

CERTIFICATION OF ENROLLMENT

**ENGROSSED SENATE BILL 5935**

64th Legislature  
2015 Regular Session

Passed by the Senate April 16, 2015  
Yeas 47 Nays 1

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**President of the Senate**

Passed by the House April 14, 2015  
Yeas 96 Nays 1

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**Speaker of the House of Representatives**

Approved

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**Governor of the State of Washington**

CERTIFICATE

I, Hunter G. Goodman, Secretary of the Senate of the State of Washington, do hereby certify that the attached is **ENGROSSED SENATE BILL 5935** as passed by Senate and the House of Representatives on the dates hereon set forth.

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**Secretary**

FILED

**Secretary of State  
State of Washington**

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ENGROSSED SENATE BILL 5935

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AS AMENDED BY THE HOUSE

Passed Legislature - 2015 Regular Session

State of Washington                      64th Legislature                      2015 Regular Session

By Senators Parlette and Frockt

Read first time 02/11/15. Referred to Committee on Health Care.

1            AN ACT Relating to biological products; amending RCW 69.41.110,  
2 69.41.120, 69.41.150, and 69.41.160; adding new sections to chapter  
3 69.41 RCW; and providing expiration dates.

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

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

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

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

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

15            (3) "Substitute" means to dispense, with the practitioner's  
16 authorization, a "therapeutically equivalent" drug product (~~of the~~  
17 ~~identical base or salt as the specific drug product prescribed;~~  
18 ~~PROVIDED, That with the practitioner's prior consent, therapeutically~~  
19 ~~equivalent drugs other than the identical base or salt may be~~  
20 ~~dispensed)) or "interchangeable biological" drug product;~~

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

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

8 (6) "Biological product" means any of the following, when applied  
9 to the prevention, treatment, or cure of a disease or condition of  
10 human beings: (a) A virus; (b) a therapeutic serum; (c) a toxin; (d)  
11 an antitoxin; (e) a vaccine; (f) blood, blood component, or  
12 derivative; (g) an allergenic product; (h) a protein, other than a  
13 chemically synthesized polypeptide, or an analogous product; or (i)  
14 arsphenamine, a derivative of arsphenamine, or any trivalent organic  
15 arsenic compound; and

16 (7) "Interchangeable" means a biological product:

17 (a) Licensed by the federal food and drug administration and  
18 determined to meet the safety standards for interchangeability  
19 pursuant to 42 U.S.C. Sec. 262(k)(4); or

20 (b) Approved based on an application filed under section 505(b)  
21 of the federal food, drug, and cosmetic act that is determined by the  
22 federal food and drug administration to be therapeutically equivalent  
23 to an approved 505(b) biological product and is included in the  
24 505(b) list maintained by the pharmacy quality assurance commission  
25 pursuant to section 5 of this act.

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

28 (1) Every drug prescription shall contain an instruction on  
29 whether or not a therapeutically equivalent generic drug or  
30 interchangeable biological product may be substituted in its place,  
31 unless substitution is permitted under a prior-consent authorization.

32 If a written prescription is involved, the prescription must be  
33 legible and the form shall have two signature lines at opposite ends  
34 on the bottom of the form. Under the line at the right side shall be  
35 clearly printed the words "DISPENSE AS WRITTEN". Under the line at  
36 the left side shall be clearly printed the words "SUBSTITUTION  
37 PERMITTED". The practitioner shall communicate the instructions to  
38 the pharmacist by signing the appropriate line. No prescription shall  
39 be valid without the signature of the practitioner on one of these

1 lines. In the case of a prescription issued by a practitioner in  
2 another state that uses a one-line prescription form or variation  
3 thereof, the pharmacist may substitute a therapeutically equivalent  
4 generic drug or interchangeable biological product unless otherwise  
5 instructed by the practitioner through the use of the words "dispense  
6 as written", words of similar meaning, or some other indication.

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

12 (3) The pharmacist shall note the manufacturer of the drug  
13 dispensed on the file copy of a written or oral prescription.

14 (4) The pharmacist shall retain the file copy of a written or  
15 oral prescription for the same period of time specified in RCW  
16 18.64.245 for retention of prescription records.

17 NEW SECTION. Sec. 3. A new section is added to chapter 69.41  
18 RCW to read as follows:

19 Unless the prescribed biological product is requested by the  
20 patient or the patient's representative, if "substitution permitted"  
21 is marked on the prescription as provided in RCW 69.41.120, the  
22 pharmacist must substitute an interchangeable biological product that  
23 he or she has in stock for the biological product prescribed if the  
24 wholesale price for the interchangeable biological product to the  
25 pharmacist is less than the wholesale price for the biological  
26 product prescribed.

27 NEW SECTION. Sec. 4. A new section is added to chapter 69.41  
28 RCW to read as follows:

29 (1) Within five business days following the dispensing of a  
30 biological product, the dispensing pharmacist or the pharmacist's  
31 designee must make an entry of the specific product provided to the  
32 patient, including either the name of the product and the  
33 manufacturer or the federal food and drug administration's national  
34 drug code, provided that the name of the product and the name of the  
35 manufacturer are accessible to a practitioner in an electronic  
36 records system that can be electronically accessed by the patient's  
37 practitioner through:

38 (a) An interoperable electronic medical records system;

- 1 (b) An electronic prescribing technology;
- 2 (c) A pharmacy benefit management system; or
- 3 (d) A pharmacy record.

4 (2) Entry into an electronic records system, as described in  
5 subsection (1) of this section, is presumed to provide notice to the  
6 practitioner. Otherwise, the pharmacist must communicate to the  
7 practitioner the specific product provided to the patient, including  
8 the name of the product and manufacturer, using facsimile, telephone,  
9 electronic transmission, or other prevailing means.

10 (3) No entry or communication pursuant to this section is  
11 required if:

12 (a) There is no interchangeable biological product for the  
13 product prescribed;

14 (b) A refill prescription is not changed from the product  
15 dispensed on the prior filling of the prescription; or

16 (c) The pharmacist or the pharmacist's designee and the  
17 practitioner communicated before dispensing and the communication  
18 included confirmation of the specific product to be provided to the  
19 patient, including the name of the product and the manufacturer.

20 (4) This section expires August 1, 2020.

21 NEW SECTION. **Sec. 5.** A new section is added to chapter 69.41  
22 RCW to read as follows:

23 The pharmacy quality assurance commission shall maintain a link  
24 on its web site to the current list of all biological products  
25 determined by the federal food and drug administration as  
26 interchangeable. The commission shall maintain a list of all  
27 biological products approved as therapeutically equivalent by the  
28 federal food and drug administration through the approval process  
29 specified in 505(b) of the federal food, drug, and cosmetic act. The  
30 commission shall make the 505(b) list accessible to pharmacies.

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

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

37 (2) A pharmacist who substitutes ~~((a))~~ a therapeutically  
38 equivalent drug product pursuant to RCW 69.41.100 through 69.41.180

1 as now or hereafter amended assumes no greater liability for  
2 selecting the dispensed drug product than would be incurred in  
3 filling a prescription for a drug product prescribed by its  
4 established name.

5 (3) A pharmacist who substitutes a preferred drug for a  
6 nonpreferred drug pursuant to RCW 69.41.190 assumes no greater  
7 liability for substituting the preferred drug than would be incurred  
8 in filling a prescription for the preferred drug when prescribed by  
9 name.

10 (4) A pharmacist who selects an interchangeable biological  
11 product to be dispensed pursuant to RCW 69.41.100 through 69.41.180,  
12 and the pharmacy for which the pharmacist is providing service,  
13 assumes no greater liability for selecting the interchangeable  
14 biological product than would be incurred in filling a prescription  
15 for the interchangeable biological product when prescribed by name.  
16 The prescribing practitioner is not liable for a pharmacist's act or  
17 omission in selecting, preparing, or dispensing an interchangeable  
18 biological product under this section.

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

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

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