book") of approved drug  
15 products, the pharmacist shall select the lowest priced drug from the list which  
16 is equivalent as defined by the "Orange Book," unless otherwise instructed by  
17 the prescriber, or by the purchaser if the purchaser agrees to pay any additional  
18 cost in excess of the benefits provided by the purchaser's health benefit plan if  
19 allowed under the legal requirements applicable to the plan, otherwise to pay  
20 the full cost for the higher priced drug.

1           (2) When a pharmacist receives a prescription for a biological product,  
2           whether listed by brand name or international nonproprietary name, and the  
3           U.S. Food and Drug Administration has approved one or more additional  
4           biological products as interchangeable for the reference product, the  
5           pharmacist shall select the lowest priced biological product from among those  
6           the U.S. Food and Drug Administration has determined to be interchangeable  
7           unless otherwise instructed by the prescriber, or by the purchaser if the  
8           purchaser agrees to pay any additional cost in excess of the benefits provided  
9           by the purchaser's health benefit plan if allowed under the legal requirements  
10           applicable to the plan, otherwise to pay the full cost for the higher biological  
11           product.

12           (b) The purchaser shall be informed by the pharmacist or his or her  
13           representative that an alternative selection as provided under subsection (a) of  
14           this section will be made unless the purchaser agrees to pay any additional cost  
15           in excess of the benefits provided by the purchaser's health benefit plan if  
16           allowed under the legal requirements applicable to the plan, otherwise to pay  
17           the full cost for the higher priced drug or biological product.

18           (c) When refilling a prescription, pharmacists shall receive the consent of  
19           the prescriber to dispense a drug or biological product different from that  
20           originally dispensed, and shall inform the purchaser that a ~~generic~~ substitution  
21           shall be made pursuant to this section unless the purchaser agrees to pay any

1 additional cost in excess of the benefits provided by the purchaser's health  
2 benefit plan if allowed under the legal requirements applicable to the plan,  
3 otherwise to pay the full cost for the higher priced drug or biological product.

4 (d) Any pharmacist substituting a generically equivalent drug or  
5 interchangeable biological product shall charge no more than the usual and  
6 customary retail price for that selected drug or biological product. This charge  
7 shall not exceed the usual and customary retail price for the prescribed brand.

8 Sec. 3. 18 V.S.A. § 4606 is amended to read:

9 § 4606. BRAND CERTIFICATION

10 If the prescriber has determined that the generic equivalent of a drug or the  
11 interchangeable biological product for the reference product being prescribed  
12 has not been effective or with reasonable certainty is not expected to be  
13 effective in treating the patient's medical condition or causes or is reasonably  
14 expected to cause adverse or harmful reactions in the patient, the prescriber  
15 shall indicate "brand necessary," "no substitution," "dispense as written," or  
16 "DAW" in the prescriber's own handwriting on the prescription blank and the  
17 pharmacist shall not substitute the generic equivalent drug or interchangeable  
18 biological product. If a prescription is unwritten and the prescriber has  
19 determined that the generic equivalent of the drug or the interchangeable  
20 biological product for the reference product being prescribed has not been  
21 effective or with reasonable certainty is not expected to be effective in treating

1 the patient's medical condition or causes or is reasonably expected to cause  
2 adverse or harmful reactions in the patient, the prescriber shall expressly  
3 indicate to the pharmacist that the brand-name drug or biological product is  
4 necessary and substitution is not allowed and the pharmacist shall not  
5 substitute the generic equivalent drug or interchangeable biological product.

6 Sec. 4. 18 V.S.A. § 4607 is amended to read:

7 § 4607. INFORMATION; LABELING

8 (a) Every pharmacy in the ~~state~~ State shall have posted a sign in a  
9 prominent place that is in clear unobstructed view which shall read: "Vermont  
10 law requires pharmacists in some cases to select a less expensive generic  
11 equivalent drug or interchangeable biological product for the drug or product  
12 prescribed unless you or your physician direct otherwise. Ask your  
13 pharmacist."

14 (b) The label of the container of all drugs and biological products dispensed  
15 by a pharmacist under this chapter shall indicate the generic name using an  
16 abbreviation if necessary or the international nonproprietary name for a  
17 biological product, the strength of the drug or product, if applicable, and the  
18 name or number of the manufacturer or distributor.

1 Sec. 5. 18 V.S.A. § 4608 is amended to read:

2 § 4608. LIABILITY

3 (a) Nothing in this chapter shall affect a licensed hospital with the  
4 development and maintenance of a hospital formulary system in accordance  
5 with that institution's policies and procedures that pertain to its drug  
6 distribution system developed by the medical staff in cooperation with the  
7 hospital's pharmacist and administration.

8 (b) The substitution of a drug or biological product by a pharmacist under  
9 the provisions of this chapter does not constitute the practice of medicine.

10 Sec. 6. EFFECTIVE DATE

11 This act shall take effect on July 1, 2014.