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SENATE BILL 6091

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State of Washington

63rd Legislature

2014 Regular Session

By Senators Dammeier, Frockt, Rivers, Keiser, Bailey, Hill, Ericksen, Kohl-Welles, and Hatfield

Read first time 01/15/14. Referred to Committee on Health Care .

1 AN ACT Relating to the prescription of biological products and  
2 interchangeable biological products; amending RCW 69.41.110, 69.41.120,  
3 69.41.150, 69.41.130, 69.41.160, and 69.41.050; and adding a new  
4 section to chapter 69.41 RCW.

5 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

6 **Sec. 1.** RCW 69.41.110 and 1979 c 110 s 1 are each amended to read  
7 as follows:

8 As used in RCW 69.41.100 through 69.41.180, the following words  
9 shall have the following meanings:

10 (1) "Brand name" means the proprietary or trade name selected by  
11 the manufacturer and placed upon a drug, its container, label, or  
12 wrapping at the time of packaging;

13 (2) "Generic name" means the official title of a drug or drug  
14 ingredients published in the latest edition of a nationally recognized  
15 pharmacopoeia or formulary;

16 (3) "Substitute" means to dispense, with the practitioner's  
17 authorization, a "therapeutically equivalent" drug product (~~(of the~~  
18 ~~identical base or salt as the specific drug product prescribed)) or~~

1 "interchangeable biological" drug product: PROVIDED, That with the  
2 practitioner's prior consent, therapeutically equivalent drugs other  
3 than the identical base or salt may be dispensed;

4 (4) "Therapeutically equivalent" means a drug product of the  
5 identical base or salt as the specific drug product prescribed with  
6 essentially the same efficacy and toxicity when administered to an  
7 individual in the same dosage regimen; (~~and~~)

8 (5) "Practitioner" means a physician, osteopathic physician and  
9 surgeon, dentist, veterinarian, or any other person authorized to  
10 prescribe drugs under the laws of this state;

11 (6) "Biological product" means any of the following, when applied  
12 to the prevention, treatment, or cure of a disease or condition of  
13 human beings:

14 (a) A virus;

15 (b) A therapeutic serum;

16 (c) A toxin;

17 (d) An antitoxin;

18 (e) A vaccine;

19 (f) Blood, blood component, or derivative;

20 (g) An allergenic product;

21 (h) A protein, other than a chemically synthesized polypeptide, or  
22 an analogous product; or

23 (i) Arsphenamine, a derivative of arsphenamine, or any trivalent  
24 organic arsenic compound;

25 (7) "Biosimilar product" means a biological product licensed by the  
26 federal food and drug administration pursuant to 42 U.S.C. Sec.  
27 262(i)(2); and

28 (8) "Interchangeable" means, in reference to a biological product,  
29 that the federal food and drug administration has determined that a  
30 biological product meets the safety standards set forth in 42 U.S.C.  
31 Sec. 262(k)(4) and may be substituted for the reference product without  
32 the intervention of the health care provider who prescribed the  
33 reference product.

34 **Sec. 2.** RCW 69.41.120 and 2000 c 8 s 3 are each amended to read as  
35 follows:

36 (1) Every drug prescription shall contain an instruction on whether

1 or not a therapeutically equivalent generic drug or interchangeable  
2 biological product may be substituted in its place, unless substitution  
3 is permitted under a prior-consent authorization.

4 If a written prescription is involved, the prescription must be  
5 legible and the form shall have two signature lines at opposite ends on  
6 the bottom of the form. Under the line at the right side shall be  
7 clearly printed the words "DISPENSE AS WRITTEN". Under the line at the  
8 left side shall be clearly printed the words "SUBSTITUTION PERMITTED".  
9 The practitioner shall communicate the instructions to the pharmacist  
10 by signing the appropriate line. No prescription shall be valid  
11 without the signature of the practitioner on one of these lines. In  
12 the case of a prescription issued by a practitioner in another state  
13 that uses a one-line prescription form or variation thereof, the  
14 pharmacist may substitute a therapeutically equivalent generic drug or  
15 interchangeable biological product unless otherwise instructed by the  
16 practitioner through the use of the words "dispense as written", words  
17 of similar meaning, or some other indication.

18 (2) If an oral prescription is involved, the practitioner or the  
19 practitioner's agent shall instruct the pharmacist as to whether or not  
20 a therapeutically equivalent generic drug or interchangeable biological  
21 product may be substituted in its place. The pharmacist shall note the  
22 instructions on the file copy of the prescription.

23 (3) The pharmacist shall note (~~the manufacturer of the drug~~  
24 ~~dispensed~~) on the file copy of a written or oral prescription the  
25 manufacturer of the drug product dispensed, the brand name or, if there  
26 is not a brand name, the nonproprietary name.

27 (4) The pharmacist shall retain the file copy of a written or oral  
28 prescription for the same period of time specified in RCW 18.64.245 for  
29 retention of prescription records.

30 NEW SECTION. **Sec. 3.** A new section is added to chapter 69.41 RCW  
31 to read as follows:

32 (1) If a biological product is dispensed, the pharmacist or the  
33 pharmacist's designee shall within a reasonable time but not to exceed  
34 ten days following the dispensing, record the name and manufacturer of  
35 the product dispensed in an interoperable health records system shared  
36 with the prescribing practitioner, to the extent such a system is  
37 available; or, in the case that an interoperable electronic health

1 records system is not in place, communicate to the prescribing  
2 practitioner the name and the manufacturer of the biological product  
3 dispensed to the patient. No communication to the prescribing  
4 practitioner is required under this subsection where there is no  
5 interchangeable biological product for the prescribed biological  
6 product, or for a refill prescription that is not changed from the  
7 product originally dispensed.

8 (2) The pharmacy quality commission shall maintain a link on its  
9 web site to the current list of all biological products determined by  
10 the United States food and drug administration to be interchangeable  
11 with a specific reference biological product.

12 **Sec. 4.** RCW 69.41.150 and 2003 1st sp.s. c 29 s 6 are each amended  
13 to read as follows:

14 (1) A practitioner who authorizes a prescribed drug shall not be  
15 liable for any side effects or adverse reactions caused by the manner  
16 or method by which a substituted drug product is selected or dispensed.

17 (2) A pharmacist who substitutes (~~an~~) a therapeutically  
18 equivalent drug product pursuant to RCW 69.41.100 through 69.41.180 as  
19 now or hereafter amended assumes no greater liability for selecting the  
20 dispensed drug product than would be incurred in filling a prescription  
21 for a drug product prescribed by its established name.

22 (3) A pharmacist who substitutes a preferred drug for a  
23 nonpreferred drug pursuant to RCW 69.41.190 assumes no greater  
24 liability for substituting the preferred drug than would be incurred in  
25 filling a prescription for the preferred drug when prescribed by name.

26 (4) A pharmacist who selects an interchangeable biological product  
27 to be dispensed under this section assumes the same responsibility for  
28 selecting the interchangeable biological product as the pharmacist does  
29 in filling a prescription for the interchangeable biological product  
30 when prescribed by name. The prescribing practitioner is not liable  
31 for a pharmacist's act or omission in selecting, preparing, or  
32 dispensing an interchangeable biological product under this section.

33 **Sec. 5.** RCW 69.41.130 and 2012 c 117 s 365 are each amended to  
34 read as follows:

35 Unless the brand name drug or biological product is requested by  
36 the patient or the patient's representative, the pharmacist shall

1 substitute (~~an~~) a therapeutically equivalent drug or interchangeable  
2 biological product which he or she has in stock if its wholesale price  
3 to the pharmacist is less than the wholesale price of the prescribed  
4 drug product, and at least sixty percent of the savings shall be passed  
5 on to the purchaser.

6 **Sec. 6.** RCW 69.41.160 and 1979 c 110 s 6 are each amended to read  
7 as follows:

8 Every pharmacy shall post a sign in a location at the prescription  
9 counter that is readily visible to patrons stating, "Under Washington  
10 law, (~~an equivalent but~~) a less expensive interchangeable biological  
11 product or equivalent drug may in some cases be substituted for the  
12 drug prescribed by your doctor. Such substitution, however, may only  
13 be made with the consent of your doctor. Please consult your  
14 pharmacist or physician for more information."

15 **Sec. 7.** RCW 69.41.050 and 2003 c 53 s 325 are each amended to read  
16 as follows:

17 (1) To every box, bottle, jar, tube, or other container of a legend  
18 drug, which is dispensed by a practitioner authorized to prescribe  
19 legend drugs, there shall be affixed a label bearing the name of the  
20 prescriber, complete directions for use, the name of the drug either by  
21 the brand or generic name and strength per unit dose, name of the  
22 manufacturer, name of patient and date: PROVIDED, That the  
23 practitioner may omit the name and dosage of the drug if he or she  
24 determines that his or her patient should not have this information and  
25 that, if the drug dispensed is a trial sample in its original package  
26 and which is labeled in accordance with federal law or regulation,  
27 there need be set forth additionally only the name of the issuing  
28 practitioner and the name of the patient.

29 (2) A violation of this section is a misdemeanor.

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